Chapter 22

A general introduction to the regulation of GMOs and gene technology

JAN HUSBY
NORWEGIAN INSTITUTE OF GENE ECOLOGY (GENØK), TROMSØ, NORWAY

1. Introduction

In this chapter some of the historical background of regulations connected to GMOs and gene technology will be elaborated. Most of the gene technology regulations developed throughout the world have many similarities: they are based on the same regulatory and management mechanisms and principles, and have a common historical background.

During the 1970s and 1980s national research institutions, scientific societies and authorities (e.g. National Institutes of Health (NIH) and the National Academy of Sciences in the USA), international organisations (e.g. Organization for Economic Cooperation and Development) and regional unions (European Union) were heavily involved in debating safety issues linked to recombinant DNA technologies (rDNA). The different molecular methodologies used in the technology development are often combined in the terminology: *gene technology* or even the wider term of *modern biotechnology*, as defined in the Cartagena Protocol on Biosafety (see Chapter 23 on terminology and definitions). In this chapter, the term *rDNA organisms*, which stands for recombinant DNA organisms, will be used mainly synonymously with genetically modified organisms (GMOs) if not otherwise stated. 'rDNA organisms' was a terminology that was more commonly used in the earliest phase of the development of the technology, but at a later stage and at present most people use the term 'GMO'.
The majority of the OECD countries developed and enacted their regulations during the late 1980s and the beginning of the 1990s, while most developing countries are currently in the process of developing their GMO policies and regulations, or have recently finalised them. This is in accordance with the obligations prescribed in the Cartagena Protocol on Biosafety, which entered into force in September 2003 (Cartagena Protocol on Biosafety 2000). One important observation is that the OECD countries had their regulations in place when the first GMO entered the market in 1995, while most developing countries are struggling with developing their policies and regulations as an increasing number of GMOs are entering the world market today.

In this chapter I will also elaborate on some of the main systems, terminology and principles used in regulations and guidelines, and explain both the political and scientific rationale behind their development and usage in the regulatory context (e.g. case-by-case handling and the step-by-step procedure). I will describe the most common elements encompassed in regulatory approaches linked to contained use, deliberate release, and ethical, social and socio-economic considerations, including public participation, using examples from existing legislation (see Table 22.1 for definitions and use of some central terms).

Table 22.1. Explanations regarding some of the most used terminology and principles that connect regulations of GMOs to their development, application/notification and use.

Topic/ Subject	Regulatory use	Rationale behind the use
Contained use	Term used for production and research with GMOs, including general usage of gene technologies, in specific contained facilities. Usually found in most countries' GMO regulations.	Prevent the spread of GMOs and transgenic molecules outside the contained facilities. Protect the environment, animals, workers, and the public from possible known and unknown risks and hazards that might arise (e.g. when developing, doing research, production, etc.) with GMOs in laboratories or other contained facilities.
Deliberate release	Intentional release of GMOs in any way, through experimental or commercial releases into the environment or to the market. Term used in most countries' regulations.	Term used in application procedures for releases of GMOs. Separate actions conducted with GMOs from those in contained use and accidental releases. Often used in connection with risk assessments and risk management procedures and requirements for both experimental and commercial releases.
Case-by-case principle	Regulatory principle in order to separate management of specific GMO applications from other GMO applications that authorities receive.	Connected to risk assessment procedures. The rationale is that each GMO transformation event may differ, and therefore should have a separate peculiar evaluation by the authorities (and the applicant), in order to evaluate all possible hazards and risks of that specific GMO.
Step-by-step procedure	Used as a part of the scientific research in development of GMOs in order to prevent possible hazards from being realised. Knowledge gained through this stepwise procedure is an important basis for collecting information needed in risk assessments and application of specific GMOs.	The step-by-step procedure is used during research and development stages, and includes that a GMO should be characterised and carefully observed, whereby safety and performance data are collected at each research stage from e.g. laboratory, microcosms, glasshouses, before small and larger field testing is conducted. If a hazard or negative potential is identified, the organism can be brought back to a higher confinement level for safety reasons, or the experiment can be terminated.
Risk assessment	A very important part of the GMO regulation, evaluation and management system. Found in most countries' GMO regulations connected to the application and decision procedures.	A thorough systematic evaluation to identify all possible risks and hazards connected to a specific GMO and its possible usage. Risk assessments can be executed in many different ways, but should always be based on the best updated and relevant scientific data and information regarding the GMO in question, in order to be conducted appropriately. Risk assessment is a cross-cutting issue procedure with many scientific fields involved.
Risk management	Measures and strategies to regulate, manage, control and prevent risks from being realised. Different regulatory approaches to risk management are found in most countries' regulations and handling of GMOs.	The rationale is to introduce e.g. appropriate mechanisms or measures to prevent harm or hazards from GMOs that might have been identified in the GMO risk assessment or might happen unexpectedly. In many cases a risk assessment will not give a definite answer to possible risks; risk management measures may therefore be essential to prevent unexpected damage.
Traceability	Traceability is used, e.g. in EU regulations, to facilitate tracing and withdrawal of products where unforeseen effects occur. It also facilitates	Traceability can be implemented in order to facilitate control of GMOs in the market, due to lack of knowledge of possible unforeseen adverse effects from GMOs on the environment, biodiversity, human health, and society. Segregation, labelling and monitoring of GMOs after approval for marketing, are therefore a central part of

