Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	1998/0072(COD)
Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC) Amended by 2001/0180(COD) Amended by 2006/0296(COD) Amended by 2010/0208(COD) See also 2013/2974(RSP) Amended by 2018/0088(COD) Subject 3.10.06 Crop products in general, floriculture 3.10.09.06 Agro-genetics, GMOs 3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity 3.70.06 Soil pollution, deterioration 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
DELE EP Delegation to Conciliation Committee	PSE BOWE David Robert	12/09/2000
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy	PSE BOWE David Robert	19/07/1999
ENVI Environment, Public Health and Consumer Protection	PSE BOWE David Robert	06/01/1998
Former committee for opinion		
AGRI Agriculture and Rural Development	PSE HAPPART José H.G.	16/04/1998
ENER Research, Technological Development and Energy	PPE MATIKAINEN-KALLSTRÖM Marjo	17/03/1998

Council of the European Union

Council configuration	Meeting	Date
Transport, Telecommunications and Energy	2234	09/12/1999
Environment	2194	24/06/1999
Environment	2165	11/03/1999
Environment	2153	20/12/1998

	Environment	2121	06/10/1998
	Environment	2106	16/06/1998
	Environment	2062	16/12/1997
	Environment	2033	16/10/1997
	Environment	1990	03/03/1997
European Commission	Commission DG	Commissioner	
	Environment		

Key events

03/03/1997	Debate in Council	1990	
16/10/1997	Debate in Council	2033	
16/12/1997	Debate in Council	2062	
23/02/1998	Legislative proposal published	COM(1998)0085	Summary
09/03/1998	Committee referral announced in Parliament, 1st reading		
16/06/1998	Debate in Council	2106	
06/10/1998	Debate in Council	2121	
20/12/1998	Debate in Council	2153	
21/01/1999	Vote in committee, 1st reading		Summary
21/01/1999	Committee report tabled for plenary, 1st reading	A4-0024/1999	
10/02/1999	Debate in Parliament		
11/02/1999	Decision by Parliament, 1st reading	T4-0105/1999	Summary
11/03/1999	Debate in Council	2165	
26/03/1999	Modified legislative proposal published	COM(1999)0139	Summary
09/12/1999	Council position published	11216/1/1999	Summary
20/01/2000	Committee referral announced in Parliament, 2nd reading		
21/03/2000	Vote in committee, 2nd reading		Summary
21/03/2000	Committee recommendation tabled for plenary, 2nd reading	A5-0083/2000	
11/04/2000	Debate in Parliament		
12/04/2000	Decision by Parliament, 2nd reading	T5-0147/2000	Summary
12/09/2000	Parliament's amendments rejected by Council		
08/11/2000	Formal meeting of Conciliation Committee		
14/12/2000	Final decision by Conciliation Committee		Summary
20/12/2000	Joint text approved by Conciliation Committee co-chairs	3664/2000	

26/01/2001	Report tabled for plenary, 3rd reading	A5-0032/2001	
13/02/2001	Debate in Parliament		
14/02/2001	Decision by Parliament, 3rd reading	T5-0075/2001	Summary
15/02/2001	Decision by Council, 3rd reading		
12/03/2001	Final act signed		
12/03/2001	End of procedure in Parliament		
17/04/2001	Final act published in Official Journal		

Technical information

Procedure reference	1998/0072(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amended by 2001/0180(COD) Amended by 2006/0296(COD) Amended by 2010/0208(COD) See also 2013/2974(RSP) Amended by 2018/0088(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	CODE/5/13635

Documentation gateway

Legislative proposal		COM(1998)0085 OJ C 139 04.05.1998, p. 0001	23/02/1998	EC	Summary
Economic and Social Committee: opinion, report		CES1117/1998	09/09/1998	ESC	
Committee report tabled for plenary, 1st reading/single reading		A4-0024/1999 OJ C 150 28.05.1999, p. 0003	21/01/1999	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0105/1999 OJ C 150 28.05.1999, p. 0277-0380	11/02/1999	EP	Summary
Modified legislative proposal		COM(1999)0139 OJ C 139 19.05.1999, p. 0007	26/03/1999	EC	Summary
Council position		11216/1/1999 OJ C 064 06.03.2000, p. 0001	09/12/1999	CSL	Summary
Commission communication on Council's position		SEC(1999)2180	13/01/2000	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0083/2000 OJ C 040 07.02.2001, p. 0007	21/03/2000	EP	
Text adopted by Parliament, 2nd reading		T5-0147/2000 OJ C 040 07.02.2001, p.	12/04/2000	EP	Summary

		0061-0123			
Commission opinion on Parliament's position at 2nd reading		COM(2000)0293	16/05/2000	EC	Summary
Joint text approved by Conciliation Committee co-chairs		3664/2000	20/12/2000	CSL/EP	
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A5-0032/2001	26/01/2001	EP	
Text adopted by Parliament, 3rd reading		T5-0075/2001 OJ C 276 01.10.2001, p. 0050-0119	14/02/2001	EP	Summary
Document attached to the procedure		COM(2002)0359 OJ C 262 29.10.2002, p. 0325-0335 E	04/07/2002	EC	Summary
Document attached to the procedure		COM(2002)0361 OJ C 262 29.10.2002, p. 0336-0359 E	04/07/2002	EC	
Document attached to the procedure		COM(2002)0362 OJ C 262 29.10.2002, p. 0360-0389 E	04/07/2002	EC	
Implementing legislative act		32002D0623 OJ L 200 30.07.2002, p. 0022-0033	24/07/2002	EU	Summary
Implementing legislative act		32002D0811 OJ L 280 18.10.2002, p. 0027-0036	03/10/2002	EU	
Implementing legislative act		32002D0812 OJ L 280 18.10.2002, p. 0037-0061	03/10/2002	EU	
Implementing legislative act		32002D0813 OJ L 280 18.10.2002, p. 0062-0083	03/10/2002	EU	Summary
Implementing legislative act		32003D0701 OJ L 254 08.10.2003, p. 0021-0028	29/09/2003	EU	Summary
Implementing legislative act		32004D0204 OJ L 065 03.03.2004, p. 0020-0022	23/02/2004	EU	
Follow-up document		COM(2004)0575	31/08/2004	EC	Summary
Follow-up document		COM(2007)0081	05/03/2007	EC	Summary
Follow-up document		SEC(2007)0274	05/03/2007	EC	
Follow-up document		COM(2007)0336	13/06/2007	EC	Summary
Follow-up document		COM(2008)0754	18/11/2008	EC	Summary
Follow-up document		COM(2009)0012	21/01/2009	EC	Summary
Follow-up document		C(2009)8438	03/11/2009	EC	
Follow-up document		COM(2011)0214	15/04/2011	EC	Summary
Follow-up document		SEC(2011)0481	15/04/2011	EC	
Follow-up document		COM(2024)0170	19/04/2024	EC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2001/18
OJ L 106 17.04.2001, p. 0001 Summary

