Risk Assessment of Genetically Modified Crops ans Foods in the European Union

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Since the beginning of the 1990s, the marketing, processing and cultivation of genetically modified organisms and their use in animal feed has been regulated by Directive 90/220/EEC. This legislation has been strengthened by Regulation 97/258/EC, concerning foods and food ingredients. The regulatory framework for GMOs was amended and updated by the adoption of Directive 2001/18/EC, repealing Directive 90/220/EEC, and by two other regulations. One is related to GMOs in human food and animal feed (Regulation 1829/2003/EC) and the other to the labelling and traceability of GMOs (Regulation 1830/2003/EC). This paper is based on the process of legislation and examines the adventitious presence of GMOs, which is an important point to the Regulation and to the coexistence of GM and non-GM plants.

GMOs, for both human food and animal feed, are listed under European legislation according to an authorisation procedure, labelling and traceability. This risk assessment examines the expected or unexpected possible effects that the GMO is likely to have on health and on the environment. The procedure is based on scientific evaluation carried out on additives, flavourings and feed additives by the European Food Authority's Scientific Committees, and provides a single authorisation for all food and feed containing GMOs. Legislation is based on finding minute traces of GMOs in the DNA above the threshold criteria. As a result of deliberate release of GMOs into the environment, traces of GMOs in products are technically unavoidable, but will continue to be exempt from the labelling requirement unless they exceed the 0.9% threshold. This evaluation does not include the agronomic criteria for seed and we cannot exclude the adventitious presence of GMOs in traditional crops. This means that minute traces of GMOs may be present in conventional food and feed, either by accident or as a result of adventitious or technically unavoidable contamination during cultivation, harvest, transport and/or processing.

Effects linked to a GMO's potential toxicity/allergenicity or its effects on non-target organisms are evaluated by national and community scientific bodies. Coexistence is not a question of health or environmental protection, as no GMO is allowed on the EU market unless it has been proved to be completely safe. The development of efficient and cost-effective strategies to ensure coexistence between GM and non-GM products for farmers and consumers is considered vital for the coming years, although the experience with the cultivation of GM crops remains limited in the EU. For many years, commercial cultivation was limited to two types of GM maize grown in Spain since 1998, under a non-binding code of good practice. In 2006, genetically modified maize was grown on a total of nearly 60,000 hectares in Spain and on very limited territory in France, Portugal, the Czech Republic, and Germany. The GM maize crop is used exclusively for animal feed in the EU.

CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

Council Directive 90/219/EEC

In order to minimise the risk of genetically modified micro-organisms to human health and the environment, the user must adhere to certain principles of safety and health. In addition, the user must submit to the authorities a notification enabling them to ensure that the proposed installation can be used for this activity without danger. The notification will contain different information depending on the level of the risk involved. Member States may make provisions for consulting groups or the public on any aspect of the proposed use of genetically modified micro-organisms. Member States must also ensure that an emergency response plan is drawn up to ensure an effective response in the event of an accident and that the persons likely to be affected by an accident are informed about all matters relating to their safety.

In the event of an accident, the user must immediately inform the competent authority and communicate all the information necessary in order to assess its impact and to adopt the appropriate measures. In addition, the Member State must inform the Commission and any other Member State liable to be affected by the accident. The Commission must set up a register of the accidents, which have occurred, including an analysis of their causes, the experience gained and the measures taken to avoid similar accidents. To enable

the contained use of genetically modified micro-organisms, the Member States have to provide the Commission with information. Directive 90/219/EEC stipulates that every three years, Member States must send the Commission a summary report of their experience with this Directive. Commission report COM 263/2001 is based on the reports of Member States for the period of 1996–1999 and covers both installations and activities; classification and risk assessment; notification and approval systems. It considers accidents, enforcement, problems with interpreting the provisions of the Directive, public consultation and information, accident and emergency plans, protection of confidential information, waste disposal in respect of each Member State.