	risk management measures and labelling requirements of GMOs.	traceability regimes in order to reveal possible adverse effects (includes product information preservation).
Co-existence	Co-existence refers (especially in the EU) to the ability of farmers to make practical choices between conventional, organic and GMO production, in compliance with legal obligations for labelling and/or purity standards within the EU.	Cultivation of GMOs is likely to have implications for organisation of agricultural production. The possibility of unintended presence of GM crops in non-GM crops raises the question of how a producer's choice of different production types can be ensured. Co-existence regimes are therefore important in monitoring, labelling and segregation of GM crops from conventional and organic crops. Further, co-existence regimes, together with registers for cultivation and monitoring regimes, will simplify tracing of adverse effects from GMOs, if such effects occur.

2. Historical background of biosafety regulations and regulatory policy development

2.1 The first initiatives for regulations were taken in the USA

One of the first occasions where worries were clearly pronounced and debated in connection to gene technologies took place at the Gordon research conference on nucleic acids in the USA in 1973. At that time recent advances in DNA methodologies and related research activities made scientists concerned regarding the newly developed methodology of replicating bacterial plasmids with e.g. introduced virus genes. At the conference, scientists raised concerns about possible adverse effects of the ongoing recombinant DNA (rDNA) research activities. They identified, to some degree, the need for adequate methods to prevent the spread of rDNA molecules due to lack of knowledge and uncertainties in predicting possible negative effects. This led the US National Academy of Sciences to ask Dr Paul Berg to head a committee on recombinant DNA molecules.

In 1974, the 'Berg Committee' published their well-known letter in *Science* (Berg et al. 1974). The Berg committee requested the National Institutes of Health in the USA to consider the establishment of an advisory committee. They also requested scientists working in this field not to conduct certain experiments on bacterial plasmids and rDNA molecules involving antibiotic resistance, bacterial toxins, and cancer and tumour development.

The Berg committee wanted an advisory committee to be in charge of: i) overseeing an experimental programme to evaluate the potential biological and ecological hazards of certain types of rDNA molecules; ii) developing procedures which would minimise the spread of such molecules within human and other populations; and iii) devising guidelines to be followed by investigators working with potentially hazardous rDNA molecules.

As a result of the recommendations from the Berg committee and the concerns raised by scientists working in this field, the International Congress on Recombinant DNA Molecules was organised in February 1975 at the Asilomar Conference Centre in California (Berg et a1. 1975). Many of the conference participants were among the leading molecular biologists in the world, but journalists were also represented. The Asilomar Conference made a statement that was approved by its Executive Committee and the Governing Board of the National Research Council acting on behalf of the United States National Academy of Sciences. The following quotation is from the summary statement:

> *The new techniques, which permit combination of genetic information from very different organisms, place us in an area of biology with many unknowns. Even in the present, more limited conduct of research in this field, the evaluation of potential biohazards has proved to be extremely difficult. It is this ignorance that has compelled us to conclude that it would be wise to exercise considerable caution in performing this research. Nevertheless, the participants at the Conference agreed that most of the work on construction of recombinant DNA molecules should proceed provided that appropriate safeguards, principally biological and physical barriers adequate to contain the newly created organisms, are employed. Moreover, the standards of protection should be greater at the beginning and modified as improvements in the methodology occur and assessments of the risks change. Furthermore, it was agreed that there are certain experiments in which the potential risks are of such a serious nature that they ought not to be done with presently available containment facilities. In the longer term serious problems may arise in the large scale application of this methodology in industry, medicine and agriculture. But it was also recognized that future research and experience may show that many of the potential biohazards are less serious and/or less probable than we now suspect.* (Berg et a1. 1975)

