# Hazard, Risk and Responsibility in the Current Regulation of Biotechnology

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**300 Word Summary**

Recent events have shown that the release of genetically modified crops and their use as food is increasingly controversial. The confusion over the issues involved displayed by the public, the media and governments across Europe is symptomatic of deficiencies in the current regulation of biotechnology.

These deficiencies have been explained in terms of the differences between "product-based" and "process-based" models of regulation. These supposedly reflect the characteristics of, respectively, the United States and European regulatory frameworks. It has been claimed that the "process-based" model is functionally unable to distinguish real from conjectural risks. It is therefore dismissed as irrational and perpetuating the confusion experienced by the public whilst unnecessarily burdening the emerging biotechnology industry.

This dichotomy, however convenient, does not accurately reflect or explain the characteristics of current regulations and does not inform the debate over the acceptability of biotechnology. The adequacy of a regulatory framework, i.e. the legislative policy rather than the efficiency or effectiveness of its application, in an international comparative context, must be established with regard to the principles of proportionality and precaution. As well as being the only available internationally-accepted references for this task, these two emerging principles of international law offer clear guidance for the understanding of the concepts of "risk" and "hazard", and help establish the corresponding legal responsibilities in the context of biotechnology. They allow a fair and adequate evaluation of all the points of view present in the biotechnology debate.

Accordingly, both regulatory frameworks present defects, but these are not insurmountable. The frameworks are neither equivalent nor mutually exclusive, and cannot be treated as alternatives. Their differences illustrate the sovereign right of States to choose appropriate levels of safety for their jurisdictions, as long as this choice is adequately justified. This right is not a barrier to trade or to scientific understanding.

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# Chapter One: Introduction

## 1.1 The biotechnology debate and its legal boundaries.

Biotechnology has been the subject of a heated and increasingly bitter academic debate concerning the rights and wrongs of genetic engineering since its inception a quarter of a century ago. Such is the level of acrimonious disagreement over the essential issues in the debate that there is no longer any accepted common ground for discussion between opponents who advocate a total abandonment of the technology (indeed, of the very concept of manipulating genes) and proponents who call for the removal of any regulatory or economic barrier to the development of this self-styled revolutionary industry.

For example, it is even disputed whether biotechnology began with the restriction enzyme-based recombinant techniques discovered by Boyer and Cohen in the early 1970s, which enabled scientists to put into practice the theories of molecular biology,[1] or with the invention of agriculture itself, some ten thousand years ago.[2] Depending on the answer to this particular question, the issues raised by biotechnology may be seen as new and uncertain, or old and familiar. There are also wider issues common to both scenarios, such as the questions "What right has humanity to alter the environment to suit itself?" and "Who will bear responsibility when it all goes wrong?" If biotechnology is seen as new, these daunting questions have uncertain answers whereas, if biotechnology is seen as old, these questions can be answered by reference to tradition and appear to have long been settled. But is this truly the case? Biotechnology has not raised new issues but has placed old issues into a new light, causing many sections of society to question old certainties.

It is similarly disputed whether recombinant techniques are "natural" as, on the one hand, they harness intra-cellular mechanisms that occur naturally without human intervention[3] but, on the other, these mechanisms take place in the particular case of genetically modified organisms ("GMOs") only because they have been provoked by human intervention. The implications of something being described as "natural" are also disputed: does it follow that it is safer, more acceptable than something caused by human intervention?

As opponents and proponents can no longer conduct a rational debate, both call upon governments, necessary arbitrators due to their monopoly on legislative power, to take action to further their agenda. Governments have indeed taken action with regards to biotechnology, but in doing so have restricted the forum of the debate to a single legal issue. After a period of uncertainty, most governments have developed regulatory structures to ensure the human and environmental safety of applications of recombinant biotechnology, whether experimental or commercial. Questions regarding biotechnology's moral, economic or social worth have been largely excluded from the legal

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[1] **BMA (1992)**, p. 54.

[2] **Miller *et al.* (1993)**, p. 1323.

[3] **OSTP (1992)** states that US regulatory policy is to be based on the main finding of **NRC (1990)**, which is "The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods."

frameworks.[4] However, these regulations have failed to please either the opponents or the proponents of biotechnology. The former have complained that the regulations are not stringent enough whilst the latter have complained that the industry is overregulated, or not regulated sensibly. Both sides still attempt to introduce moral or economic considerations into this "safety" debate. Much of the argument presented by proponents of biotechnology has concentrated on balancing the requirements for ensuring the safety of humans and of the environment, on the one hand, and minimising the economic disincentives on an emerging industry on the other. Much of the argument presented by opponents concentrates on ensuring social and economic justice in the distribution of the risks and benefits of biotechnology. These goals may appear at first to be irreconcilable, but there is in fact considerable commonality in the aims and methods to ensure both objectives.

The exact nature of the risks of biotechnology and the adequacy of forms of management applicable to these risks have remained elusive and controversial concepts. Similarly, the expected benefits of biotechnology have not been precisely defined. In these circumstances it is difficult to assess the risks of biotechnology in the context of its benefits. This is particularly so where deliberate releases of viable and self-propagating GMOs to the environment are concerned. Opponents believe that the risks, whether they are moral (losing respect for the environment, "Nature" or "Creation"), environmental (upsetting the delicate balance of natural ecosystems) and human (introducing health risks or upsetting economic relations), outweigh any benefits, whereas the proponents believe that the economic and technical advances brought on by the new technology outweigh any such risks. Whether at all a balance can be achieved is denied by certain opponents of the technology.[5] The difficulty is further heightened when these GMOs are destined to be used as human food. The issues raised by the release of GMOs to the environment and the issues raised by the human consumption of GMOs are very different, if united within the context of agriculture. The concepts of environmental safety and of food safety are very different. Regulations that attempt to address the one with methods more appropriate for the other are unlikely to achieve their aims. Both regulatory aims are excellent examples of the need for a measurement of regulatory adequacy as the biotechnology debate often confuses the two, as shown below. However, both sets of issues concern safety and require the same considerations of hazard, risk and responsibility. This thesis concentrates on the agricultural applications of biotechnology, examining both environmental and food safety, rather than on contained uses of GMOs or the uses of GMOs for medical purposes for the following reasons. The agricultural applications of biotechnology are the more topical due to the current hysteria over the so-called "Frankenstein foods". The use of agricultural GMOs in food is seen to affect a larger proportion of the population than contained uses of GMOs (which is not entirely correct as fermentation processes using GMOs or GM products may affect most foods on the market in future). Contained uses of GMOs do not present the same issues of social risk management as deliberate releases due to the more extensive

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[4] With the exception of patent law, where moral values play a part in whether the State should grant a temporary monopoly over intellectual property (n.b. the requirements of patent law are outside the scope of this thesis). The extent to which such issues have been excluded from the legal frameworks remains controversial as commentators such as H I Miller insist that moral issues contaminate the determination of safety in "process" laws, as explained below in Section 1.4.

[5] H I Miller argues that these are questions of "desirability" (**Miller (1984)**) that are best answered in the marketplace (**Miller (1992a)**).

possibilities of physical and biological control over the GMOs (in the absence of accidental or incidental escape). Medical uses of GMOs benefit from well established regulatory and voluntary procedures to deal with the safety and ethical concerns that arise, whereas such procedures are entirely lacking in the field of food production. Nevertheless, comparative reference will be made throughout to contained and medical uses of GMOs as illustrations of the deficiencies in the frameworks concerning agricultural uses.

## 1.2 The context of the debate in 1996.

Despite rarely being out of the media headlines since the 1970s, the debate concerning the risks and benefits of biotechnology has largely been outside of the gaze of the general public, and remained the domain of academics, environmentalists, industry pioneers and government officials. However, in recent years, this difficult debate has become a reality rather than a theoretical exercise. The long-touted products of biotechnology are now arriving on the supermarket shelves and are causing a renewed storm of controversy which, this time, has fully captured the attention of the public and is causing rapidly-increasing uncertainty and concern.

The events that have brought the debate to a head (and which prompted the present study) concern the bulk import of American commodity crops into Europe, containing a proportion of a genetically modified ("GM") variety mixed in with the non-modified variety so as to be indistinguishable from it without the use of sophisticated test procedures. The difficulties that these imports have caused to the regulatory authorities in the European Union ("EU") have placed the spotlight on the weaknesses of the current regulatory framework. The commercial repercussions of these difficulties present an opportunity for all the elements, assumptions and viewpoints, of the biotechnology debate to be tested in the formal arena of the court of law[6] as the real possibility of a major trade war between the United States ("US") and the EU looms.[7]

The events that caused the current difficulties between the US and the EU concerned the import of two commodity crops, soybean and maize, and two GM crops in particular, Monsanto's "Roundup-ready" soybean (known to US regulators as glyphosate tolerant soybean, line 40-3-2,[8] and to EU regulators as C/UK/94/M3/1[9]) and Ciba-Geigy's "Genetec" maize (know to US regulators as

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[6] The first legal test of the current regulations for GMOs in the United Kingdom ("UK") has now taken place. The sections relevant to GMOs of the Environmental Protection Act 1990 have been judicially considered for the first time by the Court of Appeal in the *Watson case* (*R v. Secretary of State for the Environment, Transport and the Regions ex parte Watson* [1999] Env. L. R. 310).

[7] As an indication of official concern over such a possibility, the author has recently (17th May 1999) participated in a discussion meeting hosted by the Energy and Environmental Programme of the Royal Institute of International Affairs to determine the probability of such a dispute, and to examine the possible arguments that may be raised by the parties to such a dispute. The meeting was attended by staff of the Foreign and Commonwealth Office, of the Department of Trade and Industry, and of the Ministry for Agriculture Fisheries and Food amongst others. Senior personnel of the US regulatory authorities now see a trade dispute between the US and the EU over biotechnology as a near certainty (see for example **Glickman (1999)**), following the recent World Trade Organisation ("WTO") decision in favour of the US concerning the EU's ban on the use of growth hormones in cattle (see Section 4.2, below).

[8] **Payne (1994).**

[9] **House of Lords (1998)**, Appendix 4. See **Commission Decision 96/281.**

lepidopteran insect-resistant Event 176 corn[10] and to EU regulators as C/F/94/11-03[11]). Both GM crops must satisfy specific regulatory requirements prior to release in both the EU and in the US. At the time of the events in question, the GM soybean and the GM maize had been granted authorisation to be grown commercially and to be sold for human consumption in the US by the appropriate regulatory authorities,[12] whereas they had not yet been authorised for those purposes in the EU.[13] Therefore, there was a period of time where it was legal to grow and sell the GM crops in the US and illegal to do so in the EU. It was consequently illegal to import the American GM crops into the EU.

In the US, once a GM crop is given regulatory authorisation to be commercialised by the US Department of Agriculture ("USDA"), the developer of the crop may apply for it to be "deregulated". This is simply a declaration that the GM crop is no longer subject to any particular regulatory oversight by the USDA due to its GM nature, and is treated exactly like any other authorised, non-GM, variety of the same crop.[14] Once deregulated, a GM crop may be mixed with non-GM varieties of the same crop or processed into food products without any requirement for special labelling, segregation or monitoring.

It is almost universal practice in the trade of commodity crops, especially soybean (whether GM or not), for several varieties of a commodity crop to be mixed together as soon as they are harvested or when they are stored in silos. Where there is no commercial reason to separate out the varieties of a crop, they are mixed together in order to enjoy the considerable economies of scale inherent in bulk transport and bulk storage.[15] The economies of scale increase as the crop travels along the economic conveyor belt from the farm to the end consumer. The crop is transported from local silo to regional silo, in road tankers then river barges, until it reaches the export terminals where it is placed, in immense quantities, in the holds of cargo ships bound for the export markets. Since 1996, the year in which the first commercial GM crops were harvested and introduced onto the food markets, US bulk consignments of maize and soybean have contained a proportion of GM and non-GM varieties of these crops.[16]

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[10] **Payne (1995).**

[11] **House of Lords (1998)**, Appendix 4. See **Commission Decision 97/98.**

[12] Similar authorisations had also been granted by their Canadian counterparts, amongst others. For the purposes of clarity, the present thesis will concentrate on the position of the US alone, but the discussion would apply equally to a dispute between the EU and Canada.

[13] At the relevant time, the EU regulatory framework consisted of **Council Directive 90/219** ("the Contained Use Directive"), **Council Directive 90/220** ("the Deliberate Release Directive"), and **Council Directive 90/679** ("the Protection of Workers Directive").

[14] "Deregulation" does not imply that the GM crop is no longer regulated by other agencies such as the US Food and Drug Administration ("FDA") or the US Environment Protection Agency ("EPA"), nor is "deregulation" required for commercialisation. The USDA may authorise the commercialisation of a GM crop under specific conditions. In this particular case, the two GM crops satisfied the requirements of all relevant US agencies and were unconditionally approved.

[15] See **House of Lords (1998)**, paras 129 - 134 and Questions 578 and 618.

[16] This proportion is rapidly increasing. It has been estimated that a quarter of the soybean that comes to the UK from the US (its main supplier) in 1998 is GM. This proportion was expected to rise to 60 per cent in the course of 1998 and to up to 90 per cent in 1999. See **Abrams (1998a)**.

The EU regulations do not provide for such "deregulation".[17] The Deliberate Release Directive imposes labelling requirements on all approved GM products under Article 11(1). The labelling of a GM product must comprise at least the name of the GMO contained within the product, the name and address of the manufacturer or distributor, the exact conditions of use of the product, measures to take in case of unintended release or misuse of the product and specific instructions or recommendations for storage and handling to avoid accidental release to the environment.[18] Furthermore, Article 11(6) imposes a continuing duty on the producer of a GM product to revise proposed conditions for use in the light of new information, inform the competent authority and take "the measures necessary to protect human health and the environment". These labelling requirements and the continuing duties imposed on the producers place GM products under a regulatory regime separate from that of the non-GM varieties of the same crops. In practical terms, the GM crops need to remain segregated to comply with these provisions.

When the US consignments of mixed GM and non-GM crop first arrived on European shores, the EU authorities were confronted with an absurd problem. Of two apparently indistinguishable crop varieties mixed together in a bulk consignment, one variety was imported legally and the other was imported illegally as (a) it had not yet been approved for placing on the market under the Deliberate Release Directive; and (b) it did not satisfy the labelling conditions.

There were only two options available to the authorities: either the they turned the entire consignments away as the physical impossibility of separating the legal and illegal crops from the bulk could only result in the entire consignment being declared illegal, or the authorities accepted the impossibility of such a task, approved the import and disregarded the law. The second option would seem to be unacceptable in principle. It would make a nonsense of the strict EU regulatory framework concerning biotechnology if it was to simply buckle under the pressure of commercial reality.

The regulators had intended the framework to provide a stringent and comprehensive regulatory umbrella for the protection of the environment, human health and safety as well as consumer rights. The Contained Use Directive was enacted under Articles 130s and 130r of the Treaty of Rome which provide that EU policy on the environment shall "contribute to the pursuit of" the principles of (a) "preserving, protecting and improving the quality of the environment"; (b) "protecting

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[17] The Deliberate Release Directive makes clear, in Article 13, that consents for commercial releases of GMOs may provide for conditions concerning the use and storage of GM products. The consents may also restrict the type of environment and/or geographical area for which the authorisation is granted, although it is conceivable that authorisation may be given unconditionally where appropriate. Article 13(5) of the Directive provides that once a GM product is approved for commercial release, "it may be used without further notification throughout the [EU] insofar as the specific conditions of use and [the stipulation as to] the environments and/or geographical areas [set by the consent to release] are strictly adhered to". Article 15 of the Directive further provides that Member States may not prohibit, restrict or impede the placing on the market of GM products satisfying the requirements of the Directive on grounds relating the consent to release issued under the Directive. There are therefore considerable similarities between the authorisations provided by the USDA and the EU authorities.

[18] It is to be noted that Article 11(1) also provides that the releaser of a GM product may propose, in his notification to the competent authority, not to comply with one or more of the labelling requirements if, on "substantive reasoned scientific grounds" he "considers that the placing on the market and use of a product do not pose a risk to human health and the environment". This would mean that the GM product would not be identified as such. This type of request is therefore similar to the "deregulation" petition procedure of the USDA.

human health"; (c) "prudent and rational utilisation of natural resources"; and (d) international environmental co-operation.[19] The Treaty of Rome sets out that EU environmental policy shall aim at a high level of protection. This is to be achieved by taking into account the environmental diversity of European regions, adhering to the precautionary principle and to the principles

> "that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay".[20]

The above principles mean taking into account

> "available scientific and technical data [ . . . ]; the potential benefits and costs of action or of lack of action [and] the economic and social development of the Community as a whole and the balanced development of its regions."[21]

The Deliberate Release Directive was enacted under Articles 100 and 100a of the Treaty of Rome, which set out the mechanism for the approximation of the laws of the Member States directly affecting the common market. Article 100a(3), provides that the Commission will take as a base a "high level" of protection in all matters relating to "health, safety, environmental protection and consumer protection". Both Directives set out in their preambles the prevalence of the principle that preventative action shall be taken to protect the environment and human health.

In accordance with these high aims, the EU Commission took a stand against the mixed consignments that was reminiscent of that of King Canute, and declared that

> "[i]t will not be possible to import [ . . . ] genetically modified maize in accordance with the directive until the Commission has taken a decision",[22]

and called upon the Member States, in the mean time,

> "to organise inspections and other control measures to ensure the directive is complied with - which means no sale or release of the new maize inside Europe".[23]

However, the Member States of the EU are economically dependant on the imports of US crops, especially soybean which is not grown to any great extent in the EU and upon which the processed food industry relies heavily as a basic ingredient. The US also placed considerable pressure on the Member States to accept the mixed consignments. Soybean and maize are two of the largest US agricultural exports to the EU representing hundreds of millions of dollars of trade each year.[24] In the event, the EU Member States had no option but to accept the technically illegal imports. Without a clear EU-wide position on the matter, no Member State wanted to individually reject the bulk imports

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[19] Article 130r(1).

[20] Article 130r(2).

[21] Article 130r(3).

[22] **Cranford & Clover (1996).**

[23] **Cranford & Clover (1996).**

[24] It has been estimated that the dispute between the EU and the US over these two varieties has cost the US two hundred million dollars in maize sales to Europe in the first six months of 1998. See **Galvin (1998), p. 19.**

and face a potentially damaging trade dispute with the US alone.[25] The UK in particular is dependant on both soybean and maize imports as it cannot by any means satisfy its domestic demand with domestic production. Despite making clear its opposition to the GM maize, the then Department of the Environment under the previous Conservative government was powerless to do anything about the imports.[26]

The unofficial imports were eventually approved by the EU and authorisations issued. A trade war may have been averted but it was at the cost of the credibility of the EU regulatory framework.[27]

However, the problem will not be limited to these two crops in future. Numerous GM crops are commercially available in the USA at present[28] and will inevitably be exported to the EU in the same way as the GM soybean and the GM maize, widening the scope of the problem and deepening the crisis. Furthermore, the problem has arguably become worse. The labelling requirements under the European framework have become more stringent since the promulgation of the Novel Foods Regulation[29] in 1997. This Regulation requires the labelling of all foods of GM origin, whether or not they are or contain GMOs or any genetically modified DNA.[30] These labelling requirements were imposed retrospectively on Monsanto's GM soybean and Ciba-Geigy's GM maize,[31] a move which has deeply angered the biotechnology industry.

### 1.3. The questions arising from the problem of mixed imports

As the two GM crops that caused the crisis were approved shortly after the first imports of mixed consignments, it would appear that, had there been no delay in the approval of the crop in the EU, the whole issue would not have arisen. The proponents and opponents of biotechnology seized upon the question of what caused this delay. The biotechnology industry has argued that the authorisation procedures for GMOs in the EU are significantly slower and more complex than in the US, as well as more burdensome. It has also been argued that the regulatory structure took too long to be put in place (putting aside the question of whether, once they were in place, the assessment procedures were too slow or not). This is often put down to bureaucratic inefficiency. But a growing number of commentators argue that the rapid implementation of an effective regulatory system was in

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[25] **Cranford & Clover (1996).**

[26] **Burrell (1996b).**

[27] The difficulties encountered by the European framework arose from the fact that the GM crops were legally on the market in the country of origin. Greater difficulties may arise where consignments of crops are being imported from countries (such as Brazil) where GM crops are either banned or tightly regulated, which contain a proportion of GM crops in contravention of the regulations of the country of origin.

[28] **Galvin (1998)** lists 31 GM food products currently on the market in the US and 35 more expected within six years. It also lists 19 GM pesticides currently on the US market, and 8 more expected on the market within three years.

[29] **European Parliament and Council Regulation 258/97** (hereafter "the Novel Foods Regulation").

[30] DNA is the acronym for deoxyribonucleic acid, the chemical molecule that forms the structure of genes.

[31] By **Council Regulation 1139/98.**

fact prevented by the opponents of biotechnology. The first two points are examined in turn below, and the third in Section 1.4.

### 1.3.1 The argument concerning bureaucratic delay

Whether or not the authorisation procedures for GMOs in the EU are significantly slower, more complex than, or more burdensome in the US has been examined in detail elsewhere.[32] An assessment of the relative efficiencies of the US and EU approval systems (in terms of time taken to approve the same GMO or otherwise) would require that the two systems function with the same data inputs and the same purpose. This is not the case and therefore a comparative exercise solely on the basis of time taken, or cost, or any other such measure, would not address the source of the differences between the two systems. This is not to say that there are no obvious problems with either system.

The EU system is criticised as slow as it is claimed that GMO assessment times average over 18 months whereas it is claimed that the assessment times for the same GMO last less than six months in the US. This is simply incorrect.[33] The times compared are not equivalent. For the EU, time is measured between the notification to the authorities of a person's intention to release a GMO to the environment (whether experimentally or commercially) and the final EU authorisation to do so. In the US there are three separate Agencies involved in the approval of a GMO and time must be measured to take this into account. The times often quoted for the USDA generally only represent the "deregulation" procedure (mentioned above). This is separate from the (limited) review of the GMO, which takes much longer. The times often quoted for the FDA represent the approval procedure for food release only, which usually benefits from prior review and authorisation data from the EPA or USDA . Only the EPA has a review comparable to that done under the EU regulatory framework and it takes a similar time. These three separate reviews do not necessarily take place concurrently, adding to the time taken for GMO approval in the US.

Nevertheless, it is felt that the US framework provides more certainty than the EU framework because there is, in the end, a smaller number of decision-makers.[34] Under the EU framework, the principal review bodies for GMO releases are the competent authorities of the Member States. Applications for release of a GMO are presented to these authorities, which may refuse or accept the application.[35] Where no other Member State objects to the approval, the GMO is cleared for release throughout the entire EU. The approval process should take no more than 90 days for a release for

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[32] See in particular **OECD (1995)**, which demonstrated that the assessment requirements of the EU and the US are broadly similar; see also **House of Lords (1998)**.

[33] The US authorities have admitted as much when giving evidence to **House of Lords (1998)**.

[34] See **House of Lords (1998)**.

[35] Authorisation may be rejected under Article 6(2) of the Deliberate Release Directive in the case of releases of GMOs for the purposes of research and development or any purpose other than placing on the market, and under Article 12(2) of the same Directive in the case of the placing of GMOs onto the market. There does not appear to be a right of appeal on a European basis if the application for release (whether for research or for commercialisation) is rejected. Any right of appeal appears to reside with domestic forms of judicial review, if any are available.

research and development purposes.[36] Where an application for the placement of a GMO on the market is concerned, the delay is longer.

The competent authority has 90 days from receipt of an application to either refuse it or forward a favourable recommendation to the Commission for distribution to the other Member States.[37] The Commission must distribute the dossier "immediately"[38] but this term is not defined and there is no time limit specified, or for any penalties for delay.[39] The Commission must notify the competent authority of the date of distribution of the dossier. It is this unspecified date that starts the clock for EU review. If there are no objections, the originating Member State may approve the release within 60 days of the date of distribution.[40] It is therefore an erroneous assumption that the procedure takes 150 days. However, where objections are raised by another Member State, the EU framework provides for a conciliation procedure[41] between the 15 Member States.[42] This is where problems begin.

The Commission submits a draft of the measures to be taken regarding the disputed release a committee convened under Article 21 which shall vote on whether to approve the draft or not. This presumes that the Commission has proceeded either to its own review of the application, or at least to a review of the originating Member State's recommendation. There is no indication of the basis upon which this review is made or how the draft is to be established. There is no indication as to within what deadlines the Commission shall submit the draft to the committee, nor is there any indication as to whether these draft recommendations shall bear any resemblance to the recommendations of the originating Member State. The Article 21 committee establishes its own timetable for the review of the draft measures. There is no indication as to how it will proceed and no time limit other than that which it sets itself. If the committee approves the draft, the Commission adopts the draft measures. If not, or if no opinion is delivered (be it through inaction or through a split vote), the Commission shall "without delay" submit a "proposal relating to the measures to be taken" to the Council. There is no indication as to what "without delay" means, or whether the proposal bears any resemblance to the draft measures or to the original recommendation, or whether the Council is to be informed as to the

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[36] Deliberate Release Directive, Article 6(2).

[37] Deliberate Release Directive, Article 12(2). Article 12(5) of the Directive states that the 90-day period shall not take into account any period(s) of time during which the competent authority is awaiting any further information it may have requested from the proposer of the release. It is therefore not a limit.

[38] Deliberate Release Directive, Article 13(1).

[39] The internal rules of the Commission set down time limits for the process of decision making. These, however, are not always respected. Furthermore, there is no procedure by which anyone may protest if they are not.

[40] Deliberate Release Directive, Article 13(2).

[41] The conciliation procedure only applies when applications for releases to the market are accepted and protested (and not when the application is refused). It does not apply to applications for release for research and development purposes (whether or not the application is accepted). Where an application for research and development purposes is considered, the competent authority need only consider "comments by other Member States made in accordance with Article 9" of the Deliberate Release Directive, which provides only for a centrally-operated mechanism for the exchange of information and does not provide for any conciliation mechanism between the Member States or for the Commission to intervene.

[42] Between 12 Member States at the time of promulgation.

matters discussed by the Article 21 committee. The Council is given three months from the referral to it to vote on the proposal; again there is no indication as to how, or on which basis, it will proceed. No indication is given as to what happens if the vote of the Council is negative. The Commission may implement its proposal if the Council approves it, or if the Council fails to act within the three months. No indication is given as to when the Commission is to implement its proposal or how. Practice has shown that the Commission will instruct the originating Member State to approve the proposal thereby clearing the GMO for market release throughout the EU. There is no timetable for the State to do so unless provided in the instruction. The instruction sent by the Commission to the Member State does not close the matter. An individual Member State may refuse to accept the GMO on their territory if it has

> "justifiable reasons to consider that [ . . . the GMO . . .] constitutes a risk to human health or the environment."[43]

The Member State shall "immediately" (whatever this means) inform the Commission of its action and its reasons (Article 16(1)), triggering a complete review of the conciliation procedure which must take no more than three months (Article 16(2)). There is a precedent of this: Austria has invoked Article 16. Another problem arises between the instruction by the Commission and the implementation of it by the Member State. In the case of the GM maize, France, the Member State that originally approved the crop, subsequently refused to give final approval, having in the mean time changed its mind and called for a moratorium on releases of GMOs. The Commission has, so far, taken no action to force France to comply with its decision.

One of the principal reasons for the delays in the EU's approval mechanism is that, so far, no GMO release has been approved without objections being raised by another Member State. Every time the conciliatory procedure has had to be used, the Article 21 committee and the Council of ministers have failed to produce a consensus position and the Commission has had to intervene. Furthermore, it is unclear who advises the European institutions and on what basis. The conciliation procedure was expected to be the exception rather than the rule. However, the opposite is in fact true and, as the conciliation procedure has not been drawn up with sufficient clarity, problems emerge with each assessment. However, the procedural deficiencies do not cause the disagreements between the Member States but only reflect them. The true problem and the main cause of delays is one concerning the lack similarity of input data and the lack of common understanding of the purpose of the system from Member State to Member State. Essentially, there is a difference in the views of the Member States and of the Commission regarding the acceptability of GMOs. It is these different views that have caused the procedural deficiencies to come to light rather than the opposite, as the players on the political scene used all available means to protect their positions. Furthermore, the difference in views regarding the acceptability of GMOs is even more marked between the EU and the US.

Commentators questioned whether these differences were genuine or were simply tools employed to protect EU markets from US imports[44].

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[43] Deliberate Release Directive, Article16 (1).

As the declared aim of both the EU and the US regulatory regimes is to ensure safety, it appears strange that there could be any difference in the outcome of the assessment because "safety" should have the same meaning for everyone. Some commentators took the view that as the US had authorised the GM crops, there could be no reason for these crops not to be authorised in the EU, and some took the view that there was no justification for an additional review by EU authorities once the US authorities had completed theirs. However, as shown in Chapter Four, it is fully accepted in the law of international trade that each State is entitled to set its own safety standards. Nevertheless, these standards must be justifiable and not discriminatory. The fact that a given product is authorised for commercialisation in one country and not in another is not in itself an uncommon problem in the ordinary course of international trade. There is often a delay between the grant of market authorisations for the same product from country to country. The delay may be short, or sometimes prolonged. Sometimes, a product that is authorised in one country is refused an authorisation in another, or the product is allowed to be released under conditions that do not apply elsewhere. This is not in itself a matter for dispute if the refusal to grant an authorisation, or the conditions that are attached to the authorisation are justified. Grounds for trade disputes arise, however, where an imported product is subjected to restrictions that are either unjustified or discriminatory, or where the process of authorisation is so muddled, whether deliberately or innocently, that it effectively becomes, in itself, a barrier to imports due to the hidden cost of delays, uncertainty, and duplicated controls. The accusation levelled against the EU was that the restrictions of its regulatory system are arbitrary and first and foremost that the uncertainties of its approval system are discriminatory.

### 1.3.2 The argument concerning delay in promulgating the regulatory framework

It has been claimed that the difficulties over mixed consignments may have been avoided had the EU put in place, at the right time, the correct regulatory procedures; however, the claim continues, the EU made the wrong choice in promulgating a single incremental level of regulation rather than adapt pre-existing regulations as pioneered by the US.[45]

The EU developed the current regulatory framework for specific reasons. Firstly, the EU's task was to harmonise the regulatory system of 12 (now 15) States, a problem that did not affect the US.[46] The EU proceeded by way of directives, rather than regulations, in order to provide a minimal

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[44] H I Miller has claimed that the EU regulatory system is a product of self-serving regulatory imperialism (**Miller (1995b)** and **Miller (1996d)**), that it is anti-competitive (**Miller & Young (1989)** and **Miller *et al* (1996)**) and that it raises non-tariff trade barriers in breach of GATT (**Miller & Young (1989)** and **Miller (1996a)**).

[45] Young and Miller denounced "the confusion that plagues attempts in Europe to devise political solutions to scientific questions about planned introductions into the environment. Perhaps European regulators should look to the *scientific* answers to the questions provided by [**NAS (1987)**] that is clear and authoritative" (**Miller & Young (1987e)**).

[46] For the purposes of this thesis, the US position is considered only as the position of the US Federal Government as the Federal Government has a legislative monopoly on international trade. In addition to the Federal Agencies, each one of the 51 States (and the numerous Counties within the States) making up the Union have jurisdiction over GMOs on their territory as long as their policies do not impede inter-State trade. This thesis cannot investigate the differences between the various States of the US and between the States and the federal Government. Most States rely on the legal mechanisms provided by the Federal Government, but the Departments of Agriculture and the Environmental Protection Agencies of some States (such as California and Michigan) have developed their own

standard that all Member States had to achieve (and which they could freely exceed), but that they had to implement themselves. There was nothing to prevent the Member States from implementing the standard in individual product legislation, and indeed this is specifically provided for. They chose to implement the rules "as is" in order to save on the redrafting time. The EU had to provide a conciliation mechanism to protect the integrity of the internal market. Secondly, the EU did not have a comprehensive pre-existing set of regulations to adapt, whereas the Member States did, hence the use of directives providing the Member States with a standard to achieve by way of modifying pre-existing regulations. It is undeniable that the development of the EU regulatory framework took some time, however the first proposals for the current system were published as late as 1988.[47]

The US did not face such a monumental task asthe jurisdictions of its existing agencies were already long established, as was the American internal market. It is therefore not really possible to compare the US and EU regulatory frameworks as a whole. It is also to be noted that the EU is no slower in promulgating its policies than the US.

The US framework had a very long gestation. The first attempts at regulating biotechnology emerged during the 1976-1977 session as House Bills (the equivalent of the UK's private member bills) in response to the recent breakthroughs in recombinant techniques.[48] These efforts were criticised as being characterised by

> "uncontrolled imagination and excessive claims by individuals who lacked knowledge of infectious disease".[49]

These bills became mired in the lengthy process of debates, committees, consultations and studies required by the procedures of Congress; and were modified by amendments to such an extent that they were eventually abandoned in favour of other methods for the regulation of biotechnology.[50] One of the important criticisms of these early bills was their unsuitability to achieve their purpose, a criticism since levelled at the EU regulations.[51]

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policies. Some have taken a more restrictive stance towards GMOs than the Federal Government. Although these States cannot prevent GM products entering their territory from other States of the Union, they can prevent the testing and commercial planting of GMOs on their territory.

[47] The first Commission proposal: COM 88/0160 FINAL, O.J. C198/88.

[48] **Cantley (1995)**, p. 515.

[49] **Cantley (1995)**, at p. 515. It is to be noted that the accusations of ignorance and irrationality levied by proponents of biotechnology against opponents of biotechnology started even at this early stage, before a number of critical discoveries (such as introns and exons and the "fluid genome" theory) that gave weight to the opposing voices. The positions and language used by proponents and opponents have not evolved since.

[50] **Cantley (1995)**, p. 515 applauds the US legislative process for being "slow enough to prevent a stampede of unwise legislation", and for its patient and deliberate analysis of the issues and of the interests of various groups in society, which prevented the debate from going out of control and generating an "intemperate rush to establish legislation". He claims that this was "a successful example of open dialogue between the scientific and political communities [and] an object lesson in how to manage the interface between science and society in a way that [is] democratic and transparent".

[51] **Cantley (1995)**, p.515 states that "most of the legislation being considered was ill-designed for achieving its stated objective, namely, protection of the public without impeding research".

Because of the delays and difficulties encountered in the devising of complex biotechnology-specific legislation, legislative expediency was served by having recourse to the use of pre-existing statutes with the option of preparing more adequate new legislation. This is the experience on which the US claims it would be easier to adapt pre-existing regulations rather than adopt new ones. There was no urgency to regulate in the late 70s and early 80s as no GM products were near release and all laboratory activity was effectively governed by Guidelines[52] published by the National Institutes of Health Recombinant DNA Advisory Committee ("NIH RAC").[53]

Nevertheless, when GMOs were ready to leave the confinement of laboratories for field trials, NIH's authority ended and other Federal Agencies had to step in. Despite the wide powers afforded to US Agencies, their rule-making abilities are heavily restricted by stringent administrative and budgetary procedures, and by stringent considerations of economic impact of regulations. It is a very long and complex procedure to devise and develop entirely new regulatory standards. The Agencies could not afford the added uncertainty of possible blocking tactics at the budgetary review stage, which might be used in the name of keeping a control on the Federal budget but with the purpose of preventing new controls over industry.[54] The Agencies needed to take immediate action to have a regulatory policy (at least) or a regulatory structure in place before any deliberate releases of GMOs to the environment took place. The Agencies acted independently as there was no coordinated policy to commence with.[55] They could not simply rely on the other Agencies regulating biotechnology under their own jurisdictions[56] and had to use their own jurisdiction to the fullest possible extent.[57] Each Agency had to avoid any encroachment onto other Agencies' jurisdictions, which would cause endless ultra vires litigation between the Agencies, or any costly and confusing duplication of effort. However, such efforts to accomodate other Agencies could not be allowed to cause any Agency to leave any area potentially within its jurisdiction uncovered.

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[52] **NIH Guidelines**, originally published 7 July 1976.

[53] The NIH had true control only over laboratory work that received US government funding insofar that it could cancel that funding if its standards were not met. However, the NIH RAC Guidelines had a persuasive authority, being the only set of standards available and the equivalent of a stamp of approval for any future commercialisation.

[54] At the time of these regulatory developments, the Reagan / Bush Administrations and the Republican-dominated Congress were determined to reduce the amount of regulatory constraints on industry, in all sectors or guises.

[55] This was provided by the Federal Coordinated Framework for biotechnology ("Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment" published by the Office of Science and Technology Policy (OSTP) on June 26, 1986 (51 FR 23302, 23313)).

[56] There was no guarantee that other Agencies would regulate and indeed, a number of Agencies who do have authority to establish policies concerning biotechnology within their jurisdictions still have not done so (for example, Agencies of the US Department of the Interior, such as the Bureau of Land Management which is responsible for all public lands and the National Park Service, and certain Agencies of the USDA, do not as yet have a policy concerning the release of GMOs at all).

[57] However, the FDA relies on the other agencies in this way.

The EPA was the first to issue a policy (which would govern a new interpretation of its existing rules where GMOs were concerned) in 1984[58] but only finalised its new regulations in 1997.[59] The EPA chose to adapt its two main sources of regulatory authority: the Toxic Substances Control Act ("TSCA"), which controls all new chemical substances (this being defined so widely as to cover all new micro organisms), and the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), which controls all pesticides (and which could therefore cover GM plants expressing pest-resistant substances).

The USDA's Animal and Plant Health and Inspection Service ("APHIS") was the second of the three Agencies to take responsibility for GMOs. APHIS took a different approach from the EPA and introduced new rules. These were secondary legislation as opposed to primary legislation and avoided the difficulties mentioned above relating to review by Congress. These were introduced quickly in contrast to the difficult gestation of the EPA's rules.[60] APHIS adapted the Federal Plant Pest Act ("FPPA") which provides APHIS with the power to protect American agriculture against damage by foreign plant pests and diseases[61] and to control organisms that can be injurious to cultivated crops or their products, or that might later be found to be injurious to these crops or products. The FPPA could be applied to GMOs as the recombinant techniques utilised plant viruses to insert new genetic material into plants; but could also address the potential of GMOs to harm cultivated crops via the dissemination of transgenes, which at the time was an ill-understood phenomenon.

The FDA is the third Agency that took responsibility for GMOs. The FDA's approach contrasts again with the other two. The FDA is the primary federal agency for food safety in the US although it shares a number of its functions with other agencies.[62] The FDA has not produced any new

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[58] "Proposed Policy Regarding Certain Microbial Products" on December 31, 1984 (49 FR 50880) ("1984 Proposed Policy Statement").

[59] "Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act" on 11 April 1997 (62 FR 17910).

[60] The proposals were published in the *Federal Register* on June 26, 1986. The final rules were published in the *Federal Register* on June 16, 1987 and set out in 7 CFR, Chapter III, Part 340: "Introduction of Organisms and Products Altered or Produced through Genetic Engineering which are Plant Pests or for which there is Reason to Believe are Plant Pests". There are several governing Acts under which these rules are made, including the FPPA.

[61] It is very important to remember that these rules only cover plant pests, and not animal pests or diseases. APHIS has authority to regulate animal health but does not appear to have done so as yet. For example, the definition of the "regulated article" excludes control of prions, the agents of BSE (1987 Final Rules, point 21).

[62] For example, the USDA (and not the FDA) is responsible for enforcing standards of wholesomeness and quality of primary agricultural produce in the US through its inspection and grading functions. The USDA is solely responsible for meat, poultry and eggs. The USDA also has extensive functions concerning nutrition education, food grants (such as school meals) and enforcing food hygiene. Food hygiene standards are set by FDA but a sister Agency of the US Department of Health and Human Services, the Centers for Disease Control, is responsible for protecting the consumer against food-borne diseases and vector-borne diseases (and any likely GM pathogen). FDA is not responsible for alcoholic beverages (an area of significant potential use of GMOs in fermentation and brewing) except certain types of wine. This is the responsibility of the Bureau of Alcohol, Tobacco and Firearms of the US Department of the Treasury. FDA is not responsible for the oversight of seafood or aquaculture (another significant area of GM application and one which causes significant concern). This is covered by the National Marine Fisheries Service, part of the US Department of Commerce. The EPA sets tolerance limits for pesticides in food, which FDA enforces, and the FDA also enforces the EPA's

regulations concerning GMOs but has clarified its position[63] regarding the regulatory status of new foods produced by GM technology under its present legislative authority concerning foods from new plant varieties only.[64] The FDA has expressly not made a new policy with regard to "new drugs", "new animal drugs" or "pesticide chemicals" as defined by the relevant sections of the Federal Food Drugs and Cosmetics Act ("FFDCA").

It is clear from the above that any argument that the EU regulatory framework was not put in place in time cannot be sustained by comparison with the US framework, which has demonstrated growing pains of at least equivalent severity as its EU counterpart.

### 1.3.3 A comment on commercial reality

However, it is plain that the application for review was tardy, not allowing enough time between application and shipment for any regulatory framework (US or EU) to properly function before the shipments arrived on EU shores, showing bad organisation or high confidence in the EU authorities on the applicant's behalf. The latter would contradict and perception of the EU framework being slow. The application for approval for the GM crops was in fact[65] presented leaving only enough time for the EU framework's proposed time targets to be met, not taking into account the possibility of Article 21 Committee problems which occurred. The confused nature of these problems cause the importers to perceive that the market authorisations were withheld without good reason (as demonstrated by their subsequent unconditional authorisation). Therefore, the delays in granting the authorisation appeared to be discriminatory.

## 1.4. Introduction to the "product vs. process" controversy

Despite the lack of any unified approach to the regulation of biotechnology from the US Agencies, US commentators, led by H. I. Miller,[66] condemned the EU decision to go for a new unified regulatory framework rather than utilising existing regulatory frameworks as the US had done. Miller

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standards for bottled water quality. FDA shares responsibilities with the Federal Trade Commission concerning the labelling and advertising of foods, a contentious issue concerning consumer choice to accept GMO foods or not. It is to be noted that the FDA only has power over the safety of foods sold in interstate commerce. Imports to and exports from the US are the responsibility of the USDA. Each individual State has its own food safety and food hygiene agencies which have concurrent responsibilities with those of the FDA. However, as all foods produced in the US are presumed to be destined to interstate commerce, the FDA's regulations are paramount.

[63] Anon., Statement of Policy: Foods Derived From New Plant Varieties, FDA HHS, Federal Register, May 29 1992, 57 FR 22984. Hereafter referred to as 1992 Statement of Policy.

[64] The FDA has reserved the right to clarify its position regarding "foods and food ingredients regulated by FDA that have been derived from algae, microorganisms, and other nonplant organisms, including: (1) Foods produced by fermentation, where microorganisms are essential components of the food (e.g., yogurt and single cell protein); (2) food ingredients produced by fermentation, such as many enzymes, flavors, amino acids, sweeteners, thickeners, antioxidants, preservatives, colors, and other substances; (3) substances produced by new plant varieties whose purpose is to color food, and (4) foods derived from animals [ . . . ]." (1992 Statement of Policy, section III)

[65] See **Commission Decision 96/281** and **Commission Decision 97/98**.

[66] Erstwhile Special Assistant to Frank E. Young, Commissioner of the United States' Food and Drug Administration (FDA); now Robert Wesson Fellow of Scientific Philosophy and Public Policy at the Hoover Institution, and Consulting Professor at the Institute for International Studies at Stanford University, California.

has argued that the difficulties and delays in the drafting and promulgation of a new regulatory framework could have easily been avoided by imitating the more practical solution adopted by the US. Miller, in particular, has claimed that the EU's choice of the more difficult route must therefore be justified by ulterior, anti-biotechnology, political motives. He has long insisted that the EU regulatory framework was built on spurious arguments advanced by interested parties (the "anti-science movement",[67] represented chiefly by ecologists allied to empire-building bureaucrats[68]) under the cloak of science, capitalising on the irrational fears of an uneducated public in order to prevent objective scientific analysis of GMO safety and serve their own interests.[69]

Miller's comments are to be read in the context of a dichotomy that has arisen between "product-based" and "process-based" regulations and in the context of the bitter controversy over whether the first model of regulation is preferable to the second. Proponents of this dichotomy, such as Miller, describe the US regulatory system as "product-based" as the regulatory acceptability of a GMO is said to be based on an assessment of its physical characteristics which dictate whether it is safe to use, as is done for any other product on the market. The EU system is described as "process-based" as the regulatory decision is said to be based on the acceptability of the process by which the GMO was created, and not on the characteristics of the GMO itself. Some proponents of the dichotomy further argue that the US system is rational and "scientific", targeting relevant and real risks that would affect the environment or consumers, whereas the EU system is dismissed as arbitrary and "unscientific", targeting risks that are either irrelevant, because they derive from the process of creation to which there is no wide-spread exposure, or purely conjectural as the risks are not observed in the end products. The EU system is criticised as political as the assessment process takes into account socio-economic factors that do not belong in a risk assessment.