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

OBJECTIVE: to extend and clarify the scope of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms; to improve the administrative procedures; to harmonize decision-making between Member States on the basis of common principles of risk assessment; to improve the flexibility of directive 90/220/EEC while maintaining a high level of protection for human health and the environment. SUBSTANCE: the proposal takes into account the experience gained, the development of scientific knowledge and the new information in the field of biotechnology since the adoption of the 1996 report on the revision of Directive 90/220/EEC. Specifically, the Commission proposes to: - clarify the scope and definitions of Directive 90/220/EEC so as to include all direct and indirect ecological aspects; - introduce mandatory monitoring after the placing on the market of products linked to an authorization granted for a fixed time period; - confirm the possibility for the Commission to consult any committee it has created with a view to receiving advice on the ethical implications of biotechnology; - classify, on the basis of common criteria, experimental releases and to provide for a distinct administrative procedure for each category of release and a multi-state procedure; - speed up the administrative procedures through a rapid forwarding of information and to approve a system for the placing on the market of products and to introduce simplified procedures for the renewal of a consent; - provide for the obligation of formally consulting a Scientific Committee in order to assist the Commission in any matter which is likely to have an effect on human health and/or the environment under the implementation of Part C of Directive 90/220/EEC; - increase the transparency of the decision-making process by making available to the public the content of the notification for the placing on the markets of GMOs as/or in a product, the assessment reports carried out for products placed on the market and the opinion of the scientific committees; - apply the IIIb procedure for the regulatory committee to increase the role of the Member States in the decision-making process by giving the Council the possibility to reject the Commission decision by a simple majority; -detail further and broaden labelling requirements on the basis of the broad orientation for an extended Community labelling system for GMO products. ?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

A major report on genetically modified organisms (GMOs) was adopted. The final vote was 16 to 0 with 11 abstentions. The report, drafted by David BOWE (PES, UK) under the codecison procedure, concerned a Commission proposal for a new directive to amend existing directive 90/220/EEC on the deliberate (ie non-accidental) release of GMOs into the environment, whether for research purposes or in order to place them on the market. The large number of abstentions brought together those who thought the report went too far in the direction of caution (and so might hamper the development of this new technology) and those who thought it did not go far enough (and so might jeopardize public health). The rapporteur thought he had got the balance "just right". Members tabled 188 amendments to the proposal. Among those adopted, a key amendment introduced into the text an obligation on Member States and on the Commission to adopt the precautionary principle (ie "safety first") so as to avoid adverse effects on human health or the environment from the deliberate release of GMOs. Nor should the lack of full scientific certainty be a reason to postpone preventive measures. In the event of unauthorized or accidental release of a GMO, the Member State concerned must terminate the release, initiate remedial action and inform other Member States, the Commission and the public. Another amendment excludes human beings from the definition of organisms which can be genetically modified. A certification system must ensure that GMOs placed on the market can be traced subsequently. All GMOs authorized for release must carry unique genetic tags to identify them. In the case of products placed on the market, the label must indicate that the product contains or consists of GMOs. The existence of genetically modified proteins or DNA, the committee thinks, is currently the best criterion for determining whether GMOs are present or not. The label must not say (as the Commission had proposed) that the product "may" contain GMOs. Those legally responsible for the deliberate release of GMOs should have full civil and criminal liability for any resulting damage to human health or the environment. However, a more general EU-wide environment liability law should ultimately be introduced.The committee also thought that the export of GMOs from the EU should be dependent on export authorization from the competent Member State authority and import consent from the country of destination.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

In its first reading, the Parliament approved the Commission's proposal concerning the deliberate release into the environment of GMOs subject to a number of amendments. 101 amendments to the report, drafted by Mr. David BOWE (UK, PES), were tabled. The Parliament voted to limit consent for the authorisation of new GMOs licences to twelve years, as against 7 years proposed by the Commission. The EP demanded stricter rules on compulsory labelling of all GMOs authorised for release, as well as the notification to the competent authorities of a description of the identification methods of the GMO to ensure its traceability. It also called for measures to make GMO manufacturers liable for any damage to human health or the environment caused by their products. The Parliament also voted to modify some of the definitions in Article 1 of the Directive, including, for example, extending the scope of 'environmental risk assessment' to include the evaluation of secondary

and long-term effects. The Parliament also inserted an amendment requiring the Member States and the Commission to ensure that no GMO and/or products thereof leave the territory of the EU without the prior informed consent of the importing party/country. A further amendment takes up health concerns and stipulates that GMOs must not contain any antibiotic-resistant genes or traces of toxic substances. Other amendments are designed to enforce strict monitoring of GMOs when they are placed on the market.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

