The EU Policy on Genetically Modified Foods in the International Environment

A review after the publication of the WHO study „*Modern food biotechnology, human health and development*“ of June 2005

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Since the first genetically modified food was introduced on the market in the mid-1990s, several varieties of such foods have been marketed internationally. The introduction of a transgene into a recipient organism is not a precisely controlled process, and can result in a variety of outcomes. The scientifically possible, but not yet proven threat to public health has resulted in the domestic establishment of specific pre-market regulatory systems requiring the rigorous assessment of genetically modified food and genetically modified foods prior to their release into the environment and/or use in the food supply.

The European Union is a forerunner in this field and its precautious regulations have already been contested by the international society. The Department of Food Safety, Zoonoses and Foodborne Diseases[1] within WHO finalized in June 2005 an evidence-based study of the implications of modern food biotechnology on human health and development. The primary aim was to create an accessible knowledge base to assist member states, international standards bodies and other stakeholders to achieve transparent and inclusive consensus on the evaluation and application of biotechnology. This event gives reason to review the European legislation and policy on genetically modified foods in an international context.

I. Food biotechnology – an issue of international controversy

The global commercialization of agriculture has increased competition in domestic and international markets. Modern food biotechnology promises a new range of products and processes proclaimed to be for the public good, some related to agricultural benefits[2], others directly[3] or indirectly[4] to health. However, as the use of genetically modified organisms (GMOs) in the food supply may involve potential risks for

1 http://www.who.int/foodsafety/en/ .
2 E.g. increased productivity.
3 E.g. improved quality, nutritional and processing values.
4 E.g. reduction in agricultural chemical usage, enhanced farm income, crop sustainability, food security.

human health and environment[5], safety assessments of genetically modified (GM) foods were introduced.

Conflicting assessment and incomplete substantiation of the benefits, risks and limitations of GMOs have resulted in national and international controversies. An example was the reluctance to receive U.S. food aid that contained GMOs offered to countries in southern Africa in 2002. Zimbabwe, Zambia and Mozambique doubted the safety of the genetically modified corn and feared that the use of the genetically modified crops by domestic farmers could endanger the „gene-free"-corn export to the European Union. This international debate highlighted the lack of consensus within and between countries concerning the use of GMOs in the food supply, which are not primarily linked to health and environment, but also to socioeconomic and ethical issues.

The development of products of modern biotechnology is capital-intensive. It opens the seed market to the chemical industry, whose research tools are protected by Intellectual Property Rights. All this has prompted concerns about an increasing and possible dependency on a few multinationals, the so called „Agro-Industry"[6], which could hinder a global share of the benefits of this new technology. Furthermore the natural pollen flow between adjacent fields leads to the problem of co-existence between conventional, organic and GM crop cultivation, which represents another international matter in relation to biotechnology.

II. International Harmonization

To provide international consistency in risk analysis of GMOs and GM foods international regulations have introduced uniform standards concerning human health and environmental safety assessment, as well as the notification of their movement across national borders. These are primarily the *Codex Alimentarius Principles for the Risk Analysis of Food Derived from Modern Biotechnology*[7] and the *Cartagena Protocol on Biosafety*[8].

5 Directly, as they have never been in food before; indirectly through detrimental impacts on the environment or unfavorable impacts on economic, trade, social and ethical factors.

6 *Chataway/Tait/Wield*, „From Live Sciences to a new Agro-Industry", Technology Policy Briefs (2002), vol. 1, Issue 2, United Nations University, INTECH; *Graff/Newcomb*, Agricultural Biotechnology at the Crossroads, Part I: The Changing Structure of the Industry, Bio Economic Research Associates (2003), see also www.fao.org/biotech/C6doc.htm .

7 Codex Alimentarius Commission, FAO/WHO, Rome 2003 (CAC/GL 44-2003).

8 Annexed to the United Nations Environment Programme (UNEP) Convention on Biological Diversity, 2000. It entered into force on 11 September 2003.

The Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius Commission has existed since 1963 to develop international standards, guidelines and related texts, such as codes of practice, for food safety. The *Codex Alimentarius* has no binding effect on national legislation, but is formally recognized by the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (SPS-Agreement)[9]. The SPS-Agreement ensures that internationally-traded food meets minimum standards. If countries apply the *Codex Alimentarius* standards and have a mechanism for monitoring its compliance in their food chains, then their food safety measures are presumed to be consistent with the SPS provisions. There has not been much progress in the development of international standards concerning GMOs and biotechnology in foods. With GM foods deal the *Principles for the Risk Analysis of Food Derived from Modern Biotechnology* and the *Guidelines* for risk/safety assessment of such foods[10]. According to these the safety assessment of GM foods is based on the comparison of a final product with one having an acceptable standard of safety („substantial equivalence")[11]. As far as the problem of co-existence is concerned the *Codex Alimentarius Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*[12] consider the potential risk of outcrossing and contamination by dispersed material from GM plants as a possible problem for organic farming.

The *Cartagena Protocol* has established legally-binding rules for environmental risk assessments of genetically modified organisms (known as living modified organisms under the Protocol)[13]. The overall purpose of this United Nations agreement is to develop common rules to be followed in transboundary movements of GMOs in order to ensure, on a global scale, the protection of biodiversity and of human health. Before the first shipment of GMOs intended for release into the environment the party of export must seek consent form the party of import („Advanced Informed Agreement Procedure", Article 7). Furthermore commodity trading is based on a proactive information exchange between the trading parties via an Internet-based

9 Art. 3.4 of the Agreement on Sanitary and Phytosanitary Measures. World Trade Organization, into force since 1995, http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

10 Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants and Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms, Codex Alimentarius Commission, FAO/WHO, 2003 (CAC/GL 45-2003; CAC GL 46-2003); http://www.codexalimentarius.net/download/standards/10007/CXG_004e.pdf .

11 WHO Strategies for Assessing the Safety of Foods Produced by Biotechnology. Report of a Joint FAO/WHO Consultation, World Health Organization, Geneva, Switzerland, 5-10.11.1990, http://www.who.int/foodsafety/publications/biotech/1990/en .

12 Joint FAO/WHO Foods Standards Programme, Codex Alimentarius Commission, Rome, Italy 2001 (GL 32–1999; Rev. 1–2001).

13 Art. 15 and Annex III of the Cartagena Protocol on Biosafety, Convention on Biological Diversity, UNEP, http://www.biodiv.org/biosafety/issues/risk.aspx

„Biosafety Clearing House" (Article 20)[14]. The process is intended to facilitate trade by providing easy access to data and thereby enabling early assessments in prospective recipient countries.

III. EU policy

The EU is a party to the *Cartagena Protocol*. The incorporation of the *Cartagena Protocol* into European legislation relies on a wide range of biotechnology legislation governing the use of GMOs within the European Union (including imports) as well as outside of the European Union. The following chapter shall give an overview of the most important European Regulations and Directives in this field.

1. Import–EU Regulations and Directives

European regulations about genetically modified foods and organisms exist since 1990. They aim in the first place to protect health and environment as well as to ensure the free movement of safe and healthy genetically modified products in the European Union.

a) Authorization procedures

Directive 2001/18/EC[15] is applicable for the deliberate release of GMOs in the environment[16] for experimental purposes and the placing on the market[17] of GMOs by cultivation, import or transformation of GMOs into commercial products. The **Regulation (EC) No 1829/2003**[18] stipulates the conditions for the placing on the market of GMO for food and feed use or of food and feed consisting of, containing or produced from GMO (genetically modified food and feed).

According to Article 174 par. 2 of the Treaty[19], action by the European Community relating to the environment should be based on the principle that preventive action

14 http://bch.biodiv.org .

15 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC–Commission Declaration, *Official Journal L 106, 17/04/2001 P. 0001–0039*.

16 According to Article 2 (3) „deliberate release" means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

17 Article 2 (4) defines „placing on the market" as making available to third parties, whether in return for payment or free of charge.

18 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *Official Journal L 268, 18/10/2003 P. 0001–0023*.

19 Treaty establishing the European Community, *Official Journal C 325, 24/12/2002 P. 0033–0148*.

should be taken (recital 6) Directive 2001/18/EC). In general any purpose of use of GMOs or GM food and feed in the European Union requires the passing of a complex authorization procedure and cannot take place before the consent or authorization of the responsible authority (cf. Article 4 – 6, 13 – 15 Directive 2001/18/EC; Article 7, 9 Regulation (EC) No 1829/2003).

