

Brussels, 24 July 2001

## **Question and Answers on the regulation of GMOs in the EU**

### **1. What are GMOs and GMMs?**

Genetically modified organisms (GMOs) and genetically modified micro-organisms (GMMs) can be defined as organisms (and micro-organisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species.

### **2. What is the current legislation in the EU on GMOs?**

Community legislation on GMOs has been in place since the early 1990s and throughout the decade, this regulatory framework has been further extended and refined. The EU introduced specific legislation designed to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology.

The main legislation which authorises experimental releases and placing on the market of genetically modified organisms (GMOs) in the Community is currently Directive 90/220/EEC. A new, updated Directive 2001/18/EC on the deliberate release of genetically modified organisms was adopted by the European Parliament and the Council of Ministers in February 2001 and will enter into force on 17 October 2002.

Directive 90/220/EEC put in place a step-by-step approval process on a case by case assessment of the risks to human health, animal health and the environment before any GMO or product consisting or containing GMOs can be released into the environment or placed on the market.

Products derived from GMOs, such as paste or ketchup from a GMO tomato are not covered by this horizontal Directive but by vertical, sectoral legislation, for example the Regulation on Novel Foods and Novel Food Ingredients of 27 January 1997 (Regulation (EC) 258/97). Directive 90/219/EEC as amended by Council Directive 98/81/EC on the contained use of GMMs which regulates the contained use of GMMs for research and industrial purposes.

### **3. What is the current procedure for approval of the release of GMOs into the environment?**

Under Directive 90/220/EEC (or Directive 2001/18/EC from October 2002), a company intending to market a GMO must first submit an application to the competent national authority of the Member State where the product is to be first placed on the market. For experimental releases it is the competent authority of the Member State where the product shall first be released for research or development purposes.

The application must include a full risk assessment. If the national authority gives a favourable opinion on the placing on the market of the GMO concerned, this Member State informs the other Member States via the Commission. If there are no objections, the competent authority that carried out the original evaluation grants the consent for the placing on the market of the product. The product may then be placed on the market throughout the European Union in conformity with any conditions required in that consent.

If any objections are raised, a decision has to be taken at Community level. The Commission first asks for the opinion of its Scientific Committees. If the scientific opinion is favourable, the Commission then proposes a draft Decision to the Regulatory Committee composed of representatives of Member States for opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the Decision. If not, the draft Decision is submitted to the Council of Ministers for unanimous adoption or rejection. If the Council does not act within 3 months, the Commission can adopt the decision.

#### **4. What is the current risk assessment procedure?**

There is no scientific evidence that the use of the technology is itself inherently unsafe. The safety of GMOs depends on the characteristics of the inserted gene(s), the final organism that is produced and its application. The objective of the risk assessment is to identify and evaluate potential adverse effects of the GMO(s), either direct or indirect, immediate or delayed, taking also into account the cumulative and long term effects on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The risk assessment also looks specifically how the GM product was developed and examines the risks associated with the gene products in the product (for example toxic or allergenic proteins), and the possibility of a gene-transfer (for example of antibiotic resistance genes).

The methodology of the risk assessment is as follows.

- Identification of any characteristics of the GMO(s) which may cause adverse effects
- Evaluation of the potential consequences of each adverse effect
- Evaluation of the likelihood of the occurrence of each identified potential adverse effect
- Estimation of the risk posed by each identified characteristic of the GMO(s)
- Application of management strategies for risks from the deliberate release or placing on the market of GMO(s)
- Determination of the overall risk of the GMO(s)

The Scientific Committee on Plants (SCP) has issued opinions on 17 GM plants under Directive 90/220/EEC. In one case an unfavourable opinion was given due to an insufficient risk assessment of the presence of a number of uncharacterised genes and particularly the gene which confers resistance to amikacin, a clinically important antibiotic.

Therefore, this product was not allowed onto the market. The Scientific Committee on Food is responsible for opinions relating to Novel Foods. This Committee has issued one favourable opinion on food of plant origin (processed tomato) and 4 on products of microbial origin.

#### **5. What will change when Directive 2001/18 comes into force?**

The revised Directive updates and strengthens the existing rules of the risk assessment and the decision-making process on the release of GMO's into the environment. In particular it introduces mandatory information to the public and general rules on mandatory labelling and traceability at all stages of the placing on the market.

The new Directive also foresees mandatory monitoring requirements of long-term effects associated with the interaction with other GMOs and the environment. Such effects will also be taken into account in the risk assessment carried out prior to authorisation. First approvals for the release of GMO's will be limited to a maximum of ten years, and consultation of the Scientific Committee(s) becomes obligatory. The new Directive also introduces an obligation to consult the European Parliament on decisions to authorise the release of GMO's and the possibility for Council of Ministers to adopt or reject a Commission proposal for authorisation of a GMO by qualified majority.