Generally speaking, the Commission's amended proposal does not take up European Parliament that seek to modify the balance in the safety mechanism contained in the proposal, or which do not respect the basic principles of the Directive, such as the analysis on a case-by-case basis. Nevertheless, the Commission accepted, partially or wholly, the amendments (40 in total) that deal with the following aspects : - the introduction of methods to facilitate the identification, monitoring and recovery of GMOs; - the strengthening of the link between the Directive and the legislation on the products in such a way as to guarantee an exhaustive evaluation of risks for the environment from one end to the other of the legislative framework as regards biotechnology; - all the conditions, including those relating to the monitoring and the period of validity of the authorisation, are subject to revision before the renewal of the authorisation; - the optional character of the period of validity of the authorisation, in the event of renewal; - possibility for the Council and the European Parliament to ask the Commission to consult the Ethics Committee regarding general questions about the release of GMOs; - clarification of the definition of the word 'organism', which does not cover human beings; - taking into account of the precautionary principle as an essential element of the authorisation procedure; - obligation for the Member States to take all the necessary measures in the event of the unauthorised release of GMOs: information to the other Member States and the public; - provision of information concerning plans for decontamination and a detailed follow-up plan in the file notifying releases coming under part B; - public consultation regarding experimental releases; - obligation on the Member States to evaluate all complementary information brought to their attention following the issuing of an authorisation; - reports to be drawn up on releases, as well as the periodicity of these reports are laid down in the authorisation; the summaries of the results have to be communicated to the Member States; - possibility for Member States to obtain complete files on experimental releases; - the risk evaluation report has to specify that the GMO in question must not be placed on the market; - obigation to terminate the release of a GMO and, in the event of acute risk, to recover as far as possible the released GMO; an absolute requirement to inform citizens; - introduction of a precision regarding the circumstances in which the Commission can consult the Scientific Committee and the setting of a deadline for consultations; - introduction of the idea of 'pathogenic effect on micro-organisms in the chapter dealing with potentially damaging effects in Annex II regarding the principles applicable to the evaluation of risks for the environment; - necessity to interrupt the release of a GMO and, to the extent that it is possible, to counteract the effects when therisk is deemed to be unacceptable; this release can only take place when its conditions are modified in such a way as to significantly reduce the risks; - the information provided by the applicant concerning the monitoring plan has to specify the length and frequency of this monitoring; - the competent authorities may require that the applicant modifies the conditions of the release, that it be suspended or that it be terminated, and that he takes all necessary corrective measures.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Council's common position has adopted verbatim, partially or in substance - 38 out of the 39 European Parliament amendments included by the Commission in its amended proposal, together with a large number of amendments that the Commission did not include. Firstly, the amendment not taken up by the Council was the amendment 16 which sought to define the term "use". It was not accepted insofar as this term was used in its ordinary sense in the common position. The changes made by the Council to the amended proposal relate to: - the extension of the procedural time limits in the proposal so that further information can be supplied and the information itself can be processed more effectively; - making a clearer distinction between activities regulated by Part B of the Directive and those covered in Part C; - regrouping the exceptions in a single Article; - ensuring consistency between this Directive and Directive 90/219/EEC on the contained use of micro-organisms, as amended by Directive 98/81/EC; - clarifying the definition of "placing on the market" to ensure that it does not apply to the supplying of GMOs for activities regulated under Directive 90/219 or subject to similar containment measures, or for research and development activities covered by Part B of Directive 90/220. The definition thus takes account of amendment 13; - the reference to the exception of "human beings" to be included in the definition of GMO rather than in the definition of organism, where it seemed somewhat illogical. In conclusion, these specific changes have been introduced in order to strengthen the principles of the risk assessment procedure and the inclusion of public consultation linked with mandatory labelling at all stages of the placing on the market of GMOs increases transparency.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The common position maintains in principle the basic structure of the Commission proposal but builds on specific elements to provide for a more stringent and transparent regulatory framework. Specific changes have been introduced in order to strengthen the principles of the risk assessment procedure and the inclusion of public consultation linked with mandatory labelling at all stages of the placing on the market of GMOs increases transparency. In response to the growing public concerns about potential adverse effects of GMOs, the need for a more transparent and stringent regulatory system for the deliberate release of genetically modified organisms into the environment has now become clear. The common position has built upon the original proposal and the Commission is satisfied it will provide for an effective and efficient regulatory framework that takes into account both public concerns and the interests of industry. Furthermore, the Commission believes that a rapid revision of Directive 90/220/EEC may contribute significantly to the resolution of the problems that have been encountered in the implementation of the Directive and welcomes the fact that the common position was adopted by unanimity.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive

90/220/EEC)

The committee adopted the recommendation for second reading (codecision procedure) by David BOWE (PES, UK) with a large number of amendments to the Council's common position. The debate in committee focused on the dangers of the deliberate release of genetically modified organisms (GMOs) into the environment. One of the amendments adopted by the committee refused authorisation for the release of GMOs containing antibiotic-resistant genes, even for research. The Council's common position only envisaged taking such GMOs "into particular consideration when carrying out an environmental risk assessment" and had not accepted a similar amendment from Parliament's first reading. The other amendments focused mainly on: - environmental liability: the committee called for the party legally responsible for a deliberate release to bear strict civil liability for any damage to human health and the environment; - exports of GMOs outside the EU: GMOs should not leave EU territory without the prior consent of the importing country, which should be informed of the authorisation procedure in the EU; - socio-economic costs and benefits: environmental risk assessment should be strengthened through a yearly study on socio-economic costs and benefits of proposed deliberate releases; this risk assesment, which should be carried out before submitting a notification for a release, should also include the evaluation of risks to animal or plant health and public or private property; - the Biosafety Protocol: this protocol, drawn up in Montreal in January 2000, had not yet been ratified, but the committee asked for it to be taken into account and for the directive to be further amended and clarified in the context of the protocol. ?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