The authorization procedure includes a scientific risk assessment (Article 2 (8), 4 2. Directive 2001/18/EC) to evaluate direct or indirect, immediate or delayed risks to human health and the environment. The public is consulted and informed (Article 9, 20 (4), 24, 31 Directive 2001/18/EC)[20]. The authorization for a GMO that covers at the same time all its different possibilities of use (cultivation, import, processing to commercial products etc.), for food or feeding purposes requires an opinion from the European Food Safety Authority (Article 6 Regulation (EC) No 1829/2003)[21] and the Committee on the Food Chain and Animal Health[22] (Article 7 1. Regulation (EC) No 1829/2003).

The authorized food is entered in a Community register of genetically modified food and feed (Article 28 Regulation (EC) No 1829/2003)[23] and can be valid for a maximum period of ten years (Article 15 4. Directive 2001/18/EC; Article 7 5. Regulation (EC) No 1829/2003)[24].

According to the EU regulations several GMOs have already been approved for different purposes of use[25] and numerous genetically modified products can be placed on the European market[26]. Many applications for authorization are pending in differ-

20 http://gmoinfo.jrc.it ; http://www.efsa.eu.int/index–de.html .

21 The EFSA has published a Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed at http://www.efsa.eu.int/science/gmo/gmo–guidance/660–en.html .

22 Set up by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *Official Journal L 31 1/2/2002 p. 1.*

23 http://europa.eu.int/comm/food/dyna/gm–register/index–en.cfm.

24 Article 8 and 20 of Regulation (EC) No 1829/2003 stipulate that genetically modified food or feed products, which have been lawfully placed on the market in the Community before the date of application of this Regulation (so called „existing products“) may continue to be placed on the market, used and processed provided that some conditions are met. For transparency the operators have to notify the European Commission of their products in order to get them registered.

25 Approved under Directive 90/220/EEC http://europa.eu.int/comm/environment/biotechnology/authorised–prod–1.htm ; approved under Directive 2001/18/EC http://europa.eu.int/comm/environment/biotechnology/authorised–prod–2.htm .

26 Authorised in accordance with Regulation (EC) No 258/97 http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec–authorised–en.pdf ; authorised GMO for feed use in accordance with Directive 90/220/EEC and 2001/18/EC http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec–authorised–en.pdf .

ent stadiums of the procedure[27]. European member states may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive (Article 22 Directive 2001/18/EC). According to the safeguard clause in Article 23 Directive 2001/18/EC (former Article 16 Directive 90/220/EEC) a state can provisionally restrict or prohibit the use or the sale of a GM product authorized on the market in its territory, if it has detailed grounds for considering that the product constitutes a risk to human health or the environment. The clause has already been used in different cases[28]. Every time the responsible European Committees came to the conclusion, that no new insights could support a revocation of the authorisations.

b) Monitoring, Traceability and Labelling

In order to ensure a targeted monitoring of potential effects on health and the environment as well as the withdrawal of products where an unforeseen risk to human health or the environment is established, GMOs have to be traceable, and labelling shall allow the consumer and user of the product to make an informed choice.

As far as the authorization for the release in the environment is concerned the operator has to ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent (Article 20 **Directive 2001/18/EC**). This monitoring shall help to identify any cumulative long-term effects associated with the interaction with the eco-system and other GMOs. Furthermore the product has to be clearly labelled as one containing genetically modified organisms (Article 21, 26, Directive 2001/18/EC).

GMOs and genetically modified food and feed, which are placed on the market, are subject to the traceability and labelling requirements laid down in **Regulation (EC) No 1829/2003** and in **Regulation (EC) No 1830/2003**[29]. The traceability[30] rules (Article

27 See: http://europa.eu.int/comm/environment/biotechnology/pending–products.htm; concerning applications in accordance with Regulation (EC) No 258/97 http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec–pending–authos_en.pdf; for feed consisting of or containing GMO, notified in accordance with Directive 2001/18/EC http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec–pending–authos–en.pdf; concerning applications in accordance with Regulation (EC) No 1829/2003 http://www.efsa.eu.int/science/gmo/gm–ff–applications/catindex–en.html.

28 See for a list of the pending safeguard clauses in the EU http://europa.eu.int/comm/environment/biotechnology/safeguard–clauses.htm .