## **6. How many GMO's have been approved for release into the environment?**

Since Directive 90/220/EEC entered into force in October 1991, the commercial release of 18 GMO's has been authorised in the EU by a Commission Decision, mostly following a qualified majority vote in the Regulatory Committee. In two cases the Commission Decision has not yet been implemented by the Member State (see Annex 1). Since October 1998 no further authorisations have been granted and there are currently 14 applications pending (see Annex 2).

Some Member States have invoked Article 16, the so-called safeguard clause, of Directive 90/220/EEC to temporarily ban the placing on the market of genetically modified maize and oilseed rape products in their territories. There are currently eight ongoing Article 16 cases involving Austria, Luxembourg, France, Greece and Germany. These cases have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by Member States did not justify their bans.

## **7. What are the rules on the marketing of GM foods?**

Regulation (EC) 258/97 on Novel Foods and Novel Food Ingredients sets out rules for authorisation and labelling of novel foods including food products containing, consisting or produced from GMOs.

The first step of an authorisation procedure is an assessment of an application to market a GM food product by the Member State where the food is to be first placed on the market. In case of a favourable opinion, this Member State informs the other Member States via the Commission. If there are no objections against the application, this Member State can authorise the product for marketing in the entire EU.

If there are objections by other Member States, a decision at Community level is required. The Commission consults the Scientific Committees on matters relating to public health and adopts a decision after receiving a favourable opinion from the Regulatory Committee. Once a Decision at Community level is required, the time frame for authorisation is necessarily extended.

As a derogation from the full authorisation procedure, the Novel Foods Regulation provides for a simplified procedure for foods derived from GMOs but no longer containing GMOs which are "substantially equivalent" to existing foods with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances. In such cases, the companies only have to notify the Commission when placing a product on the market together with either scientific justification that the product is substantially equivalent or an opinion to the same effect, delivered by the competent authorities of a Member State.

## **8. How many GMO's have been approved for use in food products?**

Two genetically modified plants, a variety of soya and a variety of maize have been authorised under Directive 90/220/EEC prior to the entry into force of the Novel Foods Regulation, to be on the European market for the use in food. Under the Novel Foods Regulation no products consisting of or containing live GMOs have so far been authorised. Eleven applications concerning such products are pending at different stages in the procedure. Several products produced from GMOs have been notified to the Commission as being substantially equivalent (see Annex 3). The list of notifications is published in the Official Journal of the EU once a year.

## **9. What are the rules on Genetically modified feed?**

No specific Community legislation on GM feed is in place yet. However, eight GMOs are authorised in accordance with Directive 90/220/EEC for the purpose of use in feed; these are four maize varieties, three rape varieties and one soya variety.

## **10. What are the rules on genetically modified seeds?**

Community legislation on seeds, notably Directive- 98/95/EC, specifies that national authorities that have agreed to the use of a seed on their territory must notify this acceptance to the Commission. The Commission examines the information supplied by the Member State concerned and its compliance with the provisions of Community seeds legislation. If such is the case, the Commission includes the variety concerned in the "Common Catalogue of varieties of Agricultural Plant Species" which means the seed can be marketed throughout the EU. The seed legislation furthermore requires that GMO seed varieties have to be authorised in accordance with Directive 90/220/EEC before they are included in the Common Catalogue and marketed in the EU. If the seed is intended for use in food, it also has to be authorised in accordance with the Novel Foods Regulation.

Legislation on the marketing of forestry reproductive material also requires prior authorisation of GM material in line with the requirements of Directive 90/220. The Commission has proposed to amend the Community rules governing the marketing of vine material in line with Directive 90/220/EEC.

In the White Paper on Food Safety the Commission has announced a proposal for a Regulation specifying the conditions for the environmental risk assessment for GM plant varieties. Further rules on growing conditions and other requirements for purity concerning the presence of GM seeds in seed lots of traditional varieties, as well as detailed labelling rules are also to be proposed.

## **11. How many GM seeds have been authorised**

So far only two GMO seed varieties have been included in the Common Catalogue for seed varieties which can be marketed in the EU, after prior authorisation under Directive 90/220/EEC. Applications for the inclusion of three new GMO seed varieties, already approved under 90/220/EEC, are pending.

## **12. What are the rules for Medicines, Protection of workers & Transport**

Authorisation of medicinal products for human and veterinary use (including such derived from genetically modified organisms) is regulated under Regulation (EEC) 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use.