In adopting the report by Mr. David Robert BOWE (PES, Uk), the European Parliament approved the legislative resolution on the Council common position for adopting a European Parliament and Council Directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. This report was subject to amendments which relate to: - respecting the requirements of the Cartegena Biosafety Protocol concluded in Montreal in January 2000; - the introduction of EU-wide environment liability rules to provide wide-ranging regulation of possible cases of damage. In addition, the Commission will, after discussion with the European Parliament and the Council, bring forward a proposal, before the end of 2001, which shall include the impact of biotechnology on all areas of the Euoepan Union; - risk-assessments: these should be made of the accumulated long-term effects associated with granting consent and releasing any new genetically modified organism. The accumulated long-term effects should also form a compulsory part of the monitoring process; - the need for necessary resources to be secured to carry out research and the right for independent researchers to be given access to all relevant material; - regulations to ensure that risk assessment, risk management, labelling, monitoring as appropriate, information to the public and safeguard clauses are equivalent to those laid down in this Directive: these should be implemented in cooperation with the relevant authorities responsible for implementation of this Directive in the Commission and the Member States; - the Commission conducting a study of the possibility of centralised monitoring of the release of GMOs; - the intention of studies to be carried out annually of the likely socio-economic costs and benefits of the proposed deliberate release/market authorisation; - the identification and phasing out of antibiotic resistance markers by 2005; - the exportation of GMOs and/or products containing GMOs to non-Member States: the exporter or importer must obtain consent to the import from the country of destination and export authorisation from the authority of the competent Member State. In addition, the country of destination must give its consent to the import before the authority of the competent Member State can issue its authorisation. Furthermore, the Commission shall bring forward a legislative proposal for implementing in detail the Cartegena Protocol on Biosafety within 6 months of signature. It shall also take the necessary measures to ensure that these consultation procedures are conducted under clear rules of openness and transparency with full public access. In conclusion, a new paragraph was introduced which relates to the general principle for environmental risk assessment. This shall also be an assessment/analysis of the "accumulated long-term effects". The term "accumulated long-term effects" refers to the accumulated effects of all consents on natural flora, other crops, soil fertility, soil degradation of organic material, the food chain, biological diversity, human health and resistance problems in relation to antibiotics.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Commission can accept fully four amendments adopted by the European Parliament and nine in principle. The remaining 16 amendments are not acceptable. The amendments accepted by the Commission relate to the reintroduction of the term 'use' in the text as defined by the existing Directive; the obligation of the competent authorities of Member States to state reasons when demanding further information from the notifier under Part B of the Directive; the clarification that Member States are to inform the public when information becomes available which could have significant consequences for human health and the environment; and finally, sanctions that these should include penalties for the negligent release of GMOs. In addition, the amendments accepted in principle by the Commission concern: - the submission of proposals for the implementation of the recently agreed Protocol for Biosafety in the context of ratification. However,the Commission cannot accept to include provisions in the text of the Directive on export obligations in the present revision and therefore rejects the first part of the amendment; - the addition of a new paragraph which states that "it should also take due account of potential culminative long-term effects associated with the interaction between different GMOs in the environment"; - the introduction of a new recital which stresses the need for independent, systematic research on potential risk associated with the release of GMOs and that researchers should be given all relevant information; - the three-year reports of the Commission which should include a study of the likely socio-economic implications of the deliberate release or the placing on the market of GMOs; - the analysis carried out on comments received from the public on a proposal for establishing criteria and information for specified GMOs should only be done where it is deemed appropriate; - the addition of a recital which refers to the need for Community wide environmental liability rules and that the Commission is to submit a prposal which includes the impact of biotechnolgy on all areas of the European Union before the end of 2001; - the requirement that Member States ensure that the implication of gene transfer are accurately assessed on a case by case basis; - the importance of phasing-out of antibiotic resistance marker genes.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Conciliation Committee reached agreement on the joint text of the directive. The compromise package covered the following issues: a timetable for the phasing out of antibiotic resistance makers in GMOs, namely end of 2004 for commercial releases (part C) and end of 2008 for research purposes (part B); a Commission undertaking to bring forward a legislative proposal on environmental liability before the end of 2001, which would also cover damage resulting from GMOs; consideration of potential cumulative long-term effects associated with the interaction with other GMOs and the environment in the context of the risk assessment carried out prior to authorisation; pharmaceuticals - exemptions for GM pharmaceuticals for human use for research purposes (part B of the directive) provided that the sectoral Community legislation that governed their authorisation fulfilled certain criteria (e.g. an equivalent risk assessment); Cartagena Protocol - the Commission was invited to bring forward a legislative proposal by July 2001. As the key issue in this connection was the export of GMOs to third countries, the text agreed also contained provisions that the importing country should be notified of any imports and provided with accurate information about them and that its consent should be obtained; public registers - GMOs released in the trial period (part B of the directive) should be registered and details made available to the public. As regards the release of GMOs for commercial purposes (part C of the directive), their locations would have to be notified to the competent authorities and made known to the public in a manner deemed appropriate by the authorities; renewal of authorisation - the first-time consent for a release of GMOs was limited to a maximum of ten years. It was agreed that the renewal of an initial authorisation would also be limited in time: as a general rule, the renewed consent would be valid for an additional ten-year period. This period could be limited or extended for specific reasons; labelling and traceability of GMOs - Parliament insisted on clear labelling and traceability rules for GMOs and derived products as they were essential for consumers. In a written declaration, the Commission committed itself to bringing forward appropriate legislative proposals on labelling and traceability in the course of 2001 which would supplement the existing labelling regime in accordance with the White Paper on Food Safety. ?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The European Parliament adopted the report by Mr David Robert BOWE (PES, UK). The compromise reached at conciliation on genetically modified organisms (GMOs) was endorsed by 338 votes to 52 with 85 abstentions. (Please refer to the previous documents).?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

PURPOSE: to protect human health in view of the deliberate release into the environment of genetically modified organisms and the placing on the market of products either completely or partially genetically modified.

COMMUNITY MEASURE: Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

CONTENT: in accordance with the joint text approved by the Conciliation Committee, the Council formally adopted the directive (with the abstention of the Italian and the French delegates). This directive concerns the experimental release of GMOs (for research and development purposes) as well as the placing of GMOs on the market. In accordance with the precautionary principle, the new directive requires that an environmental risk assessment be carried out before the authorisation procedure. Furthermore, the directive foresees the identification and the elimination of GMOs which contain genes resistent to antibiotiques used in medical and veterinary treatments.