DIRECTIVE ON THE RELEASE OF GENETICALLY MODIFIED ORGANISMS

Directive 2001/18/EC of the European Parliament and of the Council

The aim of Directive 2001/18/EC is to make the procedure for granting consent to the deliberate release and placing on the market of GMOs more efficient and more transparent, to limit such consent to a period of ten years (renewable) and to introduce compulsory monitoring after GMOs have been placed on the market. It also provides for a common methodology to assess the risks associated with the release of GMOs. Where new information becomes available on the risks of such release, the mechanism allowing the release of the GMOs is to be modified, suspended or terminated. Public consultation and GMO labelling are made compulsory. The Commission must establish one or more registers recording information on genetic modifications in GMOs, which contain information accessible to the public, and information accessible only to the Member States, the Commission and the European Food Safety Authority. The information includes (i) detailed information on the person responsible for the deliberate release or marketing; (ii) general information concerning the GMO(s) including the commercial and scientific names, the Member State concerned, the decision to authorise the GMO); (iii) information on the DNA inserted into the GMO; (iv) information on detection and identification tools; (v) information on the lodging, storage and supply of samples. The system of information exchange is maintained and operated under the new Directive and the Commission is obliged to consult the competent scientific committees on any questions which may affect human health and/or the environment. The Commission may also consult ethical committees and establish registers for the purpose of recording information on genetic modifications in GMOs and on the location of GMOs. Rules on the operation of these registers are laid down in Decision 2004/204/EC.

Every three years, the Commission is to publish a summary of the measures taken in the Member States to implement the Directive, and a report on experience with GMOs placed on the market. The majority of GMOs that has been developed for deliberate release is transgenic crop plants, modified to tolerate certain herbicides or to resist certain insect pests. Despite the fairly limited experience gained since the Directive entered into force, the report stresses that the Directive and the relevant Regulations help to increase confidence in the legislative framework and to increase the predictability of the decision-making process.

REGULATION (EC NO) 1829/2003 ON GENETICALLY MODIFIED FOOD AND FEED

Regulation 1829/2003/EC of the European Parliament and of the Council

Regulation aims to harmonise national rules on genetically modified food and feed. It established a common EU marketing authorisation procedure and outlines labelling requirements. The authorisation procedure includes safety assessments for the protection of human and animal health and the environment. To be eligible for authorisation foods containing, consisting of or produced from genetically modified organisms must not (i) have adverse effects on human health, animal health or the environment; (ii) mislead the consumer; (iii) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer. Applications for authorisation are to be made to the national competent authority of the Member State in which the applicant is based. The application is forwarded to the European Food Safety Authority (EFSA), which will inform the Commission, Member States and the public of the application. The EFSA provides an opinion on the application within six months – it is then considered by the European Commission. The Committee is to provide its opinion within three months. If the Committee agrees with the Commission's decision it will be adopted, if not the Commission must submit a proposal to the European Council for approval. Once a decision is adopted the Commission is responsible for informing the applicant of the decision. See http://www.efsa. europa.eu/en/science/gmo/gm_ff_applications.html for list of applications. Authorisations will include labelling proposals, any necessary restrictions on handling and use, and details for monitoring and detection.

Detailed guidance for applicants is provided in Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003. A Community Reference Laboratory will test and validate the method of detection and identification proposed by the applicant. In regard to ethical issues the Commission may refer to the European Group on Ethics in Science and New Technologies for advice.

TRACEABILITY AND LABELLING OF GENETICALLY MODIFIED ORGANISMS

Regulation (EC) No 1830/2003 of the European Parliament and of the Council

Regulation 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms stipulates that traceability will be required throughout the food chain. The objective of this measure is to inform consumers through the compulsory labelling of these types of products and create a "safety net" based on the traceability of these products at all stages of production and marking. This "safety net" will facilitate the monitoring and checking of nutritional claims made on labels, the targeted surveillance of the potential effects on human health or the environment and the withdrawal of products if an unforeseen risk to human health or the environment is identified. The 1830/2003 Regulation covers all foodstuffs produced from GMOs, without making any distinctions between those containing DNA or genetic modifications in the chromosomes and those containing proteins derived from GMOs. The old legislation on GMOs covered only foods with traces of the GMOs in the DNA. The Regulation stipulates that operators who place pre-packaged products consisting of or containing GMOs on the market must, at all stages of the production and distribution chain, ensure that the words "This product contains genetically modified organisms" or "This product is produced from GM (name of organism)" appear on a label affixed to the product. In the case of products, which are not packaged and/or the use of a label is impossible, the operator must ensure that this information is transmitted with the accompanying documents. In order to facilitate the traceability of GMOs and also to protect the environment, the Regulation requires operators to transmit an indication that the products consist of or contain GMOs and the unique identifier(s) assigned to the GMOs contained in the products. Through this system of unique GMO identifiers, it will be possible to know these product features and characteristics for the surveillance of traceability.