The entire "product vs. process controversy" is rejected by this thesis in Chapter Five as being at the least unhelpful and at the most obstructive to the understanding of the issues that need to be addressed by any discussion of the regulatory control of biotechnology. Miller's views are nevertheless important for two reasons. Firstly, Miller has accused the EU of raising unjustified obstacles against the import of American GM goods ever since the EU announced its proposed regulations.[70] This accusation, in the light of the confusion over the treatment of the mixed imports and over subsequent applications for authorisations for release onto the market, appears to ring true. As discussed above, such unjustified obstacles to imports could be grounds for a trade dispute. Secondly, Miller's view that "process-based" regulatory frameworks are functionally unable to distinguish real risks from conjectural risks raises the concern that the EU framework is unable to achieve its stated aim, which is to ensure safety. It is this concern that originally prompted this study. Again, the difficulties caused by the import crisis offer an illustration of how this prediction appears to be coming true.

The true importance of the question whether the differences between frameworks are "political" hangs on the meaning ascribed to this word. For Miller, "political" is a derogatory term

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[67] **Miller (1993b), p.1075.**

[68] **Miller (1995b), Miller (1996d).**

[69] **Miller (1993b).**

[70] **Miller & Young (1989).**

meaning "arbitrary"; and, in this light, it is argued that such differences would indeed be illegal in international trade law. However, "political" can also mean that differences between the policies of various States are justified on different interpretations or uses of scientific data or on economic, moral or religious grounds. These justifications are legal in international trade law, as long as they meet certain standards, as discussed in Chapter Four.

## 1.5 Examples of the different views on the acceptability of GMOs amongst Member States

The differences in views between EU Member States, and between the Member States and the Commission, concerning the acceptability of GMOs are clearly demonstrated by the controversies that arose concerning the GM soybean and the GM maize. The EU framework was perceived, by governments, industry and the public alike, as a unitary system that would address all aspects of GMO safety. This perception was shown to be wrong by the assessment of the two imported crops: (a) the regulations are not all-encompassing as thought; and (b) the "high level of protection" demanded by the regulations remained undefined and therefore was given different meanings from Member State to Member State.

### 1.5.1 The scope of the EU regulations: defining a "GMO"

As mentioned above, the EU framework has been described as "process-based", which implies that all products deriving from GM processes are regulated in the same way, regardless of their individual characteristics. This is clearly incorrect, as demonstrated by the first wave of mixed grain imports which involved Ciba-Geigy's GM maize. This was, at first, imported in the processed form of gluten for the production of animal feed. There was considerable controversy over whether the gluten was subject to the European GMO regulations or not.[71] The importers of the GM gluten argued that the gluten was not covered by the Directives despite its origins in a GM crop. They claimed that the import of maize gluten was legal because it had been processed:

> "[t]he importers [ . . . ] say the European directive does not cover this material, because heating and mashing has in effect destroyed the genes within it."[72]

This argument conforms largely with the US position on GMOs, where the gluten originated. In the US, GMOs are only regulated if they are "live" or "active" and able to reproduce, or if the transgene is still functional, or if the chemical expression of the transgene is still present in the product of the GMO. If the GMO is "killed" or the transgene or its chemical expression is not present, then the GMO is no longer regulated. The EU regulatory system does not expressly differentiate between live and non-live GMOs as the US does. It is entirely silent on the matter. A recent Council Regulation makes it clear that the Deliberate Release Directive, "does not cover non-viable products derived from" GMOs.[73] Before this was clarified, a decision had to be made as to whether the importers' argument was correct that the EU regulations did not cover non-live GMOs. This question was

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[71] **Burrell (1996a).**

[72] **Cranford & Clover (1996).**

[73] **Council Regulation 1139/98,** paragraph 3 of preamble.

answered by a strict interpretation of the definition of GMO given in both Directives. These define GMOs in terms of an "organism" and define organisms as

> "any biological entity capable of replication or of transferring genetic material".[74]

It is this capacity to replicate or to transfer genetic material that appears to be the essential part of the definition of a GMO for the purposes of the Deliberate Release Directive.[75] This requirement is tantamount to reducing the scope of the Directives to covering only "live" GMOs. With this definition in mind, the description of a "process-based" framework does not appear to fit: a large proportion of products deriving from GM processes are simply not covered. For example, gluten, being processed maize, can be said to be a "biological entity" but cannot be said to be capable of transferring genes. The gluten was therefore able to proceed into the EU without an official clearance as it is not covered by the Deliberate Release Directive.

The strict interpretation of the meaning of GMO would, at first, appear to reduce the differences between the EU and US regulatory frameworks. Their respective scopes would coincide as both would regulate GMOs only if they are "live". However, this interpretation also highlights a major deficiency in the EU framework. Whereas the US framework does not entirely ignore non-live GMOs, and regulates products that are not themselves GMOs in the same manner as GMOs if the transgene or its expression are still in presence, the EU framework would have no provision for products that are not themselves "organisms" for the purpose of the Directives but which may contain a transgene or its chemical expression. This provides for a major, and potentially dangerous, loophole in the regulations:

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[74] **Council Directive 90/220**, Article 2(1).

[75] The UK regulations concerning GMOs reflect the importance of this capacity for the definition of GMOs and their scope (although acellular, unicellular or multicellular entities fall within the definition of "organism" whether or not they have this capacity). The Environmental Protection Act, ss. 106(2) and (3) provide:

> "(2) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form), other than humans or human embryos; and, unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter.
>
> (3) For the purpose of subsection (2) above "biological matter" means anything (other than an entity mentioned in that subsection) which consists of or includes --
>
> (a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material, or
>
> (b) genes or other genetic material, in any form, which are so capable,
>
> and it is immaterial, in determining if something is or is not an organism or biological matter, whether it is the product of natural or artificial processes of reproduction and, in the case of biological matter, whether it has ever been part of a whole organism."

The DOE/ACRE Guidance Note 1, concerning Part VI of the Environmental Protection Act 1990 and The Genetically Modified Organisms (Deliberate Release) Regulations 1992, in Guidance note 3.2, clarify that

> "[t]he only GMOs which are regulated are those with the ability to replicate or to transfer genes or other genetic material [ . . . ]. Non-living GMOs or products derived from GMO processes which are not themselves GMOs - for example, bread made from genetically modified wheat - are not covered. Naked DNA and plasmids are not considered to fall within the scope of regulation because they are themselves not capable of transferring or replicating genetic material."

in order to ensure that its GM crop falls outside of the scope of the Directive, all an importer would have to do is process the GM crop before import in order to render it "non-viable".

### 1.5.2 The concept of human safety: the applicability of the regulations to food

It is this apparent deficiency, amongst others, that causes alarm amongst opponents of biotechnology. The health concerns held by these groups are applicable not only to "live" GMOs but also to the transgenes and the proteins encoded by these transgenes. They hold that processing a GMO does not alleviate any risk the raw GMO may pose to a consumer's health: some processing methods may indeed cause the breakdown of DNA but not of the proteins encoded by the transgenes.[76] It is these proteins that carry the health risk to the consumer, if any.

The stated purpose (in Article 1(1)) of the Deliberate Release Directive is to protect human health as well as the environment. It would appear that, because of the strict interpretation of "organism", a large area of human health is ignored by the Directive. There is indeed not only a major non-explicit distinction in place between "live" and "non-live" GMOs, but also a major non-explicit distinction in the meaning of human safety between safety from environmental exposure to GMOs and safety from consuming GMOs as food. The Deliberate Release Directive only takes into account the former definition of human safety and not the latter. This is demonstrated only by an examination of the list of considerations to take into account when assessing the potential of a GMO to cause harm to humans, as provided by the annexes to the Directive. These considerations are concerned almost exclusively with the GMO's capacity for pathogenicity, that is to say the GMO's infectivity, toxigenicity, virulence and allergenicity (Annex II(II)(A)(11)(d)).[77] Such traits are only relevant when considering the effects of exposure of humans to the GMO, in exactly the same terms as exposure to non-GM pathogens or toxic chemicals.

This particular choice of definition of human safety can be explained historically. When the regulations began their development, GMOs were still laboratory-bound and mostly in the form of microorganisms. Higher organisms, and the safety aspects relevant to their specific characteristics, were not then considered at all, as they were not yet being developed. The regulators' view of GMOs had not changed by the time the Deliberate Release Directive was first promulgated. The Directive has been updated with regard to technical progress, to take into account the characteristics of higher organisms and the specific issues that surround their release to the environment, but it remains essentially concerned with safety in terms of environmental exposure and not with safety concerns relating to the consumption of GM food as this was not envisaged at the time.

The adequacy or otherwise of the Directive for the assessment of GM foods was a central question to the concerns over the second wave of imports involving the imports of GM soybean. Not only was the crop imported as unprocessed grain, it was destined exclusively for human consumption rather than animal feed or sowing. The form of unprocessed grain being considered "viable" for the

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[76] This is recognised in **Council Regulation 1139/98**, preamble para. 18.

[77] The only possible exception to this could be the consideration of the "toxic or allergenic effects of the non-viable GMOs and / or their metabolic products" (Annex II(II)(C)(2)(i)(i)), however, it remains unclear whether these effects are still to be considered in terms of exposure from the environment rather than via consumption as food or not.

purpose of the definition of an organism, however narrowly interpreted, the GM soybean required an application under the Deliberate Release Directive. The GM soybean was granted a permit despite a number of Member States raising objections, by way of a recommendation to the Commission by the Article 21 Committee which stated that:

> "there is no reason to believe that there will be any adverse effects on human health and the environment from the introduction into soybean of the genes coding for glyphosate tolerance and the chloroplast transit peptide; [ . . . ] there are no safety reasons which justify the segregation of the product from other soybean beans; [ . . . ] there are no safety reasons for labelling which mentions that the product has been obtained by genetic modification techniques".[78]

The finding that there are no reasons to segregate the crop conveniently allowed the mixed imports to continue.

As the Directives provide no formal basis upon which the Commission could make a determination that there are "no safety reasons" for segregation or identification of the GM soybean with regard to human exposure to the GMOs via consumption of it as food, and as there was significant disagreement between Member States which prompted recourse to the Article 21 Committee, an unelected, unaccountable and misunderstood body, the general public was not reassured that scientific opinion was clear cut on the matter. Public opposition to this particular import, as explained below, was (and still is) particularly strident as soybean is a very important component of the modern human diet, finding its way into "60 per cent of processed foods".[79]

This particular deficiency of the Deliberate Release Directive has now been recognised, and in part alleviated by the promulgation, in 1997, of the Novel Foods Regulation.[80] This Regulation puts into place the assessment mechanisms for GM foods that were lacking in the Deliberate Release Directive, albeit too late to address the problems caused by the import crisis and reassure the public. Action taken recently by the Commission under the Novel Foods Regulation only confirms that the approval of GM crops with regards to human consumption under the Deliberate Release Directive was inadequate. In particular, Monsanto's GM soybean and Ciba-Geigy's GM maize have been retrospectively submitted to the requirements of the Novel Foods Regulation.[81] Member States have been allowed to label products deriving from these crops as GMOs despite the fact that they were allowed onto the market without such restrictions. The Novel Foods Regulation provides that foods containing a transgene or its protein product after processing are not equivalent to similar foods that do not contain either of these two items, and should accordingly be labelled as containing GM ingredients.

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[78] **Commission Decision 96/281.**

[79] **Abrams (1998a)**

[80] **European Parliament and Council Regulation 258/97** ("the Novel Foods Regulation"). Neither the Contained Use nor the Deliberate Release Directives were concerned with the safety aspects of GM foods. They were destined to govern environmental safety of contained uses and deliberate release of GMOs. The flaw, if any, of the EU framework was the delay in promulgating the Novel Foods Regulation.

[81] **By Council Regulation 1139/98.**

These labelling requirements are not based on safety, as are the requirements of the Deliberate Release Directive, but on consumer information: the consumer is entitled to be informed of any changes in composition of the food, whether these affect safety or not. The Novel Foods Regulation recognises that the safety concerns, whether justified or not, attached to the consumption of GMOs similarly cover live GMOs, processed GMOs and the products of GMOs as long as transgenic DNA or the proteins it encodes may be in presence. This is a considerable change from the narrow view of the Deliberate Release Directive that appeared to prevail in the case of GM maize gluten.

This action is also, potentially, a cause for a trade dispute between the US and the EU. The labelling requirements for GM foods in the EU are significantly different from those in the US, possibly more so than the differences between the safety assessments. The justifications for these differences are disputed by the US authorities, and the retroactive application of the labelling requirements to GM products that were previously authorised may give rise to claims that the requirements are applied in a discriminatory manner.

### 1.5.3 The meaning of environmental safety: the concept of acceptability of harm

The purpose of the Directives is to protect the environment and human beings from harm caused by exposure to active GMOs. Where the Contained Use Directive covers the possibility of accidental release of GMOs from containment and the measures to be taken to prevent this from happening and minimising harm if it does happen, the Deliberate Release Directive regulates the deliberate release of GMOs from containment and the measures to be taken to ensure that the GMOs released do not cause harm.

The concept of harm itself is not defined, but can be deduced by the considerations that are to be taken into account. The environment is to be protected from colonisation by GMOs and from damage caused by the GMO, either directly or indirectly through the transfer outwards of a harmful trait. Human health is to be protected from illness caused by the actions of GMOs and from allergenicity to the GMOs, including, in this particular case, non-viable GMOs and their metabolites. Within these terms of reference, only active GMOs and GMOs capable of reproducing or transferring a hazardous trait introduced by genetic techniques, that is to say "live" GMOs, need to be controlled. This is the purpose for the narrow definition of "organism" given above.

Because harm is not defined in the Directives, the need to prevent harm raises a series of questions that have not been satisfactorily clarified in the context of the imports of mixed grain.

#### 1.5.3.1 How does harm arise?

It is unclear what exactly is meant by a "release" of a GMO. The GM gluten and the GM soybean were treated differently in this regard. A strict reading of the Deliberate Release Directive shows that a product, defined in Article 2(4) as

> "a preparation consisting of, or containing, a GMO or a combination of GMOs which is placed on the market",

is only regulated if the GMOs it consists of or contains are

> "intended for subsequent release into the environment" (Article 1(1)).

Neither the gluten nor the soybean were intended to be released to the environment. They were both intended to proceed, within the physical containment of the containers they were transported in, directly to processing. It cannot be arguable that they would then be subsequently released into the environment in the form of processed cattle feed pellets or in the form of processed human food, as these would not be considered to be GMOs any more due to processing according to the discussion of the definition of a GMO, above. Nevertheless, the GM soybean appeared to raise environmental concerns that the GM gluten did not.

The reason for this is that the soybean was imported in a viable form: unprocessed grain. The authorities were concerned by accidental spillage of viable grain during transit to the processing plant, in case the GM grain took hold in the environment and caused harm. However, the Deliberate Release Directive does not appear to cover accidental releases. The Directive defines "deliberate release" in Article 2(3) as meaning

> "any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment" (underlining added).

The UK, being the Member State where the GM soybean was originally notified for placing on the market, regulates releases to the environment whether they are intentional or accidental.[82] Because of this, the UK authorities decided that the GM soybean fell under the ambit of the English regulations implementing the Deliberate Release Directive and required an assessment. In response to the concerns of the UK authorities, the consent issued by the EU specified, in Article 1(3), that

> "[t]he consent shall cover the following uses of the product: handling in the environment during import before and during storage, and before and during its processing to non-viable products".[83]

In the same way that it was unclear how the Commission came to the conclusion that the GM soybean presented no risk to human health, it remains unclear what considerations the Commission took into account to find that the soybean presented no risk to the environment. The decision could be based on the characteristics of the GM soybean or the relative unlikelihood of it being released to the environment due to the level of containment it will be subject to during transit and processing. The basis of the Commission's decision was never made explicit.

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[82] Article 106(1) of the Environmental Protection Act 1990 provides:

> "This Part has effect for the purpose of preventing or minimising any damage to the environment which may arise from the escape or release from human control of [GMOs]."

Article 107(10) provides:

> "An organism under a person's control is "released" if he deliberately causes or permits it to cease to be under his control [note that this therefore covers "incidental" release, such as spillage of grain] or the control of any other person and to enter the environment; and such an organism "escapes" if, otherwise than by being released, it ceases to be under his control or that of any other person and enters the environment."

[83] **Commission Decision 96/281.**

If the definition of "deliberate release" is to include the possibility of accidental or incidental releases in this way, the assessing authority must be empowered to determine the likelihood of such releases and the adequacy of containment measures, as it does under the Contained Use Directive. These considerations are entirely lacking in the Deliberate Release Directive. This is one of the reasons why the provisions for containment of the Contained Use Directive, which only cover microorganisms in the EU version, have been widened to cover all GMOs by a number of Member States including the UK.

The definition of "intended for subsequent release to the environment" also appears to be a contested issue. A release to the environment of a product, that is not composed of non-viable GMOs or of other products of GMOs that are not GMOs themselves, subsequent to the placing of the product on the market would only cover fresh agricultural produce.

### 1.5.3.2 The acceptability of harm

Aside the matters of causation of harm to the environment, there is also divergence of views within the EU on the nature of harm. This divergence appears to be based on the concept of acceptability of harm. This was most clearly apparent with regard to the third wave of GM crop imports, involving Ciba-Geigy's GM maize once more, but this time in the form of unprocessed grain destined for cattle feed.

Objections concerning environmental impact were raised by the Member States before the Commission approved the crop.[84] These were caused by a new gene conferring pest-resistance on the plant. It was feared that this resistance could spread to wild relatives via pollination and thereby damage the insect population. This argument was rejected by the Commission, upon scientific evidence that this scenario was sufficiently improbable not to warrant not approving the new crop for release. Indeed neither crop has wild relatives in the EU and neither would grow to maturity in the UK. This fear of outcrossing only has relevance where a GM crop of maize could "contaminate" by pollination a crop of non-GM maize, and where this distinction has commercial (rather than environmental) value, such as in the situation discussed in Chapter Two where an "organic" crop was threatened with the loss of its lucrative status should it be so "contaminated". This divergence of views demonstrated that there was a divergence of opinion regarding the probability of outcrossing, on the one hand, and on the acceptability of the consequences of such an outcrossing should it occur. The dispute concerned the point at which the concern would be such to warrant refusing consent to the release. In both cases, the views presented, that the risks were either acceptable or not acceptable, were backed up with scientific opinion. The question must be raised whether the science presented was adequate to back up the regulatory views taken.

It was also feared that the pest-resisting plant could put evolutionary pressure on the targeted pest, the European corn borer, to develop pesticide resistance and become a worse pest. However, the Commission was of the view that

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[84] **Commission Decision 97/98.**

> "possible development of resistance [ . . . ] in insects cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available".[85]

Here too, the Commission presented a very different level of concern regarding this problem compared to the Member States that raised the objections. The EU's level of concern had been diminished by consideration of available techniques for the management of the problem, rather than concentrating on the problem in isolation. This demonstrates a very different approach to the problems raised by biotechnology between Member States and the Commission. One must ask, again, which of these approaches is adequate.

Another concern raised was that the plant's herbicide resistance would have an environmental impact by changing the pattern of usage of the pesticides used on the plant. The Commission stated that the environmental impact of the new maize would be considered separately, as part of the consideration of the new use of the linked herbicide, through normal regulatory channels for pesticides:

> "Whereas authorization of chemical herbicides, and assessment of how their use impacts on human health and the environment, are governed by Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market as last amended by Commission Directive 96/68/EC, and not by Directive 90/220/EEC."[86]

The Commission had effectively sidestepped the issue, but made reassuring noises to placate the environmental lobby:

> "[t]he impact on human health and the environment from the use of one herbicide on the genetically-modified maize will be assessed before authorisation is given for its use on [Ciba-Geigy maize]".[87]

Objections concerning human health were also raised against approval of the GM maize with regard to the presence in the plant of a gene for resistance to the antibiotic ampicillin. The function of this gene predates the production of the GM plant. It is a bacterial promoter (i.e. only has function within the bacterial genome) used as a marker to detect bacterial cells which have taken up the desired transgene, bacterial cells which are then used to introduce the transgene into plant cells. Plant cells which have taken up the transgene are then selected using another marker and are grown into GM plants. Because the gene could easily have been removed, and the controversy would therefore not have arisen (at least amongst the regulatory authorities), the development of the GM maize has been dubbed "sloppy genetic engineering"[88] by UK experts.

Fears were expressed that the ampicillin resistance gene may cause bacteria in the gut of cattle to acquire antibiotic resistance through absorbing the novel gene, as the crop was at first destined to be

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[85] Idem, in the preamble.

[86] Idem.

[87] **Cranford & Clover (1996).**

[88] **Cranford & Clover (1996).**

used as animal feed; this in turn could compromise the treatment of disease in cattle and possibly in the human population. This concern raised a very indirect way in which a GMO may cause harm to human health, and one that is not covered by the Directive's annexes. Furthermore, it also bypasses the strict definition of a GMO, discussed above which emphasises the ability of the GMO to transfer genetic material.[89]

The response to this concern demonstrates differences in views on the problem's acceptability rather than differences over whether the concern reflects a real problem or not. Ciba-Geigy argued that the problem was not novel.[90] Antibiotic resistance is already a problem due to the over-use of antibiotics in the farming industry. An additional use of antibiotics would not present an additional hazard. Furthermore, Ciba-Geigy was confident that any bacterial ampicillin resistance could be overcome by constantly developing modified versions of ampicillin. This demonstrates a difference of opinion regarding the acceptability of the problem. The Commission appears to have accepted these arguments and simply rejected the concerns on the basis of probability: again, the Commission and the Member States demonstrated different views on the acceptability of the risk of ampicillin resistance becoming a widespread problem.

### 1.6 Points raised by the import of mixed crops

The extent of the controversy surrounding the commercialisation of the products of biotechnology leads to ask whether the current regulatory frameworks for biotechnology in Europe are adequate to ensure the safety of the consumers of these products and of the environment as a whole, or whether the complexities of the debate have adversely affected the ability of the authorities to ensure this goal. A further question must be asked, in view of the highly emotional and volatile nature of the debate surrounding biotechnology, whether the regulatory frameworks can also restore the consumer's confidence in their effectiveness.

It is clear from the discussion above that the aim of a regulation must be made clear before the adequacy of the measures taken, the requirements placed on the regulated products or the powers of the authorities, can be established. Two examples of this can be given, as shown in the following chapter.

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[89] The fear that naked DNA, present in the gut of cattle as the GMO containing it is broken down by digestion, could be absorbed by another organism (so-called "passive" transfer) has no scientific basis.

[90] **Cranford & Clover (1996).**

## Chapter Two: The Uncertainties Caused

The regulatory inadequacies revealed by the import of mixed consignments of GM and non-GM crops into the EU have caused, or at least contributed to, a climate of uncertainty surrounding biotechnology and its regulation.

### 2.1 The uncertainty amongst the public

Unsurprisingly, due to the confusion amongst the regulatory and scientific authorities as to whether the imports of GM crops were legal or not, and whether they were sufficiently safe or not, the wider public became alarmed at the prospect of vast imports of potentially illegal and potentially unsafe GM foodstuffs finding their way into the majority of the food products on the supermarket shelves.

#### 2.1.1 Postulated reasons for public hostility

The strength of the public's reaction has left the industry[91] and commentators baffled. Many explanations have been advanced, including the following:

Firstly, it has been argued that the public, being "scientifically illiterate", is prey to irrational hysteria when faced with unfamiliar issues.[92] It has been further argued that this problem can only be palliated by a comprehensive and vigorous public education programme led by governments,[93] whilst keeping the decision-making process within the hands of experts.[94] This argument demonstrates a dramatic misunderstanding of the motivations of the public and a political paternalism that is totally unacceptable in a modern democracy. It is completely out of step with the development of regulatory risk assessment, which is increasingly geared to involving stakeholders and providing the public with a high degree of openness and accountability. Some of the commentators in this group also argue that this education programme must not be interfered with by overloading the public with information, especially on food labels.[95] These commentators explain their view by stating that labelling GM

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[91] For example, Unilever, the parent company of the "Batchelors" range of processed foods, voluntarily labelled one of its products as containing GM soybean derivatives at a time where few other products out of the hundreds using GM soybean were so labelled. This caused a demonstration by Greenpeace and Friends of the Earth outside a Safeway supermarket selling the product. Unilever complained that they "did what everybody was asking [them] to in declaring that a product has GMO contents" but received only criticism for their troubles: **Schoon (1998)**.

[92] **Miller (1993b)**, at p.1075.

[93] **Miller (1995d)**, p.65.

[94] **Miller (1984), Miller & Huttner (1991), Miller (1993b)**, at p. 1075, **Miller (1994b), Miller (1995b)**. However, Miller has not been consistent in this argument. Although he argues that a regulatory agency tasked to oversee developments in biotechnology would "in the absence of real issues [ . . . ] be tempted to become a busybody, imposing [ . . . ] restrictions best left to regulation at the local level" **(Miller (1984))**, he argues that the NIH RAC was ideally placed to review all the issues arising as it "boasts a nice balance among scientists, physicians, attorneys and other lay people" **(Miller (1984))**. Miller further argued that "government cannot perform regulatory oversight of scientific and commercial endeavours in a vacuum. [It requires] the advice and criticism of academics and of the public" **(Miller & Young (1986))**.

[95] **Miller (1993b)**, p. 1075. Miller further argues that "[a]ntibiotechnology activists deluge the public with irrelevant, untrue, or (still more pernicious) partly true information that leaves the non-expert bewildered, leading to snap decisions and poor judgement. Overabundant information, especially when it involves emotionally laden and lurid scenarios, has another drawback. It may encourage some of the

products confuses consumers, prevents them from making informed choices and from expressing their confidence in biotechnology in the marketplace. These arguments are simply self-contradictory and must be rejected out of hand. It is impossible to express a choice in favour or against a given product in the marketplace if the product cannot be identified.

These views nevertheless are important as they raise the issues of consumer information and whether this information should be presented as part of product labelling requirements, which are discussed below.

Secondly, it has been argued that the public does not understand the concept of risk.[96] Numerous studies demonstrate that the public, like educated experts but more so, tend to underestimate familiar risks and to overestimate unfamiliar risks.[97] This causes the public to worry more about vanishingly small risks, such as illness caused by GM foods of which there is no evidence at all, and to ignore very serious risks, such as food poisoning from inadequate kitchen hygiene which affects tens of thousands of people a year and is on an alarming increase. This argument is largely correct insofar as it describes the results of empirical studies. However, it fails to provide an explanation as to why the public's view of risk is so, and what should be done about it.

Finally, it is claimed that the ignorant public is manipulated by organised opposition to biotechnology.[98] Opposition movements are accused of confusing the issues and using inflammatory tactics (such as vandalising crops[99]) to prevent the public from making rational decisions concerning the acceptability of GM foods. It is true that sensationalist views presented in the media can harm the debate over biotechnology, but to place all the blame for the public's apparent rejection of biotechnology on the convenient scapegoat of "environmentalist manipulation" is a weak and self-deluding argument. Furthermore, the argument, taken *a contrario*, implies that the public would be

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public who are interested in the subject but inexpert, to focus on unusual and dramatic aspects of the problems instead of on representative data and statistics"(at p.1075).

[96] **Miller (1993b)** argues that the general public has a tendency to "underestimate familiar risks [such as "using a chain saw or riding a motorcycle" which present risks that are "relatively clear and comprehensible in their nature"] and to overestimate risks that are unfamiliar, hard to understand, invisible, involuntary and / or potentially catastrophic [examples of which include "electromagnetic radiation or trace amounts of pesticides in foods"]" (at p. 1075). He further argues that the public does not understand the concept of alternative risk (i.e. the risk of not using new technology and of persevering with older, less safe technology).

[97] For example, **Morgan & Henrion (1990)**, pp.102-140; **Glickman & Gough (1990)**, pp. 5-41, 55-74; **Sandman (1993)**.

[98] **Miller (1993b)** argues that "environmental organisations, political leaders, and the media profit by raising levels of fear, suspicion and anxiety [ . . . ]. [M]any regulators have regarded public apprehension as a meal ticket" (at p.1076). He exposes the "dishonest" antitechnology ideologues as people who are "seldom either educable or misinformed; rather they are waging a calculated campaign against the new technology, for reasons that are naive, self-serving, or both. No strategy is out of bounds to them - they threaten, misrepresent, and litigate" (at p. 1076). Miller argues that the "antitechnology ideologues" demonise their adversaries as the enemies of the public and projecting "onto <u>them</u> culpability and iniquitous intentions. [ . . . ] These mechanisms may be especially easy when the "enemy" is painted as faceless, profit-hungry, multinational companies that will benefit from selling the products of new biotechnology" (at p. 1075).

[99] See **Miller (1996d)**, p. 362.

able to make rational decisions in the absence of manipulation, which contradicts the basic premise of the public's ignorance. This argument too must be rejected.

Organised opposition to genetic modification has undoubtedly seized upon the uncertainties concerning biotechnology, easily using them to further its cause which is wider than simply opposition to biotechnology. Demonstrations by pressure groups dominated the news in the early days of the mixed import quandary. Greenpeace attempted to prevent imports of GM crops by climbing onto the cranes that were to unload the commodity.[100] Other protesters disrupted the final news conference at the UN-sponsored World Food Summit in Rome, by attempting to eat the summit declaration; others embarrassed the US Agriculture Secretary by protesting naked against GM soybean.[101] More extreme reactions have occurred: soybean silos containing mixed-in GM crop from the US have been attacked by saboteurs who claimed to have poisoned the batch to prevent it from being consumed, although this was probably a hoax and a word-play on the belief that the GM nature of the crop itself is the contaminant. The company involved condemned the "irresponsible and criminal act"[102] that would have been committed if the scare had been real, but some environmental groups, including Earth First!, regrettably applauded the action[103] demonstrating the extreme nature of some of the views in contention. As the number of GM crop trials increases in this country, so too do the number of trial sabotages organised by the environmental movements.

However, the concerns of the public generally, and the environmental groups do not entirely coincide. It is arguable that the wider public shares some of the environmental concerns of the environmental movements, but their concerns are mostly based on other issues that are much wider than the controversies over biotechnology. Very few attempts have been made to understand the reasons of public hostility, as opposed to environmental opposition, towards biotechnology. This has led to much of the biotechnology debate ignoring the considerable commonality of issues presented by proponents of biotechnology and the general public.

### 2.1.2 The issue of segregation of GM products

Where purely environmental concerns (i.e. relating to harm that GMOs may cause to the natural environment or to human health) are shown to be unlikely to be realised (for example, the risk of outcrossing where there are no wild relatives), opponents of biotechnology concentrate on the acceptability of GMOs as human food. A ban on the end-use of the GMO would be effective to halt its production. Calls have been raised for bans on GM food, for moratoriums for research and for the segregation of GM products from conventional products in order to allow members of the public to express their right to chose whether to consume these products or not. The segregation issue is a good illustration of the need to understand the purpose of a measure, namely segregation, in order to determine whether the measure is commensurate with the objective sought.

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[100] **Schoon (1996a) and (1996b).**

[101] **Anon. (1996a).**

[102] **Arthur (1996b).**

[103] **Arthur & Schoon (1996).**

#### 2.1.2.1 segregation for safety purposes

Opponents of biotechnology claim that GM foods be harmful to human health when consumed as food, as they allegedly have not been subjected to a rigorous testing programme to discover their possible harmful effects. Therefore opponents demand either a complete ban on GM foods, or a moratorium on their commercial production until testing can be carried out, or, at the very least, segregation of GM foods from conventional foods, so that individuals who are willing to undergo the risk of consuming an unproven product may do so whilst those that are not so willing are not subjected to what is often described as human experimentation without their consent.

A ban on GM foods, imposed before any harm has been caused by them, can only be justified if it is demonstrated that there is sufficient probability that harm will be caused to override the rights of the persons wanting to produce and sell GM foods. There is no such evidence in the case of GM foods so far, and so a ban cannot be justified.

Similarly, a moratorium must be justified, although the justification is different. In this case, it must be demonstrated that harm may be caused by the GM food, and testing is required to establish whether harm can indeed be caused, whether the probability of this harm is within acceptable levels, on the one hand, and whether the consequences of this harm are within acceptable levels, on the other. The difficulty is establishing the nature of the harm to be investigated and the levels at which the harm may be considered acceptable before proceeding. A moratorium, which implies a temporary measure, cannot logically serve any other purpose. A precise accusation must be made and tried. If the accusation is borne out, the ban becomes permanent. If it is not, then matters resume their course as before the moratorium, with whatever conditions that may have been proven necessary without justifying in themselves or severally that a permanent ban be put into place. In the case of GM foods, no convincing preliminary case has been made concerning either the nature of the harm that may be caused or the levels of acceptability to accompany the calls for a moratorium. With regard to environmental impact, a number of concerns have been clearly expressed, for example whether GM crops could become weeds. With regard to the consumption of GM foods, no convincing claim has been made that a particular type of harm may be caused to humans and calls for a moratorium are based on the possibility of unknown dangers being discovered when it is too late to counter them.

The demand for testing of GM foods is unusual as generic testing of foods before their release onto the market is not the norm in European law. Food producers are under a general legal duty to ensure the safety of their foods and it is up to them to discharge their duty, which often involves extensive research and development including safety testing. Only certain specific foods (such as infant mixtures) and certain specific ingredients (such as artificial colours and preservatives) are regulated under specific food safety laws, and this only when the harm they may cause is known and not just conjectural. The demand for generic testing of GM foods has therefore been accused of being contrary to legal tradition, which is characterised by an "innocent until proven guilty" attitude. It has also been claimed that testing a product for unknown characteristics is unscientific, irrational, and most importantly – impossible.[104] The Novel Foods Regulation is a departure from legal tradition in the EU

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[104] **Miller & Gunary (1993).**

in that it provides for an assessment mechanism that covers all aspects of all novel foods,[105] whether GM or not, prior to their release onto the market. It is part of a wider shift towards precautionary legislation in the EU.

The Consumer's Association has called for segregation of GM products as part of an ongoing monitoring programme to keep track of GM foods and ingredients, assess their safety and allow for recalls if a product shows signs of a safety concern.[106] If there is no segregation of GM products, they will remain untraceable. Monitoring for problems and taking action if a problem arises would therefore be impossible. This would also be a departure from the norm, at least regarding normal practice for foods. However, monitoring and traceability of all foods, whether GM or not, is a real possibility in future. Unprocessed foods are not considered "products" for the purposes of European consumer protection law, a position that seems abnormal. There are moves to abolish the exemption given to agricultural produce, which would impose strict legal responsibilities on producers and distributors than can only be discharged by developing traceability measures for all foods. Food safety is an area of law on the brink of major changes that are unprovoked by biotechnology, but the need for which is clearly illustrated by the concerns raised by biotechnology.

#### 2.1.2.2 segregation and the issues of trust in the food safety authorities, consumer choice and product labelling

The issue of public understanding of risks, mentioned above, is extremely important, especially when regulatory authorities make a decisions concerning the acceptable level of safety on behalf of their citizens. It was shown in Chapter One, for example, that the question "How safe is safe enough?" received a number of different answers with regard to the possible development of ampicillin resistance in bacteria. If the public is unable to understand the basis of the regulatory decision, they are unlikely to accept it, as shown by the continuing difficulties over the BSE crisis. Similarly, as the authorities have not been able to demonstrate the absolute safety of GM foods in the face of constant criticism, the public remains concerned about risks.

According to the supermarket chain Iceland, consumer opinion on GM foods has been strongly negative[107] and several food retailers in the UK are now taking a strong stand against GM crops. Iceland has taken the most negative view of GM soybean and has declared its intention to reject food which may contain it and guarantee its own-label goods to be GM-free on grounds of human safety. The company's management has claimed that the introduction of such crops is

> "probably the most "potentially dangerous" development in food production this century".[108]

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[105] Novel foods are defined by Articles 1(2) of the Novel Foods Regulation as, amongst others, foods consisting of or containing GMOs, foods produced from but not containing or consisting of GMOs, modified foods, foods isolated from certain species, foods that do not have a history of safe use, foods that have been subjected to a novel process, as long as these foods cannot be demonstrated as being equivalent to a non-novel food.

[106] **Abrams (1998a).**

[107] **Arthur (1998).**

[108] **Irwin (1998).**

It has described the introduction of GM products without clear labelling as "unacceptable and frightening",[109] claiming that

> "[m]illions of ordinary people are very worried about genetically modified foods".[110]

Iceland imposed its own ban on GM products, declaring that it will rely on dwindling but "totally traceable"[111] resources of non-GM soybean for its products. Many other retailers have followed suit, but not with the same purpose. Rather than rejecting GM foods entirely, they call for a moratorium until the foods are proven safe. Their bans on GM foods, are simply to reassure consumers rather than protect them.

It is widely acknowledged that there is little consumer trust in the regulatory authorities. For example, the Consumer's Association has pointed out that

> "[t]he difference is that in the States they trust the Food and Drink Administration. Over here, because of the crises we have had there is a general distrust".[112]

Opinion polls show that environmental movements are trusted by the public, whereas government officials are not, and that they greatly influence public opinion in Europe.[113] The wisdom and integrity of government and industry scientists are increasingly challenged by consumers, who no longer trust these institutions to make risk choices on their behalf. Consumers are increasingly intent on seeing that regulatory authorities discharge their duty to protect the health of consumers, rather than pander to the desires of the food industry.[114]

A lack of trust in the regulatory authorities can only be expressed by consumers by their purchasing habits: if they do not believe a particular product is safe, they will avoid it. However, GM foods present two problems: firstly, they are generally indistinguishable from conventional foods, unless they are modified specifically to have an unusual characteristic (e.g. unusual colour, shape, taste or even totally unusual characteristics, such as luminosity); secondly, GM commodity crops are processed into foods so that their presence is undetectable without specialist equipment. It is essential for the consumer to be able to identify the product he or she wishes to avoid. This is the issue that causes the most concern. For example, other GM products have been present on supermarkets shelves without creating such opposition: paste from GM tomatoes and cheese made with GM-produced rennet have been clearly labelled as genetically modified, giving the consumer the choice whether to purchase

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[109] **Arthur (1996c).**

[110] **Arthur (1996c).**

[111] **Schoon (1998).**

[112] **Abrams (1998a).**

[113] **Galvin (1998)** includes part of a Europe-wide poll (no precise indication of source or date was provided) of consumers indicating that 23% trust environmental organisations to "tell the truth", and 17% trust consumer organisations; whereas only 4%, 3% and 1% trust the media, national government, and industry respectively, to "tell the truth".

[114] **McIlroy (1996).**

them or not.[115] With regard to the unlabelled and untraceable nature of the imports of GM maize and soybean, the chairman of Iceland declared that

> "[i]t is totally unacceptable that American companies should dictate to us in this way. We must demand total traceability for all food and clear labelling."[116]

In January of 1998, the British Retail Consortium ("BRC"), representing ninety per cent of retailers, declared that it would abandon its requests to US soybean producers to segregate the GM varieties from the non-GM varieties. Despite its stated preference for segregation of GM crops, it was "giving up the fight"[117] and admitting economic defeat. The American Soybean Association ("ASA") had decided that it

> "would be too expensive for its members to separate out the genetically engineered crop",[118]

from the non-GM varieties. It did not rely on the argument that such a separation would be physically impossible, nor did it claim that it would be too expensive and thereby unfair for the consumer. The ASA relied on the belief that it is easier to label all soybean products as containing GM soybean, even if they do not, and to conduct a massive publicity drive to regain the consumer's trust in GM products. Retailers are nevertheless unhappy that their pledge to the consumers to label all GM products in their stores has been made impossible to fulfil by the US's refusal to segregate exported GM crops from normal crops.[119]

This situation caused a recrudescence of public opposition. Other supermarkets, such as Sainsbury and Asda had taken a less radical position than Iceland or the BRC and were relying on purchasing policy to provide alternative sources of unmodified crops. This clearly was not going to be enough to answer public fears. Consequently, most supermarkets have now pledged to remove all GM products from their shelves whilst making it clear that they are not doing so out of any belief that GM crops are unsafe, but in order to satisfy customer demand. This causes a spiralling situation: the public is further alarmed by the retailer's response to their concerns.

The question of labelling is one that is wider than the GM crop issue. Labelling of food, whether GM or not, is often insufficient, unclear, or purely wrong. The current regulations for food labelling, where applicable, do not cover a number of hidden additives such as dyes fed to fish or chicken to enhance their colour[120] or deal with standard industry practices the consumer would certainly object to.[121] Major difficulties concern, for example, unproven health and nutrition claims.

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[115] See the discussion in **House of Lords (1998)**, Q80-83.

[116] **Arthur (1996c).**

[117] **Abrams (1998a).**

[118] **Arthur (1996a).**

[119] **Arthur (1996a).**

[120] These are not considered as controlled additives to a food, as they are fed to the unprocessed animal, nor are they considered a controlled veterinary substance as these substances have no medical effect on the animal; therefore a number of such substances are not controlled at all: **Anon. (1998).**

[121] These often dubious practices are aimed at producing benefits for, or reducing the costs of, the food processing industry rather than producing benefits for the consumers. For example, soybean derivatives are used in meat processing: soybean extract in brine is injected into meat to make them

The entire area is in disarray. The new Food Standards Agency has been set up in order to address these problems,[122] but it is too soon to pass judgement on its efforts. This thesis cannot address the wider issues of labelling as it concentrates on aspects of GM food safety. However, the labelling of GM foods depends, in part, on safety matters as well as consumer information. The acceptability of labelling, as a barrier to international trade, depends on the justification given for it. The strict labelling requirements imposed by the Novel Foods Regulation must function in a very uncertain environment, and are open to accusations of arbitrariness and inefficiency from critics on both sides of the fence. It has been claimed that the Regulation contains loopholes that will do nothing to reassure the consumers,[123] and that the Government's interpretation of the Regulation results in the majority of GM foodstuffs not having to be labelled, as the Government believes that only living GMOs in food products will have to be labelled:

> "products which had been processed so that the GMO was killed and its genetic material damaged would need no label".[124]

The Regulation had been hoped to remedy the problem but it apparently fails to live up to its aim as it does not provide for food traceability or clear labelling.[125]

#### 2.1.2.3 is segregation commensurate with the concerns expressed?

As mentioned above, measures such as bans and moratoria must be justified. So must segregation. The justification of segregation depends on whether it commensurate with the concerns expressed. Segregation has a particular meaning and must be distinguished from crop purity measures and identity preservation.

There are no requirements for segregation of GM foods from conventional foods, either in the EU or in the US. Segregation of GM crops is not a mandatory requirement, but can be imposed as part of the permits issued, both in the EU and in the US, for research and development.[126] In both the US and the EU, once a GM crop has been approved for commercial release to the environment, there are no more requirements for segregation.[127]

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draw in water and increase in bulk. The consumer is meant to benefit by lower prices in meat, but there is no guarantee of this, nor is there a guarantee that the consumer would agree to this trade-off between price and quality: **Schoon (1996b)**.

[122] **Anon. (1998).**

[123] **Schoon (1996c).**

[124] **Schoon (1996c).**

[125] **Arthur (1996c).**

[126] The requirements of segregation during experimental trials can be imposed in the US by the USDA and the EPA, respectively, under their GMO regulations and by the European competent authorities or the Commission under the Deliberate Release Directive.

[127] In the US, this is achieved by a registration procedure under the EPA's rules (once registered, a GMO can be used freely without regulatory oversight, within any restrictions imposed as part of the registration), and by a deregulation procedure under the USDA (whereby a GMO is no longer regulated by USDA provisions). In the EU, this is achieved by a permit for the placing of a GMO on the market under the Deliberate Release Directive. The permit may nevertheless contain restrictions on use.

The justification of segregation, in relation to the stated aims of the Deliberate Release and Contained Use Directives appears to be a desire to avoid the possibility of gene transfer between the GMO and non-GMOs. Segregation is appropriate to achieve this aim in the field but is not appropriate for grain in transit, and even less so once the grain has been processed, as cross-pollination cannot occur. It is to be noted, however, that segregation cannot achieve total prevention of cross-pollination. This is recognised by international crop purity standards which allow for a degree of cross-pollination which is effectively a form of gene transfer. These are justified by a concern to maintain the quality of the crop as a product, not safety.