This elimination will take place before the end of 2004 in the case of GMOs on the market and before tne end of 2008 in the case of GMOs authorised for experimental research. GMOs cannot be released on a voluntary basis, into the environment or on the market, except in the case of the provisions in part B of the directive (deliberate release of GMOs for any other purpose than for placing on the market) or in part C (placing on the market of GMOs as or in products). Each part is characterised by a standard procedure according to which the principal competent authority (which,in the Member State, has received notification) gives its authorisation to voluntary release or placing on the market. Only one competent national authority is accredited to give an authorisation in the framework of the standard procedure in part B; however, all competent authorities participate in the differentiated procedure (simple) foreseen in part B and the standard procedure in part C. As regards placing on the market, which concerns all the Member States, authorisation is prohibited except in the case of possible objections or if a decision is taken by the committee procedure and the main competent authority does not oppose the plan to place GMOs as or in products on the market. Such authorisation is given after a large consultation (public, scientific committees) and for a maximum of 10 years for the first authorisation. After 10 years, a new request must be presented which, in principle, is subject to the same deadline of 10 years. The authorisation defines obligations relating to monitoring and labelling. Labelling is obligatory for all stages of the placing on the market and the label must indicate clearly that 'the product contains genetically modified organisms'. Thresholds may be established for each product below which products containing accidental or inevitable technical traces of GMOs need not be labelled. In addition to labelling requirements, provisions relating to the traceability of GMOs allow competent authorities to follow GMOs at all stages on the market. The directive provides for the obligatory public consultation for part B and C, both for the standard and the differentiatedprocedures. With regard to part B, information on all releases and their location, is accessible to the public via public registers. Member States shall also establish registers for recording the location of GMOs grown under part C. These are made known to the public in the manner deemed appropriate by the competent authorities and in accordance with the national provision. In part B, the standard procedure is supplemented by a differentiated procedure concerning, for example, obligations regarding information and deadlines, by which and after the obligatory consultation of scientifc committees and the public, a committee defines differentiated procedures which may apply in the case of releases fulfilling certain security criteria. The decisions of the committee are taken by a regulatory committee procedure. Additional procedures are foreseen for the renewing of authorisation, the treatment of authorisations granted in the framework of the directive in force as well as the monitoring and the treatment of new information and objections to GMOs which have already been authorised. The requirements contained in part C are not applicable to products authorised by other Community legislation which, from the point of view of evaluation and risk management, monitoring - where appropriate - labelling, public information and the safeguard clause, is 'equivalent' to the directive in question. A similar derogation relating to the provisions of part B is applicable to medicinal substances.

ENTRY INTO FORCE: 17.04.2001.

DEADLINE FOR TRANSPOSTION: 17.10.2001.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

In the context of the implementation of Directive 2001/18/EC concerning the deliberate release into the environment of genetically modified organisms, the European Commission has presented : 1) a proposal for a Council Decision establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC; 2) a proposal for a Council Decision establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market. That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment. The Summary Notification Information Format consists of a Part 1 and a Part 2. Part 1 applies to products consisting of or containing genetically modified higher plants. The term "higher plants" means plants which belong to the taxonomic group Gymnospermae and Angiospermae. Part 2 applies to products consisting of or containing genetically modified organisms other than higher plants. 3) a proposal for a Council Decision establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products. That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment. Under Part C of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned placing on the market of a genetically modified organism (GMO), or a combination of such organisms. That notification comprises, inter alia, a summary of the relevant dossier, which the competent authority must send to the competent authorities of the other Member States and to the Commission, and which the Commission must immediately make available to the public. That summary must be drawn up in accordance with a particular format. Article 13(2)(h) of the Directive stipulates that the summary notification information format must be drawn up in accordance with the procedure laid down in Article 30. A draft of the measures to be taken has accordingly been submitted for opinion to the committee set up under Article 30 of the Directive. The committee has not delivered an opinion on the proposal. In such a case, Article 30 stipulates that the Commission must forthwith propose to the Council the measures to be adopted and inform the European Parliament thereof. The Council must then act by qualified majority. If, by the expiry of the time limit, the Council has not adopted the proposed implementing measures or has not indicated itsopposition to the proposed implementing measures, they shall be adopted by the Commission.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The European Commission adopted Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. These guidance notes include the objectives, the elements, general principles and methodology of the environmental risk assessment referred to above. ?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

COMMUNITY MEASURE : Council Decision establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release in the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. CONTENT : in the context of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs), the Council adopted the following decisions: - Decision 2001/811/EC establishing guidance notes supplementing Annex VII of directive 2001/18/EC. Annex VII describes the objective to be achieved and the general principle to be followed in designing a monitoring plan to trace and identify any effects on human health or the environment resulting from the placing on the market of GMOs; - Decision 2001/812/EC establishing a "Summary Information Format" for the placing on the market of GMOs. Pursuant to the directive, the competent national authority must be notified prior to the placing on the market of GMOs. The notification comprises a summary of the relevant dossier, and the decision sets the format to be used for that summary; - Decision 2001/813/EC establishing a "Summary Notification Information Format", concerning the release into the environment of GMOs for purposes other than for placing on the market. The format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standarised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

LEGISLATIVE ACT : Commission Decision establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market. CONTENT : to date, most GMOs deliberately released in the Community pursuant to Part B of Directive 2001/18/EC are genetically modified higher plants (GMHP). It is necessary, therefore, with regard to those plants, to establish the format to be used by the notifier when presenting the results of the release to the competent authority. That format should reflect the need to enable the fullest possible

exchange of relevant information, presented in a standardised and easily comprehensible manner. The format should be kept as general as possible so that, where appropriate, multi-sites, multi-annual releases or releases of several GMOs can be covered by a single report.?

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Commission presents this report which specifically concerns Directive 2001/18/EC and the deliberate release of GMOs, although the wider legislative framework is also considered.

It should be noted that this first report relates only to 15 Member States given that the reporting period in question ended prior to the date of entry for accession countries (1 May 2004). Subsequent three-year reports will, however, include these additional Member States.

The Commission also includes a specific report on the operation of part B and part C of the Directive which includes issues such as an assessment of its implications; the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission; the socioeconomic implications of deliberate releases and placing on the market of GMOs.

Given that the Directive became fully applicable as of 17 October 2002, there is still relatively little experience of its implementation. The lack of transposition by a number of Member States also hinders implementation. Nevertheless, there is general agreement that the Directive, together with the recent Regulations on GM Food and Feed and Traceability and Labelling, help to increase confidence in the legislative framework and to increase the predictability of the decision-making process.