The conference identified some experimental designs and conditions that should be followed when conducting research with rDNA molecules. These included containment levels for minimal, low-, moderate- and high-risk experiments, and matching types of containment with types of experiments. They also identified certain experiments that should be deferred, such as cloning of recombinant DNA derived from highly pathogenic organisms, DNA containing toxin genes and large-scale experiments using rDNA that are able to make products potentially harmful to humans, animals or plants. Due to the recommendations and discussions from the Gordon research conference, the Berg committee and the Asilomar conference, the first NIH guideline on rDNA was developed and entered into force in 1976. The intended application of the NIH guideline was for scientific research on bacteria and rDNA molecules in containment. The NIH guidelines were effective only for research conducted within the USA and funded by the US Government. The guideline was voluntary for privately funded research institutions and industry. Many national authorities and research communities in other countries followed the discussions in the USA closely and took steps to introduce similar management strategies in their countries. In the years to come, the NIH guidelines were revised many times.

Already in 1975 the first basic outline of what we can call the GMO regulatory approach was drawn up. This includes an advisory committee, something that is common in many countries today, and ‘containment guidelines’ or regulations to minimise unintended release and possible negative effects. This first NIH ‘containment guideline’ was mainly linked to safe handling and possible spread of rDNA molecules and recombinant microorganisms from laboratory research and development facilities. Later, due to scientific developments, the safety focus shifted from contained research and production systems to deliberate release of GMOs for different types of usage in the release environment, or as marketed products.

During the next ten years the development of methodologies improved and research progressed greatly, including experiments with both recombinant plants and animals. At the same time, the potential of the methodologies within many different biological research fields and production systems was clearly recognised, and was also regarded as having a very optimistic future by both the private sector and governments. Modern biotechnology therefore became a fast, hot growth area for future research development and economic investment.

2.2 OECD (Organisation for Economic Cooperation and Development)

In 1983, OECD member countries established an ad hoc group of governmental experts on safety and regulations in biotechnology. This was due to the ongoing discussions regarding safety issues, rDNA guidelines and different regulatory processes, where the wish for future harmonisation of guidelines and regulations between the member countries was also an issue. The group’s mandate was to:

> *i) Review country positions as to the safety in use of genetically engineered organisms at the industrial, agricultural and environmental levels, against the background of existing or planned legislation and regulations for the handling of microorganisms*

> *ii) Identify what criteria have been or may be adopted for the monitoring or authorisation for production and use of genetically engineered organisms in: industry, agriculture and the environment. Explore possible ways and means for monitoring future production and use of rDNA organisms in: industry, agriculture and the environment.*

In 1986 the OECD published the report from the Ad Hoc Committee, titled *Recombinant DNA Safety Considerations*, the so-called 'Blue Book' (OECD 1986). Although the committee stated that they '*recognised that there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms*', paradoxically the work of the Ad Hoc Committee, and the introduction of safety considerations and risk assessment procedures, which to some degree were outlined in the Blue Book, in many respects became the basis for regulations of GMOs and gene technology in the Western world.
The first chapter of the OECD book lists examples of successful ongoing research activities, and gives a particularly optimistic perspective for the future application of rDNA techniques within many areas. Most of these optimistically predicted applications have never been successfully realised, but in some areas, especially in contained production with rDNA microorganisms, the 'dream came true' to some extent. Today, there are many products on the market developed from contained production with microorganisms, e.g. enzymes for pharmaceutical and industrial usage. In other areas, especially rDNA-plants for crop production, experimental release trials increased dramatically during the beginning of the 1990s, and marketing of GMOs for production as food and feed, after 1995. This contributed to bringing forward the scientific and regulatory political controversies linked to possible negative effects from rDNA plants on the human health, the environment including biodiversity.

In the second chapter of the OECD book, safety considerations are outlined, and we are given a first introduction to risk assessment methods and considerations linked to rDNA organisms. Linked to application of rDNA micro-organisms, much of the methods described were adopted from a report by the US Office of Technology Assessment (OTA 1981). However, the Ad Hoc Committee had intended for the methods described to be also, in principle, applicable to plants and animals.