29 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, *Official Journal L 268 , 18/10/2003 P. 0024–0028.*

30 According to the definition in Article 3 15. of Regulation (EC) No 178/2002 (Article 2 2. Regulation (EC) No 1829/2003) „*traceability*“ means „*the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution*“.

3 3. Regulation (EC) No 1830/2003) make it mandatory on the business operators at all stages, to be able to identify their supplier and the companies to which the products have been supplied. In general they have to provide information, whether or not their products contain GMOs or genetically modified food or feed. The indication „This product contains genetically modified organisms" or „This product contains genetically modified [(name of organism(s)]" has to be labelled on pre-packaged products[31] (Article 4 6. (a) Regulation (EC) No 1830/2003) as well as be visible in connection with the display of non-pre-packaged products (Article 4 6. (b) Regulation (EC) No 1830/2003). Genetically modified food which is delivered as such to the final consumer or mass caterers (restaurants, hospitals, canteens and similar caterers) must be labelled, regardless of whether DNA or proteins derived from genetic modification are contained in the final product or not (Article 12 Regulation (EC) No 1829/2003). The same rules apply to animal feed (Article 25 Regulation (EC) No 1829/2003).

The requirements of traceability and labelling do not apply to products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products. Furthermore conventional products accidentally „contaminated" by authorized GMOs are not subject to traceability and labelling requirements, if they contain traces of these (authorized) GMOs below a limit of 0.9 %, provided the presence of this material is adventitious or technically unavoidable (Article 12 2., 24 2. Regulation (EC) No 1829/2003; Article 4 8. Regulation (EC) No 1830/2003). This is the case when operators demonstrate to the competent authorities that they have taken adequate measures to avoid the presence of this material[32].

c) Co-existence

In the EU the development and implementation of management measures concerning co-existence is under the responsibility of the member states, in accordance with the subsidiarity principle. The European Commission adopted a Recommendation (2003/556/EC)[33] on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

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31 Article 3 12. Regulation (EC) No 1830/2003 „Pre-packaged product" means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

32 The Commission has published a list of GM material which has not been authorised but which has had a favourable scientific assessment, see http://www.europa.eu.int/comm/food/food/biotechnology/gmfood/events–en.pdf .

33 Adopted on 23 July 2003, http://europa.eu.int/comm/agriculture/publi/reports/coexistence2/guide_en.pdf.

The guidelines state that approaches to co-existence need to be developed in a transparent way, based on technical guidelines and in co-operation with all stakeholders concerned. They should be specific to different types of crop, since the probability of admixture varies greatly from one crop to another. As a general principle, during the phase of introduction of a new production type in a region, farmers who introduce the new production type should bear the responsibility of implementing the actions necessary to limit admixture. Continuous monitoring and evaluation and the timely sharing of best practices are indicated as imperatives for improving the measures adopted. If it can be demonstrated that these measures can not ensure co-existence, regional measures could be considered (e.g. restriction on the cultivation of a certain type of GMO in a region).

2. Export – EU Regulations and Directives

The cornerstones of this legal framework, as partly described above, are supplemented by the Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms[34].

This Regulation provides the obligation to notify exports of GMOs intended for deliberate release into the environment or to be used as food, feed or for processing. It shall secure express consent prior to a first transboundary movement and the possibility to identify GMOs for export. This includes the obligation to provide information to the public and to the international partners on EU practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs.

According to recital 13) and Article 32 Directive 2001/18/EC the Directive duly takes into account international experience in this field and international trade commitments and should respect the requirements of the *Cartagena Protocol* to the Convention on Biological Diversity (see also Article 44 Regulation (EC) No 1829/2003).

IV. Results of the WHO study on modern biotechnology in view of the respective EU policy

The WHO study on „*Modern food biotechnology, human health and development: an evidence based study*“[35] (WHO study) reviews evidence in several broad areas related to genetically modified foods, including currently available products, the assessment of risks and benefits, the broader impact on societies, and the existing regulatory

34 Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, *Official Journal L 287, 05/11/2003 P. 0001 – 0010.*

35 http://www.who.int/foodsafety/publications/biotech/biotech–en.pdf ; the numbers given in brackets refer to the section of the study.

capacity in countries. With regard to developing countries, which seem to have been so far by-passed by the benefits of globalization, the study was looking to place the overall contribution that modern food biotechnology can make to human health and development in context.