Currently, most concerns relate to the need for guidance in interpreting elements of the Directive such as post-market monitoring, the phasing out of antibiotic resistance marker genes which may have adverse effects on human health and the environment, and non-plant GMOs. In addition, guidance is required on the interaction of the various pieces of legislation.

Lastly, the Commission and Member States are already working on guidance for post-market monitoring and antibiotic resistance marker genes.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

In accordance with the requirement in Article 31.6 of Directive 2001/18/EC, the Commission reports on experience of Member States with GMOs placed on the market under Directive. All Member States (MS) were required to submit three-year reports to the Commission for the period 17 October 2002 ? 17 October 2005, on the measures taken to implement the provisions of the Directive, including a brief factual report on their experience with GMOs placed on the market in or as products under the Directive. All MS except Portugal submitted their three-year reports to the Commission. The report also includes experience with GMOs for purposes other than placing on the market, i.e. research and development (Part B of the Directive) as well as contributions from other stakeholders such as industry/trade organisations, farmers' associations and environmental NGOs.

Placing on the market of GMOS as or in products (Part C of the Directive): a total of 26 Part C notifications for GM plants was submitted under the Directive to eight MS. However, following the introduction of Regulation 1829/2003/EC on GM food and feed, thirteen applications remained under the Directive. Out of these 13 applications, 5 products have been authorised, 4 from Monsanto. The majority of MS concur that the implementation of the Directive has helped to restore confidence in the authorisation process for the placing on the market of GM products. A number of MS have commented on the largely negative attitude of non-industry stakeholders towards new authorisations. Industry reported that, in its experience, the implementation of Directive 2001/18/EC has not helped to restore confidence in the EU decision making process for Part C applications and points in particular to the fact that no consents for cultivation have been issued since 1998.

On thresholds, MS reported difficulties with managing conventional seed lots which may contain adventitious presence of authorised GMOs, in the absence of seeds' thresholds for adventitious presence. Industry reported on the need to establish thresholds for authorised GMOs as well as for those not yet authorized in the EU, but which have already been approved for deliberate release in third countries. NGOs and some MS have demanded that thresholds be set at the level of detection of GM traces. Industry noted that many EU farmers are reluctant to grow GM varieties in many MS where large food processors, traders and retailers remain cautious about the use of GM material in the light of increasingly negative public opinion and of the costs associated with traceability. In addition, as first generation GMO products become obsolete and are no longer commercially marketed, industry has requested proportionate renewal procedures to cover any remaining adventitious traces of these GMOs in order to ensure legal certainty following the expiry of consents.

A majority of MS reported that there is a need for a more consistent approach to post-market monitoring while retaining the possibility for specific monitoring depending on the specific climate and natural environment in a MS. Several MS considered that monitoring plans submitted to date had tended to lack detail and a clear allocation of responsibilities. NGOs reported that, as more GMOs are marketed, there would be a need for a more coordinated approach with allocation of responsibility to an independent body rather than to the consent-holder alone, to carry out assessment of all monitoring and surveillance data relating to deliberate releases.

Many MS have reported that the protocols included in Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms are complex, time-consuming and expensive and that results are not in proportion to the time and expense involved.

Concerning the presence of antibiotic resistance marker genes, the majority of MS reported that the Opinion of the GMO Panel of the European Food Safety Authority (EFSA) dated 2 April 2004 has proven useful for the phasing-out of such genes. NGOs however have called for a new assessment of ARM genes to look solely at potential adverse effects on human health and the environment, without reference to their use by industry as a means to ensure the efficient selection of transgenic events in plants.

Research and Development (Part B of the Directive): 245 applications for the release of GMOs for purposes other than for placing on the market were submitted to 13 MS during the reporting period of 17 October 2002 ? 17 October 2005. The highest numbers of applications were

submitted in Spain (89), France (54), Germany (25), Hungary (21), Sweden (18) and Netherlands (13). Twelve MS did not receive any applications. Of the total of 245 applications 191 consents were issued, and 27 applications were refused. The highest percentage of refusals was in Hungary. A majority of MS consider that the Directive has provided a more transparent and predictable regime. Concerns were expressed, however, about the lack of consistency among MS, given that the authorisation process is largely at the national level, and about the possibility of contamination of neighbouring crops from Part B trials. A number of MS also highlighted the specific issue of clinical trials on gene therapy, given that some MS currently apply the provisions of Directive 90/219/EC on contained use whilst others apply Directive 2001/18/EC on deliberate release into the environment. This issue will be discussed with the competent authorities appointed under both pieces of legislation in 2007.

Industry also called for greater harmonisation of Part B applications across the EU, citing differences amongst MS regarding data requirements, timelines and information to the public which decreased the predictability of the current system. Industry expressed particular concern about the timing of consents which were sometimes issued after the planting season.

A majority of MS considered that the Commission had provided clear guidance on what is required in the environmental risk assessment. Nevertheless a number of MS would appreciate additional guidance on what are considered to be acceptable and unacceptable risks and on long-term cumulative effects. Industry also called for more harmonisation of the environmental risk assessment requirements. NGOs pointed to the need for stronger guidelines for allergenicity testing.

Industry also expressed concern about the release of the exact location of field trials which often resulted in the harassment of farmers and ultimately in the destruction of the trials by anti-GM activists. This had clear adverse effects on biosafety research and on biotechnology product development in the EU. NGOs called for information of public interest to be easily and quickly accessible.

Conclusions: those Member States which have handled applications are generally positive about their experience with the implementation of the Directive, despite a number of technical issues which have yet to be adequately addressed such as a cost-effective and practical sampling and detection system, as well as greater consistency, more detail and better allocation of responsibilities in post-market monitoring measures. Other stakeholders have tended to be less positive in their assessment of the Directive.

The Commission is committed to working with EFSA to further develop guidelines as part of an overall framework for risk assessment with a view to increasing the overall transparency of, and confidence in, the evaluation process. The majority of Member States would also welcome increased harmonisation on the process for Part B releases, including gene therapy trials, the definition of ?location? of field trials, additional guidance on environmental risk assessment and management measures to prevent contamination of neighbouring crops.