Council Directive 90/679/EEC on the protection of workers from the risks related to exposure to biological agents at work also regulates GMOs alongside other biological agents.

Several pieces of legislation regulate transport of GMOs, in particular the Council Directives on the approximation of laws of Member States with regard to transport of dangerous goods carried by road, rail and inland seaways, the Council Directives on the appointment and vocational qualification of safety advisers for the transport of dangerous goods in the same sectors, as well as a Council Directive on uniform procedures for checks on the transport of dangerous goods by road.

### **13. What are the current rules on labelling?**

The EU recognises the consumers' right for information and labelling as a tool to make an informed choice.

Since 1997 labelling to indicate the presence of GMOs as such or in a product is mandatory.

The Novel Foods Regulation provides for the mandatory labelling of foods and food ingredients which contain or consist of a GMO without prejudice to the other labelling requirements of Community law. The labelling requirements for foods derived from GMO, but no longer containing GMO are more complicated and based on the concept of equivalence<sup>1</sup>. Council Regulation 1139/98 lays down provisions for the labelling of foods and food ingredients derived from one maize and one soya<sup>2</sup> variety based on the presence of DNA or protein resulting from genetic modification. This criterion serves as a model providing the rules applicable to labelling of all foods and food ingredients derived from GMO.

In January 2000, the Commission adopted Regulation (EC) 50/2000 ensuring that also additives and flavourings have to be labelled if DNA or protein of GMO origin is present in the final product.

Regulation (EC) 49/2000 addresses the problem of adventitious contamination of GM material in conventional food. It introduces a 1% *de minimis* threshold for DNA or protein resulting from genetic modification below which labelling is not required, if operators can demonstrate that they have used appropriate steps to avoid the presence of GM material.

Genetically modified seed varieties must be labelled, in accordance with Council Directive 98/95/EEC. The label has to show clearly that it is a GM variety.

Currently, there is no specific Community legislation on the labelling of GMO feed. The general labelling rules under Directive 90/220/EEC apply. A new Novel Feed legislation will foresee provisions for labelling.

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<sup>1</sup> This means that if a characteristic or property (composition, nutritional value or nutritional effects, intended use) renders a food or food ingredient no longer equivalent to an existing counterpart, it has to be labelled indicating the method (i.e. genetic modification) by which the characteristic or property was obtained.

<sup>2</sup> These varieties were approved before the entering into force of the Novel Foods Regulation under Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

**GMO PRODUCTS – APPROVED UNDER DIRECTIVE 90/220/EEC  
as of March 2001**

<b>Product</b>	<b>Notifier</b>	<b>Date of Commission Decision<sup>3</sup> / Member State Consent<sup>4</sup></b>
1. Vaccine against Aujeszky's disease	Vemie Veterinär Chemie GmbH	18.12.92
2. Vaccine against rabies	Rhône-Mérieux C/B/92/B28 & C/F/93/03-02	19.10.93
3. Tobacco tolerant to bromoxynil	SEITA C/F/93/08-02	08.06.94
4. Vaccine against Aujeszky's disease (further uses) <sup>5</sup>	Vemie Veterinär Chemie GmbH C/D/92/I-1	18.07.94
5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1) <u>Uses</u> : breeding activities	Plant Genetic Systems C/UK/94/M1/1	06.02.96
6. Soybeans tolerant to glyphosate <u>Uses</u> : import and processing	Monsanto C/UK/94/M3/1	03.04.96
7. Male sterile chicory tolerant to glufosinate ammonium <u>Uses</u> : breeding activities	Bejo-Zaden BV C/NL/94/25	20.05.96
8. Bt-maize tolerant to glufosinate ammonium (Bt-176)	Ciba-Geigy C/F/94/11-03	23.01.97
9. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1) <sup>6</sup>	Plant Genetic Systems C/F/95/05/01/A	06.06.97

<sup>3</sup> where objections were raised by Member State authorities

<sup>4</sup> in the absence of objections by Member State authorities

<sup>5</sup> linked to item 1 (same product, further uses)

<sup>6</sup> linked to item 5 (same product, further uses)