The WHO study is divided in six chapters. With regard to the European concerns this article only deals with Chapter 3 „Risk of GMOs and GM foods for human health and the environment“ and Chapter 6 „Social and ethical concerns about GM foods“.

1. Risks for human health and the environment

The WHO study discusses extensively the difficulties of the assessment of the impact of GM foods on human health (3.2.2 -3.2.9). It finds that the objectives of food safety are more clearly realized and harmonized internationally than the objectives of nature protection, environmental safety and sustainable agriculture. Even the environmental risk assessment set up in the *Cartagena Protocol* (3.3) is not sufficient for the international regulation of GM foods, as it only considers GMOs and not GM foods. Its scope on health effects is limited, given that its primary focus is biodiversity. Environmental risk assessments for GMOs have often resulted in different conclusions on the environmental safety of GMOs, especially as far as indirect or long-term effects on the ecosystem were concerned[36] (3.3.2 and 3.4). Thus monitoring of the environmental impacts of GM crops in various regions and from investigations over longer time periods may be necessary to conclude on effects and consequences (3.5).

In general the WHO study comes to the conclusion (3.6) that GM foods currently on the market have undergone risk assessments and are not likely to present risks for human health in any other form than their conventional counterparts. Depending on the regional and agricultural conditions the development of GMOs can even contribute directly and indirectly to enhancing human health and environment. The risk assessment guidelines specified by the Codex Alimentarius Commission in combination with them under the *Cartagena Protocol* are adequate for the safety assessment of GM foods.

The WHO study suggests that the assessment shall take into account the characteristics of the GMO or the GM food and possible differences of the receiving environments. It demands subsequent improvement for the risk management and new methologies for the development of GM organisms. To conclude on effects and consequences it will be necessary to monitor the post market environmental and health

36 Emerging Risks Related to the Environment and New Technologies (GF 2/12). Second FAO/WHO Global Forum of Food Safety Regulators, Bangkok, Thailand, October 2004, FAO, Rome 2005, ftp://ftp.fao.org/docrep/fao/meeting/008/j3255e/j3255e00.pdf .

impacts of GM crops and GM foods over longer time periods. This requires a product tracing system, as it has been attempted in the European Union[37] (3.4 and 3.5).

2. Social and ethical concerns about GM foods

The WHO study explains that any analysis of problems and ways for improvement has to take into account the current challenges in society, as the human population growth and demographic shift, the pressure on natural resources, the industrialization of agriculture, the concentration of economic power, globalization, human-induced environmental changes as well as new biotechnologies. It emphasizes that the increasing demand in the civil society to more closely consider its social and ethical impacts comes from the mere fact that biotechnology interferes with nature[38]. The acceptance of biotechnology in food depends very much on the benefits to society. Although the sceptical consumer does not demand „zero risk", the WHO study suggests the inclusion of social and ethical consideration in all safety assessment (6.6).

a) Labelling

The WHO study refers to the GM food labelling policies that have been established in order to give consumers meaningful information to choose the products they want to buy. The WHO study notes that divergent regulatory approaches have been applied for identifying through labelling the use of gene-technology processes in food production (6.2. Table 3). Voluntary labelling systems[39] established in the major GM commodity-exporting countries (e.g. Canada and U.S.A.) are being re-evaluated as increasing numbers of mainly importing countries establish mandatory process-based labelling regulations. Mandatory labelling can apply to all foods derived from GMOs (e.g. in the European Union), to designated food items or ingredients containing GMOs (e.g. in China, Japan, Thailand), to foods containing GMOs (e.g. in Australia, New Zealand, Russian Federation) or only to GM foods that is significantly different from its conventional counterpart (e.g. in Canada, U.S.A.). Furthermore labelling standards rely on different triggers of the determination, when food is to be con-

37 Reference is made to the European Network of GMO Laboratories. European Commission, 2002, http://engl.jrc.it/ ; see also *Amanor-Boadu/Amanor-Boadu*, A Survey of Post-Marketing Surveillance of Potential Human Late Health Effects of Genetically Modified Foods' Initiatives: Lessons for Canada's Strategy, Centre for Surveillance Coordination, Health Canada, http://www.phac-aspc.gc.ca/csc-ccs/pdf/Biotech–GMF–GlobalScan–English.pdf.

38 International agreements related to nature and food production, Ethical Issues in Food and Agriculture. FAO Ethics Series 1, Food and Agriculture Organization of the United Nations (FAO), Rome 2001, ftp://ftp.fao.org/docrep/fao/003/X9601e/X9601e00.pdf .