ESTABLISHING A SYSTEM FOR THE DEVELOPMENT AND ASSIGNMENT OF UNIQUE IDENTIFIERS FOR GENETICALLY MODIFIED ORGANISMS

Commission Regulation (EC) NO 65/2004

All GMOs must be assessed before they can be sown or placed on the market. Unique identifiers make it possible to identify easily a specific GMO on the labelling. The code is uniform and is made up of letters and numbers, enabling each product type to be identified precisely. The identifier is made up of 9 characters, including letters and numbers, combined in a uniform way. This format was approved within the framework of the Organisation for Economic Cooperation and Development (OECD). The identifier for each specific GMO is therefore listed in the OECD's BioTrack database. It contributes to the traceability of GMOs and to consumer information. Set up under the Cartagena Bio-safety Protocol, the Commission or the authority that approved the product's marketing must inform the Bio-safety Clearing-House of this unique identifier in writing.

TRANSBOUNDARY MOVEMENT OF GENETICALLY MODIFIED ORGANISMS

Regulation (EC) No 1946/2003 of the European Parliament and of the Council

The origins of the Bio-safety Protocol are to be found in the UN Convention on Biological Diversity, which was signed by over 150 governments at the Rio "Earth Summit" in 1992, and which came into force in December 1993. In the Convention on Biological Diversity (CBD), it was acknowledged that releases of GMOs (referred as 'living modified organisms' or LMOs) may have adverse effects on the conservation and sustainable use of biological diversity. All countries that signed up to the CBD were expected to (i) establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts, taking also into account the risks to human health and (ii) consider the need for and modalities of a protocol setting out appropriate procedures in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Biological diversity is at the heart of the Bio-safety Protocol, which applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also risks to human health into account. In the preamble, the Protocol recognizes the crucial importance of centres of origin and centres of genetic diversity discovered by Vavilov. The Protocol reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, and notes that the Parties are aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also risks to human health into account.

Regulation (EC) No 1946/2003 aims to set up a common system for notifying and exchanging information on the transboundary movements of GMOs to third countries. The

ultimate goal is to ensure that GMOs movements that may have adverse effects on the sustainable use of biological diversity and on human health take due account of the environment and human health. This Regulation distinguishes between GMOs intended for deliberate release into the environment and GMOs intended for use as food or feed, or for processing. Exporters of GMOs intended for deliberate release into the environment must notify, in writing, the competent national authority of the country of import prior to the transboundary movement. The notification must contain the information specified in Annex I to the Regulation. This notification gives importers the option of only accepting the products for which they have given their prior informed consent. If the importer does not reply within 270 days from the date of receiving the notification, the exporter must send a reminder to the competent national authority of the country of import, with a deadline for response of 60 days from receipt. The exporter must send a copy of the notification and of the acknowledgement of receipt to the competent authority of his Member State and to the Commission. Under no circumstances may transboundary movements take place without the prior written consent from the importer. Exporters must keep the notification, the acknowledgement of receipt and the importer's decision for at least 5 years. They must also notify the transit of the GMOs to any country upon request.

The Commission or the State which took the decision must notify the Bio-safety Clearing House (BCH), set up by the Cartagena Protocol, of any decision regarding the use, including placement on markets, of GMOs intended for food or feed, or for processing, which may be subject to transboundary movements. The Bio-safety Clearing-House Focal Point contact person is Ferenc Sárosi, Department of International Treaties on Nature Conservation Ministry of Environment and Water H-1121 Budapest, Költő utca 21. Cartagena Protocol on Bio-safety, Secondary National Focal Point, Emergency Measures (Article 17) contact person is Hajnalka Homoki, Nature Conservation Officer Department of International Treaties on Nature Conservation Ministry of Environment and Water, H-1121 Budapest, Költő utca 21.

