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Questions and Answers on Genetically Modified Organisms (GMO's)

Why is the Commission taking this Decision for the cultivation of the GM Amflora potato now?

The favourable European Food Safety Authority (EFSA) opinion on the cultivation of this starch potato was issued in February 2006. This opinion confirmed the favourable opinion of Sweden of 2004. Since that time, the Commission has been very carefully and very seriously reflecting on the situation. In particular, the Commission decided, during its College meeting of 8 May 2008, to request a new EFSA opinion. The objective was to obtain a new and authoritative opinion on the Antibiotic Resistance Marker (ARM) gene. The College also indicated that in case of a new positive EFSA opinion, decisions would have to be taken accordingly.

On 11 June 2009, EFSA, in collaboration with scientists from EMEA and ECDC, provided a new positive opinion. When the analysis of this opinion was finalised, the Commission was already in the transitional period brought about by the delay in the implementation of the Lisbon Treaty. It was, therefore, decided that it would be more appropriate to proceed with this authorisation when normal business would resume under the new College.

Given the high scrutiny that was devoted to this dossier, given the fact that there are presently no new scientific issues which merit a further assessment and in view of the repeated scientific opinions, it is now appropriate to proceed with this authorisation. This is also in line with the principle of responsible innovation.

Is this Decision on Amflora scientifically backed?

A considerable amount of sound scientific work constitutes the basis of this decision.

The request of authorisation for the placing on the market of Amflora potato received a first favourable opinion in Sweden that was initially in charge of the risk assessment. While some Member States had objections to this assessment, EFSA repeatedly confirmed the favourable safety assessment.

Potato is by nature a crop that poses little risk of spreading into the environment or of transferring its genes to other plants. As outlined in the EFSA opinion: "Potato rarely survives outside the cultivated environment and there is no indication of enhanced weediness or invasiveness of the GM potato. Potato has no cross-compatible wild relatives in Europe. Since it is vegetatively propagated and the natural exchange of genetic material is only possible with other varieties of potato, there is negligible risk to the environment of any transgene flow. Therefore, no unintended environmental effects due to the establishment and spread are anticipated."

However, the fact that the GM potato harbours an ARM gene has deserved high scrutiny.

The first opinion of EFSA on ARM genes was adopted in April 2004. It considered that nptII (the gene that is in the GM potato) can be used in commercially cultivated plants because:

- the risk of gene transfer from plant to bacteria is remote (a common feature for all ARMs);
- the resistance to the antibiotics at stake can already be found in the soil and in bacteria in animal and human intestines;
- these antibiotics have only minor therapeutic relevance in human medicine.

In 2007, EFSA agreed with EMEA that the preservation of the therapeutic relevance of the antibiotics kanamycin and neomycin is important (the World Health Organisation (WHO) considers them as "highly important antimicrobials"). Notwithstanding these considerations, EFSA confirmed the safety of nptII by indicating that the use of this gene in GM plant will not affect the therapeutic effect of these antibiotics.

In June 2009, EFSA issued a new opinion. In accordance with the mandate of the Commission, this opinion focuses on the safety of the nptII gene and it was made with the assistance of experts from EMEA and ECDC. It reiterates the favourable opinion on the Amflora potato (although with 2 minority opinions).

EFSA has always issued favourable opinions for GM plants containing the ARM gene present in the Amflora potato. EFSA also refers to several scientific reviews confirming the safety of the nptII gene.

Why is the Commission adopting two decisions on the GM starch potato?

The first decision is related to the Cultivation and is adopted under Directive 2001/18/EC.

The complementary authorisation is taken under Regulation (EC) No 1829/2003 on GM food and feed. It covers the by-products of the starch extraction when they are used as feed. It also covers the unintended presence of GM potato tubers in food and feed. While all measures are in place to prevent that the starch potato is mixed with potato for food and feed, it can never be totally excluded. This is why this unintended presence has also been thoroughly assessed by EFSA and covered by an authorisation up to a level of 0.9%.

What are Antibiotic Resistance Marker (ARM) genes?

The process of introducing new genes for the production of GM plants involves, in its first stage, many plant cells out of which only a fraction successfully incorporates the new genes. In order to easily identify and select the cells with the newly introduced genes, the genes carrying the desired traits are associated from the beginning to so-called "marker genes." The first development of GMO's has been associated with the use of genes coding for antibiotic resistance as marker genes. Using these markers, only the cells that are genetically modified are resistant to the antibiotics in question and are kept in the process of selection for a GM plant.

The use of these ARM genes has always generated concerns regarding potential development of antibiotic resistance. This is the reason why Directive 2001/18 on the deliberate release of GMO's provides that "Member States and the Commission shall ensure that GMO's, which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment, are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out ARMs in GMO's which may have adverse effects on human health and the environment."

Are there other GM products that are already authorised and that contain antibiotic resistance marker genes?

Yes. MON863 maize contains the *nptII* gene that confers resistance to the antibiotics kanamycin and neomycin. The placing on the market of this maize for all uses with the exception of cultivation is authorised in the EU since 2006.

The cottons MON531, MON1445, MON15985, MON15985xMON1445, and MON531xMON1445 contain both the *nptII* and the *aadA* (that confers resistance to the antibiotic Streptomycin) genes.

Are there specific measures foreseen to control the effects on the environment and with respect to coexistence?

It has to be noted that, contrary to the situation with many other crops, the potato species does not rely on cross-pollination with other potatoes to reproduce. It is vegetatively propagated.

With respect to risk management measures, the potato will be cultivated and harvested before it produces seeds, eliminating the possibility of inadvertent seed dissemination and persistence into the wider environment.