39 This regime applies in Canada and the U.S.A. to GM food, which is similar to conventional counterparts, and relies on general provisions in food or fair trading law relating to false, misleading and deceptive labeling or advertising, and an industry code of practice developed to assist with compliance.

sidered as GM food and what is the required tolerance and threshold for a label (below 1 %, 3 % or 5 % of total or unintended ingredients; of for top 3 or top 5 ingredients). The WHO study explains these inconsistencies as a reflection of the different cultural and social backgrounds of countries. From this it concludes that a harmonization is likely to be hard to achieve here[40].

b) Co-existence

As far as the problem of co-existence between genetically modified crops and conventional crops is concerned, the WHO study (6.3) refers to a report of the European Commission stating that co-existence of agricultural practices must respect the threshold limits set for contamination of organic products and realize the difficulty of adhering to this goal for certain plants. Concerning the possibility of implementing GM-free zones in regions with specific interest the WHO study reminds that such a political decision may raise issues of individual justice towards those producers that have a strong motivation contrary to the zoning policy.

c) Other socioeconomic concerns

The WHO study points to numerous reports on increased or decreased profitability of agricultural practices including GMOs. It criticises that possible effects of biotechnology cannot be estimated during important fluctuations in yields and prices. Thus it is in favour of long-time analyses of the profitability of GM crops. The analyses shall consider the supply and the demand side of the food chain and above all the specific conditions, under which the GMOs come into operation (e.g. the kind of crops, the different regions, the use of pesticides, the perception in the population; 6.4).

The socioeconomic consequences require an analysis that differentiates between the scale of farming and production and other specific interests in society (6.5). One of these problems arise from intellectual property rights that are thought to promote scientific progress, but also support monopolistic tendencies and the loss of crop diversity. According to the WHO study these issues need to be addressed by an international policy.

V. Conclusions and perspectives

New foods derived from genetic modification represent another significant challenge on the international food safety agenda. As much as the application of biotechnology to food has made food production more efficient and healthier, the concerns about

40 Since 1991 the Codex Committee on Food Labelling has intensely debated the nature and extent of labelling for foods produced through biotechnology. Especially the positions on process-based labelling are divergent among Member States.

the long-term effects of genetically modified foods to health and the environment increase. Besides concerns about health and safety the opposition to GM crops and foods is also based on social and political values. Therefore achieving harmonization of the international food market in this context is critical.

For methods of the risk assessment concerning human health and the environment the *Codex Alimentarius* and the *Cartagena Protocol* represent some successful international harmonization in this moving field of science. However *Codex Alimentarius* standards and the implementation of the *Cartagena Protocol* establish especially for developing countries hurdles to international trade. A limited capacity to do the required scientific risk assessment may exclude countries from international trade with products of modern biotechnology.

Since none of the international regimes give guidance on further regulations, this flexibility creates room for divergence. The European Community has set up a complex legislation for GMOs and genetically modified foods. No other foods are subject to such a rigorous authorization procedure and such stringent labelling and traceability requirements. It is questionable, whether the European regulations are consistent with the international trade rules of the World Trade Organization. While the EC's regulatory system for authorizing GMOs is clear, transparent and non-discriminatory, the exporting countries conceive the obligation of labelling and traceability as an import restriction without any scientific reason. The European legislation, however, seems to have helped to broaden the scepticism concerning GM foods in the European Union.

The recently published WHO study on modern biotechnology concludes that the current regulations on GMOs and GM products, which require for their use a complex safety assessment, suffice to prevent risk for human health and the environment. Although no contradicting scientific proof has been found yet, a monitoring of the long-term effects of these products will be necessary in order to asset the overall risk of biotechnology in foods. The European labelling and traceability requirements can meet this demand. In general the European policy in respect to GMOs and GM foods goes in line with the results of the WHO study and is not-rarely mentioned as a good example. However, considering the restricted capacities of developing countries a fully coherent international policy and regulatory framework for the application of modern food biotechnology could have better safety effects. Because of the controversial appreciation and the complexity of the effects of GMOs this will also require further progress on international harmonization in other fields, such as the protection of sustainable agriculture and biodiversity, and other socioeconomic factors of value for the society. This ambitious work still lies ahead.