<b>Product</b>	<b>Notifier</b>	<b>Date of Commission Decision<sup>7</sup> / Member State Consent<sup>8</sup></b>
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2) <sup>9</sup>	Plant Genetic Systems C/F/95/05/01/B	06.06.97
11. Test kit to detect antibiotic residues in milk	Valio Oy C/F1/96-1NA	14.07.97
12. Carnation lines with modified flower colour	Florigene C/NL/96/14	01.12.97 (MS consent)
13. Swede rape tolerant to glufosinate ammonium (Topas 19/2) <u>Uses</u> : import and processing	AgrEvo C/UK/95/M5/1	22.04.98
14. Maize tolerant to glufosinate ammonium (T25)	AgrEvo C/F/95/12/07	22.04.98
15. Maize expressing the Bt <i>cryIA(b)</i> gene (MON 810)	Monsanto C/F/95/12-02	22.04.98
16. Maize tolerant to glufosinate ammonium and expressing the Bt <i>cryIA(b)</i> gene (Bt-11) <u>Uses</u> : import and processing	Novartis (formerly Northrup King) C/UK/96/M4/1	22.04.98
17. Carnation lines with improved vase life	Florigene C/NL/97/12	20.10.98 (MS consent)
18. Carnation lines with modified flower colour	Florigene C/NL/97/13	20.10.98 (MS consent)

<sup>7</sup> where objections were raised by Member State authorities

<sup>8</sup> in the absence of objections by Member State authorities

<sup>9</sup> this product is the result of a different transformation event to that of No. 9

**GMO PRODUCTS - PENDING APPROVAL UNDER DIRECTIVE 90/220/EEC  
as of March 2001**

Product notification details	Company
<p><b>1. Maize expressing the Bt <i>cryIA(b)</i> gene (MON 809)</b> from France (C/F/95/12-01/B) Received by the Commission: 06.08.96</p> <p><u>uses:</u> as any other maize</p>	<b>Pioneer</b>
<p><b>2. Male sterile chicory<sup>10</sup></b> from the Netherlands (C/NL/94/25/A) Received by the Commission: 20.09.96</p> <p><u>uses:</u> food and feed</p>	<b>Bejo-Zaden BV</b>
<p><b>3. Swede rape tolerant to glufosinate ammonium (FALCON GS40/90)</b> from Germany (C/DE/96/5) Received by the Commission: 25.11.96</p> <p><u>uses:</u> as any other swede rape</p>	<b>AgrEvo GmbH</b>
<p><b>4. Male sterile swede rape tolerant to glufosinate ammonium (MS8, RF3)</b> from Belgium (C/BE/96/01) Received by the Commission: 16.01.97</p> <p><u>uses:</u> as any other swede rape</p>	<b>Plant Genetic Systems</b>
<p><b>5. Fodder beet tolerant to glyphosate</b> from Denmark (C/DK/97/01) Received by the Commission: 09.10.97</p> <p><u>uses:</u> production of seeds and roots, animal feed</p>	<b>DLF-Trifolium, Monsanto and Danisco Seed</b>
<p><b>6. Tomato with reduced activity of the expression of the endogenous tomato fruit PG gene</b> from Spain (C/ES/96/01) Received by the Commission: 24.11.97</p> <p><u>uses:</u> as any other processing tomato</p>	<b>Zeneca</b>

<sup>10</sup> This is the same product as No. 7 on the list of approved GMOs, which was restricted to breeding activities.

Product notification details	Company
<p><b>6. Cotton expressing the Bt <i>cryIA(c)</i> gene (line 531)</b>  from Spain (C/ES/96/02)  Received by the Commission: 24.11.97</p> <p><u>uses</u>: as any other cotton</p>	<p><b>Monsanto</b></p>
<p><b>7. Cotton tolerant to herbicide (line 1445)</b>  from Spain (C/ES/97/01)  Received by the Commission: 24.11.97</p> <p><u>uses</u>: as any other cotton</p>	<p><b>Monsanto</b></p>
<p><b>8. Potato with altered starch composition</b>  from Sweden (C/SE/96/3501)  Received by the Commission: 20.05.98</p> <p><u>uses</u>: as any other starch potato</p>	<p><b>AMYLOGENE</b></p>
<p><b>9. Swede rape tolerant to glufosinate ammonium (Liberator)</b>  from Germany (C/DE/98/6)  Received by the Commission: 29.10.98</p> <p><u>uses</u>: as any other swede rape</p>	<p><b>AgrEvo GmbH</b></p>
<p><b>10. Maize tolerant to glufosinate ammonium and expressing the Bt <i>cryIA(b)</i> gene (Bt-11)<sup>11</sup></b>  from France (C/F/96/05-10) and Spain (C/ES/98/02)  Received by the Commission: 12.04.99 and 03.05.99 respectively  <u>Uses</u> : cultivation</p>	<p><b>Novartis</b></p>
<p><b>11. Maize tolerant to glufosinate ammonium and expressing the Bt <i>cryIA(b)</i> gene (T25 + MON810)<sup>12</sup></b>  from the Netherlands (C/NL/98/08)  Received by the Commission: 29.04.99</p> <p><u>uses</u>: as any other maize</p>	<p><b>Pioneer</b></p>