Lastly, the majority of Member States has emphasised the need for a legal instrument establishing seeds? thresholds, based on the difficulties they have experienced in managing the labelling and traceability of conventional seed lots without such thresholds for adventitious presence. The Commission is currently exploring various options in relation to this issue.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Commission has presented a proposal for a Council Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

In accordance with Directive 2001/18/EC, the Swedish authorities received from BASF Plant Science a notification (Reference C/SE/96/35-01) concerning the placing on the market of a potato (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch. In accordance with the Directive, the Swedish competent authority forwarded to the Commission its assessment report of the notification, which concluded that genetically modified potato should be placed on the market for its intended uses.

On 9 December 2005, BASF Plant Science informed the Swedish competent authority of its intention to exclude feed uses from the notification under Directive 2001/18/EC, limiting its scope to cultivation and production of starch for industrial uses. The Commission forwarded the assessment report to all other Member States, some of which raised and maintained objections to the placing on the market of the products in terms of molecular characterisation, allergenicity, toxicity, an inadequate monitoring plan and the detection method of the product.

In light of these objections, the Commission consulted with the European Food Safety Authority (EFSA), which delivered its opinion on 24 February 2006 concluding that, from all evidence provided, the genetically modified potato (Solanum tuberosum L. line EH92-527-1) is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

A draft of the measures to be taken was submitted for opinion to the Committee set up in accordance with Article 30 of Directive 2001/18/EC. The Committee which was consulted on 4 December 2006 has not delivered an opinion. Therefore, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament; the European Parliament was informed on 8 December 2006. The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

On 26 February 2007, in the light of a report published by the World Health Organisation listing kanamycin and neomycin as 'critically important antibacterial agents for human medicine and for risk management strategies of non-human use', the European Medicines Agency issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine.

On 23 March 2007, taking into account this statement, EFSA confirmed its previous assessment of the safe use of the antibiotic resistance marker gene nptII in genetically modified organisms and their derived products for food and feed uses. Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority on the proposal within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it; whereas if, on expiry of that period, the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

A number of strict conditions are included in the proposal. The specified conditions include the following requirements:

- the consent will be valid for a period of ten years starting from the date at which the consent is issued;

- the unique identifies of the products are BPS-25271-9;
- the consent holder provides positive and negative control samples of the product and its genetic material and reference material to the competent authorities;
- a detection method specific to the modified potato is made available, which has to be validated by the Community Reference Laboratory;
- the product is adequately labelled in accordance with EU provisions;
- operators and users are informed on the safety and general characteristics of the product;
- in view of the fact that the Decision covers only cultivation and industrial use, BASF Plant Sciences is obliged to ensure that the modified potato is: i) physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling ii) that they are delivered exclusively to designated starch processing plants for processing into industrial starch, avoiding any co-mingling with material derived from potatoes intended for food or feed; and iii) only processed into industrial starch. Any by products from the process should be used exclusively for industrial purposes or destroyed.

Strict monitoring conditions have also been set out including, inter alia, monitoring for any adverse effects on human and animal health or adverse effects on the environment, the submission of annual reports and the preparation of a monitoring plan.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Commission presents a proposal regarding giving consent to the placing on the market, in accordance with Directive 2001/18/EC of a carnation genetically modified for flower colour. In accordance with Article 13 of Directive 2001/18/EC, the Dutch authorities received in October 2006 by Florigene Ltd, Melbourne, Australia, a notification concerning the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line 123.8.12). The notification covers import, distribution and retailing of Dianthus caryophyllus L., line 123.8.12 as for any other carnation.

In accordance with the procedure provided for in Article 14 of the Directive, the Dutch competent authority prepared an assessment report, which concluded that the genetically modified carnation (Dianthus caryophyllus L., line 123.8.12) should be placed on the market for import, distribution and retailing as for any other carnation.

The Commission forwarded the assessment report to all other Member States some of whom raised and maintained objections to the placing on the market of the products in terms of monitoring plan, allergenicity and toxicity, and detection of the product.

In light of these objections, the European Food Safety Authority (EFSA) was consulted and delivered its opinion in March 2008 concluding, from all evidence provided, that cut flowers of the genetically modified carnation (Dianthuscaryophyllus L., line 123.8.12) are unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed ornamental use. The EFSA also found that the scope of the monitoring plan provided by the consent holder is in line with the intended use of the carnation.

The Commission, in accordance with Article 18 of Directive 2001/18/EC, is required to take a decision in accordance with the procedure laid down in Article 30(2) of the Directive to which Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

A draft of the measures to be taken was submitted in accordance with the relevant comitolgy procedure. The Committee, consulted on 15 September 2008, has not delivered an opinion, which requires that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament. The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

Article 5(6) of Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority on the proposal within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period, the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it. If, on expiry of that period, the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

By Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON810), it was decided that consent was to be given for the placing on the market of that product.

On 3 August 1998, the French authorities granted consent for the placing on the market of genetically modified maize. However, the Hungarian authorities informed the Commission on 20 January 2005 of their decision to provisionally prohibit the use and sale of the genetically modified maize in question and gave reasons therefore. The Commission sought the opinion of the European Food Safety Authority (EFSA), which considered that the information submitted by Hungary did not constitute new scientific evidence which would invalidate the environmental risk assessment of Zea mays L. line MON810 and therefore would justify a prohibition of the use and sale of this product in Hungary.

The Commission took note of the declaration of the Environment Council on 24 June 2005, which, in order to indicate its opposition to a proposal requesting another Member State to repeal its safeguard clause measure on the same GMO, stated that there was still a degree of uncertainty in relation to the safeguard measure associated with the placing on the market of MON810 maize and called on the Commission to gather further scientific evidence and to further assess whether the national measure was justified and whether the authorisation of the GMO under Directive 90/220/EEC still met the safety requirements of Directive 2001/18/EC.

Therefore, the Commission consulted EFSA in November 2005 as to whether there was any scientific reason to believe that the continued placing on the market of the GMOs subject to the safeguard clause measures, including Zea mays L. line MON810, was likely to cause any

adverse effects to human health or the environment under the conditions of consent, and requested EFSA to take account of any further scientific information that has arisen subsequent to the previous scientific opinions that assessed the safety of these GMOs. It was considered appropriate to await this new EFSA opinion on Zea mays L. line MON810 before taking any action on the corresponding safeguard measure notified by Hungary.