It has been noted above that varieties of commodity crops, in particular soybean, are often mixed together for transit, be they GM or not. It is important to understand in this context the difference between "segregation" and "identity preservation". Different varieties of the same commodity crop are not separated during transit unless there is a well-defined commercial reason to do so. The reason for this is that the slight differences in the characteristics of the varieties of the crop matter little to the end-consumer's enjoyment of the processed food product into which they are incorporated. They are generally important only to the grower, to the transporter or to the producer of the processed food. For example, agronomic characteristics such as natural resistance to pests, drought, or adverse soil conditions will allow the farmer to pick the variety that will grow best on his land and which will maximise the yield (and therefore the profit) from his harvest. Other characteristics such as ripening speed, timing of ripening and resistance to the stresses of transport allow the transporter of the crop to minimise the losses that occur through damage in transit. These characteristics will generally not affect the taste or consistency of the end product these crops are incorporated into. The traceability of the origin of these crops is, commercially at least, unimportant. Producers along the chain generally only know their immediate supplier and their immediate client. However, where the crop is sold as an end-product itself, its variety becomes an important factor of consumer choice, as witnessed by the bewildering array of dried beans that can be purchased in supermarkets today or by the growing importance of certified regional products. Certain crops are also developed specifically to enhance the taste, colour or texture of the end product, and the identity of their variety becomes highly important for the final purchaser who, in this case, is the producer of processed foods. In these two cases, individual varieties are kept separate in order to ensure that the added value derived from the identity of the variety is protected, and traceability is all-important. In both cases, the varieties of the crops are grown separately in the field. This must be distinguished from segregation of crops in the field, and the identity preservation mentioned above[128] must be distinguished from segregation in transit.

## 2.2 The uncertainty amongst environmental organisations

It would appear, from the increasing numbers of crop sabotage incidents, that some environmental movements favour the destruction of all GM crops, whereas others call for more testing of GM products, which is the very reason for these trials. Opponents to biotechnology are not presenting a united front with regard to presenting solutions to their concerns. This is due to

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[128] **House of Lords (1998)** uses the terminology "identity preservation" to describe the traceability (and therefore segregation) of GM crops demanded by critics of the industry: see para. 133. This terminology may cause confusion in future and will need to be formalised.

uncertainty as to the nature of the concern as much as uncertainty as to what measures may be taken to alleviate these concerns. The correlation between the concern and the measures proposed to address it is essential in law, as demonstrated by the following study.

The question whether destruction of a crop is a commensurate legal remedy to concerns arising from the GM nature of a crop has been tested by the Court of Appeal in the *Watson* case.[129] This case has attracted a large amount of attention, not only because the farmer's cause was supported by respected organisations such as Friends of the Earth and the Soil Association, but because it was the very first judicial consideration of the relevant sections of the Environmental Protection Act 1990, which governs GMOs, and also because it has put in jeopardy the validity of all new plant trials, be they GM or otherwise, of the last five years.

### 2.2.1 The facts of the case

In this case, the applicant, one of Britain's largest organic farmers challenged the decision to allow a GM maize trial to take place near his land. His concern was that the GM maize would pollinate his own maize crop with the effect of cancelling its "organic" status under the rules of the Soil Association, which provides the organic accreditation vital to his business. The Soil Association takes an extreme position with regard to the accreditation of its members:

> "Not merely would the organic status of the applicant's present sweet corn crop be imperilled; so too would the rest of his farming enterprise".[130]

The crop trial concerned a variety of GM maize being developed by Sharpes International (now known as Advanta Holdings). It was one of several being conducted by the National Institute of Agricultural Botany ("NIAB") on behalf of the Ministry of Agriculture, Food and Fisheries ("MAFF") under an arrangement made between MAFF and the British Society of Plant Breeders ("BSPB") for the purposes of applying for inclusion on the National List of varieties, a step vital to commercialisation in the UK. These trials are undertaken under The Seeds (National Lists of Varieties) Regulations 1982 ("the Regulations"),[131] and in particular Regulation 11(1). Their aim is to establish

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[129] R v. Secretary of State for the Environment, Transport and the Regions *ex parte* Watson [1999] Env. L. R. 310. Information obtained from Brown LJ's draft judgement, dated 21 July 1998 prior to reporting, hereafter the "*Watson* Transcript". This document was obtained via Dr. J. Kinderlerer and Mr A. Mackersie, Clerk to the House of Lords European Communities Committee.

[130] *Watson* Transcript, at p. 6.

[131] The relevant Regulations, as presented by Brown LJ, are:

*5(1) At any time after the publication of a National List the Ministers may-*

*(a) entertain applications from persons seeking additions to ... any such List and may, subject to the following provisions of these Regulations ... grant or refuse such applications ...*

*11(1) The Ministers shall conduct or make arrangements for such tests and trials of a plant variety which is the subject of an application for entry in a National List as appear to them to be necessary to establish that it conforms to the requirements of Schedule 2.*

*11(3) ... no application shall be entertained for the entry in a National List of a variety of* ... [maize was specifically added to the list by amendment in 1990] ... *unless in each case the applicant submits to the Ministers with the application the results of two replicated trials conducted in the United Kingdom* [the words "or a Member State" were deleted by the 1990 amendments] ...

whether the variety conforms with Schedule 2 of the Regulations, that is to say whether the variety is "distinct, uniform and stable" ("DUS") and has "value for cultivation and use" ("VCU"). These characteristics are essential for entry on the National List.

As this trial necessarily involves the release of GMOs under section 107(10) of the Environmental Protection Act 1990 ("the Act"), it had to be

"in pursuance of a consent granted by the Secretary of State" (section 111(1) of the Act).

This permit was granted to Sharpes.

Because of the threat to his organic status, the applicant requested of MAFF, firstly, that the trial not be commenced, and secondly, once this request was rejected, that the permit granted to Sharpes be revoked or varied to take into account his concerns. In response, the Advisory Committee on Releases to the Environment ("ACRE") advised MAFF, and the applicant, that the threat of cross-pollination to his crop was minimal. Accordingly, MAFF and the Department for the Environment, Transport and the Regions ("DETR") notified the applicant their decision not to vary or revoke the consent.

The applicant applied for judicial review of this refusal. The application was at first turned down by the court, but the applicant appealed and the appeal hearing was treated as the substantive hearing for judicial review. As the trial had, in the meantime gone ahead, the applicant sought an order that the plants be destroyed before cross-pollination could take place, as they were grown contrary to law. In support of this motion, the applicant presented three arguments:

(a) The DETR and MAFF's decision to refuse revocation or variation of the consent granted under the Act, in reliance on the advice that the amount of cross-pollination "was likely to be zero", was irrational.

(b) The continuation of the plant variety trial was contrary to law because:-

(i) of a breach of the provisions of the Act: the consent holder for the purposes of the Act was Sharpes, and not NIAB who were carrying out the trials on behalf of MAFF, and that therefore the trial was not pursuant to a consent under the Act;

(ii) of a breach of the provisions of the Regulations: these prohibit MAFF from entertaining an application for inclusion on the National List, let alone carrying out tests in pursuance of the application, if there had not been two previous trials the results of which must be submitted with the application for entry on the list. In this particular case, these preliminary trials had not taken place, as MAFF had stated its policy of no longer requiring them, and therefore MAFF had entertained the application illegally.

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*12 The ministers shall refuse an application for entry of a plant variety in a National List if it appears to them that-*

*(a) the variety does not conform to the requirements of Schedule 2 ...*

### 2.2.2 The irrationality argument

The applicant claimed that the government's reliance on ACRE's advice was irrational. He claimed that the advice given was

> "too narrow an approach which does not adequately address the actual degree of risk nor the consequences were that risk to eventuate".[132]

Specifically it does not take into account the

> "devastating effect on the applicant's business, reputation and livelihood",[133]

due to the Soil Association's absolute stance on the matter.

The court could not express an opinion on the correctness of either ACRE's advice or the Soil Association's absolute stance. It could only decide whether the decision of the government to follow whatever advice given to it was reasonable.

ACRE advised that there was no reason to stop the GM maize trial as there was no threat to the environment or to human health. The particular variety had already been approved for marketing under the Deliberate Release Directive. ACRE considered the possibility of cross-pollination and estimated that, on the basis of a standard separation of 200 metres between the GM and organic crops, the worst case scenario of the two crops flowering at the same time and the wind blowing in the direction of the organic crop would not result in more than one kernel (as opposed to cob) in every thousand being a GM hybrid. This worst measure would still be compatible with the Basic Seed standard of 99.9% purity set by the UK Seeds Regulations, EC Seeds Directive and OECD Maize Seed Scheme.[134] Taking into account the original placing of the organic crop alongside the trial site, and the lay-out of the site, ACRE estimated that not more than one kernel in every 40,000 would be a GM hybrid. As the applicant had moved his organic crop more than two kilometres from the trial site in this particular case, the likelihood of a single kernel in the entire crop being a GM maize hybrid is effectively zero. ACRE affirmed that it was

> "sensitive to the concerns of organic farmers but considered that it was not for [ACRE] to decide what level of cross-pollination might be considered by organic standards representatives to compromise the organic status of the sweetcorn".[135]

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[132] *Watson* Transcript, at p. 6.

[133] *Watson* Transcript, at p. 6.

[134] Note that the Court did not refer to the EU Directive defining organic products (2092/91). In its format of the time, this Directive required that only 95% of the ingredients of an organic product needed to comply with the Directive's provisions for the organic status to be granted. See **House of Lords (1998)** Minutes of Evidence for Wednesday 3 June 1998, Memorandum by Zeneca Agrochemicals and Zeneca Plant Science, para. 12. Clearly the Soil Association demanded a higher level of protection than is recognised by law: this is another argument in favour of the government's decision.

[135] **DETR (1998), p. 3.**

The only standards that ACRE could consider within its remit were the crop purity standards, as a relative measure of the tolerances that could be used by the organic accreditation bodies. The court found that this was

> "a perfectly reasonable point at which to strike the balance between the competing interests in play".[136]

As even the worse case scenario considered produced a result which would

> "surpass by a considerable margin all internationally recognised standards for seed purity",[137]

the court found that the decision by the government to allow the trial to continue, on the basis of this advice, could not be said to be irrational.

The court found that ACRE's advice to the government was adequate in that it was a "confident assessment of minimal risk", not in that it was necessarily correct. No opinion was expressed on the reasonableness of the assessment of harm to the applicant, but it is almost implicit that the court found the Soil Association unreasonable in rejecting the standard referred to by ACRE's advice.

This matter of reasonableness is central to the understanding of the concept of "safety". Safety cannot be taken as an absolute concept, or a single measure: it can only be seen, in law but this is true in science and in philosophy as well, as an acceptable balance of competing interests.

### 2.2.3 The alleged breach of the Act

This argument turned on a simple matter of statutory interpretation. The applicant claimed that the body conducting the crop trail, NIAB, was not the beneficiary of a permit under the Act to release GMOs, which was granted to Sharpes, and that the crop trial was therefore in breach of the Act. The court found that the words of the Act are clear: section 111(1) states that

> "no person shall release any [GMOs] except <u>in pursuance of</u> a consent granted by the Secretary of State" (my emphasis),

which means that the identity of the consent holder is immaterial as long as a permit is in existence and the release is connected to that permit. This would cover, for example, releases by an employee of the consent holder, or by a contractor of the consent holder; and it would cover, in this case, a release carried out in pursuance of an application for entry on the National Lists made by the consent holder in accordance with the Regulations.

### 2.2.4 The alleged breach of the Regulations

The Regulations prohibit MAFF from entertaining an application for entry on the National List if there are not included with the application the results of two previous trials. As these trials had not been done, due to MAFF's policy of not requiring them since 1995, the applicant argued that MAFF's entertainment of the application and the arrangement of the trials had been contrary to law.

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[136] *Watson* Transcript at p. 7.

[137] **DETR (1998), p. 5.**

The court agreed as Regulations 5(1) and 11(3) are quite clear on the matter. The court declared that MAFF's policy of not requiring these previous trials was illegal. This policy was

> "referred to in a written statement made by the Minister in the House of Commons on 14th May 1998"[138]

and, in answer to a parliamentary question, the Minister said:

> "Regulation 11(3) of the 1982 Regulations requires applicants to submit the results of their own value trials on varieties within their National List applications. However, experience has shown that this information is of little value in assessing National List applications and the Department has not required applicants to comply with these (sic) provision since 1995."[139]

The court referred to this as "a most remarkable and, indeed, regrettable statement"[140] and stated that

> "[t]his is impermissible. Administrative convenience, even sensible or necessary administrative practice, cannot provide the foundation for the exercise of a "pretended" dispensing power. No such power exists".[141]

Counsel for MAFF conceded that the approach taken by MAFF is "clearly contrary to law",[142] and the consequences are plain:

> "the present trial planting cannot properly be regarded as a Regulation 11(1) trial and its results could not properly be taken into account in evaluating Schedule 2 requirements".[143]

The impact of this on all the trials undertaken since 1995 is dramatic, but this will be examined in section **2.2.6**, below.

### 2.2.5 Concerning the remedies claimed by the applicant

The applicant submitted that, because of the breach of the Regulations, the crop should be destroyed as grown contrary to law. The court disagreed. The planting of the crop was not conditional on the consent under the Regulations, and was therefore not rendered illegal by a breach of those Regulations. The only consequence of the breach is that the trial cannot be regarded as a Regulation 11(1) trial, and the application for inclusion on the National Lists is void. Discontinuing the trial would only mean that the results would be discarded, not that the crops would be destroyed. The court found that the Minister had no power to order such destruction under the Regulations, and could not therefore declare that the Minister's refusal to destroy the crop was irrational. The growing of the crop was, however, conditional on the consent under the Act and, under the Act, there is such a power but, as there had been no breach of the Act and as the refusal to revoke or vary the consent was not irrational, the court could not order the Minister to destroy the crop. Such an order would be outside of the

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[138] *Watson* Transcript at p. 10.

[139] *Watson* Transcript at p. 10.

[140] *Watson* Transcript at p. 10.

[141] *Watson* Transcript at p. 18.

[142] *Watson* Transcript at p. 10.

[143] *Watson* Transcript at p. 11.

court's remit under judicial review. Similarly, the court could not force the Minister to use the powers under one set of rules to remedy the breach of another set of rules. The court declared the relief sought by the applicant was "fundamentally misconceived".[144]

### 2.2.6 Points raised by the *Watson* case

The case raised several important points.

Firstly, with regard to the interaction of the requirements of the Regulations and of the Act, Brown LJ found, *obiter*, that if

> "consents for GMO releases were available only in respect of National List VCU trials, then the applicant's case would be a powerful one indeed."[145]

This argument raises the question whether it is adequate for the safety requirements concerning GMO releases to be kept separate from the quality requirements for the entry on the National List. If the listing requirements and the safety requirements were part of the same review, then the outcome of the case would have been very different. This argument is important in the light of the "product vs. process controversy" mentioned previously: it is the first time that the fact that GMO-specific regulations impose separate requirements was demonstrated as causing confusion amongst the regulated community.

Secondly, the finding that MAFF's policy of disregarding the trials required by the Regulations is illegal has far-reaching consequences for the National List and all seed developers, not just the agro-biotechnology sector. Indeed, the BSPB was

> "greatly concerned at the suggestion that no application under the Seeds Regulations since 1995 for entry of a new variety on the National List has been lawfully entertained".[146]

This would in effect cancel the listing of thousands of listed varieties. Brown LJ stated that the Regulations would have to be amended if MAFF wanted to continue its policy and that consideration would have to be made to retrospectively approving the thousands illegal trials conducted since 1995. Both of these measures will cause difficulties: they are both likely to be vigorously challenged by the anti-biotechnology lobby and will plunge the seed industry, whether biotechnology-based or not into chaos for the foreseeable future.

Thirdly, the respondents claimed, in response to the court's declaration, that Regulation 11(3) is contrary to European law and unenforceable as placing an unreasonable restraint upon the free movement of goods as well as breaching Sharpes' directly enforceable rights. This claim was made on two grounds:

- The first ground, of little interest to the present thesis, derives from an ill-judged amendment to Regulation 11(3), which effectively imposed a blanket ban on trial results from other Member States being accepted for the purposes of the application for listing on the National List. The court

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[144] *Watson* Transcript at p. 23.

[145] *Watson* Transcript at p. 14.

[146] *Watson* Transcript at p. 16.

recognised that this Regulation would indeed need to be amended to comply with European law, but declared that the basic requirement of the Regulation, that the results of two test trials be presented with the application, remains unaffected by this problem.

- The second ground is central to this thesis. The respondents claimed that the Regulation was contrary to European law as, in the light of MAFF's view that replicated trials are of little value for the purpose of the Regulations, the requirement to conduct such replicated trials is disproportionate as well as needlessly onerous. The respondents claimed that this is contrary to the European law principle of proportionality.

The court found that if the Regulations were indeed contrary to European Law, MAFF's position would be

"not merely unobjectionable but, given the primacy of Community law, inevitable",[147]

and that the alleged breach of the Regulations would be ratified by European law. MAFF's policy would cease to be "impermissible" and would become law. There would also be no need to retroactively approve the allegedly illegal entries on the National List. However, in the absence of arguments from either of the parties concerning this

"serious and perhaps even promising argument",[148]

the Court could not reach any conclusions upon it.

The Watson case is, in the light of this last point, a remarkable missed opportunity to develop the European principle of proportionality in English law. This is an essential legal principle that answers the question whether a measure taken is commensurate with the concern that prompted it. The principle of proportionality is studied in the following Chapter.

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[147] *Watson* Transcript at p.15.

[148] *Watson* Transcript at p. 15.

## Chapter Three: The Criterion of Adequacy of a Regulation

In Chapter One, the question was raised whether the current regulatory frameworks for biotechnology in Europe are adequate. The problems revealed by the import crisis and the issue of segregation of GM foods, and the questions left unresolved by the *Watson* case, show that there is considerable confusion over the nature and extent of the issues raised by biotechnology, and over the nature and extent of the measures to be taken to address these issues.

If one is to ask whether the regulatory frameworks are adequate, one must define a measure of adequacy by which to judge them.

This thesis cannot address all the issues that appertain to the biotechnology debate and to the development of the policies required to deal with them, as they spill out into domains as diverse as global agricultural economics, environmental philosophy and even religion. However, a legal thesis can tackle the *adequacy of the mechanisms for decision-making that are employed in the development of policies* regarding biotechnology. These policies incorporate the *making* of the regulations as well as the methods of *enforcement* of the regulations, both of which have been criticised in the light of the import crisis.

This author takes the view that one of the central purposes of law is to set standards for the adequacy of decision-making, be it administrative by way of judicial review, or personal by way of examination of the reasonableness or fairness of an individual's actions in the context of tort law or contract law. These standards can be assessed after the fact, by means of trial in a court of law, as in disputes in tort and contract and in judicial review. They can be set before the fact, by the promulgations of laws that will govern future decision-making and sanction any decision that falls below the requisite standards. The law, however, cannot judge the adequacy of the data upon which decisions are made (the "inputs" to the decision-making mechanism), nor the adequacy or merits of the decision itself (the "output" of the decision-making mechanism), as lawyers have neither the requisite expertise nor the jurisdiction to do so. The law *can* judge the appropriateness of the inputs (i.e. the logical link between the inputs and the subject matter of the decision) and, essentially, *the functional adequacy of the decision-making mechanism itself.*

This assessment of the decision-making process was demonstrated in action in the *Watson* case as described in Chapter Two: the court could not judge the adequacy of the specialist advice given to the government by ACRE (just one[149] of the "inputs" to the mechanism), i.e. whether it was *correct* or not, but only its appropriateness (whether it related to the matter at hand), nor could it judge the appropriateness of the final decision (the "output" of the mechanism) as the merits of the decision remained within the ambit of government rather than the ambit of the court. However, the court could judge whether the process of decision-making was rational.

In this particular case, the criterion for the adequacy of the decision-making process was "rationality". This is a highly specialised concept of English judicial review with a precise meaning

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[149] It is important to understand that decision-making by administrative bodies will have to take into account many "inputs", and not only scientific advice. Getting the science right is only one of the tasks to complete as part of the decision-making mechanism.

developed over hundreds of court cases. It is insufficient as a criterion of adequacy for the examination of the EU regulatory framework for biotechnology in the context of a possible trade dispute with the US. Although judicial review is recognised and applied in all European jurisdictions and the vast majority of jurisdictions across the world, and is therefore an almost universal legal technique for the assessment of administrative action, "judicial review" as applied in English and Welsh Courts is insufficient for the present purpose as it remains restricted to the review of administrative acts (and prerogative powers) *taken in pursuance of an Act of Parliament.* In English law, the decisions of Parliament are presumed rational. This presumption would prevent the assessment of whether the current regulatory frameworks are adequate, and allow only an assessment of whether the frameworks are rationally applied.[150] This author argues that the restriction encountered in English judicial review must be transcended, and another criterion of adequacy must be found in order to assess the adequacy of legal instruments. This thesis, although written from the perspective of English law (as part of the European legal order), must look further afield for a criterion of adequacy.

This author takes the view that it is logically impossible to assess the adequacy of the means taken to achieve an end if that end is unknown, or at the least not defined. It follows that it is impossible to judge the efficiency of the means taken to achieve an end if the adequacy of the end itself cannot be assessed. In the present context, it follows that only once the purpose of the regulatory frameworks concerning biotechnology has been assessed as adequate can one question whether the measures applied to achieve that purpose are adequate. For example, it was shown in Chapter One that the purpose of the frameworks was unclear: the aim of protection of human health and safety clearly has wider and narrower meanings. Measures taken to achieve one type of protection are inadequate to achieve the other. It is therefore critical that regulatory purpose be clearly identified.

This author therefore aims to identify and define the purpose of the EU regulatory frameworks and to determine *whether at all* the provisions of the frameworks allow them to achieve their purpose. Due to constraints of time and space, this thesis will concentrate only on the adequacy of the aims of the frameworks and not on the adequacy of their enforcement, however important this may be in the real world, as the latter would involve examining the efficiency of the means used to achieve the purpose of the regulatory framework, having taken the purpose of the framework as given. The study of the efficiency of enforcement of the frameworks is left to other researchers to determine.

It is argued for the purposes of this thesis that European Law and the rules of the World Trade Organisation ("WTO") provide a clear and reliable measure of the adequacy of a legal instrument. This measure is provided by the *principle of proportionality* as informed by the *principle of precaution*. It is argued, also for the purposes of this thesis, that the principle of precaution, as expressed in international instruments such as Agenda 21, is a logically necessary component of the principle of proportionality and that the acceptance of the latter requires acceptance of the former.

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[150] To find that inadequate laws are applied in an exemplary fashion, for example, would speak volumes concerning the relations between the English judiciary and the British executive and concerning the law-making process, but would not say much concerning the adequacy of policies regarding biotechnology.

## 3.1 Is it legitimate to ask whether the laws are adequate?

This author does not reject the principles of English judicial review in any way. It only argues that English judicial review is inapplicable to the study of legal instruments, a proposition that is entirely without controversy. However, bearing in mind that this is a legal study from the point of view of English law, can such a study be justified? It would appear at first that assessing the adequacy of law would be alien to the English legal tradition. It is argued here that this is not so.

**As Green (1999)** explains,

> "[i]n the United Kingdom the judiciary has historically viewed itself as subservient to the will of Parliament".[151]

The reason for the supremacy of Parliament was the recognition by the unelected judiciary that the will of Parliament as embodied in its Acts was the democratic expression of the will of the people. The judiciary therefore accepted the "unimpeachability of Parliament", and refused to substitute its judgements for those of Parliament. There has not been a tradition in English law of allowing judicial challenges to the legality or appropriateness of an Act of Parliament.[152] Nevertheless, the judiciary

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[151] At p. 147, as per all the quotes in this, and the following, paragraphs unless otherwise stated.

[152] There is, however, an emerging Parliamentary tradition of limiting its own action. The first report of the Select Committee for the Modernisation of the House of Commons (*The Legislative Process*, HMSO, 29 July 1997, HC 190, ISBN 0 10 200798 5) recommended a number of measures to improve the legislative process, including greater use of parliamentary pre-legislative scrutiny. This means that the House would have access to drafts of the legislation, before it is presented before them, as well as access to the reasoning of the government or the private member sponsoring the Bill. This would allow better understanding of the purpose of the law by Parliament, greater input into the legislation from Members and from those affected by the legislation, via the Members. Effectively, Parliament would hear out the sponsor of a Bill who must give *a full account of the justification for the legislation*, as required by the principle of proportionality in its legislative form. Paragraph 20 of the Report states that pre-legislative scrutiny

> "can be of real benefit to the Government. It could, and indeed should, lead to less time being needed at later stages of the legislative process [ . . . and . . .] it should lead to better legislation and less likelihood of subsequent amending legislation".

So far, this only concerns benefits to Parliament itself. The extending of pre-legislation should also benefit the quality - and *adequacy*, in the meaning of this thesis - of the laws. Paragraph 14 of the Report sets out a series of

> "essential criteria which must be met in making any reforms"

of the legislative process. These criteria include: the proper consideration of all parts of the Bill (14(c)); the better use of time and expertise of Members (14(d)); the provision of

> "*full and direct information on the meaning and effect of the proposed legislation* from those most directly concerned, and *full published explanations from the Government on the detailed provisions* of [the] Bill" (my emphasis)

to the House as whole and the legislative Committees in particular (14(e)); greater accessibility to the public (14(f)); making provision for the subsequent monitoring and amendment of the legislation (14(i)), which can best be achieved through participation at all stages.

Recent Bills laid before Parliament are now generally accompanied by Explanatory Notes incorporating an assessment of the financial effects of the Bill, the effects of the Bill on public service manpower, and a summary of a Regulatory Impact Assessment. Furthermore, section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House of Parliament to make a statement, before second reading, about the compatibility of the provisions of the Bill with the European Convention rights as defined by section 1 of the 1998 Act.

adopted the role of guardian of the will of Parliament against the administrative acts of the executive where these diverged from it, under the familiar judicial review doctrine of *ultra vires*. However,

> "since the United Kingdom joined the [European] Community, [Parliament] is no longer sovereign"

due to the doctrine of supremacy of European law. Since the case of *Factortame*,[153] the English judiciary has undertaken the difficult and often controversial new role of guardian of the supremacy of European law over the Acts of Parliament. This involves implementing the European general legal principle of proportionality. Stated in its simplest form, the principle is a standard of legality for the actions of administrative bodies as used by the European Court of Justice ("ECJ") in its judicial review of EU administrative acts which applies to UK bodies when they take a decision in pursuance of European law. The principle determines

> "whether the measures adopted [are] commensurate with the objectives in question and whether less intrusive methods could, *in fact*, [be] used to achieve those objectives".[154]

Despite the judiciary's willingness to undertake the role of guardian of the superiority of European law over domestic law in matters of European law, the principle of proportionality is still not accepted in English law for purely domestic matters. As **Green (1999)** further explains, the House of Lords had

> "ruled that proportionality played no part in English administrative law"

in the case of *Brind*.[155] The main reason was that the principle of proportionality was

> "a more exacting test for judicial review than that permitted under traditional English law".[156]

This view has been taken by a number of commentators who are critical of the principle of proportionality, which remains unclear and changeable in the jurisprudence of the European Court of Justice.[157] In this light, it is understandable that the court did not want to examine the points raised concerning the principle in the *Watson* case.

Other commentators have recently argued that the principle of proportionality is not as alien to English law as previously thought.[158] For example, **Green (1999)** finds that there is "nothing intrinsically remarkable or novel" in the proposition that Parliament's

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This however, is only an emerging tradition of Parliament for its own purposes. It cannot replace the ability of citizens to challenge legislation in the courts, and cannot necessarily prepare governments to defend and justify their regulatory measures in the face of a challenge under the World Trade Organisation. It is nevertheless a step in the right direction.

[153] *R. v. Secretary for Transport, ex parte Factortame* (No. 2) [1991] 1 AC 603.

[154] **Green (1999)** at p. 162.

[155] **Green (1999)** at p. 152. *R. v. Home Secretary, ex parte Brind* [1991] 1 AC 696.

[156] **Green (1999)** at p. 153.

[157] See for example **Van Gerven (1999)**, at pp. 58-63.

[158] See for example **Craig (1999)**.

> "processes may be subjected to judicial scrutiny and criticism upon application of the principle of proportionality. [ . . . ] Judges are not usurping any democratic function."[159]

Judicial review of the creation of legislative instruments does not necessarily imply the substitution of judges' political views with those of Parliament, but implies a form of quality control and prevention of the adverse results of "bad law" on citizens' affairs.

The recent case of *First City Trading*[160] has clarified the juxtaposition of the principles of proportionality and reasonableness. Arguing that proportionality is an integral part of the doctrine of non-discrimination,[161] Laws J stated that

> "[t]he court's task is to decide whether the measure in fact adopted falls within the range of options *legally* open to the decision-maker. [ . . . T]he court has no business to give effect to any preference for one possible measure over another when both lie within proper legal limits",[162]

as this choice remains within the decision-maker's margin of appreciation which derives from his political authority and consequent political responsibility. Where the traditional English test of reasonableness requires that the Minister

> "set out the problem, and assert that within his discretion [he] chose this or that solution, constrained only by the requirement that his decision must have been one which a reasonable Minister might make",

the principle of proportionality goes further and

> "requires the decision-maker to provide a fully reasoned case",

that is to say

> "substantial factual considerations must be put forward in [the decision-maker's] justification: considerations which are relevant, reasonable and proportionate to the aim in view".

Importantly, Laws J asserts that

> "the court is not concerned to agree or disagree with the decision",

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[159] **Green (1999), at p.147.**

[160] *R. v. MAFF, ex parte First City Trading Ltd* [1997] 1 CMLR 250.

[161] This argument is not entirely exact. The doctrine of non-discrimination in the meaning given to it by Laws J, is the doctrine generally known as the "rule of law", whereby all citizens are equal before the law. It is also known as the principle of equality. **Emiliou (1996)** describes the principle of equality as "protection against differential treatment of comparable situations which is not justified rationally on the basis of objective criteria", at p. 152. The principle of equality and the principle of proportionality must not be confused. They overlap, but are not interchangeable. However, they share certain characteristics, which were used by Laws J for the purpose of his judgement, namely, in both cases, the perpetrator of the unequal or disproportionate act can be called to account, and must satisfy stringent criteria of justification for the transgression for it to stand. Both principles of equality and proportionality are weapons against "arbitrary power".

[162] *R. v. MAFF, ex parte First City Trading Ltd* [1997] 1 CMLR 250, at pp. 278-9, as per all subsequent quotes in the following paragraphs unless otherwise stated.

only to find that it has been taken *on the basis of the considerations advanced in justification*. This is to say, the control is limited to determining whether the grounds advanced support the decision and not deciding which, of a range of decisions thus supported, is the best decision.

> Laws J concludes that English review and
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> "European review are different models - one looser, one tighter - of the same juridical concept, which is the imposition of compulsory standards on decision-makers so as to require the repudiation of arbitrary power".

*This is an important statement which I adopt for the purposes of this thesis*. The European principle of proportionality imposes a strict but not unduly onerous measure for the justification of legal instruments as well as administrative measures. *It requires that measures are demonstrated to be taken on the basis of substantial considerations that are relevant, reasonable and proportionate, that is to say commensurate with the concern addressed by the instrument or measure*. These criteria are conducive to achieving "adequacy", as explained in the next section.

The judicial tradition of challenging the validity or adequacy of legal instruments is well established in EU law, as the following discussion of the principle of proportionality will show. It is also, importantly, well established in the rules of the WTO. Article XVI (4) of the Agreement establishing the WTO (hereafter **WTO (1994)**) requires every contracting party to

> "ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the [ . . . ] Agreements" forming the WTO's legal order.

This establishes the corresponding power of the WTO to judge the adequacy of the legal instruments of its members as well as their administrative actions, within its terms of reference, under the provisions of the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereafter the Understanding on Disputes). For example, the Agreement on the Application of Sanitary and Phytosanitary Measures (hereafter the SPS Agreement) allows the WTO to judge the adequacy of a contracting party's health and safety measures, be they

> "laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety".[163]

The WTO imposes conditions on the adequacy of contracting parties' measures that are virtually identical in nature to the European principle of proportionality, as will be shown in Chapter Four.

Finally, this tradition is also firmly established in the US where not only can the judiciary strike down legislative instruments that are unconstitutional but the judiciary also ensures that the

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[163] Annex A(1) of the SPS Agreement.

plethora of laws governing the efficiency and responsibilities of lawmakers towards the regulated communities are respected.[164]

## 3.2 What does "adequacy" entail?

This author proposes the principle of proportionality as a measure of adequacy of a law. The question must be raised, how it follows that the proportionality of a measure leads to this measure being considered "adequate". From the discussion above, it appears that not *all* considerations *need* be taken into account to achieve proportion, as long as those considerations that *are* taken into account suffice in themselves to demonstrate the proportionality of the measure in question. This, of course, leaves any demonstration open to the charge of being insufficient or incorrect by persons who take the view that other considerations are more relevant.

Any legislative instrument may be challenged in the light of any consideration that has an equal claim to be relevant, reasonable and proportionate. In the case of biotechnology, this standard is particularly difficult to achieve. Because of the formidable range of possible applications of recombinant technology, the number of issues that may be relevant, reasonable and proportionate is almost infinite. Every challenge nevertheless requires a justification in reply.[165] The choice of the principle of proportionality as a measure of adequacy allows for a dynamic mechanism of reasonable challenge leading to reasonable justification. *It provides for a forum in which a debate may take place in a reasonable, rational and constructive manner, as opposed to the situation presently found in the biotechnology debate where non-justified absolute notions, such as the sanctity of the environment or the sanctity of scientific progress, are used as ammunition in an unwinnable war of words.* The principle of proportionality allows the notion of adequacy to be dynamic and responsive, without straying into arbitrariness.

It is argued that proportion, and indeed adequacy, need not be absolute or immutable notions. This thesis takes the position that there is no absolute and permanent proportion or adequacy of a law. There are many ideals, but no such thing as a "true" value in the absolute. The characteristics of proportion and adequacy can only be established at, and for, a particular moment in time. Law is a time

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[164] These include, for example, Executive Order 12866, under which all "significant rules" (i.e. rules that cause a certain level of government expenditure and / or impose a certain level of costs on the regulated community) must be reviewed by Congress' Office of Management and Budget and must be tailored to impose the least burden on society consistent with attaining its regulatory objectives; and the Regulatory Reform Initiative of the President's Office which directs agencies to consider the question "Could private business, setting its own standards and being subject to public accountability, do the job as well?". These two rules are consistent with the European concept of proportionality and go much further: the latter represents a form of subsidiarity between the government and *publicly accountable* private business, whereas subsidiarity exists in Europe only between levels of government. Other examples of laws governing legislative decision-making include: the Regulatory Flexibility Act; Executive Order 12372, which requires intergovernmental consultation with State and local officials; Executive order 12988 which prevents clashes with State and local laws, retroactive effects and the imposition of administrative proceedings that may prevent parties from challenging the rule; and the Paperwork Reduction Act 1995, which submits all information collecting requirements imposed on the regulated community to be vetted by the Office of Management and Budget. All of these requirements were imposed on USDA APHIS's final rule concerning the regulation of GMOs (*Federal Register*: May 2, 1997, Volume 62, Number 85,pp. 23945-23958).

[165] Within reasonable limits of course, otherwise governments would spend more time justifying legislation than promulgating or enforcing it.

bounding mechanism: legal judgements can only be laid down at a given time, in the light of the known facts at that time. The discovery of new evidence that was in existence before the judgement may lead to the reversal of that judgement. On the other hand, subsequent developments that may have enabled a person to win a case had they happened sooner will be of no avail. The judgement stands in the light of the circumstances of the time it was handed down. The adequacy of a law, similarly, is relative to the circumstances of its time. Adequacy is necessarily a dynamic, evolutionary and responsive notion.

The use of the principle of proportionality as a measure of adequacy of a law can also be justified by the following considerations.

### 3.2.1 The need to justify State intervention in the form of law

In all areas of regulation, and not only those concerning biotechnology, the question must be raised, why regulate at all? The justification of State intervention in the affairs of citizens, be it moral, economic, or legal, is a much debated matter. It is not the purpose of this thesis to demonstrate the need for such justification, which is discussed in numerous other studies,[166] but to use some of the concepts of this debate to illustrate the need for clarity of a law's purpose.

State intervention is usually justified where natural societal mechanisms (e.g.: market forces, patterns of behaviour governed by moral or religious considerations, formal procedures such as application of the Common law) fail to promote the most efficient distribution of risks and resources, however defined, available to the population.[167] In particular, it is justified where these natural mechanisms fail to prevent events with adverse effects. These events must be precisely identified in the justification of State intervention in order to prevent disproportionate (that is to say excessive, inconsistent or arbitrary) applications of the law. First of all, the targeted event itself must be clearly defined. Secondly, the nature of the event's effects must be defined as adverse. This may be an absolute qualification, or the adverse characteristic of the effects may be a matter of degree, or result from the transgression of an acceptable threshold. Finally, the causal connection between the event and the adverse effects must be established.[168] In the context of this thesis, adverse effects of an event would be the causation of harm to human health and safety or to the environment; and the failure of the natural mechanisms, justifying State intervention, would give rise to or allow events that would have these effects.

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[166] Such is the number of available studies regarding the nature of law and the justification for State intervention into the affairs of citizens, it is proposed not to include a bibliography here.

[167] This definition does not take into account the concept of consent. It is assumed, for the sake of argument, that the population consents to State intervention when this "economic" justification is triggered. In most jurisdictions, the source of legislation no longer has a "divine right" to rule, but derives its powers of law making from the embodiments of the will of the electorate, namely the Constitution, and (or) the mandate derived from general elections.

[168] It will be seen that the first and third criteria are objective, that is to say they must be demonstrated. The second, however, is subjective. There is a wide discretion in the setting of the *level of concern* in the principle of proportionality

It has been argued[169] that market forces often fail to protect the environment, however environmentally aware the consumers may be. The principal reason for this is that the economic models of efficient markets rarely translate into the real world, as the models are built on unrealistic assumptions, such as perfect information of the perfect consumer. In particular, it has been shown that the cost of environmental pollution (known as externalities in economic jargon) is not always reflected in the price of goods as they appear on the market. Inefficient production methods which cause pollution (or other harmful effects, such as worker injuries, child labour, etc.) are often cheaper to employ than efficient methods of production which lessen the pollution caused. Unless the producer is economically penalised for the harmful effects of the pollution, or forced by law to use more expensive production methods in order to diminish pollution, and able to pass on the higher costs involved to the consumer, the consumer will remain uninformed of the costs of pollution from the product's price. The costs of externalities are not always apparent from inspection of the product's characteristics, either. Unless the consumer is informed of the precise costs of these externalities, which is an extremely difficult aim to achieve, the consumer's purchasing behaviour cannot be used to deduce the consumer's opinions regarding the acceptability of the externalities. Similarly, the economic pricing of goods rarely takes into account the ethical preferences of consumers. Market forces alone, therefore, are not able to develop policies concerning the assessment of the acceptability of GMOs, nor are they able to demonstrate the public's acceptance of them.

Legal institutions such as contract law and the law of negligence also are limited in their prevention of the adverse effects an event may have. Until recently, contract law failed to prevent adverse effects where third parties are concerned: unless specifically provided for, third parties had no remedy under the contract for any harm caused them. In English law, the Contracts (Rights of Third Parties Act) 1999 now provides limited protection for identified third parties. Prior to this third parties could only seek a remedy under the law of negligence, but this too often failed them. The environment cannot represent itself in court, and therefore most environmental harm escapes the ambit of the law of negligence. This law is only able to remedy harm where a duty of care is established between a person shown to be responsible for the event that caused the harmful effects and the person affected by these adverse effects. This is particularly difficult in cases of environmental exposure because the chain of causality remains unclear, or uncertain, or requires substantial scientific evidence which may be expensive to provide or inconclusive. Furthermore, the duty of care needs to be established on the basis of foreseeability of the adverse effects. Again, in areas of scientific uncertainty, this may be difficult to establish, if not entirely excluded by the defendant's defence of using the "state of the art". Finally, the law of negligence may fail to provide adequate remedies: it may be impossible or impractical to physically remedy the harm, and financial compensation may not be a solution. Insurance has often

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[169] In the particular case of environmental protection, these arguments have been discussed in detail by **Ball & Bell (1991)**, at pp. 72-101. In the case of product liability and consumer protection, the same arguments have been presented by **Howells (1998)**, at pp. 3-59. The same arguments are applicable in any economic analysis of the efficiency of legal standards, such as the efficiency of protection of workers from accidents, etc... It is not the purpose of this study to demonstrate the validity of these arguments or otherwise, but only to use these arguments for the purposes of demonstrating the usefulness of the principle of proportionality in assessing the adequacy of legal instruments.

been touted as a replacement for contract and negligence remedies, as well as for preventative regulation, but again money is not a remedy for everything.

This author has found that no commentator has doubted the necessity for State regulation of biotechnology in an unqualified manner. It is true that, at the very earliest stage of development of the recombinant techniques, there were calls for self-regulation by the scientists concerned rather than for the imposition of regulatory controls. This, however, is to be understood not as rejecting all regulation of the activities of the scientists involved, who were subject to applicable health and safety rules and controls of the use of hazardous substances, but as rejecting the creation of an extra tier of regulation specifically to control the recombinant techniques, over and above what was already in existence.

Nevertheless, there are considerable differences in views concerning the acceptable level of State intervention in the form of regulations.

The more extreme proponents of "science-based regulations"[170] insist that safety regulations (i.e. coercive measures taken by the State against free citizens) are only justified (economically, politically and morally in a liberal capitalist system) where there is complete predictability of cause and effect: i.e., where the target activity is defined with certainty, where it is certain that precisely defined harm will result from the conduct of that activity, and where the measures to be taken are certain to alleviate the harm only to the precise extent where the harm becomes "scientifically" acceptable to society. Insofar as this argument states that intervention is only acceptable when absolutely necessary and confined to the absolute minimum required to be effective, that is to say the proposed measures are exactly commensurate with, or proportional to, the target problem, it is correct. However, despite its elegance, this argument demonstrates a misunderstanding of what proportionality entails and is therefore self-defeating. Firstly, if the harm resulting from an activity was completely predictable and, secondly, if the effect of a measure was also completely predictable, there would be no need for the State to regulate as there would be no failures of market forces or of the legal remedies to justify its intervention.[171] Market forces fail to prevent harm precisely because nothing is completely predictable and nothing is as efficient in fact as it may be in theory. Market forces, i.e. the choices of perfectly informed consumers, would make any harmful product impossible or totally uneconomical to sell. Effective application of the principles of the law of negligence would deter any producer from making harmful products. The only scenario where predictably harmful products would still be placed on the market would involve a society in which ruthlessness or recklessness defined the moral order. Short of accepting that a "free society" allows or even encourages psychopaths to run on the rampage, such arguments must be rejected. Proportionality necessarily entails a margin of uncertainty both in the knowledge of the problem and in the knowledge of the measure to combat it.

### 3.2.2 The nature of law: the control of human responsibilities

Once it is accepted that State intervention in the form of law (in the specific area of human and environmental safety of biotechnology) is legitimate, the next question arises as to how the State

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[170] **Gori (1996)**, at pp. 307-309.

[171] This is the same circular thought process demonstrated by the claim that there should be no regulatory risk assessment unless where there is a demonstrable risk. The very exercise of demonstrating that there is a risk is a risk assessment.

may regulate in order to prevent the occurrence of events with adverse effects, or to mitigate the adverse nature of these effects, at least.

This thesis takes the position that laws, by nature, form a matrix of human responsibilities which may be enforced by various mechanisms. The question whether a law is adequate is in fact the question whether the responsibilities imposed by the intervention of the State are adequate.