With special references to agriculture and environmental applications, the OECD Ad Hoc Committee stated that an independent review of potential risks, on a case-by-case basis, of rDNA organisms was recommended. This is still the main requirement in governmental regulations connected to handling of GMO applications and risk assessment procedures, but there are options for fast track procedures in some countries' regulations, and also in the EU directive on deliberate release of GMOs.

The OECD's Blue Book describes the step-by-step procedure, a process of progressively decreasing physical containment, and recommends that the procedure should be used as a part of the scientific research and development of GMOs in order to prevent possible hazards from being realised. The knowledge gained through these stepwise procedures would therefore be important in the risk assessment of a specific GMO. The step-by-step process conducted during research and development stages means that a GMO should be characterised and carefully observed, whereby safety and performance data are collected at each research stage from laboratories, in microcosms or other contained environments, before small and larger field testing is conducted. In this way, predictions can be made of the organism's behaviour in subsequent less confined stages of development. If a hazard or negative potential is identified, the organism can be brought back to a higher containment level for safety reasons, or the experiment can be terminated.

The OECD's Group of National Experts (GNE) on safety in biotechnology continued the discussions throughout meetings and workshops for many years. Since 1995, the OECD's working group on Harmonisation of Regulatory Oversight in Biotechnology has been active (complemented by the OECD's Task Force for the Safety of Novel Food and Feed), although probably not as important in setting the international agenda for discussion today as during the

1980s. The different OECD groups and workshops that have been arranged have made a considerable contribution to risk assessment guidelines and biosafety regulations that are documented through a huge number of OECD publications (for further information see the OECD's database BioTrack at: http://www.oecd.org).

2.3 Some examples of national regulatory approaches

Although most OECD countries in the earliest years of GMO discussions did not have separate regulations, some of the aspects of modern biotechnology were regulated through already existing regulations, such as regulations on industrial production, pollution control, product certification, etc. Some countries had introduced recombinant advisory committees, that gave advice both to authorities and researchers, and in many cases the committees also initiated and arranged conferences, workshops and informed the public about modern biotechnology.

Due to scientific progress, especially with genetically modified (GM) plants, scientists and the emerging biotechnology industry wanted to conduct field trials. There was therefore an increased focus on environmental safety in connection with GM plants and field releases. Some countries (e.g. USA and England) developed guidelines for safe field experiments with GM plants. Later, during the first half of the 1990s, some countries also developed experimental guidelines for aquatic animals (fish), microorganisms and viruses.

Denmark was one of the first OECD countries that developed a separate Act regulating gene technology in connection with the environment. The purpose of the Danish Act, enacted in 1986, was '*to protect the environment, nature and health, including considerations of nutrition in connection with the application of gene technology*'. At the end of the 1980s many European countries considered following the Danish example and developing specific regulations on modern biotechnology (e.g. Norway), while many other countries in the world preferred voluntary guidelines (e.g. Australia and USA). During this period, the discussion regarding the need for new EU regulations on biosafety started, and at the beginning of the 1990s all contained use of GM microorganisms, and experimental and commercial releases of GMOs, were regulated with the implementation of the new GMO directives (Directive 90/220/EEC and Directive 90/219/EEC).

How to manage the regulations by national authorities was also intensely debated in many countries. Some countries chose to divide the management of the regulations among those authorities with jurisdiction over similar problem areas related to conventional organisms or production systems, while others invented new solutions. In most cases, the ministries of environment, agriculture, fisheries, and health, and their underlying institutions or authorities, are involved in the management of biosafety regulations, GMO applications and risk assessments in some way or another. It is also common that different types of national committees are more or less involved in the regulatory processes, give guidance to authorities, and in some countries they are also the appointed authority connected to GMO applications. During this period, public debate started to increase, especially in Europe. In many countries the debate had political influence on the development of new regulations, including e.g. requirements for labelling.

2.4 The European Union regulatory approach

The EU regulatory system linked to GMOs and gene technology has developed into one of the most comprehensive and advanced regulations in the world. I will therefore, to a large extent, use the regulations and management system in EU as an example and basis for explaining regulatory approaches, problem areas and the reasoning behind regulations. This will later be linked to the definitions of GMOs and what is usually not covered in existing regulations (Chapter 23), which is also a challenge linked to the Cartagena Protocol on Biosafety and for all countries' authorities. First, I will briefly explain the general regulatory system in the EU and some of the history behind the revision of the directives.