In its opinion of 29 March 2006, EFSA concluded that there is no reason to believe that the continued placing on the market of Zea mays L. line MON810 is likely to cause any adverse effects for human and animal health or the environment under the conditions of their respective consents. Therefore, the Commission prepared a draft Decision asking Hungary to repeal its measures concerning Zea mays L. line MON810.

The Committee established under Article 30 of Directive 2001/18/EC did not deliver an opinion on the measures laid down in a draft Commission Decision, following its consultation, so the Commission was required to submit a proposal to the Council relating to the measures to be taken. The Environment Council indicated its opposition to the proposal by qualified majority. In its Decision, the Council referred to the environmental risk assessment as provided in Directive 2001/18/EC and indicated that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment'.

Hungary submitted to the Commission on 30 November 2007 additional information regarding the cultivation of Zea mays L. line MON810 to support its measure. Consequently, EFSA was requested to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment such that detailed grounds exist to consider the above maize, for the uses laid down in the corresponding consent, constitute a risk to the environment. In its opinion of 2 July 2008, EFSA reaffirmed its previous conclusions on the safety of Zea mays L. line MON810 and stated that it did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on this product. EFSA also concluded that the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU.

Under these circumstances, Hungary should repeal its safeguard measure with regard to the use and sale of Zea mays L. line MON810. Therefore, following the Council Decision of February 2007, and in accordance with Article 5(6)(2) of Council Decision 1999/468/EC, the Commission re-submitted its proposal relating to the measures to be taken and informed the European Parliament.

Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

The Commission presents its report on socio-economic implications of GMO cultivation on the basis of Member States contributions, as requested by the Conclusions of the Environment Council of December 2008. Through questionnaires, Member States were invited to report ex post on the socio-economic impact of GMOs cultivated in their territory, and also assess ex ante the possible socio-economic implications of future cultivation of GMOs.

Analysis of the answers: the Commission identified the following main elements:

- understanding of the meaning and scope of the socio-economic dimension of GMO cultivation varies widely among the Member States and stakeholders. The questionnaire helped to frame thinking, but several participants regretted that the terms, indicators and baseline for comparison (conventional and/or organic sectors) were not sufficiently defined;
- many contributions appeared to be raw catalogues of the wide diversity of opinions on GMO cultivation at national level, without further filtering or analysis by Member States on the ground of relevance or quality before being forwarded to the Commission. It was therefore difficult, and often impossible to pinpoint clear positions or trends at national or European levels;
- in general, the contributions seemed to reflect polarised opinions built upon a limited fact-based background on the specific European context, and influenced by the initial positive or negative perception of contributors on Bt and HT crops cultivation in Europe and worldwide. The core of the discussion concerns the co-existence between the GM and conventional/organic approaches all along the seed-to-shelves chain (control of GM adventitious presence in neighbouring fields, constraints of GM/non-GM products segregation along the feed/food chain, consumer's choice), impact on biodiversity, modification of farming practices and marketability of products, with a wide range of different views on almost all these matters;
- answers covered all the items raised in the questionnaire, though comments largely focused on the social and economic impacts of GMO cultivation at the initial stages of the seed-to-shelves chain (i.e. seed production, cultivation, apiculture, and livestock breeding);

The scientific literature and studies referred to by contributors were mostly focused on economic impacts of GMO cultivation on the in-farm level. Member States? national studies show the following results:

(i)Bt maize yields would increase in regions infested with corn-borers. For instance, Estonia mentioned a study performed by the (JRC)

showing that, for some pest-infested Spanish provinces, Bt maize growers experienced higher average yields than conventional farmers

over a period of 3 years (up to 11.8% in the province of Zaragoza) as well as increased gross margin.

(ii)Romania reported that HT soybean cultivated on the Romanian territory until 2007 generated yield gains of an average of 31%.

(iii) certain contributions included detailed suggestions on whether and how to analyse socio-economic factors and address them in the management of GMO cultivation in Europe. Several Member States also made reference to the legislation and experience of NO on consideration of socioeconomic elements in the authorisation of GMOs.

(iv)many contributions underlined that, if carried out in the future, the evaluations of socio-economic factors should also consider ethics, and take into account other European policies (internal market, Common Agriculture Policy, environment protection), as well as the legal opportunities and constraints at international levels.

The report goes on to discuss the Commission?s review of knowledge of the socio-economic dimensions of cultivation of GMOs in Europe and worldwide, through different channels, including European an international research programs and scientific publications. It notes that economic analyses have provided a good picture on economic impacts at farmer level world-wide, but less on social impacts.

Next steps: the contributions provided by Member States have been helpful in clarifying where statistically relevant data on socio-economic

impacts of GMO cultivation in Europe are already available (mainly economic impacts on farming). Otherwise, facts and statistics pertinent to the European context are missing to support the views expressed by the respondents. Therefore the contributions highlight that, for the time being, the present or future socio-economic impacts of GMO cultivation in Europe, across the food chain and the society as a whole, are often not analysed in an objective manner.

The Commission considers that it would be inappropriate to perform a more targeted analysis of the peculiar items developed in the individual contributions provided by the Member States. Nevertheless, it believes that discussions on this sensitive topic should be deepened, to move from polarised perceptions to more tangible and objective results. Therefore the Commission suggests grouping the primary highlights of this consultation together with other initiatives on socio-economics impacts of GMOs (e.g. research projects under the 6th Framework Research Programme and, when relevant, findings in third countries), and initiating an advanced reflection at

European level, with sound scientific basis, aiming at:

- defining a robust set of factors to properly capture the actual ex ante and ex post socio-economic consequences of the cultivation of GMOs, from seed production to consumers across the EU. A methodological framework should be built-up to define precise socio-economic indicators to be monitored in the long run, and the appropriate rules for data collection. The pool of consulted parties should embrace all the regulatory and economic actors of the "seed-to-shelves" chain, as well as the wider society;
- exploring different approaches to make use of the increased understanding of these multi-dimensional socio-economic factors in the management of GMO cultivation in the EU. Member States? expertise and that of stakeholders should be taken into consideration.