Laws are inescapably rules of human behaviour and only human beings can be subjects of law.[172] Only human beings can perceive the existence of a law and act accordingly.[173] Much as legislators may try, law cannot command the actions or characteristics of objects, whether natural or man-made, or natural phenomena, such as the weather. The characteristics of an object, whatever they may be, are natural phenomena. They are physical facts. These facts, however, are perceived by humans via our senses. It is the human perception of these physical facts that leads to actions by humans in respect of these physical facts. It is these actions that give rise to circumstances in which the physical characteristics of an object are perceived to be beneficial or perilous to human interests. In particular, it is human-made circumstances that lead to certain characteristics of a things to be perceived as more or less hazardous or risky, or more or less beneficial. For example, certain bacteria are harmful to human beings. Laws cannot make the bacteria less harmful, or make the bacteria disappear. Laws can only dictate circumstances (brought about by human actions) that make the harmful characteristic of the bacteria, a physical fact, less likely to impact on human interests, namely human health. In particular, laws can enforce standards of hygiene to reduce the prevalence of these bacteria in certain areas of human activity, such as the commercial preparation of food. The nature of law is therefore the control of human responsibilities. By controlling the actions of subjects of law via the imposition of responsibilities, State intervention seeks to create circumstances in which events with adverse effects are prevented from arising, or in which the effects of these events are rendered less adverse.

Responsibility is to be distinguished from liability. Liability arises as a consequence of a failure of responsibility. A responsibility is a required standard of behaviour. A liability is the logical connection between a proven course of action of a subject of law and harm caused to another subject of law (or to a thing protected by law in the name of all subjects of law, i.e. the environment, which cannot act by itself). Sanctions attached by law to liability, be they civil or criminal, are interventions of the State to ensure that the liable make good the harm caused or receive their "just deserts" where the natural societal mechanisms fail to correctly ensure that this happens.

### 3.2.3 The nature of "reactive" and "proactive" law

Having accepted that the core of legislative action is the imposition of responsibilities, it is necessary to establish how the State can determine which responsibilities to impose, and on whom.

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[172] Companies are considered separate legal entities to their members and therefore are considered to be subjects of law in their own right. This is not a fact, however, but an abstract construct: companies are in reality no more than the convenient generic description given to combined human action.

[173] It is not the purpose of this thesis to enter into detailed discussions of the nature of law, or of the reasons why subjects of law may chose to adhere to the laws or not, and the consequences of such choices. This is covered by a number of other studies that need not be listed here.

Using safety regulations as an illustration, it is easily demonstrable that law can be either reactive or pro-active in its action. A reactive law is one that is promulgated after the occurrence of a problem in order to prevent a reoccurrence. A pro-active law is one promulgated before the occurrence of the problem it addresses, to prevent it from occurring at all. Historically, most safety and environmental laws have been reactive, promulgated in response to a tragic accident or in response to an industrial or environmental disaster. More and more regulations are becoming pro-active where accumulated experience allows the prediction of disasters stemming from the occurrence of given events in order to avoid the effects of predictable adverse events which compensation or insurance cannot repair. There is a further subdivision within the pro-active laws between "just-in-time" and "just-in-case" laws, the former addressing a probable event, and the latter a potential event.

These descriptions are, however, misleading. Laws are only seen to be "reactive" or "pro-active" in relation to the occurrence of a historic (or potential) event. Their function is the same: to prevent an event from occurring. Both "reactive" and "pro-active" laws look to the future.[174] The only difference between them is that, for "reactive" laws, the problem has occurred and is therefore relatively well known whereas, for "pro-active" laws, the problem has not occurred and its nature therefore can only be speculative. This is more so when "just-in-case" laws are considered, as the event they address may never occur at all even though it remains possible. As a result, "reactive" laws are more likely to be commensurate to the problem they address than "pro-active" laws because of the greater certainty of knowledge (although this is by no means certain). "Pro-active" measures run the risk of being either insufficient or excessive with regard to the problem they address, due to the uncertainty inherent in the understanding of the problem itself. Being insufficient could defeat the purpose of regulation which is to improve on the deficiencies of the societal mechanisms (unless it is still better than them). Being excessive may affect legitimate expectations, overstepping the justification of the intervention.

If one follows the logic of market failure for the justification of State intervention (via safety regulation), it also establishes the limits of the intervention. The regulation must not overstep its purpose. This is the requirement that a measure be commensurate or proportional to the problem it addresses. Rather than classifying laws as being "reactive" or "pro-active", it is better to classify laws according to how commensurate, or proportional, they are to the problem they address.

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[174] The action of laws generally begins from promulgation. Obviously, this does not apply to retroactive legislation. This is a highly controversial aspect of law whereby the legal *status quo* is changed, or responsibilities imposed after the fact. It is not proposed to discuss the issue of retroactive laws for the purposes of this thesis, although retroactive laws would be required to remedy the problem caused by MAFF's disregard for the provisions of The Seeds (National Lists of Varieties) Regulations 1982, as discussed in Chapter Two; and retroactive regulation has effectively taken place with **Council Regulation 1139/98** which imposes the labelling requirements of the Novel Foods Regulation on two specific GMOs marketed before the Regulation was promulgated. The latter situation is discussed below, as it arguably may attract a charge of unjustifiable discrimination against these products in the context of a WTO trade dispute between the US and the EU. Nevertheless, in the light of the present discussion, it is *asserted* here (rather than demonstrated) that retroactive laws should be placed under greater scrutiny than other types of laws by the principle of proportionality as they benefit from the position of hindsight: there is therefore no scope or justification for any deviation from the standard of proportion. These laws must be subject to the highest standards of justification.

## 3.3 The principle of proportionality in European Law

Proportionality, as a concept, can be stated in simple terms, as above. It has nevertheless acquired a specialised meaning in European law, as has the concept of reasonableness in English law. The legal concept must be stated here. **Emiliou (1996)** provides a comprehensive analysis of the principle of proportionality as applied by the European Court of Justice and as embodied in the Treaty on European Union. A number of his conclusions will be adopted here for the purposes of this thesis.

### 3.3.1 the nature of the principle

The principle of proportionality has been a central part of Community law since the 1950s.[175] It is considered a general principle of Community law, an expression of the concept of rule of law or of the principle of justice, derived from the general principle of international law prohibiting the abuse of fundamental rights.[176] It is the logical counterpart of the fundamental right that an individual

> "should not have his freedom of action limited beyond the degree necessary in the general interest".[177]

In recent years, the principle has been more formally stated as a legislative doctrine governing the decision-making functions of the Community institutions, as well as being a judicial doctrine for the assessment of the legality of Community actions. The definition of the principle given by the ECJ in the *Fromançais* case states:

> "In order to establish whether a provision of Community law is consonant with the principle of proportionality it is necessary to establish, in the first place, whether the means it employs to achieve the aims corresponds [sic] to the importance of the aim and, in the second place, whether they are necessary for its achievement".[178]

The principle has two parts, again as summarised by **Green (1999)**: the application of the principle of proportionality determines

> "whether the measures adopted were commensurate with the objectives in question and whether less intrusive methods could, *in fact*, have been used to achieve those objectives".[179]

The two parts of the principle, that a measure be suitable ("appropriate"[180]) and necessary to achieve its aim, appear to have been joined by a third in recent cases, known as proportionality *stricto sensu* and deriving from the German interpretation of the principle. This third part is not always employed by the court and appears to have taken a particular meaning in the ECJ's application of the principle of proportionality. It is the requirement that the impact of the measure on affected persons not exceed the benefit derived:

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[175] **Emiliou (1996)**, at p. 134, states that the first appearance of the principle can be traced to the case of *Fédéchar*, Case C-8/55 [1954-1956] ECR I-292.

[176] **Emiliou (1996)**, at pp. 135-139.

[177] **Emiliou (1996)**, at p. 136.

[178] Case C-66/82 [1983] ECR I-395, p. 404.

[179] At p. 162.

[180] Case C-331/88 *Fedesa* [1990] ECR I-4023, p. 4063.

> "when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused are not to be disproportionate to the aims pursued".[181]

The meaning of "suitable" has not been fully clarified by the ECJ. This is understandable as, explained by **Emiliou (1996)** at pp. 191-192, the suitability of any regulatory measure is subject to the existence of wide discretionary powers of the regulatory body to deal with, *inter alia*, "complex economic situations". **Emiliou (1996)** argues[182] that "suitability" amounts to no more than a control whether the measure was taken in a blatantly arbitrary way, that is to say whether the measure could be said to be rationally connected with the aim. The German interpretation of the principle states that a measure is suitable if it can further the desired result. It does not need to be sufficient to attain the objective, but it must be effective in its assistance in achieving the objective.[183] The connection required between the measure taken and its objective, therefore, does not need to be substantial, but it must be rational. The ECJ has stated, adopting terminology that is very close to that employed by French courts in their judicial review of administrative action,[184] that

> "The legality of a Community act cannot depend on retrospective considerations of its efficacy. Where Community legislature is obliged to assess the future effects of rules to be adopted and those effects cannot be accurately foreseen, its assessment is open to criticism only if it appears manifestly incorrect in the light of information available to it at the time of the adoption of the rules in question".[185]

Effectively, unless there is no rational connection between a measure and the objective sought, that measure will be considered "suitable".

Whereas suitability is not an onerous criterion to satisfy, "necessity" is more stringent. Necessity requires that where there is a discretion between several legal courses of action, the least restrictive or onerous be followed. The necessity of the measure is established by finding that there is no less onerous manner of attaining the objective. If there is, then the measure is no longer necessary, but the alternative is. Necessity does not imply that there must be only one way to achieve the objective, or that only one way can be adequate in the absolute. Importantly, the ECJ has made it clear that *it is up to the body taking the measure to form the opinion that the measure taken is necessary*, the most effective to achieve the objective sought, taking into account all relevant circumstances. *This discretion remains sovereign*, rather than submitted to any given version of absolute truth or adequacy or acceptability. In the case of *Fedesa*, the ECJ found that the administrative body in that case was

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[181] Idem.

[182] At p. 192.

[183] **Emiliou (1996)**, pp. 26-27.

[184] **Emiliou (1996)** describes the concept of *erreur manifeste d'appreciation des faits* at pp. 84-87. French courts cannot strike down administrative decisions without the presence of a mistake of law, unless, in the case where the administrative body may have a wide discretion in its action, it makes a flagrant mistake in the evaluation of the facts upon which it has based its decision. **Emiliou (1996)** argues, at p. 84, that this is the equivalent of an English court finding "that no reasonable administrator could have reached that view of the facts in question".

[185] Case C-40/72 *Schroeder* [1973] ECR I-125, p. 142.

> "entitled to take the view that, [bearing in mind relevant circumstances, in this case] the requirements of health protection, the [objectives of the measure] could not be achieved by means of less onerous measures".[186]

The onerous or restrictive nature of the measure, in the case of necessity, appears to be socio-economic. Therefore, the European criterion of necessity resembles more closely the formalistic French concept of *bilan coût-avantages*,[187] which is, largely, an economic risk-benefit assessment, than the more abstract German concept whereby the "mildest" (in all meanings of the word) of equally effective measures must be pursued within the envelope of creative freedom of the legislator (*Gestaltungsfreiheit*).[188] This "mildest" measure could be translated in English legal jargon as being the most "reasonable" or sensible option. Necessity therefore refers to the proportion between the *economic impact* of a measure and the aim it seeks to achieve.

Where applied, the third criterion, proportionality *stricto sensu*, resembles the German concept, but has taken on a more specific meaning. **Emiliou (1996)** argues that this part of the principle requires that the least onerous option be chosen with regards to the impact on individual rights, be they fundamental human rights, rights granted by the EEC Treaty, or rights otherwise recognised by the ECJ.[189] Any interference with, or derogation to, a right must be counterbalanced by the need to protect another right. The German interpretation of the principle has established an order of hierarchy between rights that must be followed for the measure to be proportionate.[190] This hierarchy is particular to Germany, and is not followed by the ECJ. It would appear nevertheless that the discretion of administrative bodies to justify their actions is less extensive in the case of proportionality *stricto sensu* than it is in the case of necessity. The State's interference with individual fundamental rights requires a much higher level of justification than interference with their economic rights. Proportionality *stricto sensu* therefore refers to the balance between impact on the individual and the benefit obtained.

### 3.3.2 the two forms of the principle in European Law

The first form was described above. This is the judicial or substantive manifestation of the principle of proportionality. Derived largely from German law[191] and principles of international law, the principle of proportionality is an expression of the prohibition against the abuse of fundamental rights, a manifestation of the concept of "rule of law", and an instrument for the judicial review of the legality of Community action.

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[186] Case C-331/88 *Fedesa* [1990] ECR I-4023, p. 4063.

[187] Described by **Emiliou (1996)** at p. 88.

[188] Described by **Emiliou (1996)** at pp. 29-30.

[189] At pp. 192-194.

[190] **Emiliou (1996)**, pp. 32-37.

[191] It is to be noted that the principle of proportionality is not formally recognised in French law. However, this is largely a matter of terminology as the combination of certain French legal doctrines in the process of judicial review (for example, the *principe de legalité* by which government bodies are formally subjected to the "rule of law", the concepts of *erreur manifeste d'appréciation* and of *bilan coût-avantages*, which have been discussed above) amount to the application of the principle of proportionality: **Emiliou (1996)**, pp. 88-91.

The second form is legislative or formal proportionality: derived from French law and principles of international law, proportionality forms a set of rules for institutions to observe in the exercise of the decision-making functions that are delegated to them under the constitutional instrument (*compétence d'attribution*), in the case of the EU: under the Treaty. This form of proportionality is implemented at the legislative stage, as explained by **Emiliou (1996)** at pp. 139-142. Proportionality is formally recognised as a constitutional principle of EU law: it is enshrined in the third paragraph of Article 3b of the EEC Treaty, as inserted by the Treaty on European Union. It states, simply, that

> "Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty".

The principle has been further explained by guidelines issued at the Edinburgh European Council of December 1992:[192]

> "(ii) Any burdens, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators, and citizens, should be minimised and should be proportional to the objective to be achieved
>
> (iii) Community measures should leave as much scope for national decision as possible, consistent with securing the aim of the measure and observing the requirements of the Treaty. [ . . . ]
>
> (iv) Where it is necessary to set standards at Community level, consideration should be given to setting minimum standards, with freedom for Member States to set higher standards where this would not conflict with the objectives of the proposed measure or with the Treaty.
>
> (v) The form of action should be as simple as possible, consistent with satisfactory achievement of the objective of the measure and the need for effective enforcement. The Community should legislate only to the extent necessary. [ . . . ]"[193]

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[192] *Overall Approach to the Application by the Council of the Subsidiarity Principle and Article 3b of the Treaty on European Union*, Annex 1 to Part A of the *Conclusions of the Presidency*, European Council in Edinburgh, 11-12 December 1992.

[193] Idem, at pp. 8-9. **Emiliou (1996)** explains the interaction between the principles of subsidiarity, a constitutional principle specific to the federal nature of the EU, and the principle of proportionality, a general principle of good legal governance, at pp. 139-142. The two principles are complimentary but not interchangeable. The following guidelines, in the same series as those in the text, show the interrelation well in the context of EU legislative action:

> "(v) [ . . . ] Other things being equal, directives should be preferred to regulations and framework directives to detailed measures. Non-binding measures such as recommendations should be preferred where appropriate. Consideration should be given where appropriate to the use of voluntary codes of conduct.
>
> (vi) Where appropriate under the Treaty, and provided this is sufficient to achieve its objectives, preference in choosing the type of Community action should be given to encouraging co-operation between Member States, co-ordinating national action or to complementing, supplementing or supporting such action.
>
> (vii) Where difficulties are localised and only certain Member States are affected, any necessary Community action should not be extended to other Member States unless this is necessary to achieve an objective of the Treaty."

### 3.3.3 the principle of proportionality and the principle of non-discrimination

Although both principles derive from the "rule of law" and the almost universal prohibition on arbitrary legislation, the principles of proportionality and non-discrimination must not be confused.[194] European law has a large and complex body of case law on discrimination, but the essential rules are that dissimilar treatment of comparable situations (whether the situations or treatments are proportional or not) constitutes discrimination, unless objectively justified, usually on the basis of protecting a "higher" right; whereas dissimilar treatment of non-comparable situations does not necessarily indicate discrimination. Disproportion in a measure does not necessarily imply discrimination but may establish the existence of discrimination. On the other hand, a discriminatory measure does not necessarily entail disproportion: a deliberately discriminatory measure may well be perfectly proportionate. Discrimination

> "is concerned with the relationship between various groups of persons and takes the form of equality of treatment by bodies vested with public authority, whereas the principle of proportionality means that the burdens imposed on the persons concerned must not exceed the steps required in order to meet the public interest involved".[195]

It is true that the third element of proportionality, where applied, is germane to the principle of non-discrimination, but the latter is wider: it touches all dissimilar treatments and not just interference with fundamental rights. The principle of proportionality can be seen as a measure of *technical* adequacy as it is mechanistic in nature whereas the principle of non-discrimination can be seen as a measure of moral adequacy. However, even though human rights are considered fundamental, they are nevertheless policies of a given society and themselves subject to justification under the principle of proportionality. The latter remains the only measure of functional adequacy of a legal mechanism. Furthermore, the action of the two principles is entirely different. The application of the principle of proportionality grants the person whose rights are disproportionately affected protection from the action of that measure (or the abrogation of that measure in certain cases) whereas the application of the principle of non-discrimination grants the affected person a right to claim the benefits of the measure which are granted to others.

Disproportion is often simpler to establish than discrimination. Disproportion is demonstrated on objective grounds, whereas discrimination requires the examination of individual circumstances to be proven. On the other hand, differential treatment is often easier to justify against a charge of discrimination than against a charge of disproportion as discrimination generally affects economic rights, which can be overridden by fundamental rights, whereas disproportion generally concerns breaches of fundamental rights.

The interaction of disproportion and discrimination is explored in the next Chapter, using the example of safety regulations in the context of international trade.

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[194] **Emiliou (1996)** provides a comprehensive analysis at pp. 148-161.

[195] Case C-114/76 *Bela-Muhle* [1977] ECR I-1211, pp. 1232-1233 per Advocate General Capotorti.

### 3.3.4 the precautionary principle

It has been argued above that the proportionality of a measure to the problem it addresses necessarily entails a margin of uncertainty. If all the problems encountered in real life were predictable enough to make unacceptable any measure that does not precisely cater for each and every aspect of the problem it addresses, there would be no need for preventative measures at all, at least in the meaning of regulations: each and every individual would be able to avoid the circumstances in which problems would arise. They would, effectively, have perfect foresight.

In the real world, however, no problem is perfectly knowable in advance, and is rarely perfectly knowable after the fact despite the advances in forensic techniques and the deduction of causes of failures. It is also almost impossible to have perfect knowledge, in advance, of all the means available to alleviate the problem when it occurs. It is therefore extremely difficult to establish preventative measures that approach proportion in the natural meaning of the word.

Proportion, in the legal meaning given above, establishes a high standard of justification for measures taken to alleviate a problem, but this standard is far from absolute. It is largely a requirement that decision-makers must do the best they can within the sphere of their reasonable capabilities and competence. *Effectively, the proportion required of the measure is not in relation to the problem it addresses, but in relation to the level of available knowledge about the problem and the resources available to mitigate the effects of the problem.* Proportion is therefore a function of the certainty or uncertainty of available knowledge concerning the problem in question.

Where there is any level of uncertainty, which is virtually always the case, the standard for proportionality of a measure can only err either on the side of prudence, doing a little more than would appear necessary just in case some variable has been overlooked, or on the side of risk, leaving such an eventuality to chance. The former alternative is known as the *precautionary principle*, or the precautionary approach as the existence of a legal principle is still controversial.

It was shown above that State intervention in the form of regulations is justified by the failure of natural societal mechanisms to avoid all the adverse effects of certain events. It was stated that this justification establishes the limits of the intervention in that the regulation or measure must not overstep its purpose. The measure must be justified in terms of suitability and necessity and it must not infringe fundamental rights. Arguably, the same justification for intervention establishes that the measure must not understep its purpose. If the regulation leaves certain matters to chance, its justification is compromised: the natural societal mechanisms will have to cope with the residual risk not covered by the regulation, just as they would have had to without the regulation. The benefit provided by the regulation may be out of proportion with the restrictions it imposes. The measure may be shown not to be suitable or necessary because of its limitations. Where the high standards of justification of the principle of proportionality are applied, only the adoption of prudence stands to scrutiny. The principle, by nature, prohibits excessive laws, but it can also strike down inefficient and unnecessary laws: the legislative quality control provided by the principle defines an acceptable area for State intervention between excessive action and inaction.

The correlation between the principle of proportionality and the precautionary approach is such that the latter can only be seen as a logically necessary part of the former. The principle of proportionality cannot be accepted without accepting the principle of precaution. The principle of proportionality requires that decision-makers take into account considerations that are relevant, reasonable and commensurate to the objective of the measure they propose: one of these considerations must be the treatment of uncertainty. The criterion of necessity, by requiring that the course of action chosen be the least onerous to achieve the objective with regard to all relevant circumstance, also requires that the course of action be *sufficient* to achieve that purpose. The case of *Fedesa* made it clear that the balance is finely set at the point where the objectives of the measure *could not be achieved* by means of less onerous measures. It therefore sets a minimum requirement that, to be proportional, a measure must not fail to achieve its objective. Within these parameters, only slightly excessive regulation, where the excess is justified by uncertainty in knowledge, is acceptable as proportional, whereas insufficient or ineffective regulation is no longer proportional because the restrictions and obligations it imposes are no longer justified its by meeting the objective.

The question is not whether the precautionary approach should be chosen, but what is the acceptable extent of the margin of precaution? Just how far is it reasonable to err on the side of prudence? This is also governed by the requirements of the proportionality principle. The suitability of the measure, and of the margin of prudence it provides for, is established if there is a rational connection between the information (or lack of information) used by the decision-maker and the decision. The information used must justify (a) the reason for concern; and (b) the level of concern. The necessity of the measure, and of the margin of prudence, is determined sovereignly by the decision-maker in relation to all the relevant circumstances that fall within his remit. This includes the certainty or uncertainty of the knowledge concerning any given course of action. The decision-maker may therefore choose to take the least uncertain route rather than the most economically efficient. The proportion *stricto sensu* of the measure, and of the chosen level of prudence, is determined by the nature and extent of the rights this course of action may interfere with as compared with the nature and extent of the rights that prudent action seeks to protect. The choice of the precautionary approach itself, as opposed to choosing the risk-taking approach under uncertainty, is a decision that is subject to the principle of proportionality: it must be shown to be suitable, necessary and not in contravention of fundamental rights.

The precautionary approach has had a chequered legal history up to the present. There are many reasons for this, the main reason being that the principle is often considered in isolation, without placing it in the context of other principles of good governance, be they economic, moral or legal.

**O'Riordan & Cameron (1994)** present an unflattering portrait of the principle: it is described as a

> "culturally framed concept that takes its cue from changing social conceptions about the appropriate roles of science economics, ethics, politics and the law in pro-active environmental protection and management. [ . . . ] it is a rather shambolic concept, muddled in policy advice and subject to whims of international diplomacy and the unpredictable public mood over the true cost of [environmental sustainability]".

It need not be so. One of the problems in defining the precautionary principle resides in its association with the nebulous, highly uncertain, concept of environmental sustainability.

The precautionary principle came to the fore at the UN Conference on Environment and Sustainability, held in Rio de Janeiro in 1992, simultaneously with the concept of sustainability, although both are much older.[196] The precautionary principle must not be confused with sustainability. There are two aspects to the quest for environmental sustainability, but only one is reflected in the statement of the principle of precaution in the Convention that emerged from the conference. Sustainability requires prevention *and* conservation. Prevention, in that sustainability requires that action is taken to prevent harm before evidence of harm becomes available, i.e. remediation is insufficient to attain sustainability because remediation implies that harm has occurred which implies degradation from the present level. Conservation, as sustainability implies, at the very least, a continuation of the present state of the environment or environmental status quo. Sustainability allows for improvements in the environment but, if and when improvements are possible, the new status quo achieved through these improvements must be preserved. Sustainability does not allow for decreases in environmental quality.

Sustainability is a policy which is precautionary due to the level of uncertainty in relevant knowledge. It is subject to scrutiny by the principle of proportionality which, it has been shown, incorporated precaution as a mechanism for dealing with uncertainty. As with non-discrimination, sustainability is not a measure of adequacy but an end that can be assessed as adequate. However, sustainability shares precaution's onus-shifting characteristics. Sustainability requires a sea change in societal attitudes. Rather than pursuing economic growth and technical progress regardless of the effect on the environment, society is required to show restraint and demonstrate the requirement for any change, whether positive or negative, from the status quo. The onus of proof would therefore shift from those that oppose change onto those that promote change. A shift in the onus of proof is present in the precautionary approach as stated in legal instruments, but it does not imply conservation. The precautionary principle is dynamic rather than being static as conservation necessarily is. Rather than promoting the shift as a policy goal, the precautionary principle has an onus-shifting effect due to the overriding principle of proportionality's requirement of justification. Rather than imposing legislation relying on power alone to sustain it, and rebutting challenges on unanswerable grounds such as national security, the principle of proportionality requires the promoter of a measure to justify it in the face of challenge. It will be shown below that a *prima facie* case must be made to bring a challenge, but the onus of proof has effectively (rather than by design) been shifted from the challenger to the justifier of a regulation.

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[196] This is shown in particular by **Bodansky (1994)**, at p. 214. He quotes from a celebrated US environmental law case (Ethyl Corporation v. Environmental Protection Agency 541 F.2d 1 (DC Cir. 1976)) where the District of Columbia Court of Appeals commented, "A statute allowing for regulation in the face of danger is, necessarily, a precautionary statute [ . . . ]". It added, "Awaiting certainty will allow for only reactive, not preventative regulation [ . . . ]" which would obviate the precautionary purpose of the statute.

**Haigh (1994)** lists a number of legal instruments defining the precautionary principle.[197] Part of that list is presented here:

(a) The final document of the Second Conference on the North Sea of November 1987, held in London, stated that:

> "a precautionary approach is necessary which may require action to control inputs of [dangerous] substances [to the North Sea] even before a causal link has been established by absolutely clear scientific evidence".

(b) The final recommendations of the Paris Convention for the Prevention of Marine Pollution from Land Based Sources (PARCOM) of 22 June 1989, at recommendation 89/1 stated:

> "[the principle of precautionary action] applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused [ . . . ] even where there is no scientific evidence to prove a causal link between emissions and effects".

(c) The final document of the Third Conference on the North Sea of March 1990, held in The Hague, stated that:

> "The participants [ . . . ] will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances [ . . . ] even when there is no scientific evidence to prove a causal link between emissions and effects".

(d) The Bergen Ministerial Declaration of May 1990 described the principle in the following terms:

> "where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation".

(e) Principle 15 of Agenda 21, the final document of the 1992 Rio Conference states:

> "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

(f) Article 3 of the Framework Convention on Climate Change of June 1992 provides:

> "where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing [ . . . ] measures [to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects] "

(g) The Convention on Protection of the Environment of the North East Atlantic of September 1992 in Paris stated:

> "by virtue of [the precautionary principle] preventative measures are taken when there are reasonable grounds for concern that substances [...] may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other

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[197] At pp. 243-251.

legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects".

It is clear from these statements of the precautionary principle that it is not a requirement to maintain a *status quo*: it is in fact a mechanism for promoting changes. It is also to be noted that the principle calls for reasonable grounds, and implies that precautionary measures are temporary. They are only justifiable by, and reflect, the measure of uncertainty. Precautionary measures must not be confused with arbitrary knee-jerk regulation. The measure of precaution must be proportional to the uncertainty.

The precautionary principle says that lack of scientific knowledge will not prevent the imposition of safety measures. This means that where it is impossible to devise proportionate regulation due to lack of knowledge of the problem and of its solutions, regulation will be adopted rather than not adopted, in order to minimise the problem, even if the regulation is eventually shown to be disproportionate.

The principle of precaution necessarily implies a balancing act between proportionality and uncertainty. When knowledge becomes more certain, precaution is less justified. There comes a point, where knowledge and concern balance, at which the adverse effects of a problem become *acceptable*. This point is dictated by the criterion of necessity in the principle of proportionality: it is up to the decision-maker to set - and justify - the chosen level of concern above which the adverse effects are unacceptable, and below which they are acceptable.

The setting of a level of safety is recognised as being a sovereign right, as explained in the next Chapter. However, this does not mean that the setting of the level is arbitrary or irrational.

As a final point for this Chapter, it follows from the above that the principle of proportionality informed by the principle of precaution calls for clarity and openness in justification, rationality and predictability of the measures imposed. The requirements of a measure must be set out as clearly as possible for the persons affected by the regulation not to be unduly restricted, and to enable the regulated community to derive the optimum benefit from it.

## Chapter Four: "Safety" in the context of Proportionality and Precaution

It has been shown that, for a law to be described as adequate, its provisions must be demonstrated to be proportional to its purpose. This demonstration need not be made prior to its promulgation or be incorporated in the text of the law,[198] but will be required in reply to a legal challenge. The WTO example in Section 4.2 below shows that, when the adequacy of a law is challenged, it suffices to show that an assessment of the law's proportionality was conducted at some stage of the legislative process for the law to be judged adequate. In the specific case of the WTO, the assessment can be done post-promulgation to demonstrate that it is adequate to *maintain* a law.

It will be shown in this Chapter, with references to the WTO's treatment of safety regulations, that the demonstration of a regulation's proportionality requires two things, subject to the general proviso that the measure does not affect fundamental rights as *per* proportionality *stricto sensu*:

- a stated problem: this is the event with adverse effects of Chapter Three. In the context of regulations governing safety such as the European GMO regulations, such an event is known as a **hazard**. The appropriateness of the measures specified in the regulation is measured with regard to the hazard and its consequences; and

- a level of concern: taking into account all relevant information, the hazard and its consequences may require drastic action or slight intervention. The level of concern is synonymous with the necessity, established sovereignly by the decision-maker, of the measure. The level of concern is generally known in the context of safety regulations as the appropriate level of **risk**.

The concepts of hazard and risk are essential to the assessment of any regulation concerning GMOs. A "hazard" is a specified adverse event; a "risk" is a measure of the likelihood of an event taking place. These are simple definitions: the matter is considerably complicated by the different concepts of risk currently used in regulatory assessments. The specific "risk" associated with a given hazard is a measure of the likelihood of that particular hazard occurring, but also of the likelihood of the range of possible consequences occurring, and a measure of the severity of those consequences. All of these elements of risk only form part of an assessment of risks as they do not indicate the availability of measures to prevent the hazard or its consequences from occurring or to palliate the effects of those consequences if they cannot be prevented; nor do they indicate the acceptability of the adverse effects.

Acceptability of risks is the central aspect of the regulatory treatment of risks, but is often neglected as it cannot be easily assessed, quantified or measured. Not all adverse consequences of an

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[198] American regulations are extensively justified in the *Federal Register* prior to promulgation , as part of a permanent public consultation process. Reference can therefore be made to the reasoning and the available knowledge backing up the "appropriateness", "necessity" and "proportionality *stricto sensu*" of the instrument. If the recommendations of the Committee for the Modernisation of the House of Commons are put into place, a similar level of pre-legislative scrutiny will take place in the UK. Similar developments would be welcome in the EU. The *Official Journal* carries the text of proposals and reports of studies but there is no systematic justification of each legislative proposal. This would considerably aid the implementation by Member States of EU instruments.

event can be prevented or palliated but, if the event also has beneficial effects that are sufficiently desired by society, these risks are acceptable. In other words, the benefit outweighs the risk. A prime example is medical surgery: all operations carry a risk of death or injury worse than the disease or injury intended to be cured but the cure is more likely than the adverse outcome, so the risk is acceptable to those willing to undergo it. This elusive point where the risk becomes acceptable is the point where the activity or the product bearing the hazard can be described as "safe". The level of safety depends on the activity or the product: it is accepted that skydiving is riskier than taking a bath and the level at which risks become acceptable to those who undertake them is accordingly different.

Where there is uncertainty as to the exact nature of the hazard or to the nature and extent of its consequences, setting a level at which the risks become acceptable is made even more difficult. The function of the precautionary approach is to allow the reducing of the level of acceptable risk, i.e. the widening of the scope of safety or the increase in the level of safety, to allow for this uncertainty in knowledge. Measures taken to prevent or palliate the harm and its consequences remain necessary, in the meaning of the principle of proportionality, even where there is a less onerous alternative which would be adopted if the uncertainty was disregarded. Precaution allows a deviation from the *prima facie* proportional response to the stated problem.

## 4.1 Legal definitions of safety

How can a measure define the level of "safety", and do so in a predictable and non-arbitrary fashion? To answer this question, it is necessary to explore the meaning of the term "safety" in current law.

One of the main problems of the EU regulations is that they attempt to promote a general level of "safety", rather than address specific hazards. "Safety" is a much more difficult concept to define than individual hazards. It is an open-ended concept; that is to say it is impossible to define its limits. "Safe", in the absolute, means absence of all hazards. "Averagely safe" or "very safe" are both contradictions in terms. They both mean that some hazards remain but, in the first case, they are averagely unlikely to occur and, in the second case, they are very unlikely to occur. It follows that safety can only be defined in the negative, and indeed there are no universal *positive* definitions of "safety" in law,[199] but *proving a negative* is extremely difficult.

Three legal techniques have been developed to get around this problem.

### 4.1.1 Three definitions of safety

These are:

- definition by implication, i.e. that which is not prohibited is implied to be safe;
- definition by negative reference via specifying the avoidance of harm or prescribing the reduction or elimination of the risk of harm (the terms "harm" and "risk of harm" being themselves subject to definition);

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[199] This author has found that there is no positive Common law definition of "safety", and "safety" is not defined in any English statute governing food safety, environmental protection, plant and animal health or plant varieties, other than negatively.

- eschewing fixed definitions and providing for a *mechanism* to determine an acceptable level of hazards and their consequences, whatever they may be, i.e. a *relative* measure of "safety".

As this thesis concentrates on agricultural GMOs and their eventual use as food, the relevant areas of enquiry are food safety and consumer products. The regulations in these areas are not helpful in order to define "safety".

The Food and Drugs Act 1955 ("FDA 1955"), s.1, provided that it was an offence to

> "add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food, or subject food to any other process or treatment so as (in any such case) to render the food injurious to health, with the intent that the food be sold for human consumption in that state."

Foods that avoided the definition of "injurious to health", developed by judicial consideration, were safe by implication. It was not necessary for the food to be injurious to the health of all the population: it was deemed to be injurious to health if it was injurious to a substantial proportion of the community. Furthermore regard was to be had not only to the immediate effect of the food but also its cumulative effect, and the cumulative effect of "articles of substantially the same composition", over long periods of normal dietary exposure.

The Food Safety Act 1990 ("FSA 1990") replaced the reference to "food rendered injurious to health" with the concept of "food failing to comply with food safety requirements". Such food is defined in s.8(2) FSA 1990 as being (a) food that has been rendered injurious to health by any of the operations described in s.1 FDA 1955, above; (b) food that is unfit for human consumption; or (c) food that is

> "so contaminated, whether by extraneous matter or otherwise, that it would not be reasonable to expect it to be used for human consumption in that state".

The Secretary of State was empowered to make regulations under the FSA 1990 setting the safety requirements of classes of foods. These, however, only enumerated the activities or events that would cause the foods to fail the food safety requirements rather than giving a positive definition of "safety". Again, food that did not fail to comply with food safety requirements was safe by implication

Before the Consumer Safety Act 1978 ("CSA 1978"), "safety" was not defined in the area of consumer goods either. A person committed an offence if that person sold a good that did not comply with the requirements of the applicable regulations, for example the Sale of Goods Act 1893 (replaced by the Sale of Goods Act 1979, in particular its sections 13 to 15) and sections 9 to 11 of the Supply of Goods (Implied Terms) Act 1973, which govern the good's *fitness for purpose*.[200] This concept does not govern safety, especially where the purpose of the good is unsafe by nature. The CSA 1978 used the same approach as the FDA 1955: that which is not prohibited is safe. Outside of the scope of these regulatory requirements, the duty to provide a "safe" product was defined by the principles of duty of care and reasonable forseeability with regard to the harm caused imposed by the law of negligence.

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[200] These were largely insufficient to provide for adequate consumer protection as discussed by **Howells (1998)**, pp. 3-13 and 15-46.

The CSA 1978 empowered the Secretary of State to make regulations appropriate for ensuring that a particular good or class of goods are "safe", and to make orders prohibiting the sale of goods which the Secretary of State did not consider "safe". In this context, "safe" was defined by negative reference as being such as to prevent or adequately to reduce any risk of death and any risk of personal injury from the goods in question or from circumstances in which the goods might be used or kept.

It was not until the Consumer Protection Act 1987 ("CPA 1987") that a general safety requirement ("GSR") was introduced.[201] A person now commits an offence if he sells a consumer good that does not comply with the GSR. Under s.10(2) CPA 1987, a consumer good fails to comply with the GSR if it is not

> "reasonably safe having regard to all the circumstances including the following: (a) the manner in which, and purposes for which, the goods are being or would be marketed, the get-up of the goods, the use of any mark in relation to the goods and any instructions or warnings which are given or would be given with respect to the keeping, use or consumption of the goods; (b) any standards of safety published by any person either for goods of a description which applies to the goods in question or for matters relating to goods of that description; and (c) the existence of any means by which it would have been reasonable (taking into account the cost, likelihood and extent of any improvement) for the goods to have been made safer."

For the purposes of s.10(2), s.19(1) CPA 1987 defines "safe" as meaning

> "such that there is no risk, or no risk apart from one reduced to a minimum, that any of the following will (whether immediately or after a definite or indefinite period) cause the death of, or any personal injury to, any person whatsoever, i.e. (a) the goods; (b) the keeping, use or consumption of the goods; [ . . . ] (d) any emission or leakage from the goods or, as a result of the keeping, use or consumption of the goods, from anything else [ . . . ]."

Safety is still confined to considerations of personal injury, but its scope is now completely open-ended to encompass all hazards that may cause injury rather than a finite list of hazards or injuries.

The 1987 Act is reinforced by the General Product Safety Regulations 1994 ("GPSR 1994")[202], regulation 2, which defines a safe consumer product as

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[201] Part I of the CPA 1987 implemented the EC Council Directive 85/374 (O.J. L210, 7.8.85, p. 29) relating to product liability, which was subsequently amended by EC Council Directive 99/34 (O.J. L141, 4.6.99, p. 20). The effect of the amendment was to extend the application of the provisions relating to defective products to "primary agricultural products" which had until then controversially been exempt from these provisions. Part II of the CPA 1987 introduced a separate product safety regime built around the GSR. A history of the development of English product safety law is provided by **Howells (1998)**, pp. 253-286. Prior to 1961 and the Consumer Protection Act 1961, product safety regulations had been specific to certain product sectors such as foods, medicines and sundry others such as fireworks. The 1961 Act introduced the Secretary of State's wide powers to impose regulations on any class of goods in order to prevent or reduce the risk of death or personal injury. The 1961 Act was replaced by the Consumer Safety Act 1978, itself updated by the Consumer Safety (Amendment) Act 1986, and replaced by the 1987 Act.

[202] Enacted to implement the European product safety directive which the GPSR largely replicate: Council Directive 92/59/EEC on General Product Safety: O.J. 1992 L228/24.

"any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance, the effect on other products, where it is reasonably foreseeable that it will be used with other products, the presentation of the product, the labelling, any instructions for its use or disposal and any other indication or information provided by the producer and the categories of consumers at serious risk when using the product, in particular children. The fact that higher levels of safety may be obtained or other products presenting a lesser degree of risk may be available does not of itself cause the product to be considered other than a safe product."

Regulation 10 GPSR 1994 provides further that:

> "[ . . . ] Where no [ . . . ] specific rules exist, the conformity of a product to the [GSR] must be assessed taking into account voluntary national standards of the United Kingdom giving effect to a European standard or EC technical specifications or, if there are no such [standards or specifications], standards drawn up in the United Kingdom or the codes of good practice in respect of health and safety in the product sector concerned or the state of the art and technology and the safety which consumers may reasonably expect."

The GSR represents a departure from the previous two approaches to defining safety. Under the safety by implication technique and under the safety by reference to a particular type of harm, legal responsibility arose when it was shown that the prohibited action or harm actually occurred. Under the GSR, responsibility arises when a particular standard of care has not been achieved, whatever the action or the harm that occurred. Focus has shifted from the factual, objective question whether an act or harm can be proven to have occurred to the subjective question whether the person who perpetrated the action or provoked the harm can justify their actions. The GSR is therefore more flexible and responsibility-based rather than solely dependant on establishing a fact: it provides for a more consistent, more widely applicable method for assessing the adequacy of measures taken to prevent harm from arising. It is adaptable to more situations. It is also more responsive to the nature and extent of the harm, and to the context of the harm: this makes it more proportional than the inflexible yes-no alternatives of responsibility arising from a matter of fact alone. The GSR demonstrates that "safety" cannot be regarded as a positive concept and cannot be narrowly defined. On the contrary, with regard to the range of considerations that need to be taken into account to establish compliance with the GSR, it is clear that "safety" - at least in the context of product safety - is a *relative* concept. Safety can only be a judgement formed from the perception of physical facts and their impact on the subjective human interests - as discussed in the nature of law in Chapter Three.

The EU regulatory framework is accused of failing to distinguish between different levels of risk, and offering only a yes-no range of regulatory solutions to an application to use a GMO. Whether this accusation is borne out is studied below. However, it is shown in Subsection 4.1.3 of this Chapter that the EU GMO regulations do not incorporate the GSR.

The GSR differs from the other two legal techniques in that (a) it provides for a risk assessment and (b) in that the required level of safety is "reasonably expected" by the general public, i.e. the persons most likely to be affected by any safety problems.

The concept of a risk assessment, the process by which all the relevant considerations are taken into account to define the level of safety that is applicable, is a controversial concept. It was certainly not alien to English law when introduced by the European Directive of 1985. It had, in fact, been pioneered by the Health and Safety at Work Act 1974 ("HSAWA 1974"). This Act did not positively define the terms "safety", "risk", "hazard" or "harm", leaving these to be judicially considered in the light of guidance documents periodically issued by the Health and Safety Executive (the government agency overseeing the application of HSAWA 1974, amongst other, and created by that Act). The HSAWA 1974 only provided that every employer must make a suitable and sufficient assessment of (1) the risks to the health and safety of his employees to which they are exposed whilst they are at work; and (2) the risks to the health and safety of persons not in his employment arising out of or in connection with the conduct by him of his undertaking. Risk assessments were not defined either. However, guidance provided that a risk assessment should ensure that all relevant risks or hazards are addressed. The aim is to identify significant risks in the workplace. Those aspects of work which have the potential to cause harm should be identified and the risks from them addressed and reviewed".

What a regulatory risk assessment should or should not contain remains a heated debate. The core of the matter is whether the risk assessment should only assess potential harm, or whether it should, in addition, pass judgement over the acceptability of the harm in the light of the benefits that may accrue. The GSR takes a position in this matter: it assesses only potential harm. The only economic factors to take into account are those that dictate the feasibility of achieving the level of safety expected by consumers. It is a strict measure of whether a person has achieved the required level of safety for the product given the available resources.

The fact that the acceptable level is set by the reasonable expectations of consumers reflects the GSR's purpose of including stakeholders in the regulatory process concerning product safety. The negative side of this is that a relative concept is made yet more uncertain by this shifting frame of reference. In the US, the quest for *certainty* in the establishment of levels of safety has been fraught with difficulty.

### 4.1.2 the US experience

In the US, the FDA has been struggling with the concept of "safety" since the 1950s. The governing US statute for food safety, the Federal Food Drugs and Cosmetics Act of 1938, was amended in 1958 by the Food Additives Amendment in response to growing consumer fears about chemical additives in food. It is one of the first precautionary statutes of the US in that it is burden-shifting and imposes a pre-market approval process which deals with uncertainty. Before an additive may be permitted to be used in food, the producer must demonstrate its safety to FDA rather than the FDA prohibiting the use of the additive and providing evidence of danger to back up this measure.

Under the 1958 amendment, all food additives (defined at 21 USC 321(a)[203]) are deemed to adulterate (i.e. render unfit for consumption) any food that bears or contains it (21 USC 342(a)(2)(C)) if the additive is not proven safe (defined at 21 USC 348(a)). FDA has defined "safe" (at 21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The FDA's approach is clearly different from that of the EU or the UK authorities. Congress had set a very high level of safety in the Amendment, i.e. there must be reasonable certainty that *no* harm will result from the approved use of a product, rather than an acceptable level of harm, for the product to be safe. Furthermore, Congress wanted this standard to be objective, i.e. predictable and consistent. Rather than setting standards by reference to changeable consumer expectations or by reference to all "reasonable" circumstances, the FDA has attempted to narrow down the range of considerations to scientific considerations only in order to promote certainty and objectivity. This is demonstrated by the two-step definition of food additive:

- any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of, or otherwise affecting the characteristics of, food is a food additive; but
- excluded from these categories are substances that are generally recognised, among experts qualified by scientific training and experience to evaluate their safety ("qualified experts") as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1st 1958, through scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use.