The two EU Directives, 90/220/EEC on deliberate release of GMOs and 90/219/EEC on contained use of genetically modified microorganisms (GMMs), were adopted in 1990 and

entered into force in 1991. Directive 90/220 regulated both experimental and marketing releases of GMOs. Directive 90/220 did not give the member states the opportunity to have stricter regulations than what was outlined in the articles, while this was possible under Directive 90/219 on contained use of GMMs. The containment Directive was primarily implemented at the national level, while deliberate release also involved the member states at the community level.

Directive 90/220/EEC depended to a high degree on cooperation between competent authorities of the member countries in decision making. It gave authorities the opportunity to comment on experimental releases in other member countries through the summary notification information format (SNIF) system that was established for this purpose. Countries receiving comments regarding applications for national release experiments were not obliged to follow the comments or recommendations received, but would be wise to take them into consideration.

When an EU country received a notification for commercial marketing release, the competent authority in the country receiving the application conducted a risk assessment based on the information in the notification. If a country intended to approve a notification, it had to send its positive assessment to the European Commission and the other member countries for comments. After a fixed period of time, discussions and voting in the EU committee of competent authorities, a decision on whether to approve the application or not had to be taken. The EU Council (representing ministers) would take a final decision if the EU committee is not able to come up with a final decision in favour or against the application. One of the major criticisms of this approval system within the EU was that if the Council does not act within three months (or in practice does not reach an agreement), the proposed measures have to be adopted by the European Commission (in other words, the decision is taken by the Commission). In most cases, at this stage of the decision procedure, the Commission was in favour of approving the marketing.

In 1993, marketing of GMOs as medical products for human and veterinary use was lifted out of the EU Directive 90/220/EEC and regulated by a separate product regulation (EEC 1993). Pharmaceuticals that are GMOs are managed by the European Agency for the Evaluation of Medicinal Products (EMEA) which began its activities in 1995. Regulation (EC) No. 2309/93 was replaced by a new Regulation (EC) No. 726/2004 which entered into force on 20 May 2004 (EC 2004).

Mainly due to disagreement between different EU authorities on how the deliberate release directive was operated, increased criticism was raised on limitations in the regulatory framework and insufficient attention to important risk-related issues, including lack of knowledge as basis for risk assessments; a ‘de facto moratorium’ against approvals of GMOs became the consequence in 1998. In parallel, there was also an ongoing controversy between the biotech industry, scientists, non-governmental organisations (NGOs), and authorities regarding safety, risk assessments and handling of GMO applications in Europe. This debate clearly did not escape governments’ attention. With changes in government in some major EU countries between 1995 and 1996, which also entailed stricter GMO policy, it was decided to revise the 90/220 Directive. Due to the regulatory revision processes, and the finalisation of the Cartagena Protocol on Biosafety, the drafting of new regulations on GM food and feed, and traceability and transboundary movement of GMOs began in the EU.

3. The EU regulations on GMOs after 2002

Although there are many similarities in the EU regulations before and after the revision of the 90/220 Directive, there have also been many changes, both through new legislation and new management regimes. The biosafety regulatory framework follows the GMO development process from research in contained use, to deliberate release and placing on the market, to labelling and traceability of GMOs as food, feed, or for processing, and to transboundary movement that implements obligations under the Cartagena Protocol on Biosafety in the EU.

The different regulations are:
1) Contained Use Directive 90/219/EEC (EEC 1990)
2) Medicinal Products for Human and Veterinary Use Regulation (EC) No. 726/2004 (EEC 1994)
3) Deliberate Release Directive 2001/18/EC (EC 2001)
4) GM Food/Feed Regulation 1829/2003 (EC 2003)
5) Traceability Regulation 1830/2003 (EC 2003)
6) Transboundary Movements Regulation 1946/2003 (EC 2003).

The main difference between Directives and Regulations in the EU is that Directives have to be implemented via national member states' laws, while Regulations are directly applicable. Many practical guidelines have also been developed on how to interpret different regimes under the regulations. I will not describe in detail any of these guidelines (for further information see either http://gmoinfo.jrc.it/ or http://www.biosafety.be).