The notification must contain the information specified in Annex II to the Regulation. GMOs intended for food or feed, or for processing, may not be moved across boundaries if they have not been authorised within the Community and if the importer has not given his expressed consent (not withstanding the provisions in Regulation (EC) No 178/2002). Exporters must ensure that the exported GMOs are clearly identified; and must state that the product contains or consists of GMOs and produce the codes assigned to those GMOs. Exporters of GMOs intended for food or feed, or for processing, must sign a declaration on the effect that the GMOs will not be deliberately released into the environment. GMOs intended for use in a confined environment must be accompanied by safety rules for their storage, transport and use.

The Bio-safety Protocol includes several positive features, such as the explicit recognition of a precautionary approach enabling a country to ban imports of a particular GMO even if there is a lack of scientific certainty about its potential adverse effects. Advance Informed Agreement (AIA) procedure means that exporting countries must obtain explicit approvals by the importing country before the first shipment of a GMO intended to be disseminated in the environment. Sharing the information on GMOs through a Bio-safety Clearing House (BCH), facilitating the exchange of scientific, technical, environmental and legal information among Parties and assistance in the implementation of the Protocol are also important focal points. The Bio-safety Clearing House should also include information on existing laws, regulations and guidelines for the implementation of the of the Bio-safety Protocol, any bilateral, regional and multilateral agreements and arrangements, summaries of risk assessments or environmental reviews, final decisions and regular reports submitted by Parties. For the first time under international law, there is an explicit requirement that countries take precautionary measures to prevent GMOs from causing harm to biodiversity and human health.

Conclusion

The European Food Safety Authority is responsible for approving GMOs and placing them on the market. Approved GMOs have passed specific tests proving that they do not affect human or animal health. European legislation has harmonised traceability and labelling through Regulation (EC) No 1829/2003 and since 2003, all foodstuffs that are genetically modified organisms, which contain them or are derived from them, including foodstuff for animals, must be labelled GMO. In addition, EC Regulation No 1830/2003 broadens the concept of GMO foodstuff to include all types of foodstuff containing or produced from GMOs, including proteins derived from GMOs, and incorporates additives and flavourings for human consumption, as well as GMO animal feed. This allows consumers to make a choice, when buying these products.

Coexistent measures aim at protecting farmers of non-GM crops from the possible economic consequences of accidentally mixing crops with GMOs. The Commission recommendation states that coexistence measures should not go beyond what is necessary to ensure that accidental traces of GMOs in non-GM products stay below EU labelling thresholds in order to avoid any unnecessary burden for the operators concerned. Measures should be science-based and proportionate and must not generally forbid the growing of GM crops. The diverse nature of EU farming means that coexistent measures have to be adapted to local conditions and crop types, and make it imperative to ensure the maximum degree of flexibility for the Member States in developing their national approaches.

References

Directive 90/219 The contained use of GM micro-organisms.

Directive 90/220 The deliberate release into the environment of GMOs (repealed)

Directive 94/51 Adapting to technical progress for the first time 90/220 on the deliberate release of GMOs. into the environment

Regulation 258/97 Novel Foods and Novel Foods Ingredients.

Regulation 1813/97 The compulsory indication on the labelling of certain foodstuffs produced from GMOs in addition to the particulars required in food labelling laws (repealed in 1998).

Directive 97/35 Compulsory labelling of all new agricultural production or containing GMOs notified under Directive 90/220.

Directive 98/81 Amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms OJ 1998 L330/13

Regulation 50/2000 The labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced out of GMOs.

Directive 2001/18 The deliberate release of GMOs into the environment and repealing Directive 90/220.

Regulation 1829/03 New Regulation on GM Food and Feed.

Regulation 1830/03 New Regulation on GM Traceability and Labelling.

Regulation 1946/03 New Regulation on Transboundary Movement

Decision 93/572 The placement of a product containing GMOs on the market pursuant to Article 13 Directive 90/220.

Decision 93/584 Establishing the criteria for simplified procedures concerning the deliberate release of genetically modified plants into the environment pursuant to Article 6(5) Directive 90/220.

Decision 2001/204 Supplementing Directive 90/219 as regards the criteria for establishing the safety of human health and the environment, types of GMOs.

Decision 2002/812, pursuant to Directive 2001/18 summary information format relating to the placement of GMOs on the market or their elements in products.

Decision 2002/813 Establishing the summary notification information format for notifications concerning the deliberate release of GMOs into the environment for purposes other than for their original purposes on the market.