This exclusion of substances which are considered generally recognised as safe ("GRAS"), recognises that the safety of a substance cannot be demonstrated with absolute certainty. It also recognises that the standard set by Congress is very difficult to achieve, arguably impossible.

Where the proponent of an additive can demonstrate that the additive is safe, the FDA will allow its use under regulated status. The "competent scientists" who decide that the product is "safe" in the meaning of 21 CFR 170.3(i) belong to the FDA in this case: they must decide whether the product is "safe" on the basis of the information provided to them by the proponent and must justify their decision by an announcement in the *Federal Register* concerning the approval of the product.

Where the proponent believes that the product is GRAS and wants the product to escape from regulation altogether, he or she must present a higher level of justification to FDA - at least this is what was intended by Congress. The proponent must demonstrate that not only is the product safe, as required above, but that the technical evidence of safety thus presented is generally known and accepted by the scientific community. A plethora of court cases has established that the proponent must demonstrate that there is a consensus of scientific opinion regarding the adequacy of the technical evidence of safety. However, consensus - strangely - does not mean unanimity, nor even a lack of conflict between scientists. It means that only evidence of a severe conflict of opinion amongst

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[203] American references to legislation can be by reference to sections of the original statutes or by reference to the sections of the United States Code (USC) or Code of Federal Regulation (CFR) into which the legislation is integrated. This may cause confusion to English lawyers as there is no logical relation between section numbers in the one and in the other.

qualified experts regarding safety may preclude a finding of GRAS status. The "knowledge element" of the GRAS definition has two elements (neither being sufficient in itself to establish GRAS status):

- the data and information relied upon to establish the technical evidence of safety must be generally available; but this only means that publication in a peer-reviewed journal is sufficient;
- there must be a basis to conclude that there is a consensus among qualified experts; this includes
    - publication in a peer-reviewed journal (again);
    - publication in "secondary scientific literature"; i.e. reviews, textbooks and compendia;
    - opinion of a specially convened "expert panel";
    - opinion or recommendation of an authoritative body such as the National Academy of Sciences.

These criteria are inconclusive as to whether the technical evidence thus approved is sufficient or correct. The FDA will not check the technical evidence if there is evidence of scientific consensus. Effectively, FDA delegates its competence in the matter to the scientists forming the consensus. This means that FDA does not assess the quality of the information, but the quality (i.e. reputation and expertise) of the scientists approving the information, placing its faith in the diligence and integrity of unaccountable individuals. Congress' high standard, arguably difficult to achieve, has been watered down to meaninglessness by FDA's abdication of political responsibility in favour of the scientific community for the sake of "objectivity".

The changeable nature of the GSR's frame of reference is not necessarily a cause of inconsistency in regulatory treatment of products over a given period of time. Consumers' expectations are just an input to the decision-making process, a variable in the equation, whereas the mechanism of decision-making remains the same, ensuring that there is no inconsistency in treatment. By keeping the inputs to the mechanism variable, the mechanism is capable of producing decisions that are in keeping with the circumstances at that particular time (law being a time-bounding mechanism). The US believes that consistency in treatment can only be achieved by ironing out the variables and providing universally "true" inputs to the decision-making process - scientific data being considered objective fact and thereby universally true whatever the time frame they are inscribed in. This is not the correct approach: an objective decision-making procedure processing subjective inputs is more likely to succeed than a subjective decision-making procedure processing objective inputs, as is the FDA's assessment of scientists rather than of science.

For the sake of public information, FDA maintained a list of GRAS substances to which promoters could add their substances by way of a petition procedure. This was vital for certainty in the food industry as, if the GRAS determination was erroneous, FDA had the power to remove the additive from the market. This proved so cumbersome, more so than simply regulating the substances, that FDA began to provide non-binding and non publicly available opinion letters in response to the food industry's queries whether their determinations of GRAS were acceptable to the FDA. This practice was formally revoked in 1970 and FDA embarked on a comprehensive review of its list of GRAS substances in the same year, which has never been completed. During this time, FDA also reviewed its

criteria for the scientific procedures required to demonstrate safety and for the requisite experience to define familiarity on a number of occasions.

In 1997, the FDA changed approach entirely and abandoned the highly procedural, slow and expensive (both for the promoter an the FDA) petition process for a prior notification procedure for use of a deemed GRAS substance. Under this procedure, FDA would only have to take formal action where it objected to the proposal of GRAS status. Although FDA's reliance on "scientific consensus" has not ceased, FDA has established a more cohesive decision-making process for its requirement of safety. Furthermore, FDA has re-established its responsibility for review of all the evidence.

Although the EU and the US definitions of safety remain very different, the former being consumer led and the latter expert led, both are based on decision-making procedures rather than on lists of prohibited actions or targeted harm. There is therefore a basis for comparison between the two and exchange of information, as discussed at a later stage.

### 4.1.3 The exclusion of agricultural produce from product liability and product safety law

Both the CPA 1987 and the European Directive 85/374 (as originally drafted) excluded "primary agricultural produce" and "food" from the remit of product liability law. Similarly, the GPSR 1994 and the European Directive 92/59 excluded these same items from the remit of product safety law. GMOs, whether considered as growing crops or as human food, were not covered at the time of the mixed-crop import problems mentioned in Chapter One.

These exclusions had been controversial from the start, and were a major barrier to the adequacy of the EU regulatory framework for GMOs.

Although the definition of "product" (s.1(2) CPA 1987) included "goods" which in turn included "growing crops and things comprised in land by virtue of being attached to it" (s.45),[204] s.2(4) excludes liability under the CPA 1987

> "in respect of any defect in any game or agricultural produce if the only supply [ . . . ] by that person to another was at a time when it had not undergone an industrial process."[205]

The CPA 1987 did not define the term "industrial process" but it has been argued[206] that its meaning can be deduced by the definition of "producer", which includes the person who carries out an industrial or other process which directly alters the essential characteristics of a product.[207] The Government had stated that the process must be an industrial process, defined as carrying on "on a large and continuing

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[204] The definition of "goods" also includes "substances" which are defined *inter alia* as "any natural or artificial substance, whether in solid, liquid or gaseous form or in the form of a vapour". This arguably could include living creatures and GMOs.

[205] Agricultural produce is defined as "any produce of the soil, of stockfarming or of fisheries" by s.1(2), prompting some nit-picking whether vegetables grown in hydroponic cultures, where soil is not involved, would not be considered agricultural produce - but this is far-fetched: see **Nelson-Jones & Stewart (1988)**, p. 37.

[206] **Lowe & Woodroffe (1995)**, pp. 65-66.

[207] This requirement, however, does not appear in the Directive: **Oughton (1991)**, p. 249.

scale and with the intervention of machinery".[208] The Directive did not use the term "industrial process" but uses the wider term "initial processing" in its Article 2.[209] **Lowe & Woodroffe (1995),** stated that

> "the Government has expressed the view that the "process" must be something applied to the product *after* it has become a product so that, for example, spraying growing crops or injecting hormones into live animals would not qualify."

They also asserted that it "is by no means certain that a court would uphold this view".[210] **Oughton (1991)** indicates that processes such as crop-spraying or hormone treatment of cattle may well be said to be "initial" in the meaning of the Directive, but it is questionable whether such processes could be said to be "industrial" under the Act, thereby causing conflict between the two instruments.[211]

Similarly, the GSR applies to "consumer goods" the definition of which reprises the definition of "goods" mentioned above (s.10(7) CPA 1987), but excludes "growing crops or things comprised in land by virtue of being attached to it" (s.10(7)(a)) and "food" (s.10(7)(b)). This exclusion is not limited by reference to not having undergone an "industrial process". In this regard, product safety law was less stringent than product liability law.

The exemption had been considered "suspect" from the implementation of the 1985 Directive.[212] It made no sense that the producer of processed foods should bear the liability under the CPA 1987 when the foods were made defective because of defective primary agricultural produce used as ingredients.[213] It made even less sense in the light of the increasingly "high-tech" nature of farming. The exemption was justified by the lack of human intervention traditionally believed to be inherent in the growing of crops (i.e. the crops are the "bounty of the Earth", and the farmer's husbandry only helps Nature in her task) - but this was no longer applicable due to the use of fertilisers and pesticides, let alone genetic modification. It would appear that the farming lobby had succeeded in placing the interests of the farming industry above the interests of the consumer.[214]

The 1985 Directive was amended to abolish the exemption of primary agricultural produce in 1999 and the CPA 1987 was similarly amended in 2000.[215] Primary agricultural produce is now subject to the product liability regime of the CPA 1987, if not to the GSR, further widening the illogical gap between the two regimes. However, the development risk defence will apply to primary agricultural produce and hence to GMOs, i.e. it will be a defence to prove that the state of scientific and technical

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[208] **Nelson-Jones & Stewart (1988),** pp. 37-38.

[209] **Oughton (1991),** p. 249, points out that the Directive refers to an industrial process in the third recital.

[210] Both at p. 66.

[211] At p. 249.

[212] **Oughton (1991),** p. 250.

[213] Note that the producer of processed foods would still benefit from available contractual remedies.

[214] **Oughton (1991),** p. 250.

[215] By the Consumer Protection Act 1987 (Product Liability)(Modification) Order 2000 (SI 2000 no 2771).

knowledge at the time when the product was put into circulation was not such as to enable the existence of a defect to be discovered. This exemption, used by almost all Member States,[216] would counteract the opening up of liability to agricultural produce insofar as GMOs are concerned. Nevertheless, the utility in the abrogation of the agricultural exemption lies not in the imposition of liability, but the mechanism provided by the Directive and the CPA 1987 to identify whom should bear that liability: farmers and seed producers are now included in the chain of liability. The immediate effect of this is that agricultural produce effectively becomes traceable as each and every party will keep a record of their transactions in order to pass liability along the chain.[217] This might have the indirect effect of ensuring greater product safety.

As it would appear that the setting of a standard of safety is dependant on consumer perception as well as socio-economic factors, there is likely to be a large variance of safety levels between different countries. There are norms in international law that govern this. However, "safety" is not positively defined by either the WTO or the EU treaty, which make constant references to safety.

## 4.2 Safety under the WTO

The main WTO document concerning safety is Article XX of the 1947 General Agreement on Tariffs and Trade (hereafter "GATT 1947"). This Article is incorporated into the Agreement establishing the WTO (hereafter "WTO 1994") by the action of Article XVI(4) and Annex 1A of WTO 1994.

Entitled "General Exceptions" (that is general exceptions to the principles of free trade embodied in WTO 1994), Article XX states:

> "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (a) necessary to protect public morals;
>
> (b) necessary to protect human, animal or plant life or health;
>
> [. . .]"

Article XX of GATT 1947 establishes the principle that the contracting parties to the WTO are sovereignly entitled to enact safety regulations, subject only to three restrictions:

1. that they are *necessary*, the meaning of which we will explore below;
2. that they are not applied in order to *arbitrarily or unjustifiably discriminate* between countries where similar conditions prevail;
3. that they are not disguised restrictions on international trade.

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[216] Except Spain and Luxembourg which do not apply the development risk defence to food products: **Rice (1996)**.

[217] This would resolve the calls for segregation.

Restriction one constitutes the WTO's version of the proportionality principle. Restrictions two and three are much the same thing: they constitute the WTO's version of the principle of non-discrimination. However, it is to be noted that, by being listed separately, the WTO's overriding objective of preventing restrictions on international trade is given particular importance in the assessment of the adequacy of regulations in the light of WTO obligations. It effectively represents that WTO's version of the protection of the fundamental human rights by the third part of the principle of proportionality, proportionality *stricto sensu*. Under the WTO, the only fundamental right of Contracting Parties is free trade. The purpose of Article XX, within the confined legal order of the WTO, is identical to that of the principle of proportionality in laws generally: both provide the means of justifying, of demonstrating the adequacy, of regulatory interventions that affect the rights of subjects of law.

Certain EU safety regulations have been assessed by the WTO, as shown below. The findings of the WTO as to this assessment help clarify the form such an assessment would take in the case of a US - EU dispute over GMOs as mentioned in Chapter One, and generally clarify how such an assessment would take place under the wider requirements of the principle of proportionality.

It is proposed to concentrate on the requirement of necessity. Whether a measure is applied with the intent of arbitrarily or unjustifiably discriminating against goods from other countries, whether the actual effect of the measure is to discriminate in this way, or whether a measure is a disguised restriction on international trade, are all questions of fact that can be demonstrated objectively.

The application of Article XX by the Agreement on Sanitary and Phytosanitary Measures (the "SPS Agreement" appended to WTO 1994) is designed to provide an objective measure of necessity by imposing strict requirements for the measure to meet. As with judicial review, or the principle of proportionality of the ECJ, the WTO is not in measure to assess the merits of the decision that a measure is necessary, but can assess whether the decision was taken correctly.

The necessity of measures, in the WTO meaning of the term, is determined with regard to the requirements of the SPS Agreement. There is no Agreement concerning public morals, and, to date, no WTO consideration of what would be a measure necessary to protect public morals. The debate as to whether moral opposition to GM foods is justified or not will presumably not be solved in the light of a WTO trade dispute. However, as it will be shown below, moral considerations are relevant to the necessity of a safety measure under the SPS Agreement.

The principle embodied in Article XX is reaffirmed by the SPS Agreement. Firstly, in the Preamble, the SPS Agreement reaffirms as a guiding principle that no contracting party (known as a "Member" in the SPS Agreement) should be prevented from enacting sanitary or phytosanitary measures (hereafter SPS measures)[218] as long as they conform to the requirements set out in Article

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[218] SPS measures are broadly equivalent to the concept of "safety regulations" although the SPS Agreement has a much narrower definition of the measures which fall into its scope. These are defined as any measure applied

> "(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

XX and in the body of the SPS Agreement. Article 2(1) establishes that this is a *right* of the Member, and Article 2(4) establishes a presumption (which is rebuttable) that, where the measures conform to the requirements of the SPS Agreement, the Member has acted in accordance with its obligations under Article XX(b) of GATT 1947, and therefore under the WTO Agreement.

The right of a Member to enact SPS measures is not absolute: it is subject to the three restrictions mentioned above. The purpose of the SPS Agreement is to clarify the first and most difficult qualification of the right, that the measures must be necessary. Article 2 of the SPS Agreement, entitled "Basic Rights and Obligations", and in particular Article 2(2) provides that SPS measures must (a) be applied only "to the extent necessary" to protect human, animal, or plant life or health; and (b) be based on scientific principles and not maintained without sufficient scientific evidence except "where relevant scientific evidence is insufficient" as provided by Article 5(7).

There is no explicit definition of the word "necessary", just as there is no definition of the words "safety" and "safe", in the SPS Agreement or in WTO 1994. The necessity of the measure can be perceived by its confinement within a series of safeguards imposed on the Member's right to enact SPS measures by Articles 3 and 5. This procedure of confinement can be likened to the weighing up of factors that is necessary in order to determine whether a measure is proportional to the problem it is aimed to address. The SPS Agreement provides for the possibility for Members to err on the precautionary side of proportion through its provision in Article 5(7), mentioned above. This allows Members to provisionally adopt SPS measures on the basis of "available pertinent information"; but Members must

> "seek to obtain the additional information necessary for a more objective assessment of risk and review the [safety regulation] accordingly within a reasonable period of time".

Clearly, the WTO recognises a need for a precautionary approach, albeit one phrased in the most restrictive terms. The WTO provides Members with a temporary exemption from the full extent of its general obligations and imposes a duty on the Member to actively reduce the scope for the exemption.

In order to avoid the difficulties that a proliferation of different safety standards may cause to international trade, the SPS Agreement, in its Article 3, entitled "Harmonisation", provides for a system by which all standards may eventually converge. This aim is in accordance with the temporary nature ascribed to the precautionary principle by the WTO. Article 3(1) provides:

> "Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist".

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(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." (Annex A(1))

Where there are no such international standards, the requirements of Article 2(2), i.e. necessity and scientific base, still apply. In this situation, as in the situation where a Member wishes to depart from existing international standards, the necessity of the measure is governed by the requirements of Article 5, explained below.

Notwithstanding the aim to harmonise standards, Article 3(3) provides Members with considerable discretion to set their own safety standards where international standards exist. Members may enact SPS measures which

> "result in a higher level of [ . . . ] protection than would be achieved by measures based on the relevant international standards"

in two circumstances, insofar as they are not inconsistent with any other provision of the SPS Agreement:

1. A higher level of safety than the international norm is justified where there is a *scientific justification* for the higher level of protection, which, for the purposes, of the SPS Agreement, means that the Member has proceeded to

   > "an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement"

   and determined that

   > "the relevant international standards [ . . . ] are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection".

   The "appropriate level" is defined as

   > "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."

   Annex A(5) explains that this "appropriate level" of protection is equivalent to "the acceptable level of risk", mentioned above. Members are therefore able to set an "adequate level" above any incorrect or outdated level of protection set down by international agreements without breaching GATT 1947 or the WTO Agreement.

2. A higher level of safety than the international norm is also justified where the Member determines that a higher level of protection is required *as a consequence of the level of protection the Member determines to be appropriate* in accordance with the relevant requirements of Article 5 (entitled "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection"), being:

   - that the Member has ensured that the safety regulation is

     > "based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations";

   - that in this assessment, the Member has taken

"into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment";

- that in this assessment, the Member has taken

"into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks";

- that in this assessment, the Member has taken

"into account the objective of minimizing negative trade effects";

and, when implementing the safety regulation, the Member will ensure

"that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility",

which means that the Member has not unjustifiably rejected

"another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of [ . . . ] protection and is significantly less restrictive to trade";

- that the Member

"shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade"

and participate in the production of guidelines to further implement this provision.[219]

This exception allows Members to *justify* levels of safety over and above international norms without breaching their WTO commitments.

It is to be noted that the "appropriate level" of protection does not itself require the scientific justification set down in option 1 above. It is the determination that the international standard will not deliver the "appropriate level" of protection that must have a scientific justification. The setting of an "appropriate level" remains within the sovereign discretion of each Member. It has been argued, however, that the discretion afforded to Members to sovereignly set an "appropriate level" of protection is not absolute: the requirement that the SPS measure is "based on an assessment [ . . . ] of the risks" has been taken to mean that the SPS measure must *conform to* the findings of the risk

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[219] It is to be noted that these guidelines are specifically provided to

"take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves".

assessment in question. These arguments were advanced by the US and Canada in the case regarding *EC Measures Concerning Meat and Meat Products (Hormones)* and have been considered by two WTO Dispute Resolution Panels and an Appellate Body.

The United States and Canada complained to the WTO about the EC's prohibition on imports of meat and meat products derived from cattle to whom certain growth-promoting hormones had been administered except where the use had been purely therapeutic. This ban was established by various EC directives between 1981 and 1996.[220] Two Panels were established by the WTO's Dispute Settlement Body to examine the complaints.[221] The two Panels, referred to hereafter as a single Panel, circulated its reports to the WTO Members on the 18th August 1997. The Panel found[222] that (a) the EC's measures banning the import of hormone treated meat were not based on a risk assessment, and were therefore in breach of Article 5.1 of the SPS Agreement; (b) the measures constituted arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate resulting in discrimination or a disguised restriction on international trade in breach of Article 5.5 of the SPS Agreement; and (c) that the measures were not based on existing international standards and no justification for the difference was provided under Article 3.3 of the SPS Agreement, thereby breaching Article 3.1 of the same. The Panel recommended that the EC change its laws to bring its measures in conformity with its obligations under the SPS Agreement. The EC notified the Dispute Settlement Body ("DSB") of its intention to appeal the Reports of the Panel on the 24th September 1997.[223] The US and Canada also appealed certain aspects of the Reports; and Australia, New Zealand and Norway filed third party's submissions with the Appellate Body. The Appellate hearing was held on the 4th and 5th November 1997.

The Panel's finding, that the EC had acted in breach of Article 3.1 by maintaining safety regulations which are not based on existing international standards without justification under Article 3.3, was reversed by the Appellate Body.

The Panel had interpreted Article 3 as establishing a general obligation under Article 3.1 to which Article 3.3 is an exception, a view which the Appellate body reversed (paras. 104 to 106). The

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[220] Council Directive 81/602/EEC of 31 July 1981, Official Journal, No. L 222, 7 August 1981, p. 32. Council Directive 88/146/EEC of 7 March 1988, Official Journal, No. L 70, 16 March 1988, p. 16. Council Directive 88/299/EEC of 17 May 1988, Official Journal, No. L 128, 21 May 1988, p. 36. Effective as of 1 July 1997, Directives 81/602, 88/146 and 88/299 were repealed and replaced with Council Directive 96/22/EC of 29 April 1996, Official Journal, No. L 125, 23 May 1996, p. 3. It is to be noted that Directive 81/602 resembles the GMO directives insofar as it bans the use of certain growth hormones "until a detailed examination of the effects of these substances could be carried out and until the EEC could take a decision on the use of these substances for growth promotion". (Appellate Body Report, para. 3). Directive 88/146 can be considered a "fourth hurdle" regulation as it bans the use of hormones for purely commercial purposes, i.e. for fattening cattle.

[221] The Panels to examine the complaints of the US and Canada were set up, respectively, on the 20th May 1996, and the 16th October 1996. The EC and Canada agreed, on the 4th November 1996, that the latter Panel should be established with the same composition as the former as the complaint was virtually identical. As the composition of the Panels was identical the Appellate Body refers to them collectively as "the Panel" in its report, and the same practice will be adopted here.

[222] In para. 9.1 of both Reports.

[223] WTO documents numbered WT/DS26/9 of 25 September 1997 and WT/DS48/7 of 25 September 1997.

general obligation, in the eyes of the Panel, was for Members to base their safety regulations on existing international standards. The Panel interpreted the words "based on" as meaning "conforms to". That is to say, as the Appellate Body explained, the Panel interpreted the obligation as being one whereby all safety regulations had to conform to existing international standards. Because of the relationship between the obligation in Article 3.1 and the exception provided by Article 3.3, any Member whose safety regulations did not conform to existing international standards would find itself under a burden of proof to demonstrate that the regulation conforms to the requirements set down by Article 3.3, i.e. that the regulation was enacted as a result of scientific justification or as a result of a risk assessment as provided by Article 5. The Appellate body rejected the Panel's interpretation of the meaning of the words "based on" as the consequences of this interpretation would be to bind the Members to international standards that would effectively take on the nature of legally binding norms, which is clearly beyond the obligations embodied in the SPS Agreement. However, the Appellate Body declined the opportunity to reject the Panel's determination that if a safety regulation provides for a different level of safety than an international standard, it cannot be "based on" that standard.

The Appellate Body set down the correct interpretation of Article 3 (paras 170-172 Report), which applies in the situation where there is an international standard in existence. It presented three options which are slightly different from the three presented above. A Member may chose to promulgate a safety regulation that conforms to an international standard under Article 3.2. This regulation would simply incorporate the standard from international into national law; and, as a consequence, the Member would enjoy a rebuttable presumption that it has acted in accordance with its obligations under the SPS Agreement and GATT 1994.

Under Article 3.2, a Member may choose to promulgate a safety regulation "based on" the international standard. The Appellate Body took the view that such a regulation may depart from the standard in a number of ways, but would adopt the same level of protection as that implicit in the international standard. The result of this is that the Member does not benefit from the presumption under Article 3.2. However, a complaining Member would still have to establish a *prima facie* case that the regulation is inconsistent with the SPS Agreement or GATT 1994.

Under Article 3.3, a Member may choose to set a level of protection different from that implicit in the international standard, and implement it in a regulation that is not "based on" the international standard. What the Appellate Body meant by this distinction is not entirely clear. Not only is the level of protection different, but it would appear that the method of establishing the level of protection may also be different. However, the Appellate Body reaffirmed that the Member's *right* to set its own level of protection is a very important right and central to the SPS Agreement, and not an exception to a general obligation of international conformity as held by the Panel. Nevertheless, in order to take this option, a Member must comply with the requirements of Article 3.3.

The Appellate Body accepted that Article 3.3 distinguishes two situations: (a) where there is a scientific justification; and (b) as a consequence of the Member's determination of what level of protection is appropriate in accordance with the provisions of Article 5. The Appellate Body found, however, that Article 3.3, when read in context, requires both situations to be in accordance with the

requirements of Article 5. The distinction is therefore only apparent. The Appellate Body interpreted Article 5 as

> "a countervailing factor in respect of the right of Members to set their appropriate level of protection". (para. 177)

The Appellate Body summed up the purpose of Article 3 as follows:

> "In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection. The requirements of a risk assessment under Article 5.1, as well as of "sufficient scientific evidence" under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the [SPS Agreement] between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings." (para. 177)

The requirements of Article 5 are therefore of prime importance. The Appellate Body also clarified the meaning of these.

Article 5.1 provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

The Appellate Body interpreted the Panel's interpretation of this article as a "specific application" of Article 2.2 which provides that

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except"

where there is insufficient evidence. The Appellate Body stresses that Articles 5.1. and 2.2 must be read together:

> "Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1" (para. 180).

The definition of a risk assessment was a major bone of contention between the complainants and the EC. The Appellate Body found it necessary to clarify what would constitute a risk assessment for the purposes of the SPS Agreement. The Panel had restricted the meaning of "risk assessment" to

> "a "scientific" examination of data and factual studies" (para. 181)

excluding any

> ""policy" exercise involving social value judgements made by political bodies" (para. 181)

which is dismissed as "non-scientific". The Panel thereby was adopting the dichotomy between "risk assessment" and "risk management". The Appellate Body found that this distinction had no textual basis. It is arguable that the Panel was not taking into account the rest of Article 5 which lists a number of socio-economic considerations. It is regrettable that the Appellate Body did not comment on the relationship between the various parts of Article 5.

The Panel had also separated out the identification of adverse effects on health and the probability of the occurrence of these effects. Again the Appellate Body did not comment on this, but found that the Panel had not correctly interpreted "probability", implying that the Panel had adopted too strict a standard, more akin to a quantitative degree than a mere possibility. The Appellate Body also finds that the Panel, without any textual basis, refers to the concept of a "scientifically identified risk" which insinuates that there is an objective level at which concern over a risk is reasonable, and below which it is only conjecture. The Appellate Body rejects any possibility that the WTO should establish a quantitative requirement for a risk assessment. Its task is solely to establish whether or not the SPS measure is "based on" a risk assessment, and not to judge the adequacy of the risk assessment:

> "To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the *SPS Agreement*. A panel is authorized only to determine whether a given SPS measure is "based on" a risk assessment. As will be elaborated below, this means that a panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment." (para. 186)

The Appellate Body clarified what a risk assessment may contain for the purposes of setting adequate levels of protection. Although Article 5.2 requires that

> "Members shall take into account available scientific evidence",

there are no grounds to exclude

> "all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences" (para. 187)

Article 5 indicates a wide list of criteria to take into account and there is no indication that this was intended to be a closed list (para. 187). The purpose of the risk assessment is to take into account

> "not only risk that is ascertainable in a science laboratory under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die." (para. 187)

The Appellate Body does not find that Article 5 imposes a minimum procedural requirement on Members to take into account a risk assessment before enactment (para. 188) nor does it impose on the member an obligation to carry out the risk assessment relied on (para. 190). The Appellate Body found that Article 5 only requires

> "a certain *objective relationship* between two elements, that is to say, [ . . . ] an *objective situation* that persists and is observable between an SPS measure and a risk assessment" (para. 189)

whereby

> "the results of the risk assessment must sufficiently warrant - that is to say, reasonably support - the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a subjective requirement that there be a rational relationship between the measure and the risk assessment" (para. 193).

There is no requirement that the risk assessment represent the mainstream of scientific opinion (i.e. it does not have to be a "consensus" in the natural meaning of the word or in the meaning of the GRAS definition): taking into account divergent views and uncertainty does not obviate the objective relationship.

In this particular case, the Appellate Body agreed with the Panel that, *on the facts*, the EU had not relied on a risk assessment which provided an objective relationship between the problem and the SPS measure. The Appellate Body imposed an additional requirement that the risk assessment address precisely the risks the measure addresses. The rational relationship is very close (para. 200). The Appellate Body consequently found that the EU was in breach of its WTO obligations under Article 5 by not adequately justifying its higher level of protection. However, critically, the Appellate Body did not find in favour of the US and Canada's third argument, that the discrepancies between the measures and their proposed justification were indicative of arbitrary or unjustifiable distinctions resulting in discrimination or a disguised restriction on international trade. The US and Canada won a narrow victory in that the EU was ordered to bring its measures into conformity with its obligations under the WTO treaty. However, the Appellate Body did not specify what this meant: arguably, the EU could comply with this order by either providing a new and fuller justification allowing the measures to be maintained as they were or by changing the measures to suit the available scientific evidence.

To conclude, the Hormones case clearly demonstrates that safety measures are justified on the same grounds in International trade law as the European law principle of proportionality, incorporating the principle of precaution:

1. The measure must be adequate for a clearly identified problem: there must be a rational connection between the problem as identified and the measure taken. The Panel provided a test, approved by the Appellate Body:

   > "first, identify [ . . . ] the scientific conclusions reached in the risk assessment [provided as justification] and the scientific conclusions implicit in the SPS measure; and second [ . . . ], examin[e . . .] those scientific conclusions to determine whether or not one set of conclusions matches [ . . . ] the second set of conclusions" (para. 192).

2. The level of protection sovereignly chosen by the decision-maker must be necessary: the Member must not have unjustifiably rejected another measure reasonably available, all (economic) circumstances being taken into account, that is less restrictive in achieving the appropriate level of protection.

3. The measure must not be disproportionate with regards to fundamental rights - in the case of WTO the measure must not make unjustifiable distinctions that result in discrimination or disguised restrictions on international trade.

The Appellate Body's findings, stretched over 100 pages, illustrate the difficulties of carrying out these conceptually simple tasks. The difficulties present in the current debate over biotechnology, which may affect such determinations if the WTO were to consider a trade dispute over GM crops, are examined in detail in the following Chapters.

## Chapter Five: Standard Setting for Biotechnology

It was argued in Chapter Three that the requirements of proportionality create a forum for discussion where considerations claimed to be relevant, reasonable and proportionate can be exchanged and assessed rationally. Such a forum has been lacking in the debate up to now with the result that arguments are opposed to each other without a common frame of reference. The arguments of the biotechnology debate are not fundamentally opposed once analysed. However, they fail to interact, being couched in different frames of reference.

The reasons for these differences reside in the inherent difficulty in defining biotechnology itself. It is a field that is complex and its development was non-linear. As a result, many related areas of science and industry can claim a significant amount of experience concerning biotechnology. None of these, however, can offer an authoritative voice on the relevance of the many issues raised by it.

There are many reasons for this meandering development, the three most salient being the seemingly excessive division of the life sciences within the academic world,[224] the division between the academic and the industrial research communities (which biotechnology laudably attempts to bridge), and the consequent lack of communication between these estranged groups. The differences in the views concerning biotechnology held by these groups are such that there is no agreement on what the term "biotechnology" actually represents. It would appear that there can be no clear direction or common ground in any debate concerning such a nebulous subject.

The law cannot bridge the chasms that separate the various branches of the life sciences or resolve their disputes. It can, however, provide a standard by which the issues can be judged. The principle of proportionality provides a mechanism whereby all "inputs" to the decision-making process can be quality controlled. It also can provide a means for all disciplines to understand the relevance of the other disciplines. Wide consultation of experts from different fields to inform the decision-making process has been resisted by the proponents of "science-led" regulation of biotechnology. They readily question the expertise of individuals from different disciplines and question the relevance of "non-scientific" expertise in the decision-making process.[225] However, widening the scope of consultations

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[224] **Cantley (1995)**, at p.511, states: "In agricultural or medical research, in plant or animal breeding, and in the production of fermentation antibiotics, the continuing development and application of the life sciences during the early post-war decades were routinely pursued, in familiar compartments with relatively little inter-sectoral interaction, beyond a perfunctory acknowledgement of common roots in biology."

[225] **Young (1988)**, the then Commissioner of Food and Drugs at the US FDA, denied that there was any divergence of opinion amongst experts over the safety of biotechnology. Quoting from Professor Bernard Davis, he dismissed the point, stating that "[t]he problem is to recognize who the experts are", at p. 5. This is a problem inherent in the FDA's approach: the FDA needs to limit the number of "qualified experts" in order to have a chance of obtaining a consensus. **Cantley (1995)** argues that the division between "pure" and "applied" science was beneficial. At p. 566, he states: "the organised voices of industrial or agricultural interests were largely absent [in the early years of the debate]. But [ . . . ] the absence of sectoral economic interests may have contributed to the integrity of the US debate, and consequent international acceptability of its conclusions." He hints at the corrupting nature of commercial pressures, which might have prevented detailed discussion of safety matters with a view to avoid costs and increase profits. This rather innocent statement points at the wide-held belief in scientific integrity and the rational and objective development of science, which is held by both the backers of biotechnology (as evident in the early preference for self-regulation by scientists) and by a majority of the opponents of biotechnology (evident in the juxtaposition between corrupting

in itself is not enough as this could only guarantee the accumulation of divergent opinions. It is arguable that there is sufficient commonality between the various concepts of biotechnology, and between the various issues raised, to conduct a rational and constructive debate. In order to do so, however, many arguments currently used in the debate concerning the safety of biotechnology must be recognised as redundant and rejected as they obscure the true issues.

This Chapter illustrates the meandering development of biotechnology and the outcome that there is no authoritative voice in the area. Many authoritative voices from disciplines involved in biotechnology are clamouring for supremacy in the field, and taking offence when supremacy is refused by other equally authoritative voices. This leads to the participants in the debate seeking to personally discredit their adversaries, denying their expertise, their rationality or their integrity, rather than seeking to disprove their arguments.

## 5.1 Biotechnology as an "orphan science"

Biotechnology is a science with an unusual development. It can be viewed very much as an orphan science, without a clear field of "pure science" to which it can be attached as an "applied science". Being of a multifaceted nature, it cannot be regarded as a pure science in its own right. It grew up on the doorstep only of the ancestral home of biology, as a hybrid development of microbiology, molecular genetics and biochemistry, themselves very recent developments of the biology family. It owes as much to the input of physicists, chemists and engineers as it does to biologists.[226] When reviewing the literature, one can see that recombinant biotechnology is no friend of ecology, its distant cousin within the biology family tree, and biologists of many specialities have no great love for it in return. Biotechnology is an orphan science in another way: it cannot clearly be attached to an academic discipline or to an industrial activity. It has grown up torn between the apparently irreconcilable influences of "high brow" academe and "down to earth" industry research and development ("R&D") departments. Arguably, this has caused biotechnology to be marginalised from either and both of these backgrounds.

Biotechnology scientists were aware of the commercial value of the recombinant techniques long before their emergence, and also of the immense cost that recombinant research would involve. Knowing that government-provided funds could be insufficient, they sought to exploit the commercial value by setting up commercial research facilities as soon as the recombinant breakthrough was achieved.[227]

Much of the research has taken place in commercial facilities and has been dictated by the need to pay for itself as quickly as possible, rather than the need to explore the theories and

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commercial pressures and the dispassionate and uninterested world of pure research for research's sake). However, there is increasing evidence of research fraud just as there is increasing evidence of medical fraud: the rationality, objectivity and integrity of the scientific world cannot be entirely counted upon. Section 5.2 below discusses how the biotechnology sector, including "pure" research, was developed largely with the help of commercial backers rather than academic funding from the very beginning.

[226] For example, Francis Crick, one of the joint discoverers of the double-helix structure of DNA, was a physicist rather than a biologist.

[227] **Coghlan (1993), p. 26.**

assumptions of the sciences biotechnology is based on. The research has been market-dictated and product-orientated, seeking to identify the genes that produce specific traits of an organism, genes that can be exploited to produce an income for the facility, rather than knowledge-orientated, seeking to understand the functioning of the organism through understanding of the organism's genome. The drive has been towards producing GMOs rather than understanding them. This can be demonstrated by the fact that most technical reports on biotechnology safety have based their conclusions on scientific *assumptions* about the possible behaviour of GMOs rather than seeking to check these assumptions through empirical observation.[228]

This statement is obviously an oversimplification: in order to correctly identify the trait, an understanding of the organism is required. However, there is evidence that commercial biotechnology researchers, in the pharmaceutical world, have made basic mistakes in their R&D through concentrating on the gene's assumed function and not its function within a genome. These mistakes, revealed late-on in the product's development by mandatory product testing, have led to a number of product failures which have adversely affected the industry's credibility.[229] The question that is raised is whether these mistakes were caused by (a) predictable scientific errors provoked by ignorance, financial or organisational pressures, or (b) unpredictable problems arising from the "unknown" nature of the recombinant technologies. There is also evidence that commercial biotechnologists, deriving from academic backgrounds, ignored many of the practical rules of industrial research, and much of its accumulated experience. The Asilomar Conference, established to discuss safety issues in biotechnology, ignored the accumulated experience of the long-established fermentation biotechnology industry with regards to laboratory and process safety mechanisms. Biotechnology companies also chose to "go it alone" commercially, despite demonstrating a commercial immaturity which is at the root of the industry's financial and organisational problems.[230]

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[228] Such as **NAS (1987)** and **NRC (1990)**. However, it is to be noted that many of these reports rely heavily on the fact that no adverse outcomes have been observed over many years of GMO experimentation. Despite relying on this statement himself to justify his views, Miller argues that observation of GMOs in the hope of detecting an unexpected result is not the most efficient, rational or "scientific" way of proceeding (see Chapter Eight). It would be better, in his view, to *provoke* an adverse result, under strict safety conditions of course, in order to understand the pathways by which such a result can arise, to understand how likely it is to arise, and how to prevent it from arising. However, no one in the commercial world has gone about doing such a study due to the obvious "bad image" it would give biotechnology and the consequent repercussions this would have on their income. Such a study would be required to be funded by governments who are reluctant to do so, for fear of causing more controversy, and due to the expense such a study would involve. Biotechnology has been claiming that it can produce the solutions to the world's ills but the cures for cancer, and the supercrops for the Third World, have not yet materialised whereas GM tobacco - of all things - is already on the market: this alone demonstrated the industry's need to pay for its research, and the insincerity in the altruistic claims.

[229] See Chapter Seven. It is to be noted that if such problems were occurring in agricultural biotechnology, there are not any direct equivalents of the strict testing and monitoring programmes to which pharmaceutical products are subjected. The *Watson* case demonstrated the laxity of the DUS tests under the National Lists regulations.

[230] These points are further explored in Chapters Six and Seven.

## 5.2 A quick history of biotechnology[231]

The recombinant techniques themselves are relatively new. They result largely from the breakthrough achieved by Herbert Boyer and Stanley Cohen in 1973,[232] using restriction enzymes to break down and reassemble ("recombine") fragments of DNA. The science that these new techniques apply is, arguably, only slightly older. A rapid overview of the history of genetics is a telling illustration of the science's non-linear development. Most sciences develop through discovery leading to discovery. In genetics, knowledge developed through a convergence of insights, most often guided by non-biological disciplines.

Many of the basic tenets of genetics date back to the works of Gregor Mendel, an Augustinian monk in the 1860s, who, amongst others at the time, was researching the causes of heredity.[233] Mendel experimented with various types of garden peas in the gardens of a monastery in present-day Brno, Czech Republic, to discover that individual traits were passed on from generation to generation. His work, however, fell into obscurity. His findings were rediscovered in 1900 by Correns, Tschermak and DeVries and their significance only fully understood by William Bateson, an English biologist, who proposed the name "genetics" for the field of study concerned with heredity and variations between related organisms, in 1906. Mendel's inheritable factors were then given the name "genes" by Wilhelm Johannsen, a Danish biologist, in 1909.[234] The study of "genes" took off in earnest during this period with the understanding that inherited diseases in man could be linked to these "genes", or inheritable factors, but the nature of genes (as presently understood in terms of molecular structure) and their function was still mostly unknown at the time. **Passarge (1995)** explains that

> "[e]arly genetics was not based on chemistry or on cytology"[235]

as it is today, and a deplorable lack of interdisciplinary interaction held back the understanding required for establishing the nature of genes.

An illustration of how this lack of interaction has paralysed the development of genetics[236] is the fact that the nature of genes was still unknown at the time of Johannsen's work when there had already been substantial work done independently on observations of chromosomes (by Flemming in 1879 and Strasburger in 1888; the term "chromosome" itself being coined in 1888 by Waldeyer). No link between chromosomes and "genes" had been proposed, except by the "prescient" work of Theodore Boveri in 1902, which went unnoticed.

Systematic studies of "genetics" begun in 1910 with the work of T. H. Morgan, who studied the fruit fly, and finally led to a chromosome theory of inheritance, in 1915. This theory, however, was

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[231] This section has been developed with constant reference to **Passarge (1995)**, pp. 2-11, except where otherwise noted.

[232] **Coghlan (1993)**, p. 26.

[233] **Raven & Johnson (1992)**, pp. 233-53; **BMA (1992)**, pp. 10-27.

[234] **BMA (1992)**, p. 11.

[235] At p. 3. Cytology is the study of cells and their functions.

[236] **Teitelman (1990)** has argued that biotechnology has developed at a much slower pace than other technological "revolutions" such as the microchip.

strongly contested well into the 1920s. Despite the lack of this understanding, the statistical study of genetic populations began in 1908 with the work of Hardy and Weinberg, who used Mendel's theories to explain the patterns of heredity in human populations. The findings in the new field of genetics were put to good use at this time in animal and plant breeding, which developed thereon as a distant cousin of academic genetics.[237] Sadly, the field of population genetics was also put to an evil use by some proponents of eugenics in the 1930s and 1940s.[238]

Mutations were first discovered and named in 1901, by DeVries, but it took until the early 1940s for techniques to induce mutations, using radiation and certain chemicals, to be discovered. However, the causes of these mutations were still entirely unknown as the

> "physical basis for the transfer of genetic information was not known".[239]

The molecular nature of genes was postulated, if not fully understood, in the mid-1940s, with the discovery of recombination in bacteria and viruses. The link between genetics and biochemistry became more apparent, at the same time, with the discovery that genes encode enzymes. DNA was shown to carry genetic information in 1944, by Avery, McLeod and McCarty at the Rockefeller Institute, and it was proven that DNA alone carries genetic information in 1952, by Hershey and Chase.

Eventually the molecular structure of DNA was elucidated by James Watson and Francis Crick in 1953. Their seminal paper marked the birth of modern molecular genetics.[240] It also marked the successful invasion of molecular biology by chemists and physicists, which causes controversy today. This breakthrough was followed by a rapid succession of discoveries through the 1960s and 70s such as the structure of proteins, the transcription of DNA into mRNA (messenger ribonucleic acid), the internal functions of the cytoplasm, the existence of reverse transcriptase (which overturned all the contemporary theories concerning the one-way flow of genetic information, and which allowed for the analysis of genes without requiring knowledge of the gene product), the existence of restriction enzymes, amongst others. The breakthrough also led to the development of new analytical techniques for the sequencing of DNA, which were to lead to the recombinant techniques that we know today.

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[237] Agricultural applications of wide crosses and artificial breeding techniques have expanded dramatically since this time but, largely, have not developed within an academic setting. A large body of experience has been developed within agriculture but has not been used by the biotechnology industry.

[238] Issues surrounding eugenics are largely outside of the field of this thesis and are extensively studied elsewhere, but the human rights abuses perpetrated by Nazi Germany, amongst others, during the Second World War, and by numerous other countries during the 1960s and 1970s under the guises of medical treatment of handicapped persons, have caused the wider public to view the whole field of genetics with distrust. Eugenics is becoming a topical issue again due to the possibilities of early diagnosis of genetic disorders or of the presence of an inherited trait which may cause disease to develop in an individual in the future, both of which have an impact on the possibility of obtaining health insurance or even employment. All of this does not help the public's understanding or acceptance of the use of genetic engineering in agriculture or, more so, in food production.

[239] **Passarge (1995), p. 4.**

[240] **Coghlan (1993), p. 26; BMA (1992), pp. 28-30.**

The structure of genes, however, was still to spring surprises. For example, in 1977, it was discovered that eukaryotic (that is to say "higher" organisms, as opposed to the "lower" organisms, such as bacteria, or prokaryotes) DNA is made up of coding sequences (exons) and, in majority, non-coding sequences (introns), which are "left-overs" from the evolution of the organism. Many geneticists disregarded the introns, as they did not produce gene products, which were the main focus of the study of DNA, and did not study their function or activities within the genome as a whole, dismissing them as "junk DNA".