In general, the policy of the EU in relation to GMOs tries to ensure that there are safety nets available. These are put into operation via risk assessments that are based on the Precautionary Principle, monitoring and reporting requirements, and public registers of GMO release and cultivation sites, traceability and co-existence.

Transparency is another key principle of the EU policy. This is ensured by having public registers of release and cultivation sites, labelling and traceability, and facilitating public participation. This is also the intention of the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, which the EU and its member states have ratified (Aarhus Convention 1998), and the Aarhus Convention was also amended with respect to GMOs in 2005 (MOP-2).

3.1 Deliberate release in the EU

Directive 2001/18/EEC on deliberate release into the environment of GMOs that replaced Directive 90/220/EEC has been in force since 17 April 2001. Its objectives are the protection of human health and the environment, and it is based on the Precautionary Principle, which is explicitly stated in the objective of the directive. The Precautionary Principle will be dealt with later in Chapters 29 and 30.

The 2001/18 Directive sets up a mandatory pre-release authorisation procedure, which involves a case-by-case risk assessment. The risk assessments must consider the direct and indirect, immediate and delayed effects of GMOs on the environment and human health. They therefore recognise that the indirect and long-term implications of GMOs should also be taken into account. This Directive also establishes public registers of releases, including cultivation sites. Public participation is mandated in EU regulations, with opportunities for the public to comment on sub-legislation, and on each application (or notification) that is submitted by GMO applicants to the EU countries' authorities.

There is a time limit for an authorisation, which is 10 years. It is possible to renew applications after the period of authorisation. The renewal should, for example, be based on assessment of monitoring reports that have been carried out during the period of marketing and use. This is an important aspect, as approvals are not indefinite, and should take into account new scientific information and the results of monitoring. Monitoring (both case-specific and general surveillance) is mandatory, and a monitoring plan must be included in applications.

The Directive requires that unauthorised releases are terminated immediately. The Member State should also initiate remedial action if necessary, and inform its public, the EU Commission and other Member States in the case of any unauthorised release. The Directive allows for emergency measures to be taken when necessary.

There is an obligation in the 2001/18 Directive to phase-out antibiotic resistance marker genes (ARMGs) in GMOs by 2004 for those antibiotics used in commercial products, and by 2008 for experimental GMOs with ARMGs. However, this obligation only applies to ARMGs which may have adverse effects on human health and the environment, but it is not clear yet which these will be. The European Food Safety Authority (EFSA), and also a working group under the 2001/18 Directive, has evaluated the potential risks associated with specific ARMGs, taking into account their current usage in clinical and veterinary medicine. The likely occurrence of horizontal gene transfer (see Chapter 13) from genetically modified (GM) plants to microbes and also the potential impact of horizontal gene transfer, where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool, have also been evaluated to some degree. EFSA has produced an Opinion (statement) on this, which serves as guidance for member states.

The 2001/18 Directive outlines in its annexes many important issues linked to GMO application, management and regulation procedures in the EU. For example, Annex I A/B identifies techniques that, in accordance with the EU-countries' understanding, are used in development of GMOs, and which techniques or methods do not develop GMOs. Their understanding is, in principle, similar to the definition of Living Modified Organisms (LMOs) in the Cartagena Protocol on Biosafety in Article 3h (see Chapter 26). Annex II elaborates the principles for environmental risk assessment, and Annex III lists all the information required in notifications (applications). The Commission Decision 2002/623 establishes guidance notes on the objectives, elements, general principles, and methodologies of the environmental risk assessment referred to in Annex II to Directive 2001/18/EC.

Annex VII, regarding the monitoring plan is very important and a Council decision from 2002 establishes a guidance note supplementing Annex VII on monitoring (EC 2002). The issue of monitoring will be dealt with in Chapters 32 and 33.

3.2 GM Food/Feed in the EU

Regulation 1829/2004 on GM food and feed has applied since 18 April 2004. Its objectives are the protection of human and animal health, and the environment. It also ensures transparency, so that consumers are aware of the GMO content of a product.

The scope of the regulation applies to food and feed containing, consisting of, or produced or containing ingredients from GMOs, irrespective of the existence of transgenic DNA or the expressed proteins in the final product. GMO 'products thereof' therefore need to undergo a full authorisation procedure and have to be labelled accordingly.