<sup>11</sup> This is the same product as No. 16 on the list of approved GMOs, which was restricted to import and processing

<sup>12</sup> This product is obtained from conventionally derived crosses between Nos. 14 and 15 on the list of approved GMOs

Product notification details	Company
<p><b>6. Maize tolerant to glyphosate (GA21)</b>  from Spain (C/ES/98/01)  Received by the Commission: 20.05.99</p> <p><u>uses:</u> as any other maize</p>	<p><b>Monsanto</b></p>
<p><b>7. Maize tolerant to glyphosate (GA21)<sup>13</sup></b>  from the United Kingdom (C/GB/97/M3/2)  Received by the Commission: 28.10.99</p> <p><u>uses:</u> import and processing</p>	<p><b>Monsanto</b></p>

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<sup>13</sup> This is the same as product 13 on the list, but for restricted use (not cultivation)

**Notifications Pursuant to Article 5 of Regulation (EC) N° 258/97 of the European Parliament and of the Council**

	<b>Applicant</b>	<b>Description of Food or Food Ingredient</b>	<b>Scientific Evidence</b>	<b>Notification</b>	<b>Transmission to Member States</b>
1	AgrEvo UK Limited Chesterford Park Saffron Walden UK - Essex CB10 1XL	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	“Report on oil from a genetically modified (GM) glufosinate ammonium tolerant oilseed rape” (ACNFP)*	9 June 1997	24 June 1997
2 a	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B – 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF2	“Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape” (ACNFP)*	10 June 1997	24 June 1997  again  28 July 1998
2 b	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF1	“Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape” (ACNFP)*; and “Report on oil from genetically modified oilseed rape” (ACNFP)*	10 June 1997	24 June 1997  again  28 July 1998
3	Monsanto Services International S.A Avenue de Tervuren 270-272 B - 1150 Brussels	Refined oil from glyphosate tolerant oilseed rape line GT73	“Report on oil from genetically modified (GM) glyphosate tolerant oilseed rape” (ACNFP)*	10 November 1997	21 November 1997
4	Monsanto Services	Food and food ingredients	“Report on processed products	10 December 1997	6 February 1998

	International S.A Avenue de Tervuren 270-272 B - 1150 Brussels	produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil derived from the progeny of maize line MON 810	from genetically modified (GM) insect protected maize" (ACNFP)*		
5	AgrEvo France S.A. Les Algorithmes Bâtiment Thalès Saint Aubin F - 91197 Gif-sur-Yvette Cedex	i) Starch and all its derivatives; ii) crude and refined oil; iii) all heat-processed or fermented products obtained from hominys, grits and flour (dry milled fragments) obtained from the genetically modified maize, tolerant to glufosinate ammonium, transformation event T25 and all the varieties derived from	"Report on processed products from genetically modified (GM) glufosinate ammonium tolerant maize" (ACNFP)*	12 January 1998	6 February 1998
6	Novartis Seeds AG Schwarzwaldallee 215 CH - 4058 Basel	Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes	ACNFP* Report on grain from maize genetically modified for insect resistance	30 January 1998	6 February 1998
7	Pioneer Overseas Corporation Avenue Tedesco, 7 B – 1160 Brussels	Novel foods and novel food ingredients produced from genetically modified maize line MON 809	ACNFP* Report on genetically modified (GM) insect protected maize Pioneer Hi-bred International – line MON 809	14 October 1998	23 October 1998
8	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D – 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Falcon GS 40/90	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Falcon GS/40/90 gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999

9	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D – 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Liberator L62	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Liberator pHoe6/Ac gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
10	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B – 9000 Gent	Processed oil from genetically modified oilseed rape derived from: the male sterile MS8 (DBN 230-0028) oilseed rape line and all conventional crosses; the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses; the hybrid combination MS8 x RF3	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte MS8/RF3 gewonnenen, raffinierten Speiseöls	21 October 1999	8/9 November 1999
11	F. Hoffman – La Roche Ltd. Vitamins & Fine Chemicals Regulatory Affairs Bldg 241/283 CH – 4070 Basel	Riboflavin from <i>Bacillus subtilis</i> as nutrient	ACNFP* Report on Riboflavin from fermentation using genetically modified (GM) <i>Bacillus subtilis</i>	20 March 2000	26 April 2000

i\* **ACNFP** Advisory Committee on Novel Foods and Processes (UK)

\*\* **BgVV** Bundesamt für gesundheitlichen Verbraucherschutz und Veterinärmedizin (D)