However, a controversy was brewing between geneticists concerning the "dynamic" nature of DNA. Barbara McClintock had been studying mutable loci in maize DNA before the discovery of the structure of DNA, and described how genes can change locations and cause mutations at distant sites as if by "remote control", and described how encoding genes can be controlled by elements other than promoter genes. Her work on the "fluid" or "dynamic" genome was largely ignored between the 1950s and her Nobel Prize lecture in 1983. At this time, the concept of a "fluid" genome was largely accepted. However, a review of the literature can show that there is still considerable uncertainty in the science concerning movable loci and the effects on the genome as a whole and on the phenotype of an organism.

There was then a continuing controversy between geneticists who follow the "static" model and those who follow the "fluid" model, and it is this controversy amongst experts that is a major cause of the scientific uncertainty felt by the general public in the biotechnology debate. The controversies continue. Dr Antoniou is one of the leading opponents of recombinant techniques in the UK with the backing of Greenpeace.[241] He rejects any chemical-based mechanistic model of DNA in favour of an "information" model. Because the entire genome is present in all cells of the body, despite the immense differentiation of the cells, he implies that the more important study of genetics is not the identification of gene products but the identification of regulatory mechanisms which prevent unwanted functions from being expressed in the wrong cells or at the wrong times. He identifies three of such mechanisms which are still poorly understood: (i) genes are known to be grouped into interdependent families called "chromatin domains" where their functions mutually influence each other; (ii) certain genes directly influence the function of others by encoding for "transcription factors", special proteins that regulate genetic activity rather than cellular activity; (iii) genes can also influence other distant genes, on other chromosomes, through the phenomenon of "co-suppression". Dr Antoniou argues that these regulatory mechanisms are unaffected by natural gene recombination, sexual or otherwise, but are severely disrupted by the unpredictable nature of gene insertion that characterises man-made recombination.[242]

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[241] **Antoniou (199?).**

[242] The unpredictability of insertion of transgenes is one of the main points of controversy surrounding biotechnology. Genetic engineers aim to control the place where the new genetic material they wish to add to a genome (the transgene) is inserted into the genome sequence. In order to do so, each extremity of the transgene sequence can be constructed so as to fit at only specific points of the host genome, in the manner of a key fitting into a lock. If the "key" is specific enough, then the insertion will happen at only the point where the "key" will fit into the "lock". However, this precision is difficult to achieve, especially when the entirety of the genome is not known: the "lock" may be repeated at many points of the genome, causing unpredictability of the point of insertion and of the possibly disruptive effects

It can be seen that, despite now being established as a scientific discipline in its own right, molecular genetics is still a highly changeable field with a wide variety of opinions as to the very basics of the science. This is normal in such a young science. Genetics remained a very arcane and obscure science, far removed from the glare of public interest until the discovery of recombinant techniques. Its obscurity, even amongst related academic disciplines, can be demonstrated by the following scientific gaffe: as late as 1965, the Nobel Prize-winning immunologist Sir Macfarlane Burnet dismissed the importance of this

> "fascinating [ . . . ] scholarly achievement"[243]

and insisted that it had not produced anything of practical value and

> "was most unlikely to do so in future".[244]

Just as genetics is a convergence of disciplines, it had a number of off shoots very early on in its history. We have seen that animal and plant breeding, and population genetics were quickly established. Other academic fields absorbed much of the content of the science of genetics without either absorbing or merging with the field. One of the primary beneficiaries of the advances in genetics was the field of microbiology, itself an obscure and undervalued branch of science split amongst the field of medicine and the fermentation industry. Sir Macfarlane Burnet would not have ignored the medical aspects, being an immunologist (although he clearly lacked the foresight of current uses of microbiology in medicine), but was clearly unaware of the applications of microbiology and genetics in the food industries such as brewing, bread-making, and the dairy industry; and indeed he was clearly unaware of the already important use of microbiology in the pharmaceutical industry.

This ignorance can be explained largely by the lack of interaction between the academic and medical setting of microbiology and its independent industry-based cousin. And in turn, the lack of interaction can be explained by the academic world's tendency to overlook activities as traditional and mundane as these. Indeed, these uses of microbiology were so traditional that the public ignored the microbiological nature of the daily loaf of bread.

## 5.3 Difficulties defining "biotechnology"

Having developed from such wide range of scientific disciplines and in such a disjointed way, it is understandable that the field of biotechnology is characterised by a multiplication of conflicting

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of that insertion on other genes. The actual mechanism of insertion of the transgene into the genome remains unknown. All that recombinant biotechnology has achieved is the ability to isolate genetic sequences and the ability to insert them within the natural barriers of the cell. After that, it is still up to the natural processes of the cell to ensure that the transgene is inserted into the genome, if at all. These processes are still wholly unknown, and consequently unpredictable. Plant biotechnology researchers are not interested in studying these mechanisms, which are part of the field of cytology (rather than genetics), because, statistically, they will obtain at least one cell that is modified in the way that they wanted if they start off with a large enough sample, and can multiply the chosen cell through natural cell division. Plants can be grown from single cells, unlike animals, and developing more precise methods is not yet required.

[243] **BMA (1992)**, p. 53.

[244] Idem.

conceptual models applicable to similar phenomena. This is illustrated by the fact that chromosomes were extensively studied before their role was accepted by other students of genetic inheritance.

One of the central difficulties in understanding the field of biotechnology, and therefore in the debate concerning the adequacy of current regulation of biotechnology, is whether it is possible to formulate a single definition of biotechnology – or whether there is a single field that can be called biotechnology at all.

### 5.3.1 The importance of a clear definition of biotechnology

The difficulties in defining biotechnology as a concept derive, in part, from a lack of terminological clarity. Miller has argued that it is a terminological misconception to talk of either "genetic engineering" or "biotechnology" as single concepts or discrete or homogenous industries and worse to confuse the two, because of the diversity of techniques and applications that are covered by these terms.[245] He describes "genetic engineering" as

> "merely a catch-all term for a broad group of useful enabling technologies with wide and diverse applications in industry and commerce."[246]

Miller insists that broad terms such as "biotechnology" or "genetic engineering"

> "do not represent natural groupings of processes or products"[247]

and argues that

> "[w]e would do well to return to more specific and descriptive terms among the myriad constituent processes and products that are now lumped arbitrarily as "biotechnology" or "genetic engineering"."[248]

However, Miller argues that there is a fundamental concept common to all of these techniques, which is that they result in the genetic "alteration" of organisms (as opposed to the genetic "modification", "manipulation" or "engineering" of organisms, words which are closely associated with recombinant methods alone).[249] According to Miller it is a mistake to assume that only "genetic engineering" or recombinant manipulations result in organisms being genetically altered. This outcome is also shared by a vast number of other, more traditional and more widely accepted techniques known collectively as "agriculture", which includes selective breeding and plant grafts.

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[245] **Miller & Young (1986), p. 1135. Miller & Young (1987b), p. 184.**

[246] **Miller (1995c), p. 41.**

[247] **Miller & Young (1987b), p. 184.**

[248] **Miller & Young (1987b), p. 184, column 1.** This is a view which is shared by many others, including the General Accounting Office of the United States which stated: "[b]ecause of the inconsistent interpretation of the term "biotechnology" . . . . [i]t may be useful, for the purposes of discussing possible regulatory approaches, to avoid the term "biotechnology" and instead use more specific terms".

[249] **Miller & Young (1987e) and Miller & Huttner (1991), p. 204.**

Miller argues that genetic "alteration" is the same concept, whether it is provoked by man or naturally occurring and whatever the method used to provoke it. His views are largely based[250] on the findings of **NAS (1987)**, which states that:

> "[t]he risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods."[251]

and on the findings of **NRC (1990)**, which added:

> "[t]he same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods"[252]

and went on to conclude that

> "no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes".[253]

Whether the definition of "biotechnology" should be restrained to recombinant techniques or extended to everything that involves genetic "alteration" has an essential impact on regulatory policy.

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[250] Miller's endorsement is largely uncritical: "The simple, unassailably logical precepts of the NAS report provide clear perspectives on field trials of recombinant DNA-manipulated organisms. They could, if adopted *in toto,* introduce a high level of rationality and enlightenment into societal oversight of the testing of genetically engineered organisms." **Miller & Young (1987d)**, p. 1010.

[251] Miller summarised the other key conclusions and recommendations of the NAS report as follows (**Miller & Young (1987d)**, p. 1010):

- "there is adequate knowledge of the scientific principles, as well as sufficient experience with rDNA-engineered organisms, to guide the safe and prudent use of such organisms outside research laboratories"; . . . .
- "[t]here is no evidence of unique hazards associated with deliberate release – either in the use of rDNA techniques or in the movement of genes between unrelated organisms";
- "[a] regulatory process must consider previous experience in the regulation of rDNA and the regulation (or its absence) of organisms modified by traditional techniques";
- "[t]he assessment of risks associated with introducing rDNA organisms into the environment should be based on the nature of the organism; based on the environment into which the organism is to be introduced; and independent of the method of engineering *per se*";
- "[t]here must be established confidence (or risk) categories in order not to hinder testing of low-risk organisms because of a justifiably cautious approach to high-risk organisms, such as vertebrate pathogens or noxious weeds";
- "[a] classification scheme for confidence categories should rely on the nature of biological function affected or introduced by genetic engineering; the environment from which the host organism was taken; the ecological characteristics of the rDNA organism; the characteristics of the recipient environment; and the scale and frequency of the introduction".

[252] **Miller (1995d)**, pp. 47-8.

[253] **Miller *et al* (1993)**, p. 1323. The **SCOPE / COGENE (1987)** report concurred: "the properties of the introduced organism and its target environment are the key features in the assessment of risk. Such factors [are] the demographic characterisation of the introduced organisms; genetic stability, including the potential for horizontal transfer or outcrossing with weedy species; and the fit of the species to the physical and biological environment [into which it will be introduced . . .]. These considerations apply equally to both modified or unmodified organisms; and, in the case of modified organisms, they apply independently of the techniques used to achieve modification." **Miller (1994d)**, p. 293.

Notwithstanding the difficulties of designing regulations to capture a field as narrow as recombinant techniques, as opposed to regulations designed to cover a field as wide as agriculture, regulatory policy should be commensurate to the field it addresses (as explained in Chapter Three).

Miller argues against singling out any one particular technique of genetic alteration as opposed to others for special regulatory treatment, in this case the recombinant techniques, and argues that every branch of biotechnology should be given equivalent regulatory treatment (as the various techniques cannot be treated in exactly the same fashion, each having unique characteristics), or none should be regulated at all, for the sake of logic and legal certainty.[254] Miller has proposed a regulatory algorithm based on the risks of all forms of genetic alteration, i.e. including the introduction of new species to the environment or the food chain.[255] This algorithm would have the effect of imposing regulations on areas which Miller perceives as being currently under-regulated, such as the production of primary agricultural produce.[256] Miller calls for consistent regulation as opposed to seemingly arbitrary or ineffective regulation:

> "The key objective should not be to make regulatory policies lenient; rather, they should be consistent, based on scientific principles, and establish to the extent possible a degree of oversight that is both necessary and sufficient".[257]

### 5.3.2 The "singularity" of biotechnology

Miller argues that because of the wide range of laboratory methods available to the genetic engineer, and the vast range of different variable parameters each one involves, there cannot reasonably be a single demonstrable characteristic that is "systematically similar and functionally important"[258] from technique to technique or from GMO to GMO. Hence, Miller's view that there cannot be a single definition to cover these techniques.

This appears to be in direct contradiction with Miller's view that all genetic "alteration" is the same. Miller appears to be arguing that there is no one identifiable characteristic of "altered" organisms that is identical simply because of the fact of the "alteration". Miller argues that to believe that there is such a single characteristic is a fundamental mistake of science as ridiculous as believing that

> "all experiments that were performed using plastic, as opposed to glass, pipettes; or even ones that were begun on certain days of the week"[259]

also share a single important characteristic.

Because of this, Miller suggests that opposition to "biotechnology" or to "genetic engineering" as a whole is logically inconsistent and consequently ridiculous. One might as well

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[254] **Miller *et al* (1990)**, p. 491.

[255] Idem.

[256] Idem.

[257] **Miller (1995b)**, p. 125.

[258] **Miller & Gunary (1993)**, p. 1500.

[259] Idem.

protest all the food products that have been derived from animal or plant species that have been selectively bred over the millennia as all involve some form of genetic "alteration".

Miller calls the belief that there is a "systematically similar and functionally important" characteristic, a "horizontal" belief.[260] This horizontal approach uses this postulated single characteristic to make generalisations about biotechnology as a whole, hence the name. Miller argues that making such generalisations is untenable:

> "Biotechnology [. . .] encompasses myriad dissimilar processes producing ever greater numbers of dissimilar products for vastly dissimilar applications. These processes and products are so diverse and have so little in common with one another that it is difficult to construct valid generalisations about them for whatever purpose [. . .]."[261]

Miller further argues that this tendency to generalise causes proponents of the "horizontal" view to make irrelevant generalisations about GMOs. It allows the incorporation of unwelcome social, economic, ethical or even religious considerations into the regulatory assessment process. Miller believes that the only forum for such considerations (regarding the "desirability"[262] of biotechnology) should be the marketplace.[263]

### 5.3.3 The "novelty" of biotechnology

Miller argues that the "horizontal" belief also adheres to the myth that biotechnology is a new technology involving a paradigmatic change and is therefore inherently unfamiliar.[264] Miller further states that the "horizontal" belief holds that any GMO, being a novel organism,[265] is inherently unfamiliar, however slight the alteration made, and can only be released to the environment or the marketplace (if at all) after exhaustive safety tests of questionable value. Miller argues that this belief

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[260] Idem.

[261] **Miller (1995d), p. 41.**

[262] **Miller (1984).**

[263] **Miller (1992a).**

[264] **Miller & Gunary (1993), p. 1500.**

[265] Although each GMO will effectively be a new organism, being subtly different from its progenitor organisms, Miller denies that it will be "novel" in the sense that its characteristics will be unknown or unexpected. He suggests that the transferred characteristic will be well known as will be the characteristics of the receiving organism due to the level of research required before such a modification is possible let alone feasible. Furthermore, Miller argues that no GMO can be considered "novel" in the absolute as all possible genetic combinations are likely to have arisen, since life emerged on Earth, or will arise in future: "In nature, innumerable recombinations via several mechanisms between even very distantly related organisms have likely occurred. [ . . . ] [O]ver the past $10^6$ years innumerable mammalian-bacterial hybrids are likely to have appeared and been tested and discarded by natural selection. An analogous argument can be made for recombination among fungi, bacteria, viruses, and plants. [ . . . ] It is pertinent that certain kinds of gene transfers thought until recently to be impossible in nature because of the phylogenetic distances between donor and recipient have now been shown to occur in the laboratory and may well occur in nature as well. [ . . . ] Since evolution continually creates novelty, the distinction between "natural" and "unnatural" (or "novel") is not a clear one and is, arguably, irrelevant. Novel is not synonymous with dangerous, nor need it even imply uncertainty." **Miller (1995d)**, p. 44. Fatalistic arguments such as nature "has" or "will see it all" are no justification for provoking an event which might occur naturally.

goes further in holding that unfamiliarity equates with inherent, intrinsic danger[266] or in certain cases, with a moral taint arising from deliberately inflicting an unknown danger on others. Miller refutes the argument that GMOs are unfamiliar in two ways.

Firstly, he argues that neither "biotechnology" nor "genetic engineering" are unfamiliar as neither are new concepts:

> "[t]raditional biotechnology is almost as old as agriculture itself."[267]

The concept described as "biotechnology"

> "dates back at least to 6000 B.C. when the Babylonians and Sumerians used micro-organisms in fermentation to brew alcoholic beverages."[268]

Similarly, the concept described as "genetic engineering"

> "dates back from man's recognition that animals and crop plants could be selected to enhance desired characteristics."[269]

He argues that the techniques known as biotechnology are simply "extensions or refinements of older techniques for genetic modification"[270] which "retain the aims of classical domestication".[271] These arguments derive from Miller's central tenet that all forms of genetic "alteration" are fundamentally the same. As the purpose of the recombinant techniques is to extend the possibilities of traditional breeding, Miller's opinion is that most applications will concern organisms and specific characteristics of organisms that are known to cause no harm to the environment, and which can therefore be safely transferred between species or enhanced.[272]

Secondly, Miller argues that GMOs are not unfamiliar in that their characteristics and behaviour can be confidently predicted in advance using knowledge concerning the GMO's progenitor organisms, the alteration made and the intended environment for release. Miller's use of "familiarity" in suggesting predictability is suspect. There are numerous examples of failed attempts at traditional genetic "alteration" and countless examples of introductions of non-indigenous species that have gone badly wrong. Miller nevertheless argues that the old techniques of genetic alteration are well known and predictable[273] and provide relevant experience in the assessment of GMOs, due to the

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[266] **Miller (1993b), p.1075.**

[267] **Miller *et al* (1993), p. 1323.**

[268] **Miller & Young (1987b), p. 184.**

[269] Idem.

[270] **Miller & Young (1987c).** See also **Miller & Young (1987a); Miller & Young (1987d); Miller & Young (1988), p. 1385; Miller (1994d), p. 293.**

[271] **Miller (1995d), p. 41.**

[272] Arguably, the artificial nature of the agronomic environment is in itself injurious to the "natural" environment. The concept of environmental harm is mainly a question of personal sensitivities.

[273] Miller points out that: "many crops commonly grown and consumed in the United States [. . .] have resulted from interspecific or intergeneric gene transfer, yielding "genetically altered" and "transgenic" plants by any reasonable definition" **Miller & Huttner (1991)**, p. 204. See also: **Miller (1992c); Miller *et al* (1993)**, p. 1323; and **Miller (1994d)**, p. 293. There is a vast body of experience concerning releases of new organisms to draw upon: "an individual plant breeder may introduce into the field

commonality of genetic "alteration", as does experience of the introduction of non-autochthonous species.[274] This view assumes that in most cases the "donor" organism(s) and the "recipient" organism to be altered will be perfectly known (for example, they will all be crop plants) and that the environment for release will be perfectly known (the agricultural environment). These assumptions are debatable. Miller further argues that the new techniques are more precise than old agricultural breeding techniques[275] and offer even greater predictability than older techniques.[276]

On the basis of these assumptions, Miller believes that a GMO will be no more hazardous than its "natural" counterparts and will not need supplemental testing.[277] It would appear that Miller objects to "later" organisms, which are no more hazardous than "earlier" organisms, being subjected to testing that the "earlier" organisms were not subjected to.[278]

This view is not shared by the EPA or the USDA. Both Agencies are particularly wary of intergeneric organisms (i.e. GMOs whose progenitor organisms are from different genii). They also

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50,000 genotypes per year on average or 2,000,000 in a career, and [. . .] many of these are transgenic" **Miller *et al* (1991)**, p. 1600; also: **Miller & Huttner (1991)**, p. 204.

[274] There is extensive knowledge of the risks involved with localised or generalised releases of non-indigenous organisms: "[t]here are numerous past examples of successful and beneficial "releases", or uses of live organisms in the environment." **Miller & Young (1987c)**, p.14. These include the introduction of non-indigenous crops, the creation of hybrids such as nectarines, the use of predator insects and plant pathogens as herbicides or even the use of microbes to concentrate metals from ore in mining. **Miller & Young (1987c)**, p.14. Live microbial pesticides have been tested on a large scale and have presented an "extraordinary safety record". **Miller & Young (1987a)**, p. 14; **Miller (1987)**, p. 133; **Miller & Young (1987d)**, p. 1010.

[275] Young and Miller confidently claim that "rDNA techniques are expected to improve upon both the safety and the efficacy of some of the products at present produced by older methods." **Miller & Young (1987b)**,. Miller claims that GMOs are "demonstrably safe" (**Miller (1995d)**, p. 40) and are the "most precise" techniques of genetic modification (**Miller (1995d)**, p. 60).

[276] Miller suggests that the findings of **NAS (1987)**, that the same physical and biological laws govern GMOs and their unmodified counterparts, and that the risks presented by GMOs are the same in kind as non-GMOs, demonstrate that, if the vast body of knowledge and experience concerning other releases is consulted and appropriately acted upon by the developer of a GMO, there will be considerable certainty as to the risks that the GMO will carry. This suggestion begs a number of questions: (a) will the body of available knowledge and experience always be relevant? (b) will the developer of the GMO consult this body of reference, and will he act accordingly upon it, taking into account disagreements over the value, relevance and interpretation of such data, human error and commercial pressures which may lead experts to cut corners and be "selective" with the evidence, cutting out disadvantageous elements? and (c) does certainty truly arise from a body of knowledge? There is a large body of opinion which holds that certainty is illusory and predictability unattainable. All that can be done is to acknowledge areas of uncertainty. This is a fundamental point in the philosophy of science, which divides those who believe that the "laws of Nature" can be learnt and those who are resigned to a background of uncertainty.

[277] Miller flatly declares that GMOs are safe: "[d]espite extensive work in thousands of laboratories throughout the United States with millions of individual genetic clones, there has been no report of their causing a human illness nor any injury to the environment." **Miller *et al* (1990)**, p. 490. He states that: "millions of people each year throughout the world participate in effect, in "deliberate release" applications of live attenuated genetically engineered viruses, which undergo replication in the recipient and may be shed". **Miller & Young (1987c)**.

[278] Young and Miller insist that "there is no need for additional regulatory mechanisms *specific for the new techniques* to be superimposed on existing adequate regulatory mechanisms". **Miller & Young (1987e)**. Adequate is the crucial word: Miller contradicts himself by on the one hand insinuating that Europe does not need new regulations because the pre-existing ones are adequate, and by saying on the other that traditional means of genetic alteration go unregulated.

recognise that the imprecision of the current empirical taxonomy system is such that it is difficult to know when an organism is truly intergeneric or not. Species in a single genus (intrageneric species) are considered to share a common gene pool by both Agencies due to the fact that these species are, or have been, sexually compatible and descended from a recent common ancestor. The differences from species to species within a genus are not such that a trait present in one is incompatible with another - or may cause unforeseen consequences when transferred by recombinant techniques. Intrageneric GMOs are not considered by the EPA or the USDA to present unpredictable traits as a result of the modification. It is possible that some intrageneric GMOs will be identical to organisms created by alternative, traditional techniques. Intergeneric GMOs, on the other hand, may be more greatly disturbed by the presence of a gene that has been secluded by aeons of evolution and sexual incompatibility. Its insertion within a species from a different genus may cause unpredictable effects. These are truly novel creatures when viewed in the present state of evolution rather than across all time. Whether they existed millennia ago or may evolve naturally in the distant future is of no consequence to the fact that they may well disturb the present state of the environment and human health.

Similarly, the analysis made by the EPA and the USDA take into account the disturbance to the present state of the environment rather than a cosmic overview. Creating one GMO with an undesirable characteristic is not the same as introducing and maintaining a new crop on a vast industrial scale: this can result in the creation of ecological niches, or can result in the out-transfer of a particular gene (for example, anti-biotic resistance) on a vast scale. It is true that the "risks" of introducing GMOs may be the "same in kind" as the risks of introducing non-GMOs to the present state of the environment, if one interprets this statement as meaning "the same hazards may be encountered". But the likelihood, the scale and impact of these hazards (i.e. their risk) are vastly increased by industrial scale – which in itself may introduce new hazards. This was indeed one of the findings of **NAS (1987)**.

### 5.3.4 The "inherent danger" of biotechnology

As stated in Section 5.3.3 above, proponents of the "horizontal" approach tend to equate new with unfamiliar and unfamiliar with uncertain or even dangerous. This "myth" causes Miller considerable irritation: "[t]he basis of this view may be the atavistic fear of disturbing the natural order and of breaking primitive taboos."[279] Miller attacks what he perceives to be an irrational[280] fear of the unknown clothed in pseudo-moral terms.[281]

Miller does not argue that biotechnology is risk free. He acknowledges that GMOs can be dangerous as his argument that biotechnology is generally safe depends on it being applied to safe uses

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[279] **Miller (1995d), pp. 45-6.**

[280] **Miller (1996d), p. 362.**

[281] Miller does not directly address the moral / ethical discussion of recombinant techniques in his publications, but his rejection of the consideration of such issues is evident from his condemnation of the participation of lawyers and ethicists in committees regulating biotechnology. However, it is also apparent that Miller favours the use of "risk / benefit" analysis in the determination (by scientific experts) of the acceptability of assessed risk, which presumes the inclusion of economic, social and moral issues in the debate, but *only if in favour of biotechnology!*

such as agriculture, using familiar species. This leaves open the argument, raised at the origins of the biotechnology debate, that biotechnology can be used for military applications. Miller's argument is that there is nothing inherent or unique to biotechnology that is hazardous. Miller argues that "traditional" breeding methods can give rise to dangerous organisms as well, and that the introduction of non-indigenous species can have devastating and unforeseen effects. Miller's argument is that GMOs are at least as safe as other genetically "altered" or non-autochthonous organisms and represent an improvement over the cruder older techniques. Miller rejects the overblown fears expressed in the early days of the debate that the use of modern biotechnology will create uncontrollable "Armageddon bugs":

> "Both genetic and ecological constraints operate to prevent the emergence of exceedingly pathogenic viral variants, though even a single point mutation can alter virulence [ . . . ]. And while the variations that continuously arise on an enormous scale in nature do occasionally produce a modified pathogen [ . . . ], it is hardly likely that they would produce in one fell swoop a serious pathogen from a *non*-pathogen. Furthermore, the chances of such an event arising from the small-scale changes made by man do not compare with the tremendous background "noise" of recombination and selection in nature."[282]

If the use to which a technology is put is also a factor of risk, as this would appear to suggest, than arguably regulations should aim not at the end product but at the use made of the technology.

## 5.4 Conspiracy theories

As explained in Section 5.1, there is no authoritative opinion on the issues appertaining to biotechnology and proponents and opponents of biotechnology have entrenched their arguments in mutually-exclusive languages. As they cannot find common ground to debate the issues, proponents and opponents have taken to attempting to personally discredit each other in order to discredit the views upheld rather than disprove each other's theories with rational analysis. Over the years a number of conspiracy theories have developed that cloud the issues and prevent the debate from moving on from entrenched positions. The participants in the debate have all but lost credibility, not only in their own mutual regard, but in the eyes of the wider public which will be the final jury in the matter of biotechnology's success or failure.

Miller argues that an anti-technology movement is manipulating the public and hijacking the legislature.[283] He believes that the public has

> "a fear of disturbing evolutionary sanctity or the "natural order" of things [and] a wish to return to a childlike world of purity and innocence [ . . . ]. [T]his romantic view of the physical world, reflecting a wish to "flee from complex realities and difficult choices", [ . . . ], can give rise to a kind of puritanical antitechnological view of the world. Purity becomes a desired end in itself, to the exclusion of other goals".[284]

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[282] **Miller (1995d), p. 44.**

[283] **Miller (1995b) and (1996d).**

[284] **Miller (1993b), pp. 1075-1076.**

This movement is branded "unscientific".[285] The biotechnology sector bemoans the multidisciplinary nature of regulatory advisory committees, clamouring that risk assessment should be left to the "experts" only.[286] The sector's definition of "expert" is unclear: it can be assumed to mean "geneticist" (and perhaps experts in human nutrition and pathology when food is concerned). The biotechnology sector dismisses the disagreements amongst scientists tartly: "one must know who the experts are".[287]

By way of contrast, the discrediting arguments used by the detractors of biotechnology generally run along the lines of denouncing the sector's financial greed and the weakness of government in the face of the industrial lobby; denying the expertise of the scientists involved in biotechnology, either because they are not "true" biologists or because they are adherents to unacceptable political or philosophical views; and denouncing the corporatism of a sector dominated by a small number of self-serving prominent personalities.

The first two types of discrediting arguments are put forward by many commentators, but most eloquently by **Regal (1996)**. He argues that there is an alliance between recombinant scientists and the business and financial sectors, creating

> "an economically and politically powerful pressure block to oppose effective regulation [ . . . ]. Public desires to regulate biotech for safety reasons were strongly opposed by leaders of the biotech community for economic reasons. Careful regulation of biotech would mean costs in terms of time and money for laboratory workers and industrialists alike."[288]

Furthermore, **Regal (1996)** argues that the biotechnology sector has become involved with a definite political agenda:

> "the business community, with which recombinant DNA scientists were forging partnerships, had long held strong resentments against all sorts of regulation. The antiregulatory philosophy of the Regan / Bush administrations in the 1980s, and of neo-conservatives before and after the 1980s are well known."[289]

The link of this political agenda with the scientific philosophy of the biotechnology scientists is explored further on.

Commercial pressures may cause corner-cutting at the expense of scientific rigour. Being aware of these pressures, the public is unlikely to believe that assurances of product safety are objective. In response, the biotechnology industry is engaged in a concerted marketing campaign:

> "The possibility that there is a strategic campaign of attention-diverting rhetoric at work in the case of biotechnology should not be ruled out. There is an enormous amount of money and political power at stake at university, local, national, and international levels; and power has

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[285] **Young & Miller (1989), Miller (1992a), Miller (1992c), Miller et al (1993), Miller (1994e), Miller (1995b).**

[286] **Miller (1984), Miller & Huttner (1991), Miller (1994b), Miller (1995b).**

[287] **Young (1988), p.4.**

[288] **At p. 21.**

[289] **Regal (1996), p. 21.**

never confined itself to transparent strategies. Lawyers, lobbyists and corporate strategists are active at the intellectual / policy leadership level in the biotech community, and they aggressively locate centers of power in national and state capitals to shape a favorable image of biotechnology and to get laws and subsidies that will be favorable to it."[290]

As to denying expertise, **Regal (1996)** argues[291] that the driving force behind biotechnology, geneticists, are not "biologists" in the conventional sense of the term; they are physicists and chemists who have little idea of the interaction of the genome with the biological entity as a whole, let alone with the entity's environment, and are therefore not qualified to make the necessary risk assessments before the release of GMOs to the environment.[292] **Regal (1996)** argues that these geneticists are said to be reductionists, obsessed with the "precision" of static genetic models, refuting the "fluid" or "dynamic" concepts of the genome, and refusing to acknowledge the considerable uncertainties still present in the science of genetics. He contrasts the static and narrow chemical model-based approach of molecular biology with the multidisciplinary form of biology which makes

> "investigations into the structure, physiology, evolution, adaptations, and ecology of diverse life forms on earth [. . . ] in their natural habitats and in the laboratory."[293]

**Regal (1996)** argues that molecular biology is an assumption-based science rather than one which relies on empirically-verified theories. This accusation is based on biotechnology's claim to be a revolution in science, a truer science than the older form, having access to the blue-prints of organisms (as it were) rather than being obliged to guess the internal causes of externally-observed phenomena. Regal dismisses this claim as genetic insertion, the central mechanism of biotechnology, is still essentially uncontrolled and uncertain. Biotechnology cannot therefore be described as a precise science. This is borne out by the very high failure rate that still occurs at every stage of development of a GMO. Regal argues that this narrow static view of the genome, as well as the arrogant view of the geneticist as the holder of life's blueprint, is characteristic of reductionism.

He argues that this philosophy of science originated in the right-wing think tanks that dominated scientific funding in the 1930s (hence the link with antiregulatory politics), where it was promoted to preserve a sense of order in Nature as a bulwark against the perceived anarchy and uncertainty of the new quantum physics. He further argues that when the reductionists lost the battle against quantum theories in the domain of physics, they turned to the domain of biology as funders and theorists. He argues that the early promoters of biotechnology personally held reductionistic and deterministic views. Regal also argues that this philosophy of science is based on ancient philosophies and discredited ideologies that prevent adequate risk analysis and puts the proper assessment of GMOs before release in jeopardy. . He quotes extensively from science historians, tracing the dissemination of

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[290] **Regal (1996), p. 23.**

[291] At p. 17.

[292] This may have been the case in the early days of the development of biotechnology as a separate discipline within biology, but this accusation can no longer be made against "geneticists" as a whole. Although some may still adhere to reductionist principles, geneticists are now fully competent in all disciplines of biology.

[293] Idem.

reductionist thought from Greek cosmology through determinism and medieval creationist theories to a common misinterpretation of Darwinian evolution. All of these schools of thought maintain that nature is

> "harmoniously balanced nature [and] populated by perfectly adapted creatures."[294]

This school of thought lead to the view that Nature is governed by immutable laws with the consequence that these laws can be discovered, learned and harnessed by human endeavour, assuming that

> "all things would be understood if the properties of the basic atomic particle were understood".[295]

This view also holds, as a result, that the consequences of human endeavour can be quantified and accurately predicted. That is to say predictive models can be constructed on the basis of the "science" of the laws of nature. From the understanding of the gene, all aspects of "traditional" biology would be understood: structure, physiology, evolution, behaviour, adaptations and ecology (as listed above) would be studied - not on the basis of allegedly unreliable observations, but on the basis of predictive knowledge derived from the genetic blueprint.

> "Reductionist enthusiasm went beyond developing methods of analysis to determine chemical structures [ . . . ]. There was a leap in logic to the belief that knowledge from lower levels of organisation gave one knowledge at all higher levels of organisation [ . . . ]."[296]

Inherent in this school of though is also the view that the harmony of Nature *cannot* be disturbed by human actions as it is superior by definition: human creations such as GMOs are intrinsically inferior to those of Nature and cannot prevail. The search for order in Nature takes on a quasi-religious form in this case.

**Regal (1996)** explains the hostility of reductionists towards the recent trend in traditional biology as a revival of the battle against anarchic "quantum" theory. The holistic model of the genome and the latest evolutionary theories, based on chaos theory, contradicted the view that the biological laws of nature are not set, immutable or predictable, but on the contrary, the "balance" of nature is

> "relative, tenuous, ad hoc, statistical, and organisms are far from perfectly adapted to nature. There is much room for organisms to be made that are competitively superior to those that already exist, and for a tenuous "balance of nature" to be destabilised"[297]

This latter view is demonstrated in the "fluid genome" theory of Barbara McClintock which had been developed in the 1950s but was only accepted in the 1980s. It is possible that it was resisted all along by the reductionists within genetics, and it is doubtful even now if the fluid genome view prevails amongst the scientific community.

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[294] At p. 27.

[295] Regal (1996), p. 23.

[296] At p. 24.

[297] At p. 28.

These conspiracy theories do not assist the debate and obscure the extensive commonalities between proponents and opponents of biotechnology, discussed in the next Chapter.

## Chapter Six: Differences and Commonalities in the Biotechnology Debate

The scientific community originally expressed its own safety and ethical concerns regarding recombinant biotechnology and sought to resolve them through open debate with the wider community. However, the hostile response from elements of the wider community shocked the scientific community, which had expected its newfound candour to be welcomed.

### 6.1 Origins of the debate in the scientific community

The development of recombinant techniques caused the scientific community to consider the safety and ethical value of experiments using these potent new techniques. The birth of recombinant techniques was not an isolated and unexpected event, which subsequently raised a storm of controversy, but was the continuation of technical development within the "parent" sciences of biotechnology. Similarly, the debate within the scientific community following the development of recombinant techniques was not a new reaction but the continuation of the insertion of science into modern society. The scientific community was concerned by as well as enthused by the new techniques, being well aware of the acceleration of scientific development that this breakthrough would cause, and tentatively aware of the social difficulties such an acceleration would provoke.[298]

Several teams were hoping to be first to achieve the breakthrough in recombinant techniques, not as an end in itself but as an essential tool in their principal scientific quests.[299] The recombinant techniques were developed in the context of cancer research and bacterial resistance to drugs. The techniques were to be used to provoke the development of cancer in bacterial cells by inserting genes linked to cancer by way of viral vectors or to provoke the development of drug resistance in order to understand the ways such undesirable characteristics developed.[300] It is the hazardous nature of the materials used (oncogenes and vectors of bacterial drug resistance) as well as the dangerous nature of conducting experiments to provoke hazardous characteristics that caused concern within the scientific community. It was not the question whether the recombinant techniques themselves were safe. In particular, proposals to observe self-contained, viable and self-propagating recombinant viruses bearing oncogenes in animal cells rather than in the petri dish caused leading scientists to impose a moratorium on their own work. They had realised that these viruses in bacterial cells that were of a widespread type could escape from the laboratory, survive in the environment and spread uncontrollably, thereby inadvertently becoming a novel carrier of tumour-causing genes that could spread to the human population.[301] The scientific community became aware that, at that point, laboratories were not the strictly controlled environments that they are now, and the handling of hazardous substances left much to be desired in the terms of safety of laboratory researchers and staff, as well as the wider public.

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[298] **Cantley (1995)**, p. 510.

[299] **Wright (1994)**, p. 72.

[300] It is to be noted that these are "vertical" experiments in the terminology of Miller.

[301] **Wright (1994)**, at p.73.

The realisation that experimentation using the new recombinant techniques could be more hazardous than expected placed a burden of responsibility not often felt on the shoulders of scientists up to that point. These concerns provoked an unprecedented soul-searching about the need for restraint in scientific work. Although the experiments were intended to have positive outcomes (better understanding of cancer, better prevention of bacterial drug resistance), these positive outcomes were weighed against the risks run in attaining these outcomes for the first time. The acceptability of taking risks in the name of scientific progress, and in particular the acceptability of imposing risks on persons not involved in the research (such as the general public) was no longer taken for granted. The philosophy that nothing should stand in the way of science, and that all sacrifices in the name of science were justified by the benefit the new knowledge would bring, was now being abolished from scientific research. This philosophy had already been abolished from the field of medical research following the recognition, in the light of the abuses perpetrated by doctors during the Second World War, that no increase in medical knowledge, however beneficial, can justify the violation of certain basic human rights. Pure scientific research now had the potential to affect (adversely as well as beneficially) vast numbers of people. This realisation was not confined to the recombinant techniques. It was also apparent in the development of nuclear energy: the pure science of splitting the atom suddenly had immediate human consequences. Science for science's sake was disappearing as a motivation amongst the scientific community.

The field of genetic engineering acted as a bridge between the new worlds of research ethics and medical ethics: now that gene-splicing was a reality, the old fears about eugenics crossed over from the medical world into the world of molecular genetics as well. It was realised that the advent of practical recombinant techniques required some action to prevent inadvisable or unsavoury experimentation with the fundamentals of life from going ahead. There was a clear need to discuss and establish an ethical framework for pure research, just as there was an ethical framework for medicine. This was to lead to discussions concerning the self-regulation of scientists for scientific research.

At the same time as the scientific community was coming to terms with its newly felt social responsibility, it became aware of the new and vast commercial potential of pure research, provoked in part by the recombinant techniques. Recombinant research, from its very inception, linked up with venture capital to form commercial research companies. For example Herbert Boyer was approached, soon after his seminal breakthrough in recombinant techniques, by Robert Swanson, a venture capitalist, and became a founder of Genentech, the first, and today one of the most advanced, dedicated biotechnology research company.[302] The impact of this new commercialism was to switch pure research aims with commercial aims. Research into the genome almost stopped whereas research into gene products took off. Interest in the chemical expressions of DNA rather than in DNA itself soon dominated, for commercial gain. In this new commercial context, the question arose whether research risk is justifiable when the gain is financial and exclusive to a few. This is not the same as balancing a risk against a gain that is of immediate benefit to the wider population.

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[302] **Coghlan (1993), p. 26.**

## 6.2 The difficulties encountered in establishing a forum for the debate

### 6.2.1 The "Berg Committee"

The new safety concerns and ethical considerations were first publicly raised at the annual Gordon Conference on Nucleic Acids, in New Hampshire, in June 1973. The debate commenced when the Conference gave the task of setting up a committee to assess the potential hazards of the new recombinant techniques to the National Academy of Sciences ("NAS") and the Institute of Medicine.[303] This committee was known by its chairman's name, the Berg Committee. Paul Berg was one of the pioneers of the recombinant techniques, working with viruses and oncogenes, and one of the scientists to voluntarily stop his experiments in order to assess their risks. The conclusions of the committee were published in Science[304] and in Nature in July of 1974. Quite candidly, the committee admitted to the large areas of uncertainty in the new field of research:

> "our concern is based on judgements of potential rather than demonstrated risk since there are few available experimental data on the hazards of such DNA molecules [ . . . ]. Moreover, we are aware of many theoretical and practical difficulties involved in evaluating the human hazards of such DNA molecules."[305]

The committee broke new ground in openly addressing the uncertainty in the scientific knowledge, and in taking a precautionary approach to the hazards presented by the recombinant techniques. The statement above raised three points that were to dominate the development of regulations in the US: (a) the need to separate conjectural from real hazards; (b) the need to adopt control measures that are in keeping with the current level of experience with the techniques; and (c) the need to adequately address the difficulties involved in the evaluation of hazards.

The committee called for restraint in scientific research until these points could be better understood. The statement issued by the committee has unfortunately become a thing of legend. The cautious wording adopted by the committee has been blown out of all proportion; it merits recording again here:

> "Nonetheless, our concern for the possible unfortunate consequences of indiscriminate application of these techniques motivates us to urge all scientists working in this area to join us in agreeing not to initiate [certain specific types of experiments[306]] until attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved."[307]

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[303] **Singer & Soll (1973).**

[304] **Berg *et al* (1974).**

[305] **Berg *et al* (1974), p. 512.**

[306] These were specifically experiments involving autonomously-replicating DNA elements - such as plasmids or viruses - that might express antibiotic resistance or bacterial toxins or certain oncogenic or viral sequences.

[307] **Berg *et al* (1974), p. 512.**

The committee's report was chiefly aimed at the scientific community that requested the study, but also was intended for public comment in a new mood of openness in the scientific community. There were three reactions to this laudable display of openness.

Firstly, the wider scientific community became aware of the issues arising in the field of recombinant DNA. Wider scientific concerns were also added to the committee's worries about the possible dissemination of hybrid oncogenes (amongst others): other sectors of the scientific community, outside of the molecular geneticists, raised the question of possible deleterious "synergistic" effects of genome-manipulation on the wider organism. For example, the question was raised whether non-pathogenic microorganisms could acquire pathogenic characteristics from the use of vectors. The effects of genetic engineering on the recipient organisms relationship with the wider environment were also explored. This was largely the purpose of the committee's report and of the request for the committee's study: to raise awareness of the possible issues arising from the reality of recombinant methods. However, these valid scientific questions seem to have soon been perceived by the molecular biologists as attacks on their field; and enmity developed between "traditional" biologists, who maintained concerns as to the safety of the recombinant methods, and molecular biologists that insisted on their safety and predictability.

Secondly, the committee's frank concerns did not escape the attention of the wider - non-specialist - media, which was already experienced in a number of environmental controversies and the debate concerning the effects of unrestrained progress on society. As the first, widely available, public statement of concern at the possible hazards of genetic engineering emanating from the scientific community it, the committee's report was hijacked by the sensationalist press and mistakenly became known as a call for a "moratorium on genetic engineering". The topic of genetic engineering became ensnared in long-standing (and perfectly valid) debates concerning military use of new technologies, medical ethics, eugenics, pollution and intensive agriculture. As the possibilities of genetic engineering were understood, further moral, social and economic fears grew concerning the use of the techniques and its fundamental moral justification.

Thirdly, and most importantly for this chapter, by admitting to areas of uncertainty, and raising the matter of establishing new guidelines, the "Berg report" opened the door to the wider debate concerning the control of science. The question was raised: who would set these guidelines and how? Self-regulation by the scientific community - even via the NIH - as proposed by the "Berg report" was quickly criticised. It was felt that the issues were too big for the scientific community alone, especially as the recombinant techniques had the ability to affect areas beyond the scientific community such as medicine, industry, trade, and the wider environment and quality of life of ordinary citizens.

Besides the (in)famous statement, above, the Berg Committee made two important recommendations. The first was that the NIH draw up the Guidelines to be followed by scientists working in the domain of recombinant DNA and that the Director of NIH would become the central authority for recombinant activities, aided by an advisory committee which would carry out investigative experimentation into the potential hazards of biotechnology and the means of minimising

such hazards. The second recommendation was that an international conference be organised to discuss the issues arising. This took place at Asilomar in February 1975.

### 6.2.2 The Asilomar Conference

The Asilomar Conference has been described as an "innovation in scientific communication".[308] It was the first serious attempt by the scientific community to discuss its concerns and ambitions, its knowledge and uncertainties, under the glare of public scrutiny. This attempt, like the publication of the Berg committee report, was brought about in reaction to growing public mistrust of the scientific community as described by **Wright (1994)**. It is undeniable that the Asilomar Conference achieved a great deal of good scientific work, but it also caused much controversy in science, in the social discussion of biotechnology, and in the regulatory policies for biotechnology that were subsequently adopted.