The regulation mandates a mandatory pre-marketing authorisation procedure for GM food and feed. The time limit for any authorisation is 10 years. Risk assessment is conducted at the EU level (via the European Food Safety Authority, EFSA), and includes an environmental risk assessment in line with Directive 2001/18 and its annexes if the food and/or feed consists of or contains GMOs. If a GMO is likely to have dual use purposes, i.e. it is likely to be used for both food and feed, it cannot be released onto the market without approval for both purposes. This is particularly important in light of, e.g. the StarLink incident, whereby a GM corn only approved for feed use in the US entered the food chain, highlighting the difficulties in keeping the food and feed chains separate.

The regulation requires labelling of all GM food and feed irrespective of whether the transgenic DNA or protein can be detected in the final product. This is a form of consumer information labelling. Health-related labelling is also allowed for, where necessary.

The labelling threshold level that is set by the regulation is 0.9% (per GM ingredient) for adventitious or technically unavoidable presence of GM materials in the final product. There is a temporary threshold (0.5%) for non-authorised (or not yet authorised) GM materials (which expired 18 April 2007). This threshold is valid only if the GMO present in the food/feed is adventitious or technically unavoidable and if the GMO has already received a favourable EFSA opinion, including that the application has not been rejected and that the detection methods are

publicly available. Examples of GMO events that fall into this category are Bt11 and MON863 x MON 810.

3.3 Traceability in the EU
Regulation 1830/2003, on traceability and labelling of GMOs and traceability of food and feed products produced from GMOs, has been in force since 7 November 2003. Its objectives allow for the control and monitoring (from the 'field to fork') of GMO production and the marketing chain. Withdrawal of products, if they do not comply with the regulation, is therefore possible. This regulation governs labelling of GMOs, including traceability of undetectable GM food and feed products. The scope extends to food and feed containing, consisting of, or produced from GMOs. Labelling of GM food and feed coming from GMOs is regulated under 1829/2004.

At the heart of the traceability scheme is a documentation system that effectively means that at any point in the chain, one should know the origin of the product and where it will go to next ('one step forward – one step back'). The regulation requires record keeping for five years. Identification of the GMOs is based on unique codes. For GM plants, these codes are assigned by the OECD Unique Identifier system.

The only exception is for commodities that contain a range of GMOs. In such a situation, only a list of unique codes of all GMOs used to constitute the mixture is provided. The EU requires that the documentation accompanying shipments of GMOs for food, feed or for processing must indicate which and what kind of GMOs have been used to constitute that shipment. Article 18.2(a) of the Cartagena Protocol gives the possibility for different solutions regarding documentation accompanying shipments of GMOs destined for use as food, feed or for processing (see Chapter 26).

The labelling thresholds as discussed in the previous section apply to traceability. If the GMO content is below the threshold, then the traceability requirements do not apply. The scientific rationale behind the chosen threshold level has been discussed in many forums, and is, of course, arguable.

3.3 Transboundary Movements of GMOs in the EU
The scope of Regulation 1946/2003 is on the transboundary movements (export and import) of GMOs, which is but one small part of the EU's biosafety framework. This regulation implements the obligations under the Cartagena Protocol on Biosafety, and states that no export of GMOs destined for environmental release can be carried out by any European exporter without the advanced informed agreement, or prior informed consent, from the potential importing country.

The exporter is obliged to respect any decision of the importing country on the import of GMOs intended for food, feed or for processing and those intended for deliberate release. If the importing country requires that prior approval must be sought before GMOs for food, feed or for processing can be imported, then no export of such GMOs can occur without the approval of the party of import.

3.4 Co-existence in the EU
Directive 2001/18/EC also stipulates that Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.
The European Commission has issued recommended guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming (EC 2003).

However, some Member States are calling for legally binding measures that apply EU-wide, rather than leaving the development and implementation of co-existence measures to each Member State. They feel that the Commission's recommendations do not go far enough in addressing the issue of possible transgenic contamination, e.g. through cross pollination,

agricultural practices or mixing of seeds at the farm level. Different EU countries have therefore chosen different solutions in implementing co-existence regimes. Some have enacted regulations and some have developed volunteer agreements between farmers, including strict rules for GMO farming, while others have introduced GMO free zones.

For list of references see Chapter 24 – Sustainability, social and ethical considerations in regulations