With regard to the science, the Conference brought vast amounts of experience gathered over the first few years of work with recombinant techniques. Empirical evidence was presented, along with theoretical debate, which demonstrated that the dangers associated with recombinant technologies were much less pressing than previously thought. Although the uncertainties were not entirely resolved, the *a priori* presumption of danger placed on the new GMOs, was replaced by an *a priori* presumption of safety. The Conference also addressed the concepts of risk categories for GMOs and the appropriate risk management procedures through the use of physical and biological containment.

However, these achievements remained controversial. The change of assumption, from danger to safety, regarding GMOs has been criticised as premature, and it has even been said that the Conference was aimed at establishing this change whether the (admittedly meagre) scientific evidence supported it or not.[309] Indeed, many vital discoveries concerning the structure and functions of genes (such as the discovery of introns and exons and translational aberrations; and the acceptation of the "fluid genome" theory) were yet to be made.

Another concept stemming from the conference has also been criticised. The idea of classifying GMOs into "risk" categories is, according to **Cantley (1995)**, at the source of the flaw that pervades most risk assessment research: the logical impossibility of proving a negative, namely that GMOs are not dangerous (i.e. proving that GMOs are "safe"). Rational risk assessment attempts to prove a danger, and assumes safety when no danger can be shown. The lack of understanding of the concept of risk at the Conference was noted by attending journalists:

> "no one had any real idea of what the risk might be or how to assess it".[310]

This vital question was left unanswered:

> ". . . the question of evaluating the hazards of genetic engineering - an evaluation fundamental to its rational control - simply had no answers."[311]

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[308] **Cantley (1995)**, at p. 513.

[309] Because the Berg report had caused most of the experiments to be halted, one has to ask, in these circumstances, just how much experience had been gained if most experimentation had indeed halted.

[310] **Wright (1994)**, p. 151.

Experience from different branches of the life sciences, or from industry, could have highlighted certain concerns, and mitigated others, by relating the experience of using microbiology on an industrial basis (as mentioned in Section 5.1, above). However, the compartmentalisation of the life sciences prevented industry from taking part. Some state that this was a simple, but telling, oversight, as the industrial biotechnologists were not part of academic circles. Others state that the under-representation of industry was by design as it was assumed that "traditional" uses of biotechnology would not involve the pathogenic organisms (such as viruses and oncogenes) that were causing the anxieties at the time.[312] Subsequent developments show that this was a very shortsighted decision as pathogens are used as vectors in agricultural biotechnology today. Outside of the academic and medical worlds, microbiology had already built up a considerable body of scientific knowledge and expertise, especially concerning worker health and safety, physical and biological containment of organisms for product purity and safety reasons, and the prevention and consequences of environmental releases.[313] All of these were of direct relevance for the safety of recombinant biotechnology, but were ignored as they were classified under "process engineering" rather than under "biology", "microbiology" or even "genetics". Similarly, other offshoots of genetics remained obscure as well. Animal and plant breeding, like industrial microbiology, built up a large body of knowledge that remained overlooked by the academic geneticists, who were more interested in the biochemistry aspects of genetics than whole-organism aspects of genetics.

The result of this is disputed. Some commentators believe that the recommendations of the Asilomar Conference were not stringent enough, being inadequate for the scale-up to industry and leaving out vast areas that could cause more harm to human health and the environment than small-scale laboratory processes. Others thought that the recommendations were excessive.[314] The under-representation of industry caused the Conference to bear in mind only the laboratory microbiology familiar to the scientific element present, involving pathogens or potentially pathogenic organisms. This led to recommendations which were unduly restrictive and inappropriate for the industry as most of the

> "microrganisms used in industrial microbiology have . . . been harmless to man and normally present in the environment."[315]

The report of the Berg committee had called out for a broad scientific consultation on the issues raised by the recombinant methods. The Asilomar failed to provide the open forum that the report called for. The exclusion of many branches of the life sciences, with valid experience to contribute, could only force these branches to find other forums in which to air their views. Without

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[311] **Wright (1994)**, p. 152.

[312] **Wright (1992)**, pp. 136-40. The traditional fermentation biotechnology industries may not have wanted to use pathogenic organisms for their work, but this did not mean that they did not have relevant knowledge of such organisms via their experience of food hygiene problems, nor did it mean that they would not have an interest in mechanisms for the control of such organisms.

[313] See for example **Collins (1992)**, pp. 23-33.

[314] **Thorley (199?)**, pp. 5-8.

[315] **Collins & Beale (1992)**, p. *vii*.

some kind of co-ordination covering the various branches of the life sciences, any conference could only reflect an intra-sectoral point of view. The polarisation of the debate can be seen as a direct consequence of Asilomar's failure. Just as the scientific compartmentalisation has caused the scientific aspects of the debate to suffer, so has the social compartmentalisation of the debate, which stems from the "us and them" attitude of Asilomar. Safety and ethical concerns that could have been rationally debated in the early days were not aired in a forum that would have provided immediate and appropriate answers. Because of this lack of a formal question and reply format for the "Gene debate", much important information is lost in a barrage of one-way statements.

With regard to the social debate concerning biotechnology, the Conference added to the wider debate concerning the role of science in society. In this regard, **Cantley (1995)** states:

> "Some commentators nonetheless set Asilomar in the context of tradition they would describe as "elitist", characterised by the arrogant assumption that on complex matters, only those who understand the complexities should be involved in making decisions. Against such elitism it is argued that democratic procedures require the involvement of a broader constituency - of the taxpayers who have paid for publicly funded research, of the workers who might he the most immediate victims of a laboratory accident or infection, and by the same logic, of the general public who, on various conjectures, might also be victims either of an accident (such as an epidemic initiated by a recombinant organism), or be exposed to risks associated with products placed on the market."[316]

**Wright (1994)** argues that the dominant personalities of early biotechnology sought to dominate the scientific agenda within genetics in order to exclude all discussion of the scientific uncertainties in genetics research and prevent any discussion of moral or economic issues in order to secure the continuing of uncritical government funding for their work. The original "Berg" committee, the NAS committee, and the Asilomar Conference, were dominated by the same persons. **Wright (1994)** claims that there was a conflict of interest; these persons were determined to bury the issues they had "naively" raised. The agenda was controlled to avoid unwanted questions of social interest:

> "the cochair [ . . . ] opened the proceedings and reinforced the prevailing bias by moving to restrict the scope of the meeting to the question of hazards and safety and by excluding broader social and ethical issues."[317]

**Wright (1994)** argues that the Asilomar Conference was a "closed shop", as it was convened by invitation only with little press coverage rather than being the open and public debate that the Berg committee has called for. She alleges that its aim was to establish a climate in which the new technology would be seen as safe and could be developed without the constricting regulations placed on the traditional chemical and pharmaceutical industries. In order to ensure this, there was a deliberate decision not to include a representative participation from the "traditional" industries or specialists in large-scale industrial biochemical or chemical processes so that the safety questions, for which there was a considerable body of relevant experience in the chemical process industries, would not be raised:

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[316] At p. 513.

[317] Idem.

> "Thus as a result of the restriction of participation at the meeting and the design of the agenda, discussion of the major issues faced at Asilomar was skewed. Few at this meeting were inclined to raise issues that might have continued the suspension of research in order to be adequately addressed."[318]

Even the interests of

> "those most immediately at risk - technicians, students, custodial staff, etc."[319]

were ignored in the haste to adopt scientific self-regulation that would enable further research in conditions suited only to the scientists themselves, on the basis that

> "peer review and voluntary guidance would provide an appropriate basis for control."[320]

Accusations of self-interest have been made against this small community, outside of the financial matters discussed above. **Wright (1994)** has described how the scientific community developed a utopian language of "magic bullets" to entice governments and financiers to provide funding for their work. **Regal (1996)** argues further that this language was used to serve

> "the interests of physicists and chemists. They served as blueprints of an intellectual / social hierarchy that mandated a place for them at the top, and that also helped them to obtain research support."[321]

### 6.2.3 Science included in the public demand for accountability

The development of recombinant techniques had coalesced a major late-20th Century debate concerning the scientific and legal treatment of uncertainty in decision-making. With the ever increasing complex nature of our technological society, decisions regarding the acceptability of new techniques, practices and products are becoming ever more difficult (and expensive) to make, taking into account ever increasing numbers of variables. Decision making, be it on a governmental, institutional or individual level, is now increasingly in a context of managed uncertainty. The problem is, in societal decision making for technological risks, there are so many stages involved, each with a plethora of experts, that the distribution of responsibilities is lost in the faceless behemoth of government.

The public, increasingly aware of uncertainty in decision-making, and of the standards of professionalism, are increasingly demanding accountability for decisions affecting them and taken on their behalf. When the distribution of responsibility (and accountability) is obscured, by complexity or by design, the public lose confidence in the decision-making process, especially when the consequences of the decisions are, or appear, to be far-reaching. Then the public will substitute its own decision-making process to protect its own values.

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[318] At p. 148.

[319] **Wright (1994)**, p. 151.

[320] Idem, p. 150.

[321] **Regal (1996)**, p. 19.

The experts, and increasingly the general public, are also aware of the need to assess the acceptability of the scientific evidence used in decision-making and of the preventative decisions made on this evidence, as if it were trial-tested after the event, in order to establish the clarity of the decision-making process and the responsibilities that are attached to it.

The questions that are raised are not specific to biotechnology but are fundamental to our society: can we choose the risks we undergo? Trust in societal institutions, once taken for granted, is no longer in existence: confidence in Governments, business, and science have all been deeply shaken by the events of the 20th Century. There is a zeitgeist of uncertainty. Whereas there was a time when the scientific community would be trusted to make these decisions on behalf of society, society in the late 20th Century begun to demand accountability from the scientific community for two reasons: firstly, society wanted accountability for the work that was funded by tax-payer's money; secondly, society acting on the concept of demand and supply, wanted accountability for the impact that new scientific developments would have on itself.

### 6.2.4 The connection between funding and accountability

**Wright (1994)** has described in detail the changing fortunes of the scientific community in the 20th Century. She argues that the social status of scientists, and their influence on societal policies for the management of technology, and in particular biotechnology, went through four distinct phases with corresponding changes in the sense of responsibility towards society felt by the scientific community. The four phases can be described as follows.

In the first phase, generally before the Second World War, scientists were a fringe element of society which was content to exist within its Ivory Towers and content to rely on benefactors and personal fortunes for the funding of academic research. The scientific community's sense of responsibility was entirely towards Science as the *alma mater*, and not wider society. There was little interaction between pure research and wider society, and no sentiment of accountability.

In the second phase, from World War II to the height of the Cold War, scientists became a privileged class at the pinnacle of society due to the importance of scientific research for the war effort and the continued development of complex armament during the Cold War. During this time, the scientific community became accustomed to having the ear of governments, the unquestioned respect and trust of the public, and unlimited and unquestioned access to public funds. "Progress" ruled supreme. The sheer unquestioned privilege accorded to the scientific community eliminated any accountability. Rather than developing a sense of responsibility towards society, the scientific community developed the feeling that it had become society's duty to serve science.

During the third period, after the peak of the Cold War and the ensuing *détente*, there was a change of heart amongst the governmental paymasters. Partly because of budgetary constraints, partly in response to public disquiet with unrestrained research spending and the pace of progress, governments demanded that their research grants were justified by some promise of public good to result from the programs they would support. Scientists became aware of their accountability, at least to the governmental paymasters, and the need to rationalise their work.

The fourth period in Wright's thesis, extending from the 1970s to the present, covers a consolidation of governmental financial auditing with ever tightening budgetary restraints and public hostility to public spending. During this period, the scientific community realised the limits of public research funding and turned to commercial sources of funding. This shift of financial patronage was paralleled by a realisation by the scientific community that its exalted social status brought responsibilities as well as privileges towards the rest of society. The scientific community sought to explain its work to the wider public and sought its approval.

Wright's thesis concentrates on the development of the scientists' language for attracting grants, on how the scientific community trained itself to discuss the social benefits of their work in highly optimistic, utilitarian, and deliberately vague terms, in order to attract funding for their research. One of Wright's main conclusions is that the scientific community was ill-prepared or unwilling, to discuss the possible negative aspects of their work; and that this reticence is at the heart of the breakdown of communication between the scientific community and the wider population during the "Gene debate".

The language used by the participants on the debate has an immediate impact on the perception by other participants of the motive for holding any particular point of view. Although the concerns of the scientific community were originally much the same as the concerns of the wider community, any possible understanding was quickly obscured by the participants in the debate adopting "party lines". In order to continue its research and counter opposition to the new techniques, the scientific community adopted the language of the "magic bullet", promising benefits so great that not taking risks would be immoral. Effectively, the scientific community attempted to use the language used by the opponents of the new techniques. This was the language of "moral outrage", where in order to oppose any risk (and especially any conjectural risk), however slight, much is made of the injustice of taking the risk rather than the seriousness of the risk itself.

### 6.2.5 The backlash in the face of criticism

The scientific community was not prepared - or not prepared enough - for the sudden focusing of public interest on the field of biotechnology. **Wright (1994)** describes how the scientific community had successfully defined an agenda upon which to discuss funding and other needs of research with the government. The government had gradually introduced financial accountability onto the agenda. However, outside of these financial and technical matters, no other significant issues regarding the position of science was placed upon this agenda until the "Berg report". When the scientific community decided to open up the debate, it was not experienced in handling the agendas of the outside world. Although the political debate directing the reduction of research grants largely reflected a public debate concerning the control of science and progress, the scientific community was shielded from the heat of the debate by using the government as an intermediary interlocutor. The scientific community communicated with the government, using one frame of reference, and the government communicated with the wider public, using many other frames of reference developed through years of lobbying. Once the scientific community opened itself to commercial interests, effectively calling upon public subscription, it suddenly faced a wide spectrum of interlocutors. Besides the financial community - with whom the scientific community still had an easy dialogue - innumerable unrelated

interests now assailed the scientific community, questioning its aims and purposes and raising concerns in entirely new languages: moral, social and economic. The scientific community's belief in its ability to communicate effectively[322] was to be severely challenged, not necessarily by the complexity of issues they suddenly faced but by the number of interlocutors and their lack of interaction among themselves. An answer to one group caused an outcry in another prompting another response, until the original question and its answer were forgotten or completely misrepresented.

At first, it appears that the scientific community accepted that these challenges were legitimate: it had entered a wider debate and had to accept the glare of interest; and it had also accepted the communication challenge, choosing to present openly its own doubts and fears concerning the research it pursued. However, the scientific community apparently tired quickly of the continuous, repetitive attacks by third-party interests (bolstered by the equally nebulous concept of public interest) especially as they seemed unaffected and unchanged by reasonable, rational dialogue. Some commentators clearly pointed out that the scientific community took offence at these attacks and withdrew from the debate. As **Cantley (1995)** points out, at p. 513,

> "[s]cientists were often angered by the misrepresentations, and by the strident and hostile tone of the attacks they encountered".

This caused an elitist backlash amongst scientists, decrying the new Luddites and their Anti-science movement. Some commentators point out that the scientific community needed time to organise themselves. Others show that the scientific community gave up on attempting to win over an ignorant and prejudiced public, and turned back to the interlocutors they could count on: the regulators who would affect their immediate dialogue with the financial community, at the expense of the long-term acceptance of putative recombinant products by the public. With hostility on both sides, communication broke down, just as it was most needed. Norton Zinder, looking back from 1986, described the situation as "the recombinant DNA wars".

### 6.2.6 The development of the language of "moral outrage"

Despite the commonality of issues between biotechnology industry and the wider community, the debate has been unsuccessful in identifying these areas of agreement. One of the reasons for this is the caricatural nature of the arguments presented in the media. Because of the short windows of opportunity that the modern media presents to anyone wanting to express a view or clarify an issue, "soundbite" strategies have to be adopted in order to get a point across, sacrificing the subtle nuances of policy and meaning. This has led to the adoption of set languages on either side of the debate. One the side of the "moral camp", the language of outrage has developed, and on the side of the promoters of biotechnology the language of "magic bullets" has developed.

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[322] The scientific community is founded on effective communication. The validity of research is dependant on the system of publication, peer-review, public presentation, criticism and defence of data and theories. However sophisticated this system may be, and however skilled its participants in communication according to the rules of the scientific community, this frame of reference is highly specialised, steeped in jargon and generally incomprehensible to outsiders as are most professional communications - especially those of lawyers.

The development of the language of "moral outrage" began with considerations of the moral acceptability of taking risky decisions on behalf of others. The concept of precaution was presented in an embryonic form: in the face of the unknown it is immoral to press ahead without wider consideration. Other aspects of public "outrage" are in fact well understood. These often arise because of perceptions of industry arrogance and lack of accountability which lead to "not in my backyard" or NIMBY reactions. It is quite clear that, once adequately informed, the public is able to assess risks and is not "irrational". However, the question of providing adequate information in a matter as complex as biotechnology, where even the experts cannot grasp all the issues, is one of the most problematical of all.

Moral outrage quickly became dogmatic in order to present the information in an easily understood and quickly presentable package. The central argument, with regard to the safety of GM foods, is very simple and highly effective. It has three basic steps:

- acting upon incomplete information in the area of GM foods may cause exposure of the population to unknown risks;
- it is immoral to impose risks upon persons who do not consent to those risks;
- therefore pressing ahead with GM foods is immoral.

Although moral opposition to risk is essentially conditional, the complexity of moral opposition to certain applications of biotechnology made it more effective to draw lines in the sand. Certain applications of genetic engineering become "unacceptable" but, without context-relative argument, it is difficult to see why some applications are acceptable and some are not, which undermines the argument.

The proponents of the moral position have not been able to advance their case effectively. This is because the mould of the safety debate appears to be ill fitting: the "moral outrage" language tries to use science (and the concept of danger) to enforce its moral views on safety and fails because it tries to quantify morally acceptable risks. The "moral" camp has not been able to demonstrate that the real "scientific" concerns are relevant to the moral argument and conversely that moral arguments are relevant to the definition of safety as a relative notion. Because of this, it was relatively easy for the proponents of biotechnology to caricature the moral argument as meaning, "Going into the unknown is dangerous" rather than "Going into the unknown may be immoral".

Many of the scientific concerns - especially regarding the unknown - have either been conclusively dismissed or proven to be real; of the latter many have been (adequately) addressed (at least in terms of science) and the uncertainties diminished - this has undermined the "moral" camp's use of these scientific arguments. However the fact that knowledge has increased and uncertainties considerably diminished has not addressed the core moral argument that it is immoral to impose unknown - or badly quantified or badly justified - risks.

### 6.2.7 The development of the language of the "magic bullet"

It was argued above that before any commercial applications of recombinant DNA were envisaged, there was an awareness of biotechnology's commercial potential. **Wright (1994)** has

explained how the scientific community used a utilitarian discourse extolling the value of the new technologies to government and private finance in order to raise the funds required for research. Extravagant claims were made regarding the certainty of success of GM products due to the "rational" nature of their research, and the immense benefit they would bring. GM products were presented as "magic bullets" that could cure all known diseases and resolve all the problems of hunger in the world. These claims were greeted with scepticism, but there was no evidence to either prove or disprove them at the time as research had not begun in earnest. In order to silence their opponents, the backers of biotechnology developed moral arguments of their own: they were outraged that anyone could refuse to accept the risks - if there were any at all, which they denied - when there were such immense benefits to be reaped by all. These claims are still in existence: opponents to biotech are said to be "anti-progress" (as they reject potential miracle cures), "anti-consumer choice" (as they reject the vast possibilities of new products), and "anti-environment" (as they reject potential clean-up applications).

This approach has failed even more dramatically than the "moral outrage" argument. Whereas the latter is emotional and subject to caricature, the high claims of the proponents of biotechnology have been contradicted by their own actions and by the development of the industry.

Biotechnology can be seen as a technical revolution, although this is challenged in two regards. Firstly, biotechnology has failed to live up to its revolutionary promise of feeding the world and curing all diseases: GM plants are designed only to enhance profitability for the producer (as discussed in Chapter Two), and any benefit for consumers are incidental; gene therapy has not yet managed to identify its target diseases (cancer and AIDS) let alone cure them. Secondly, analysts point out that biotech is developing very slowly and haphazardly in comparison with other "revolutionary" technologies such as semi-conductors.

**Teitelman (1990)** critically asks the question: Is biotechnology the technological revolution it is claimed to be? In classic economic theory a technological revolution occurs when a new technology becomes established and replaces the older structures, accelerating economic growth. This has not happened: biotechnology companies have not swept aside the traditional structures of the pharmaceutical industry (despite the claim to replace the hit-and-miss style of traditional drug development with "rational" drug development) nor have they swept aside the traditional structures of agricultural seed growers. On the contrary: biotechnology has increasingly been absorbed by the traditional structures, and has in some cases become only a tool for development in the traditional procedures.

Not only is biotech not a revolution in the economic sense, according to **Teitelman (1990)**, it is not one in the purely technical sense either: it suffers greatly from comparison with microelectronics. The first semi-conductor was developed five years before Watson and Crick demonstrated the structure of DNA and begun the era of molecular genetics. However, the first semi-conductor

> "led almost immediately to the first products and the first leapfrogging technologies. Watson and Crick worked from a much thinner scientific base; the structure of DNA was a paradigmatic event, but it did not spawn a technological breakthrough for twenty years. And even if one begins to count from Boyer and Cohen's 1973 recombinant experiment, the first product, human insulin, took over a decade to [ . . . ]. While this is relatively rapid by

traditional pharmaceutical standards - although these standards were changing as well over this period - it is, by the time frame of semiconductors, lethally slow."

Because of this, it can be shown that biotechnology is not a commercial revolution either. Biotechnology is characterised by a failure to develop self-sufficient product lines, whereas microelectronics is a success story. **Teitelman (1990)** shows that

> "[s]emiconductor history is characterized by rapid, continuous, and nearly exponential improvements on a basic technology. Science was important, but semiconductor companies were not wanting for conceptual breakthroughs on the frontiers of physics to generate new generations of products. [ . . . ] In biotechnology, the transition of science to technology has, so far, not been so smooth."

The economic consequences of the difficulties in biotechnology product development are clear. By comparison, development of new semi-conductor products was rapid and was not costly, therefore the semi-conductor industry remained independent and self-financing, developing new products from the profits of the last. This enabled the semi-conductor sector to compete directly with the more traditional business machine sector it eventually replaced. Biotechnology companies are not in the same position. Because of the massive cost of research and the long development time between the scientific breakthrough and the product, biotechnology companies are dependant on external funding because they do not have income from products to fund their research. Reliance on external funding, especially commercial funding, impeded the sector's ability to determine its own future. Biotech companies

> "had to turn to deal making - peddling off a project here, floating a partnership there - that made the kind of long-term profits needed for self-sustaining takeoff more and more difficult to generate and that made ever-greater demands on the technology to create a breakthrough product".

Having promised "magic bullets" in order to attract the financing, biotech had tied itself up so much that it became unable to deliver, and ended up being absorbed into the traditional structures that generated the funds.

Biotechnology has failed to live up to the hype and has failed to deliver in concrete terms.[323] These failures have real-world consequences, other than economic: they distort the public's perception of biotechnology as an economic sector; they also distort the understanding of the concepts used in biotechnology and therefore distort the regulation of biotechnology. As **Teitelman (1990)** explains, these failures have placed biotechnology under commercial pressures that threaten the quality - and safety - of its products. The hype surrounding biotechnology at its inception, and maintained today for purely commercial reasons, speaks in terms of revolutions - but the claims are increasingly hollow.

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[323] Writing in 1990, the editor of **Teitelman (1990)** asserts: "biotechnology has yet to fully deliver on [ . . . ] these promises. Companies have yet to identify, much less manufacture and market, a cure for cancer or AIDS". These are two examples of biotechnology's most celebrated and earliest goals, still elusive after more than fifteen years of expensive effort.

## 6.3 Origins of the debate in the wider community

Biotechnology was introduced to the outside world in a time of considerable social change and uncertainty as discussed in Section 6.1.1, above. However, biotechnology did not engender a new debate, it only cast a new light on older debates that had been raging for a considerable time.

### 6.3.1 Religious concerns

The disputes between science and religion have ongoing since Antiquity and biotechnology added a new twist by offering humanity an opportunity to play God and change Creation. Religious concerns were also aroused by the possibility that taboo foods could be made unavoidable.

Recombinant techniques challenge many of society's preconceptions about "life" upon which many religious, moral and ethical standards are based. These standards do not take kindly to challenges using grounds and terminology that are unfamiliar. It is claimed that recombinant techniques breach the "sanctity of life", an undefined concept. The basis for this argument is a perceived lack of respect for Creation and its Divine ordinance. Being able to transcend the natural barriers in place is *ipso facto* "unnatural" and therefore "ungodly". However, this view cannot affect recombination alone without being either self-contradictory or having to split technical hairs. For example, other techniques can be said to breach the sanctity of life as well, such as mutagenesis and wide crosses. Cloning has raised concerns of this order, but is not a recombinant technique. The awe-inspiring potential of recombinant techniques has reopened the debate between creationism and science. The concept of "respect" may not necessarily impose opposition to all GMOs but it imposes a degree of moral responsibility as to what modifications are done: acceptability is defined by need and availability of less dramatic alternatives (i.e. good husbandry of natural resources. Abuse of a natural process for frivolous purposes (or solely lucrative ones) cannot be tolerated.

However, moral guidance as to the acceptability of biotechnology is in disarray. There is no better illustration of this than the actions of the Anglican Church Commissioners in the wake of the controversies over the imports of Monsanto's GM soybean: they recently sold off a £1.3m shareholding in Monsanto after hearing

> "protests that the investment was incompatible with Christian values",[324]

insisting that their action was on purely financial grounds, although Monsanto has been formidably successful and the investment highly fruitful. The Commissioners countered the criticisms, after the fact, by stating that they "were satisfied their investment was ethical"[325] as Monsanto did not engineer humans or animals. Their position has been criticised as arbitrary as the Commissioners

> "will still invest in an oil company accused of employing forced labour in Burma and two other genetic-engineering firms and an arms manufacturer".[326]

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[324] **Abrams (1998b).**

[325] Idem.

[326] Idem.

The concerns about GM foods are of greater immediate importance to certain religions. Taboos concerning food are central to certain religions. The possibility that permitted foods may contain hidden elements - even individual genes - originating from tabooed foods such as pork or even human genes places the adherents to these faiths in an untenable position between famine and religious transgression. This is perceived as a direct attack on their faith.

A report into the ethics of GM foods has been prepared under the chairmanship of Dr J. Polkinghorne,[327] which has identified a number of the moral matters raised by the various religious groups in society. The report specifically examined the concept of a "moral taint" which may be attached to the products of biotechnology and resulting from the revulsion at the unnaturalness of the process, but found that, however deeply held the principles are, there is no categorical opposition to GM techniques that would warrant a total ethical prohibition on the use of GM techniques in food.

Certain groups, generally religious groups, believe that biotechnology, or genetic engineering, is immoral *per se* as it is a form of humanity playing God or mocking the Creation. This is particularly true of the Muslim faith, and, to a lesser extent, the Hindu and Buddhist faiths.[328] However, the Christian and Jewish faiths see humanity as a steward of the Creation and empowered, or even obliged, to make use of nature for life-enhancing reasons. Nevertheless, exploitation must be avoided and reasonable ethical safeguards held in place.[329]

This opposition against biotechnology *per se* holds true whether the techniques and their products are safe or not; or whether the use of biotechnology would indeed bring about the fabled "magic bullets" of curing all diseases and banishing famine from the Globe. No amount of assurances of safety or promises of benefits can reverse this stance.

### 6.3.2 Humanist concerns

Religious concerns merge into humanist concerns when human applications of genetic engineering are considered. Many issues are raised here, such as

- the identity and self-image of humanity where gene therapy or "xenotransplants" using specially "designed" animal organs and tissue are concerned;
- respect for human rights in view of genetic discrimination in the fields of education, crime, insurance, employment, medical treatment etc.;
- the question of privacy and the right to genetic information of close relatives who may be carriers of inheritable disease;
- fears of euthanasia, selective breeding and military usage of GMOs.

All of these issues were debated before the recombinant breakthrough in the early seventies. GM techniques have only given the issues a greater urgency. Questions of degree, of acceptability and of responsibility arise in this context as well. Certain applications of genetic engineering are highly

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[327] Polkinghorne (1993), p. 8.

[328] Idem.

[329] Idem.

desirable where they can help prevent, treat or cure disease. The inherent risks become widely acceptable (except to certain groups such as the Jehovah's Witnesses who are unlikely to accept xenotransplantation) in view of the benefits.

### 6.3.3 Political concerns

As with the section immediately above, the issues in this area are too many to number let alone explain in detail. The main concerns are that biotechnology will affect economic trade patters, especially affecting north-south trade by depriving the Third world countries of the exclusivity of their agricultural resources: many of their tropical exports could be grown in colder climates, shattering their economies. Other concerns target the concentration of agricultural supplies in the hands of a few giant seed and agro-chemical companies, and the inherent risks of monopolies and monocultures. Biotechnology has highlighted a number of issues in the administration of farming policy and the industrialisation of the food industry, as well as matters of international agricultural trade. Farming has been in crisis in many years as demonstrated by the constant controversies surrounding the European Common Agricultural Policy and the disputes with trading partners about farming subsidies. Biotechnology is a wild card that could either further disturb the precarious status quo or solve many of the problems. Either way, many powerful political economic and interests will be affected.

### 6.3.4 Environmental concerns

Environmental movements have taken a strong position against biotechnology due to the effect that biotechnology would have on older issues rather than on its impact on the environment alone. Biotechnology is symbolic of humanity's arrogant domination of the planet, and represents an acceleration of the industrialisation of agriculture. Although biotechnology may present many opportunities for environmental remediation, such as in the case of marine oil spills or soil contamination, by the development of microbes capable of assimilating or breaking down toxic materials, it is the potential for the creation of new economic interests in the environment that worries the environmental movement most. By designing solutions in the laboratory rather than adapting agriculture to the capacity of the environment, it is feared that the potential for pollution and disruption of ecosystems may increase. The environmental movements have also provided a number of arguments against the current GM plants, in that they may become weeds or harm other creatures, but principally it is the changes in the usage of pesticides that is feared.

It is difficult to find environmental groups who categorically oppose all applications of biotechnology. In the same way, groups with specific moral stances, such as organic farmers and consumers who view genetic engineering as totally incompatible with their standards (see the discussion of the *Watson* case, in Chapter Two), and vegans, who reject all animal-derived foods as issued from unacceptable exploitation of sentient beings, do not oppose the medical aspects of biotechnology, only those to do with food. Conversely, the Jehovah's Witnesses, who categorically reject certain medical interventions such as blood transfusions, may well reject gene therapy in the same way; however, they may have no opposition to eating GMOs or GMO-derived food.

### 6.3.5 The distinction between absolute and partial opposition to biotechnology

Analysis shows that moral opposition to biotechnology can be classified into two groups: categorical and partial. Categorical opposition to biotechnology as a whole is extremely rare. In most cases a principle of moral opposition to the technology is balanced against approval for specific, ethical, uses of the technology.[330] Non-categorical opposition is characterised by the "acceptability" of some aspects and the "unacceptability" of other aspects of biotechnology. The distinction between the two is a matter of a balance between the perceived benefits and the perceived inconvenients.

As categorical opposition cannot be overcome by argumentation, should it be respected under the law? This much depends on the view one takes of law, positivist or natural, and a discussion of these is not the point of this project. The law does already protect some aspects of religion (and this only within the "State" religion, in the case of the UK Anglican Christianity), through some provisions concerning blasphemy, and various religion-based judicial traditions. However, in a pluralistic society, it is not up to the law, necessarily neutral in order to ensure equality of treatment of all creeds, to impose the religious views of some on the actions of others. It can however, protect the ability to chose of those who have moral or religious obligations. Thus the matter of categorical opposition is solely a matter of informed personal choice.

### 6.3.6 The concept of justice in societal risk taking

Put simply, that a thing is immoral does not make it unsafe; but that a thing is unsafe can also make it immoral. Moral acceptability and safety are two separate judgements made on very different criteria. It is argued that to be valid, each judgement must be made separately, on its own clearly defined criteria. However, the two judgements cannot function in isolation from each other. It was shown in Chapter Four that safety in Europe is largely a matter of expectations of the affected section of society, balanced against matters of technical feasibility. The acceptability of risks is as much a matter of moral judgement as economic or technical analysis.

Moral argumentation is essential for the analysis of the decision-making mechanism for societal risk-taking, due not only to the duty of care discussed in Chapter Five, but also to the determination of which measure is most appropriate, in terms of appropriateness and necessity. The issue of justice in risk imposition is controversial and much debated. Where there is an environmental risk (i.e. random and impossible for individuals to escape), there is reliance on centralised decision-making and control of risk at source; consequentially there is a duty of care, the need for transparency and stakeholder participation, and there is an issue of trust in the decision-maker. This is especially true when dealing with complex or uncertain risks: experts are available to the centralised decision-maker but they are not available to the individual who may be exposed to risk. There is a consequential duty on the decision maker to provide information to those who may be affected. Where there is an individual risk (i.e. avoidable by choice of the individual concerned), the individual will rely on his or her own decision-making abilities. In these circumstances, thecontrol of the risk is most appropriate at the point of exposure through personal choice (the so-called "market forces"). Where the risk is

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[330] **Polkinghorne (1993), p. 9.**

complex or uncertain, there are no experts available to individuals, and there is consequentially a need for trustworthy information in order to accept the risk.

## 6.4 The commonality with the concerns of industry

As shown above, the main concerns of the moral viewpoints are concerns closely allied to the proportionality of measures taken regarding biotechnology. These measures need not only be regulatory to invoke this measure of adequacy. All decisions and actions should respect the principles of proportionality and precaution. There is an awareness of the need to reduce risks involved in every decision to the greatest possible extent. This is not incompatible with the needs of industry. Proportionate actions are arguably efficient and therefore profitable and of use to industry. The need to diminish risks as much as possible and to balance risks against benefits, is important for industry as safety sells. It is a mark of quality and an anchor for goodwill that is of vital importance for industry. Where the moral viewpoints diverge from industrial priorities is in the requirement for GM applications not to be frivolous, but respectful of nature, of society and of its interests. However, industry needs to keep itself attuned to demand. Market research and knowing what applications of biotechnology are acceptable to a large proportion of the market are essential requirements for entrepreneurial biotechnology. The integration of science into the modern culture of accountability has been discussed above. Public accountability is also of benefit to industry, especially where entrepreneurial biotechnology companies take the step up from private to public ownership.

## Chapter Seven: Redundant Elements of the Debate

### 7.1 The complaint of over-regulation

Biotechnology industry analysts, on both sides of the Atlantic, have warned that the industry's growth is being stifled by a combination of red tape, excessively burdensome regulations and a hostile regulatory climate. These complaints have been repeated in a number of governmental studies on the competitiveness and the future of the industry. However, these complaints are couched in very vague terms, especially concerning the alleged hostility of the regulatory climate. This covers a multitude of sins. In order to improve the regulatory climate, the biotechnology industry constantly campaigns for deregulation of GM products, the reduction or speeding-up of the regulatory assessments required for the marketing of GM products, or for government incentives in the form of tax-breaks, better technical infrastructure or direct financial help. Very few commentators are willing to place the blame for the industry's difficulties on any particular area, preferring to blame a combination of factors. US and EU analysts alike warn that the industry will lose out in terms of new opportunities, growth and jobs unless the current regulatory frameworks are relaxed and unless the regulators swing their full support behind it in order to regain the trust of the public.

As discussed in Chapter One, there is little use in comparing the efficiencies of the US and EU regulatory frameworks unless it can be shown that these frameworks have the same purpose. Similarly, there is little to be gained in examining the entirety of the regulatory climate outside checking whether the applicable regulations are proportionate to their aim, as the aims of applicable regulations will be numerous and different. Two related areas nevertheless merit mention: patents and finance.

The biotechnology industry claims that the EU lags behind the US in the number of biotechnology companies in the industry, in the overall turnover of the industry and in the average turnover of biotechnology companies, as well as in the number of persons employed by the industry. The biotechnology industry also claims that the EU lags behind the US in the number of patents held and that, consequently, the EU lags behind the US in the number of GM products on the market.

The US biotechnology industry is very different from that in the EU, making comparisons of performance and of regulatory needs very difficult. The number of biotech companies in the market is a misleading standard: in the US, much of the biotech activity is done in entrepreneurial biotechnology-dedicated companies whereas in Europe much of biotechnology activity takes place in the commercial arms of universities and institutes, or as part of the R&D sections of large pharmaceutical or chemical companies. **Green (1994c)** reports that

> "European governments spent more than the US on funding basic research, which forms the foundation for the next series of medical advances. This meant that the present US lead in biotechnology could be [as one senior biotech executive put it] eroded over the long term".

Similarly, one must take into account the differences between the nature of the investors in the US and Europe, and the nature of the scientists-entrepreneurs who start up the biotech companies. Regarding the investor culture, **Luesby (1994)** points out that:

> "[i]n the US, a tradition of wealthy business angels, and the existence of the Nasdaq stock exchange for young and growing companies, spurred a shower of biotech start-ups in the 1970s, and a flood during the 1980s."

On the other hand, even leading UK venture capitalists long considered that

> "[b]iotechnology is the antithesis of attractive investment capital".[331]

In the US, risk-taking investors gelled with the entrepreneurial - and fiercely independent spirit - of the scientists wanting to set up their biotech ventures:

> "Leading-edge biologists are interested in commercial applications - but not in trading their autonomy for middle management posts overseeing programmes ruled by commercial considerations. Preferable by far is the option of running their own companies and their own programmes, while making the most of their academic roots through development meetings with university researchers, or by employing former colleagues as consultants."[332]

However, European investors are not convinced that scientists, however highly qualified in their own fields, are viable commercial partners:

> "Yet, such a package, while a golden opportunity for scientists, is a tall order for investors who are backing business novices in the riskiest of ventures."[333]

Backers are far more likely to be reassured if the biotech venture has proper management, with the appropriate commercial experience, sales teams and a source of revenue. This is where the demands of investors and scientist in Europe have been failing to meet: there is a large management gap. Scientists do not, generally, have the ability to manage the business, or even the actual product development half of R&D (as opposed to the pure research part), and this causes a number of young biotech companies to misdirect their financial planning or bungle the development stages, resulting in embarrassing late-stage clinical failures or "burning out" before a breakthrough is achieved. Either way, they do not live up to the promises made to their backers, which hits the confidence in the sector as a whole.

It is therefore difficult to ascertain whether there is more biotechnology activity in the US from the number of independent companies. Because of the independent nature of the US biotechnology companies, there is a greater drive in the US to obtain patents which may provide an income than there is in the EU. This may explain the greater number of patents obtained in the US. However, the EU and US patent systems are quite different (as discussed below) and the type of patent application being presented is also different with more EU patents being directly capable of industrial application whereas the US systems allows more enabling patents to be granted.

The biotechnology industry has also claimed that it is disadvantaged in relation to other sectors of industry in the regulatory framework concerning the raising of finance on stock markets. The world biotechnology sector has proved to be highly volatile market for investors in recent years, and

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[331] Luesby (1994).

[332] Idem.

[333] Idem.

this has caused the sector as a whole to build its high-risk and high-expense research programs on a very fragile financial basis. The sector, in a business sense, remains very immature[334] as it still has not developed a broad commercial infrastructure to match its R&D strengths. This lack of commercial depth still threatens the sector's commercial viability despite the ever increasing, and ever more tangible, promise of groundbreaking products.

The sector is not receiving much sympathy, at least not from the general public, as many of its growing pains are perceived to be caused by internal factors which the sector must learn to iron out by itself in order to reach maturity. The sector's alliances with big business, pharmaceutical, chemical and agro-food multinationals, also diminishes the scope for sympathy where finance is concerned, and increases the ground for public mistrust or hostility.

## 7.2 The need to distinguish side issues

It is impossible to relate all of these to the "process" nature of the EU regulations. There are a number of other factors to take into account.

A number of aspects must be eliminated from the debate. These aspects of the "regulatory climate" are largely outside of the scope of this study. However, it is important to keep in mind that:

(a) the biotechnology sector is financially unstable and placed under great commercial pressure: there are enormous pressures to cut corners in R&D; these are well documented as are the consequences of higher probabilities of product failure in clinical tests and of regulatory disapproval;

(b) there is therefore a significant risk of error and of scientific fraud in the R&D process; and

(c) it is to be noted that the medical / pharmaceutical branches of biotechnology are under considerable scrutiny by anti-fraud mechanisms (although it is clear that they are insufficient) but that these mechanisms do not exist in the agro-food branch and therefore these aspects are directly relevant to safety concerns.

### 7.2.1 the patent issue

Much of the debate about the regulation of biotechnology centres on the differences between the patent laws of the United States and the various patent laws of the European Union. It is perceived that these differences put the development of the European biotechnology industry at a disadvantage, and these differences are labelled "overregulation".[335] Whether or not this perception is true has no

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[334] Green (1996c).

[335] The differences between the US and EU systems reside in four main points. Firstly, it is often claimed that US patents are easier and cheaper to obtain than EU patents. However, US patents are beset by uncertainty and expensive litigation due to the "first to invent" system as opposed to the European "first to file" system. The US patent office issues patents and invites other companies to challenge them, rather than check them stringently before issuing. EU companies often lose out in the US because they do not document R&D well enough to be able to defend their inventions in the US litigation-based system. Secondly, European patents are not applicable to agricultural applications of biotechnology as plants and animals are not normally patentable and also because alternative intellectual property mechanisms are applicable to them, whereas US patents are more readily granted over living organisms. Thirdly, US Patents face a recently diluted the utility test. Previously, pharmaceutical companies had to "conduct [extensive] human clinical trials to prove a proposed product could become a useful drug" (Arlington (1994)). The requirements changed to help the US

impact on safety. However, pressures placed on the industry by patent requirements may adversely affect the quality of the research, and thereby the safety of the GMO.

Patents are vitally important for the biotechnology industry, often being the only asset upon which companies can raise finance for their research. Because of this, the vagaries of obtaining a patent are perceived as having a disproportionate impact on the biotechnology industry. Biotechnology companies are often independent and require immense start-up investment in state-of-the-art laboratories as well as long-term funding for highly paid scientific staff over long periods of time. Unlike most commercial ventures, they will not produce any income for periods up to and exceeding ten years, with which they could fund their research and development and service their debts. They therefore depend on massive investment by highly confident and very patient investors, often known as "angels",[336] who are attracted by the guarantee of monopoly rights to the income that will be produced by the product once patented. These "angels" gamble that the research will be successful in producing a marketable product, and that the product will be so profitable as to rapidly repay the immense accumulated debt and still offer a good rate of return in the remaining years of the patent. None of this is guaranteed, making investment in biotechnology highly risky. Anything that can adversely affect the granting of a patent is seen as an unfair impediment on the biotechnology industry. For example, the notification requirements of the permit systems inherent in safety laws are perceived as unfair because they may constitute a disclosure that would prevent the GMO involved from being patentable.[337]

Ironically, the very importance of patents for the biotechnology industry also makes them the industry's worse enemy. Due to the immense costs involved in their operation, biotechnology companies aim to produce marketable patents as quickly as possible so as to produce an income stream. Companies tend to file patents on more and more marginal inventions. In the US in particular, the patent system allows very broad patents for "enabling technologies", the processes that are required to do genetic engineering in the first place. The US patent system also accepts patents on gene sequences with minimal, or only speculative, industrial utility. This is said to provide US biotechnology companies with a competitive advantage over the European companies who must pass more stringent utility tests to obtain a patent. Patents on "enabling technologies" are also a barrier to entry into the industry as new biotechnology companies are obliged to purchase increasing numbers of licences to carry out the most basic research. This "can destroy a business opportunity".[338]

The speed of development is so fast that patent offices cannot process the highly complex and very detailed biotechnology patent applications quickly enough. Consideration of biotechnology patents take longer than any other type.[339] The backlog caused by this delay has other consequences:

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biotechnology industry in 1994. Drug companies can now use "any kind of evidence to prove the usefulness, or utility, of the invention" (Arlington (1994)). Fourthly, EU patents are in disarray over the criterion of "morality"; the European Parliament has failed at several attempts to harmonise the systems of the Member States because of this clause.

[336] Luesby (1994).

[337] See Burnett-Hall (1995), pp. 779-812 for a comprehensive review of the issues with this regard.

[338] Cookson & Clayton (1992).

[339] Idem.

developments often occur in parallel and applications overlap causing disputes over who should be granted the patent. Companies desperate for trading income are forced to market their product before full patent protection can be granted, knowing that they will have to defend their product on court.[340] Due to amounts they invest, the "angels" fight tenaciously to defend their property, devoting "proportionally more time and money to patent protection than any other industry."[341] This litigious environment acts "as a disincentive to proper investment in biotechnology by European companies".[342] Overall, the patent process is now seen as one that "hurts industry and creates uncertainty."[343]

### 7.2.2 the issue of finance

As with the issues appertaining to patents, few issues appertaining to finance are specific to the biotechnology industry and therefore the claim of over-regulation cannot be sustained. However, the nature of the biotechnology industry exaggerates the problems encountered. Because of the special nature of a biotechnology company's financial needs, the industry has claimed that the current regulation of financial markets is disproportionately unfavourable towards set-up biotechnology companies who are unable to raise required finance due to the lack of a "track record" of profitable trading. Stock markets required that the companies requesting a listing had an "adequate track record", that is to say a history of profits over a few years. The US financial markets, where investing in "blue sky"[344] companies is more commonplace, were quicker to adapt to the needs of research companies such as biotechnology ventures than the EU markets and relax their rules. Young biotech companies in the UK were effectively excluded from the listings as they were unable to generate any revenue, let alone profits, in the first decade of their lives. This clearly stunted their growth as they were unable to raise finance for their development, causing the UK, and European, companies to lag behind the US by several years. Young biotech companies had to venture across the Atlantic to raise capital, and faced the difficulty that investors generally prefer to invest locally (in this case, in the US). The changes

> "would allow a pharmaceutical company that had been in existence for three years to seek a listing even if it had no products on sale, so long as it had at least two new drugs in clinical trials."[345]

This was only a partial improvement for the biotech sector, aimed at increasing the pharmaceutical use of biotechnology.

The agricultural applications did not get a similar boost. The changes in the rules overlooked agricultural biotechnology entirely and continued to exclude it from listings.[346] This provides substance

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[340] For example Genetics Institute and Amgen simultaneously developed versions of erythropoietin, a blood-boosting drug. They made licensing and marketing arrangements simultaneously and both were awarded patents in 1987. Amgen received FDA approval for its drug before Genetics Institute and successfully sued Genetics Institute for patent infringement, having obtained the commercial clout to do so. **Cookson & Clayton (1992).**

[341] Idem.

[342] Idem.

[343] Idem.

[344] **Luesby (1994).**

[345] **Cookson (1993a).**

to the claim that *certain* biotechnology companies face discrimination, but they are very much in the minority compared to the number of pharmaceutical biotechnology companies in the industry.

**Cookson (1993a)** reports that in 1993, the UK stock market rules were changed in order to allow biotech companies to raise much needed public finance rather than relying entirely on more restrictive venture capital investment. Whereas this problem cannot be described as over-regulation of biotechnology, the industry may be correct to claim that government, indirectly via the financial markets, has been quicker to encourage the sector in the US than in the EU. However, financial analysts have pointed out that many of the sector's problems have been self-inflicted.

The development of a biotechnology company generally follows a set pattern pioneered by the Californian company Amgen. This pattern provides a business plan that is attractive to initial investors. Biotechnology companies begin with small research facilities built around an alliance of scientists who bring a patent or a patentable idea which forms the company's main asset and venture capitalists able to provide start-up capital. The company then grows by stages known as milestones. The first milestone generally is obtaining a patent. This patent provides a promise of a substantial return on investment, which is attractive to the financial markets. The company then periodically raises more finance via share offers as its product nears the market, each milestone (basic research results, clinical or field trials, submission to regulatory bodies and marketing) adding value to the investment at each step.

> "At each milestone, the risk of failure is seen to be less, making the product more valuable and capital easier to raise. Investors can also see milestones as exit routes: those who provided seed and venture capital can cash in their investments when the companies are floated or further shares are issued."[347]

This allows the company to complete the extremely expensive phases between milestones one by one. These calls for finance are important for market confidence for not only do they raise important funds, they provide investors with "exit routes". If they so wish, "seed" financiers can cash in their investment, generally at a considerable profit, when the value of the company has risen having proceeded past the milestones. The "seed" financiers are replaced with new and larger finance from more traditional industrial investors. These exit routes are essential for the confidence of investors. **Althaus (1996)**[348] reports that the lack of such "exit routes" was one of the major hurdles preventing the development of biotechnology in Germany where investors are particularly risk-averse and need the reassurance of being able to pull out of a venture.

This simple "go it alone" model hides a number of complications that have bedevilled the biotechnology sector from the start. In the early days, biotechnology companies were spectacularly successful at attracting finance. They made exaggerated claims of miracle drugs and miracle crops, using the language of the "magic bullet" as discussed in Chapter Six. As their research was several years away from product testing, such claims were not put in perspective by product failures, public

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[346] Idem.

[347] **Green (1995d).**

[348] **Althaus (1996).**

opinion had not yet swung against the industry, and the investment appeared safe. The "magic bullet" image prevailed. The sector was initially seen as "glamorous".[349] Biotechnology was perceived as the technology of the future and a profits blockbuster. Money was easy to come by (too easy, according to some commentators[350]) and the

> "biotechnology bandwagon rolled down Wall Street".[351]

until the early nineties. Biotechnology companies offered potential investors a very sleek image, and the promise of vast profits to come. However, the claims of the sector were somewhat misleading, insinuating that the very nature of biotechnology will cause R&D to be fast, efficient, inexpensive, and devoid of the nasty surprises revealed in clinical trials that plague the "hit and miss" approach of traditional pharmaceuticals:

> "To attract the money, the industry has portrayed itself as a 'rational' developer of drugs, which uses biological knowledge to devise treatments. This approach, the argument goes, has a higher chance of success than the traditional pharmaceuticals industry which uses trial and error."[352]

This image had been vital for the sector in order to attract the necessary finance for long-term R&D. Biotechnology companies are very different creatures to the pharmaceutical companies they intend to compete with. Whereas pharmaceutical companies finance research into new drugs with the revenue from sales of existing products (which they may have developed in the past, or which may be generics without the cost of development), new biotechnology companies have little or no revenue to fund their research. These funds must come entirely from investors who are required to invest hundreds of millions of dollars over periods of up to ten years, without seeing any revenue being generated.

Because of the success of the "go it alone" model, few companies made any effort to adopt a financial structure that was conducive to long-term investment or to investor confidence once business got tough. The value of the shares normally bears no relation to the company's actual assets, but reflects the confidence of the market in the value of the company's future assets. Biotechnology shares are, by nature, vastly overpriced.[353] Biotechnology companies need success in the various phases of the R&D process to keep investor confidence high, and to attract the next generation of investment without which the product cannot be developed further. Failure at any of these stages spells disaster for the biotech company: the value of its stock may disappear entirely and the company goes bankrupt, even if it is perfectly viable.

The biotechnology sector encountered a series of setbacks that shattered investor confidence in the early nineties. US health care reforms depressed the pharmaceuticals market as a whole and dragged down the biotechnology sector which relied on the ability to charge high prices for its

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[349] **Green (1995d).**

[350] **Green (1994b).**

[351] **Anon. (1993).**

[352] **Green (1995d).**

[353] And conversely, vastly underpriced if things go wrong, see below.

products.[354] Biotechnology also became the victim of its own success, with too many companies chasing investor's funds.[355] Then a spate of clinical trial failures affecting some of the most prestigious biotech companies and some of the most promising drug projects deeply shook the confidence of the sector. The sector collapsed in the mid nineties. Even companies unaffected by trial failures were faced with lay-offs and bankruptcies. New finance was not forthcoming due to the investors' realisation that the sector was spending research funds at such a rate that not all companies could survive, however viable their projects could be.[356] This resulted in a "bear market" and financial starvation for companies needing extra funds to move to next development phase. The sector rebounded spectacularly in the second half of the nineties only to crash again. This extreme cycle of boom and bust has now been acknowledged as an integral part of the biotech sector, and is felt more harshly in the US than in the UK or the rest of Europe, although the signs are that, as the European sector catches up with the US, it is becoming similarly volatile.

Hard lessons have been learnt. The number of product failures late on in the development process, once the majority of the money has been spent, has made this step-by-step approach to funding

> "simply too risky for investors. [ . . . ] there is increasing recognition that the underlying cause [of financial instability in the biotechnology market] is a brittle industrial structure that finds it hard to cope with the conflicting demands of science and finance."[357]

The rest of the sector is also affected by any bad news, as there are only rumours to comfort confidence throughout the sector, and the values of unrelated biotech companies might vary wildly. Therefore, the sector is not an attractive one: it is not for the faint hearted. Only bullish investors will take the massive financial risk of biotechnology, or investors with vast incomes to spend, such as the pharmaceutical industry which is buying up biotech and forming R&D alliances.

The instability of the market is well shown by the standard means of assessing biotechnology companies' health: their burn rate, that is to say how fast they are spending the invested money. This is the only available measure of how long they are expected to survive as they have no revenue or profit figures to present. If a breakthrough is expected within this critical time window, the company is on a firm footing as such successes will allow the company to raise more cash, but if it is not in such a position, it will be considered doomed and the money will disappear: which is a paradox it is when a company needs the money most that it disappears. **Luesby (1994)** compares watching "burn rates" with

> "calculating the distance between a lemming and the edge of a cliff".

Biotechnology companies are now looking at alternative methods of funding their R&D. According to **Green (1995d)**, the pharmaceutical sector is the main target for their advances:

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[354] **Green (1994b).**

[355] **Green (1995d).**

[356] **Green (1994b).**

[357] **Green (1995d).**

> "[e]ven cash-rich biotech companies want partners, recognising that financing uncertainty means they are unlikely to make it very big on their own."[358]

Alternatively, it can be said that the pharmaceutical industry is profiting from its would-be-rival's lack of strength in depth:

> "The pharmaceuticals companies have been quick to take advantage of the biotech sector's need for cash. [ . . . ]
>
> Such moves offer the pharmaceuticals companies the opportunity to pick up marketing rights to an important new technology for a fraction of a corporate R&D budget. For the biotech companies, they involve diluting their prized independence and giving up the dream of becoming the next Amgen."[359]

Hopefully, these alliances will prevent the shortcomings in R&D caused by financial pressures, although it is known that the pharmaceutical industry itself is restructuring its R&D and reshaping its priorities.

> "Large pharmaceuticals companies such as Zeneca try to weed out questionable projects as early as possible. They can afford to spend a little extra early to avoid a high-profile debacle closer to the market."[360]

Alternatively, biotech companies are seeking ways to ensure that all their (golden) eggs are not kept in one (volatile) basket, by seeking to diversify in order to obtain a constant, if small, income to offset the difficulties in raising finance.[361]

**Althaus (1996)** reports on how the German biotech sector has made progress in this direction, in order to thrive despite the aversion of German investors and the German public for biotechnology:

> "Germany's biotech companies have been quick to establish licensing and co-operation deals with the established drugs groups, which are increasingly looking to cut costs by outsourcing research to small, specialised companies."

German biotech companies appear to have a very different, a very pragmatic, view of their function within the market than that of American or British companies. **Althaus (1996)** reports that

> "[d]emand has changed over the last 10 years: the big [pharmaceutical] groups are turning to small innovative firms to do the research and the drug discovery phases, and the small [biotechnology] groups are increasingly seeing the big groups and not the patient as their customer".

A shift from "go-it-alone" drug development to providing services to other companies not only provides a financial basis for a biotech company, it also increases investor confidence by demonstrating that biotech research can give rise to genuine product sales and revenue.

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[358] **Green (1995d).**

[359] Idem.

[360] Idem.

[361] **Green (1995c).**

**Green (1995d and 1995c)** points out that the sector's fragility may actually be self-inflicted. Worryingly, the drive to take a new drug from one "milestone" to another as soon as possible, in order to attract the finance necessary to proceed on to the next step in product development, seems to be seriously affecting the scientific quality of biotech R&D, exposing the companies to embarrassing high-profile failures at a late stage of development, where betraying investor's confidence will hurt the most. **Green (1995d)** reports that some chief executives of UK biotech companies openly recognise the problem. He was informed by leading CEOs that

> "[t]here is a terrible pressure to move too quickly",

and that

> "[t]he pressure on biotech is much higher than in pharmaceuticals because of the need to secure financing".

He also reports that

> "[o]thers admit that the demands to reach the next milestone mean that biotech companies skimp on the early trials that might show up problems".

**Green (1995d)** was told that some biotech companies

> "do only the minimum early development and leave themselves vulnerable to shocks at a late stage".

This, along with the "sheer bad luck" reported by other biotech companies in their R&D certainly contradicts the image of "rational" drug development projected by the biotech sector.

This trend has been seen mostly in the US, but British biotech companies are learning their American counterpart's bad habits. **Green (1995c)** reports that

> "British Biotech [a leading UK biotech company] had embarked on a strategy of marketing [its main drug] as quickly as possible. The company truncated early clinical trials to move rapidly into the final stage, the one that counts for regulatory approval."

It encountered serious problems in the clinical trials, immediately causing side effects in patients. British Biotech blamed bad luck in that a new manufacturing process was the cause of the unexpected effects,[362] and claimed that the problem would easily be resolved, but marketing of the drug was nevertheless pushed back down the road. The reason for the haste was entirely financial:

> "At the same time [as truncating early clinical trials of its main drug to move rapidly into the final stage of approval, British Biotech] arranged its funding to be partly dependent upon the speed of progress. In April 1994 the company issued warrants, as part of a rights issue, exercisable in January 1996 to raise up to Pounds 48m. [ . . . ] The timing was tight. Warrant holders were going to be able to decide whether or not to exercise the warrants knowing the results of the trials."[363]

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[362] **Green (1995d).**

[363] **Green (1995c).**

**Green (1995c)** believes that as a result of the problems encountered, this is now "unlikely", which would leave British Biotech in considerable financial difficulty. The company fell into a pitfall which seems to affect many parts of the biotech sector. According to **Green (1995c)**,

> "[m]ost biotechnology companies face the same problem. They want product sales to bring in cash rather than rights issues."

He further reports that the CEO of one company stated that

> "[t]here is an incredible tendency for companies to shortcut drugs development under financial pressure".

Reducing the amount of time taken by drugs to get through the approval process is

> "more than just a convenience for biotech companies"

according to **Green (1996c)**. He reports that

> "[u]nlike their cousins in the pharmaceuticals industry, they have little sales revenue until products are launched. A delay in approval can trigger serious financial difficulties."

Nevertheless, it could also be that such haste is not just dictated by the needs of survival of the biotech company. The drive for profitability may cause the company to take unnecessary risks. When things go right and investor confidence boosts the value of a biotech company's stock manifold, the investors make massive profits. And, as most of the senior biotech executives in start-up biotech companies are paid in stock and options, they too stand to gain tremendously from their company's good fortune.[364] However, as these executives are also the scientists who conduct the R&D, there looms the spectre of conflicts of interest and even of research fraud. The pressure placed on the researchers by the investors to advance from milestone to milestone, causes problems that may have disastrous results. There is

> "a terrible pressure to move too quickly"[365] and "an incredible tendency for companies to shortcut drugs development under financial pressure"[366]

due to the special nature of biotechnology's financial needs.

> The "demands to reach the next milestone mean that biotech companies skimp on the early trials that might show up problems",

causing problems at later stages that are entirely avoidable.[367] This has led to a widespread perception in the financial markets that the sector's problems are "self inflicted".[368]

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[364] **Green (1996c).**

[365] **Green (1995d).**

[366] **Green (1995c).**

[367] **Green (1995d).**

[368] Idem.

## Chapter Eight: Assessing Risks and Establishing Responsibilities

### 8.1 The need for risk assessment

H I Miller argues that regulation of biotechnology is necessary but must be "both necessary and sufficient".[369] Insofar as this policy equates to proportionality, this argument is seconded by this author. Miller's views on over-regulation (set out in Section 5.4) suggest that Miller's concept of "necessary and sufficient" does not comprise a precautionary margin. Miller's view of what constitutes the minimum required, whatever regulatory method or framework chosen by the authorities may be, is defined by risk assessment. Miller argues that all new products and techniques should be regulated so as to reduce any possible risk, and that risk assessment should be central to any regulatory system[370].

The risk assessment procedure is meant to determine, on the basis of current knowledge, whether it is safe to proceed with a proposed action, that is to say whether harm to protected persons and things will arise. Miller identifies risk assessment as the "trigger" to regulation, that is to say, the factor that defines the regulatory framework's scope. The regulations must identify and address only those risks that may realistically arise so that the interests of those that may be affected are protected without harming the interests of those who wish to pursue activities involving biotechnology. Having identified the unreasonable risks of biotechnology, risk assessment also points the way to controlling these risks through risk management measures that are devised as a logical consequence of the identified risk.

Miller accepts that both "product-based" and "process-based" regulatory frameworks use risk assessments, but argues that they use them in different ways. This is the defining difference between the two frameworks. Both frameworks see their role as guarding human health, safety and property, as well as protecting the environment, from the risks that may arise from the use of biotechnology. Both frameworks have elected to take some form of preventative action to counteract the possible risks arising from the use of biotechnology rather than rely entirely on *ex post facto* remedies for harm caused. It is also recognised, in both systems, that some types of harm would be irreversible and impossible to quantify in monetary terms. However, Miller argues that the "process-based" systems fail to achieve this aim because they arise solely from what Miller terms the "horizontal" approach to risk assessment. At this point, it is necessary to ask what Miller believes "risk" and "risk assessment" to mean.

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[369] Miller (1995b), p. 125.

[370] "Government agencies have variously regulated new biotechnology products with previously existing regimes or newly crafted ones. Whether new or old, certain cardinal principles apply. First, triggers to regulation - the criteria for the oversight net - must be scientifically defensible. Second, the degree of oversight must be commensurate with risk. Thus, the regulation scheme generally should be risk-based. Some have contended that this is obvious in theory but difficult to achieve in practice. Critics of risk-based oversight contend that if we knew a priori what experiments were risky we would have little need for risk assessments and that at the outset we could just exempt those proposals that pose negligible risk. This is a specious assertion. The United States and other nations have often devised regulatory nets based on assumptions about the magnitude or the distribution of risk. For example, we require permits for field trials with certain organisms on the basis of a knowledgeable assessment of predictive risk; [. . .] The validity of these assumptions determines the integrity of the regulatory scheme; without them, we might as well flip a coin or exempt field trials proposed on certain days of the week." Miller *et al* (1990), p. 490.

## 8.2 The horizontal and vertical approaches to risk assessment

Miller warns that a "horizontal" approach to risk assessment can negate all the advantages of this risk-based method.[371] The "horizontal" approach is based on wide preconceptions and generalisations concerning biotechnology as a whole (hence the name "horizontal", indicating a unitary "blanket" coverage) and falls prey to the myths (that biotechnology is a single concept, that it is new and that it is uniquely hazardous) discussed in Sections 5.3.2 to 5.3.4. This causes the "horizontal" approach to be unscientific because it regulates different risks together and same risks separately, because it forces regulatory risk assessments of novel organisms to attempt to assess risks that are arguably no more than fanciful conjecture, or to attempt to test for unknown risks. Miller argues that this is simply bad science. The probability of a positive result (the detection of an unexpected hazard) is very low, making the experiments costly, unreliable, wasteful of limited resources and unnecessary. This prevents the assessments from identifying specific risks and prioritising risks in high or low categories, and causes "horizontal" risk assessments to be, at best, unnecessary and, at worst, incapable of identifying real risks.[372]

By contrast, Miller's "vertical" approach (i.e. bearing down on the individual risk characteristics of a product) is based on the findings of **NAS (1987), NRC (1990)** and **SCOPE/COGENE (1987)** and functions on the basis that the risks presented by recombinant GMOs are the same in kind as those presented by non recombinant species, that the risks are characteristics of the product and not of the process of creation, that the same biological and physical laws govern GM and non-GM organisms and therefore there is no need to change any of the existing risk assessment procedures (assuming that pre-existing assessment procedures exist and are adequate).

Because of the range of possibilities offered by rDNA techniques, certain applications may give rise to particular areas of uncertainty where the present body of knowledge is insufficient to answer all questions that arise (i.e. those GMOs that could not arise in nature and for which we have little information of direct relevance). These areas of uncertainty are not unexpected, nor are they ill defined. They can be filled by scientific investigation.[373] Miller proposes two methods to increase the understanding of the characteristics of GMOs and reduce the areas of uncertainty:

> "The first is by performing well-designed risk assessment experiments. For example, these might attempt experimentally to convert a benign, non-toxic, non-invasive plant into one that possesses an undesirable trait(s), or to induce any plant with a newly acquired trait to transfer that trait by means of outcrossing. [. . .] However, many such experiments would also have a very low probability of a positive result, unless they were carefully designed, both to maximise the occurrence of a "positive" event and to detect rare events."[374]

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[371] **Miller (1994d), p. 295.**

[372] **Miller (1994d), p. 295.**

[373] Miller appears to assume that the purpose of risk assessment is to fill in gaps in knowledge rather than determine who takes responsibility for accepting to run a given risk.

[374] **Miller (1994d), pp. 294-5.**

These experiments would fill the gaps in present knowledge or challenge assumptions based on previous experience concerning the mechanisms that can cause a GMO to acquire undesirable characteristics by seeking to provoke such an acquisition. They are meant to categorically demonstrate the low probability of a particular hazard occurring (i.e. demonstrate low risk, as risk is hazard x probability) rather than seeking to acquire data or measure the probability of a rare, or even unknown hazard through experimentation or observation. Risk assessments such as those proposed must be extremely well designed to maximise the probability of a positive result (i.e. the occurrence of the sought-after harmful trait) and the safety of the experiment for the environment. However, they are undesirable as they involve a great deal of effort (and, necessarily, expense) to provoke an event which is, with regard to present scientific knowledge, arguably very rare. They may end up with results that

> "confirm a foregone conclusion or at best, [. . .] obtain very limited information."[375]

There is a more preferable alternative:

> "The second route to a greater understanding of risk is to exploit the consensus view of biologists that, in the words of the US NRC's report: "no conceptual distinction exists between genetic modification of plants and micro organisms by classical methods or by molecular techniques that modify DNA and transfer genes", and also the vast body of knowledge about organisms modified with traditional techniques. This approach leads directly to the conclusion that risk is a function of the characteristics of the organism and the environment into which it is to be introduced, and that the range of an organism's potential characteristics is vast."[376]

Miller is concerned that, because of the range of possibilities, testing all of the GMOs would be impossible due to time and financial constraints. Furthermore, an insistence on testing all GMOs would divert resources unnecessarily from the testing of high-risk GMOs to low-risk GMOs. Therefore, to tackle the more urgent problem of high risk GMOs, low risk GMOs should be identified and excluded from the risk assessment. To do this, when risk is "not readily demonstrable (a situation sometimes referred to as "very low risk")",[377] scientists would

> "rely heavily on previous knowledge about the behaviour of genetic variants of organisms that have been manipulated by conventional methods or that are present in nature, under various conditions of testing and use. This might be thought of as a "vertical" approach to the understanding of risk."[378]

To demonstrate the greater relevance of information obtained by the "vertical" approach to risk assessment over that obtained by the "horizontal" approach, Miller gives the following example:

> "Thus a tomato breeder, or a government regulator of polio vaccines, assessing the potential risks of a new rDNA-derived tomato or vaccine, respectively, is likely to rely more heavily on

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[375] **Miller (1992d), p. 295.**

[376] **Miller (1992d), p. 295.**

[377] **Miller (1994d), p. 295.**

[378] **Miller (1992d), p. 295.**

> background information on tomatoes and polioviruses manipulated via traditional techniques, than on information about rDNA-manipulated pigs or bacteria."[379]

Miller's argument is therefore that where a GMO's risk can be assumed to be low by extrapolating from previous knowledge, there is no need to carry out a risk assessment procedure. At first view, this argument is circular: to assume that a GMO is low risk and therefore exempt from risk assessment is in itself to conduct a risk assessment. This is because Miller only calls a procedure "risk assessment" if it is a *regulatory* procedure rather than voluntary.[380] The individual scientist must assess the risks of his intended manipulation. If what he intends to do can be assumed to be low-risk (that is to say the manipulation is not expected to cause an undesirable trait to arise, or to cause an existing trait to have a deleterious effect on health or the environment), there is no need to impose a regulatory risk assessment on the experiment. If the scientist is unsure as to the level of risk, the scientist has two alternatives: either he voluntarily resorts to experiments to increase his knowledge which will answer his questions; or he resorts to a formal regulatory risk assessment, which will probably do the very same thing.

Clearly, risk assessment in Miller's analysis is more a decision-making tool than a precise prediction of the effects of a given action. It is arguable therefore that a risk assessment, which identifies hazards, quantifies the likelihood of occurrence of the hazard, and estimates the magnitude of the effect of the hazard, is only the preparatory mechanism for the decision whether or not the risk is acceptable in view of the expected benefit. It is the latter element that encompasses the assessment of proportionality of the action intended to be taken; it is the latter element which corresponds to the WTO's sovereign right of states to set an appropriate level of concern. The only true difference between "horizontal" and "vertical" approaches to risk assessment would lie in where the burden of decision-making would fall – upon a regulatory authority or upon the person proposing to undertake the action assessed for risk.

## 8.4 Analysis of the "product vs. process" controversy

Although the terms "product-based regulation" and "process-based regulation" are almost universally used in the debate concerning the adequacy of the regulation of biotechnology, these terms do not appear to have consistent meanings. These two regulatory models were put forward to describe the principal characteristics of the two main regulatory systems (of the US and of the EU, respectively), but both fail to do so because of excessive simplification and generalisation. Neither label fits the true nature and function of the regulatory systems currently in place. The concepts are in fact contradictory.

### 8.4.1 Description of the two models

A "product-based" regulation is described as one that regulates a product solely on the basis of that product's characteristics (i.e. addressing the risks which arise from those characteristics) as

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[379] **Miller (1992d), p. 295.**

[380] The early efforts at controlling rDNA applications were divided between self-regulation and regulatory intervention. Miller clearly takes position in favour of the former. His belief is that government should be minimal, that scientists should take the decisions concerning GMOs.

opposed to a "process-based" regulation, which is described as one that regulates a product solely on the basis of the characteristics of the product's production process (i.e. addressing the risks which arise from the production process' characteristics). These appellations are misleading (a "product-based" regulation not being equivalent to a product regulation and a "process-based" regulation not being equivalent to a process regulation).

Miller argues that "product-based" regulations concentrate on "real" risks, which are a function of the characteristics of the product, whereas the "process-based" regulations concentrate on "conjectural" risks, which are alleged to arise from the characteristics of the process, which are said to have bearing on the risks of the product itself. Miller argues that "product-based" regulation is better than "process-based" regulation because its narrower scope allows regulations to take better account of risks arising from the product's characteristics and to tailor the regulatory response better to the intended use, avoiding all the problems of excessive regulation.

The debate whether "product-based" regulations are better than "process-based" regulations is redundant as these two models do not stand up to scrutiny.

The two models are hybrids, built up using well-known regulatory concepts which have been engaged in the biotechnology debate but which can easily be distinguished. These concepts concern (i) scope, (ii) the use of performance and process standards, (iii) the use of pre-existing as opposed to new legislation, (iv) "incremental" models of legislation as opposed to "trigger" models, (v) "risk-based" as opposed to not "risk-based" legislation (or, as some would have it, "science-led" vs. "unscientific" legislation), and (vi) inclusion-clause as opposed to exclusion-clause legislation.

### 8.4.2 Scope

A "product-based" regulation does not equate with the regulation of a specific product (which can specify either process or performance standards). A "product-based" regulation is in fact a regulation that defines its scope by reference to a specific characteristic, which can be found in a great number of different products. A "process-based" regulation does not equate with the regulation of a given process (which also can specify either process or performance standards). It is a regulation concerning end-products defined by reference to a specific production process. Both types of regulation are concerned with the end-product, and are therefore product regulations, the essential difference between the two being the definition of their scope.

"Process-based" regulations are also described as regulations aiming at blanket coverage, regardless of the variation in types and magnitude of risks between the products they catch, hence the other appellation of "horizontal" regulation, or sector regulation. "Product-based" regulations, on the other hand, are described as tailor-made regulations aiming at specific characteristics and responding to specific risks, hence the appellation of "vertical" regulation. Proponents of "product-based" regulations argue that "horizontal" regulations are too wide to be effective. Proponents of "process-based" regulations argue that "vertical" regulations are too narrow to capture all the issues.

Paradoxically, the arguments should be reversed. Given examples of "product-based" or "vertical" regulations clearly have very wide scopes. The EPA's TSCA applies to all chemicals. The USDA's FIFRA applies to all plant pests. The FDA's remit is all food additives. So much so that under

this "vertical" legislation, a need has been felt (at least by the UDSA and the EPA) for a new set of "horizontal" regulations so as to narrow their scope to the products of the new biotechnological techniques. There is a confusion between regulatory scope and range of regulatory action.

Historically, "vertical" scope has arisen not because of the subject matter of the regulations but because of the jurisdiction of available regulatory agencies and because of the nature of the available laws used to regulate biotechnology in its infancy. The USDA, EPA, and FDA all had some remit that was immediately applicable to GMOs. It was a policy decision not to create new agencies or to create new laws (although considerable new regulation has been created under these pre-existing laws) that led the US into its regulatory framework. The EU did not have satisfactory pre-existing laws and did not have a pre-existing agency to take on this role.

### 8.4.3 Exclusion and inclusion models of regulation

Scope can also be defined by the method chosen by the regulation to control width of application. Some regulations are "exclusion-clause" regulations as opposed to "inclusion clause" regulations. The issue addressed here is that of legal certainty. With "exclusion-clause" regulations, everything is regulated except that which is specifically excluded. These regulations are all inclusive. If there is any doubt about whether a GMO would be included, it is included until it is clearly excluded. With "inclusion-clause" regulations, nothing is regulated except that which is specifically listed or defined. These regulations are exclusive. If there is any doubt about whether a GMO would be included, it is not covered until it is clearly listed or defined.

The EU framework is all-inclusive i.e. exclusion-clause based. The US framework is said to be inclusion-clause based, but this is not in fact the case: TSCA covers all chemicals except exemptions and exclusions; FIFRA covers all pesticides except exemptions and exclusions; APHIS covers all plant pests except exemptions and exclusions; FDA covers all food additives except exemptions and exclusions.

Exclusion clause systems are seen as bad because they appear to give the message of "guilty until proven innocent". They are also disliked because they impose control ab initio, without a margin of freedom from intervention. The appellation of "blanket" regulation originates from the adverse perception of this wide-as-possible scope. However, this does not make these types of regulation automatically disproportionate. They are viewed as overbearing as they (by nature) do not exclude enough negligible risk activities (an accusation that is not borne out in fact). They are viewed as bureaucratic and unwieldy (also not borne out in fact), as well as too extensive to be effective. The adequacy of scope is a question akin to the proportionality of the regulation. Arguably, scope is not as successful as proportionality.

### 8.4.4 Moment of commitment

"Product-based" regulations are said to take effect at the most appropriate moment: this is defined as the point of contact with the (end) consumer, or the moment of release into commerce or into the environment (depending on the legal authority of the regulator). This is because they are set in motion when the product comes into existence as opposes to being set in motion by the commencement of a process which will result in a product. "Process-based" regulations are said to be

inadequate because they seek to regulate an activity from its inception, hindering the research and development stages.

Directive 90/219 requires that GMO developers apply for permission to use a facility for the first time and for permission to conduct certain types of experiment for the first time, but does not impose process standards (i.e. limit the researchers to certain techniques). The aim is to ensure that the products are adequately confined. The US regulations also cover the experimental stage, even though this is supposedly the domain of the NIH. The EPA regulates the use of new chemicals or the new use of chemicals: this covers the creation of GMOs in the laboratory, which must not be released to the environment (within tolerances as with the EU regulations), and all R&D stages. EPA encourages voluntary notifications, where not mandatory, under the understanding that this will facilitate things at a later stage. The EPA regulates the use of pesticidal substances in R&D under FIFRA.USDA APHIS controls the use of plant pests, i.e. the vectors necessary for certain techniques of recombinant biotechnology and the resulting GMOs - these need to be properly confined. FDA controls the R&D stages of food additives via its requirements for registration.

"Product-based" regulation is more to do with the moment of enforcement that the subject-matter of enforcement. This is the question of the "trigger" of the regulatory framework. According to Miller, "product" regulations are triggered at a late stage: he does not equate regulatory compliance by producers with regulatory oversight. The latter happens when the regulators must take action: i.e. approve or reject or impose conditions on an application for commercial or environmental release. Miller is confusing the trigger of a regulatory framework with the "moment of commitment" where a regulator is entitled to intervene and impose costs on the regulated person.

### 8.4.5 "Design" and "performance" standards

A product regulation governs a given product, but can make specifications as to the product's characteristics (generally known as performance-related standards) or to the process by which that product is made (generally known as design standards). A process regulation governs a process and can also be made up of performance standards (which govern the end result of the process) or design standards (which specify the processes to be followed). The US decided to concentrate on performance standards (toxicity, plant-pest, allergen) rather than on design standards in order to respond to this rapid development. Miller suggests that "product-based" regulations are equivalent to performance-related standards and that "process-based" regulations are equivalent to design standards. This is why Miller believes "process-based" regulations to be incapable of keeping up with developments in biotechnology and being too inflexible. This view is incorrect. A "process" regulation need not set a prescribed process or design, it can set the performance standards that processes have to achieve. For example, the EU regulations cover all processes that result in GMOs that could not arise in nature: this is a performance standard. It is the equivalent to the standard set by the EPA and the USDA which is the novelty of the GMO as defined by its inter-generic nature (i.e. it cannot arise in nature - however, because the taxonomy system is in a mess, EPA and USDA recognise that this standard is artificial: in these terms it is actually a set standard rather than a performance standard as in "not on the list"; the EU standard is actually more certain and more flexible).

"Process-based" regulatory frameworks on the other hand are not interested in the end product but in the process by which they arise. "Product" regulations may be supplementary to these "process" regulations. Generally, "process" regulations set the processes to be used, the procedures to be followed, in order to arrive at the end product. The characteristics of the end product are unimportant as long as the correct procedures have been followed. This has the effect of stifling new product development, market-led competition, and consumer choice. "Process" regulations are also generally set in motion at an earlier stage: in order to use the regulated process, one must apply for a permit and be assessed for compliance. This is an example of paternalistic governance and is a major disincentive for new research as there are regulatory costs from the onset.

## 8.5 The need for, and role of, a legal definition of biotechnology

It was noted above that Miller refers to genetic "alteration" rather than to genetic "modification", "manipulation" or "engineering". Throughout his publications, Miller denies that there is any difference between provoked (or man-made) and naturally occurring recombination. Specifically, he denies that there is any functionally different characteristic to genomes that have been altered via any techniques, be they selective breeding, mutation, unexpected hybridisation between autochthonous and introduced organisms, mutation or recombination.

Chemically this is correct: genes may have been reorganised but the molecules involved remain the same. In terms of cytology this is also correct: it was noted above that the recombinant techniques have provided means to introduce DNA, specially selected so as to be compatible with given *loci* in the recipient cell's genome but the actual introduction of the DNA, once inside the cell, into the genome is entirely uncontrolled and dependant on the cell's own natural mechanisms.

Morally, and legally, there is a significant distinction.

Miller's use of the word "alteration" implies that a change in the genome is noted, but no responsibility for it is ascribed to the human intervention. The alteration may have been provoked by the intervention (be it the application of a breeding technique or a recombinant technique) but it took place independently via mechanisms unknown to and uncontrolled by man. Therefore, the causal connection between the end-alteration and the intervention cannot be established with certainty because of a *novus actus interveniens* (new intervening action).

Use of the words "modification", "manipulation" or "engineering" implies that the alteration was not only provoked by the intervention but also planned and expected. The chain of causality is fully established in this case, and individual responsibility for the alteration and its consequences is firmly ascribed to the intervention. By his use of the term "alteration", Miller resists this.

The scientific community has also resisted the imposition of individual responsibility on scientists or even organisations for the consequences of recombinant techniques. However, this position is untenable for a variety of reasons.

The legal meaning of causation is different from the physical meaning. Where the physical meaning alone is relied on, because unknown intervening phenomena take place between the insertion of DNA into a cell and the expression of that DNA within that cell, the insertion cannot be said to have caused the expression. It cannot be demonstrated with absolute certainty that the particular expression

results directly from the insertion and not from any other possible intervening circumstance. In the absolute, mathematical meaning of the word "demonstrate", this is correct. There is no incontrovertible scientific proof.

When this argument is challenged by the assertion that the expression could not have happened without the insertion, certain voices within the scientific community tend to answer by denying the significance of the GMO in question and its unique nature by stating that "Nature has seen it all", as above.

This justification is unacceptable from the perspective of law. It holds that, for causation to be established between act and consequence, the act should be the sole and exclusive cause of the consequences, in the absolute, irrespective of time frames. It is tantamount to saying that if "Peter" were to push "Paul" over the top of a ten-floor building, Paul's demise on the pavement is caused by the forces of gravity rather than by Peter's actions, furthermore it is tantamount to saying that there is no blame in Peter killing Paul as he is destined to die anyway, as we are all. This justification assumes that there is no moral blame in provoking something that will happen anyway. A topical example of this justification in action is the current debate about bringing material back from the Planet Mars for study. The concern here is that there may be Martian bacteria or viruses dormant in the material and they may cause an epidemic on Earth. The scientific community's answer to the concern is that it is irrelevant as such dormant life forms can find their way to Earth anyway, via rocks blasted from the Martian surface by meteorite impact. Similarly, no one should bear the blame for "creating" a bacteria or virus that could evolve independently.

Legal causation differs from physical causation in that there is no need for incontrovertible proof that Peter's actions alone caused Paul's death to the exclusion of all other possible physical causes: it suffices that Peter's actions were such as to contribute to Paul's death for legal causation to be established. Law only rules human interaction as shown in Chapter Three, not physical interaction. Where Peter's actions were the principal human intervention, they bear the burden of human responsibility. For example, if Peter was to slip and fall on an icy pavement, his injuries are caused by natural phenomena and no person can be said to have caused his fall;[381] however, if Paul - in a civil gesture - had swept the pavement of snow, and Peter had fallen on the ice that formed as a result, Paul would be held responsible for Peter's injuries even though the natural phenomena causing the fall are the same: Paul's actions have placed him within the chain of legal causation. Similarly, where a person has desired a genetic alteration to occur, has taken steps aimed at provoking this occurrence, and the desired result has in fact occurred (along with all, other expected or unexpected consequences). Legal causation is established even if there is no absolute physical claim of causation between the consequences and the actions. The physical world and the subjective world of human interaction are separate - and law controls the latter only.

Another difference between physical and legal causation resides in the nature of law as a time bounding concept. It reflects the interests in presence (based on rights which are the foundation of the

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[381] Law may, as a legal fiction, impose liability on the municipality responsible for the pavement as a matter of public policy but it is not responsible for the fall: it is responsible for not taking steps to prevent the fall.

legal system) and must balance them one against the other. It presents a snapshot of the rights, responsibilities and known facts of a particular moment in time. It defines present interests and future interests as they are grounded in the present and the past. If a given event, such as the introduction of a novel organism upsets the balance of interests in presence, it is no excuse that that event may have happened in the past or may happen in the future. It is no excuse that the novel organism may have existed naturally in the past - but is now extinct - or may evolve in the future. The event has taken place at a specific time within a matrix of time-bound interests protected by law, and legal consequences will be drawn accordingly: responsibilities will be defined and liabilities imposed.

The spurious justification advanced by some members of the scientific community shows a misunderstanding of the legal concepts of responsibility and liability. Foreseeability does not equate to prediction. It is true that the consequences of an action cannot be predicted, but some are foreseeable: that is to say, present in someone's mind as a possible outcome of their actions. It does not matter whether the consequence is likely or not, if it can be reasonably contemplated by the person at the moment of the action in question, the consequence is foreseeable. If the consequence occurs, responsibility attaches to the person that provoked it whether it was foreseeable or not; however, *liability* is only imposed where the consequence was foreseeable. Foreseeablility does not prevent responsibility, but is a defence to liability. Society may also decide whether to limit liability in order to encourage innovation: the defence of "state of the art" used in product liability law sets limits on what should be considered foreseeable, and is dependant on a standard of care: if the consequence could not be foreseen diligently using the best knowledge and resources available, liability for consequences is not imposed.

The scientific community has sought to avoid both responsibility and liability, failing to distinguish the two. By rejecting the imposition of responsibility for scientific risks, in the name of preserving the freedom of unfettered research without fear of legal pursuit, it is seeking to gain more protection than other professionals. Where a person's knowledge and skill is relied upon, as in the professions of doctor, lawyer, architect, etc. that person bears responsibility for all the consequences of their actions and of actions of others who relied on their skill and knowledge. This is a universal situation: all persons, professional or not, bear a duty of care towards others. This is a ubiquitous legal concept: all persons are required to make good the harm they cause others within whatever limits may be set by society. There is no justification to exempt scientists from such responsibilities. Liability, on the other hand, may be limited in certain circumstances, but responsibility must be fully accepted in the legal and moral sense. The distinction between responsibility and liability has a particular significance: responsibility imposes accountability - liability sanctions the lack of it.

That legal responsibility attaches to the consequences of the introduction of a GMO is not a controversial proposition. It is the norm in law for all other products. What is abnormal is that GMOs, being considered primary agricultural produce, are exempted from liability by the Consumer Protection Act 1987 and the corresponding European Directive. It is also abnormal that non-GM primary agricultural produce should be exempted, as discussed in Chapter Four.

The simple imposition of legal responsibilities is not enough in itself to legally define GMOs. All products and all human activities have a baggage of legal responsibilities. The defining aspect

comes in the *nature* and *extent* of those responsibilities. There is a double-sided aspect of GMOs that is particularly significant in this regard.

- Novel GMOs are unpredictable. Whereas in most other forms of engineering, despite the complexity of the systems involved, predictive calculations are possible on the basis of verified scientific rules and knowledge accumulated through observation of past events. This allows for a narrow margin of error in the assessment of uncertainty to accommodate variables and human error. Novel GMOs do not have such a baggage. There is no previous knowledge, no known existing equivalent to refer to, and no familiarity to rely on. Knowledge of genetics may help predict the effects of a novel (i.e. intergeneric) genetic modification, but it is insufficient to predict the outcome of the modification. The duty of care is quite *specific*: is not simply to be diligent in the anticipation of problems from the available knowledge but to be imaginative in the anticipation of problems that cannot be discerned from the available knowledge. This in itself is *not* unique, many human activities such as space travel are groundbreaking and consequently highly uncertain. However, they generally involve only a small amount of daring individuals and the public is kept at a safe distance.

- When combined with the scale of the possible usage of novel GMOs, the number of persons involved, the economic importance of the activity, and the fact that the overwhelming people involved or affected by the use of GMOs are not experts or even aware of the risks, the *extent* of the duty of care arising from the use of novel GMOs is *unique to novel GMOs*.

Nevertheless, this is not to say that only novel GMOs must be regulated as only novel GMOs present unknown characteristics. All GMOs (and indeed all agricultural produce) are inscribed on the same curve of duty of care and should be regulated according to the same principle for the sake of proportionality and non-discrimination. Only the appropriate level of safety should change in direct proportion to the precautionary approach to the higher magnitude of uncertainty. Therefore non-novel GMOs require a higher level of care due to the greater complexity of human intervention, when compared to the other non-interventionist methods of breeding. Arguably, a similar level of care is required of techniques such as mutagenesis, embryo rescue etc. because of the level of human intervention. It is disproportionate not to regulate these to a similar level of precaution as non-novel GMOs. Novel GMOs require an even higher level of care to discharge the duty. Because the outcomes of novel genetic modifications cannot be achieved by other means, they deserve particular treatment, without for as much being treated in a discriminatory manner: the techniques are different and require different treatment. The only means of administrating such a sliding scale of responsibilities it to provide a decision-making mechanism that can cope not only with the physical hazards and the risks but with the human environment into which the GMO with be introduced.

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## A. Abbreviations for European Legislation

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**Commission Decision 97/98**: Commission Decision of 23 January 1997 concerning the placing on the market of genetically modified maize (Zea mays L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC.

**Council Directive 90/219**: Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, O.J. L117 08.05.90, pp. 1-14.

**Council Directive 90/220**: Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, O.J. L117 08.05.90, pp. 15-27.

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