Measures to avoid unintentional re-growth will also be taken. The sale of the GM potato will be subject to an agreement between BASF and the operators. According to this agreement, (i) conventional potatoes can not be planted in the same field the year following the cultivation of the GM potato (ii) the fields shall be monitored during the following growing season and any volunteer potatoes shall be destroyed. Any potato volunteers that may appear post-harvest will be relatively easy to control by using pesticides, particularly as potatoes are not grown in the same field for successive growing seasons as a part of crop rotation.

Are there measures in place to prevent the mixing of this GM potato with conventional or organic potatoes?

The authorising Decision contains three obligations for the consent holder to prevent the presence of the GM potato tubers in the food and feed chain. These obligations will also be part of the contracts to be signed between BASF and the operators involved in the production chain (farmers and starch producers). In particular; measures have to be taken to:

- ensure that the potato tubers will be physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling in the environment;
- ensure that conventional potatoes can not be planted in the same field the year following the cultivation of the GM potato.
- ensure that the potato tubers shall be delivered exclusively to designated starch processing plants for processing into industrial starch within a closed system.

Adventitious presence can never be totally excluded. This is why this unintended presence of GM potato tubers in other potatoes has also been thoroughly assessed by EFSA and is authorised with a maximum level of 0.9%.

What are starch potatoes and what is the use of this genetically modified starch potato?

Starch potatoes are specific varieties of potatoes that have been selected for the production of starch. They are not used for food purposes since they do not have the necessary organoleptic properties. However, the by-product of the starch production (pulp of the potato) is used as feed.

The cultivation of starch potato is closely linked to the proximity of a starch producing plant since the transport costs are high and the conservation time of potatoes is low. Starch potatoes are mainly cultivated in the following Member States: Germany, The Netherlands, France, Denmark and Poland. Other producers include Austria, Finland, Sweden and Czech Republic.

Conventional potatoes produce a mixture of amylopectin and amylose starch. This GM potato has been developed, to produce starch composed almost exclusively of amylopectin (starch content of 98%, which is around 20% higher than starch potatoes normally have). For many technical applications, such as in the paper, textile and adhesives industries, only amylopectin is needed. This genetic modification helps to optimise the production process and to save raw materials, energy and water- and oil-based chemicals.

What is the procedure for authorising the placing on the market of GMO's?

There are two different types of authorisation procedures:

1) Procedure relating to GMOs and the environment

Under Directive 2001/18/EC, a company intending to market a GMO must submit to the competent national authority of an EU Member State an application. It must include an evaluation of the environmental risks. The national authority must issue an opinion which will take the form of an "assessment report," which may be favourable or unfavourable.

In the event of a favourable opinion, the Member State informs the other Member States via the European Commission. The other Member States and the Commission examine the assessment report and may issue observations and objections.

If there are no objections by other Member States or by the European Commission, the competent authority that carried out the original assessment authorises the placing on the market of the product throughout the European Union. The authorisation has a maximum duration of ten years and may be renewed. If objections are raised (which is the majority of the cases), the procedure provides for a conciliation phase among the Member States, the Commission and the notifier. The objective of this phase is to resolve the outstanding questions.

If at the end of the conciliation phase the objections are maintained, a decision must be taken at European level. The Commission first asks for the opinion of the EFSA. The Commission then presents a draft decision to the Regulatory Committee composed of representatives of the Member States for an opinion. If the Committee gives a favourable opinion by qualified majority, the Commission adopts the decision.

If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months, the Commission shall adopt the decision. During the notification process, the public is also informed and has access to the publicly available data on the Internet

2) Procedure relating to GM food and feed

Regulation (EC) No 1829/2003 on genetically modified food and feed lays down a procedure for issuing authorisations for placing on the market of genetically modified food and feed as well as for cultivation for the production of food and feed. In this procedure, the Commission's role is crucial. Notably, it is up to the Commission to adopt the final decision and grant or reject the authorisation if the Committee composed of representatives of the Member States, and the Council do not manage to adopt the decision by qualified majority within a given time frame.

Applications are submitted first to the competent authority of a Member State. The application must clearly define the scope of the application, indicate which parts are confidential and must include a monitoring plan, a labelling proposal and a detection method.

The application and any supplementary information supplied by the applicant must be made available to EFSA, which is responsible for the scientific risk assessment covering both the environmental risk and the human and animal health safety assessment. Its opinion will be made available to the public and the public will have the opportunity to make comments.

In general, there is a time limit of six months for EFSA to deliver its opinion. This time limit can be extended if EFSA has to request further information from the applicant. Within three months of receiving the opinion of EFSA, the Commission will draft a proposal for granting or refusing authorisation. The Commission may diverge from EFSA's opinion, but it must then justify its position. The Commission's proposal must be approved through qualified majority by the Member States within the Standing Committee on the Food Chain and Animal Health (SCoFAH), composed of representatives of the Member States.

If the Committee gives a favourable opinion, the Commission adopts the Decision. If not, or in the event the Committee rejects the Commission's proposal by qualified majority, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority.

If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision.

What is the procedure that has been followed for the authorisation of the cultivation of the GM potato?

The German company BASF Plant Science submitted a request for authorisation in Sweden in January 2003.

In April 2004, the Swedish competent authority forwarded its assessment report to the Commission. It concluded that the genetically modified potato should be placed on the market for its intended uses. The Commission forwarded the full notification and assessment report to the other Member States in May 2004.

The competent authorities of some Member States raised objections to the placing on the market of the products on the basis of molecular characterisation, allergenicity, toxicity, an inadequate monitoring plan and the detection method of the product.

In light of these objections, EFSA was consulted and delivered its opinion on 24 February 2006. It concluded that the genetically modified potato (*Solanum tuberosum* L. line EH92-527-1) is unlikely to have an adverse effect on human and animal health or on the environment in the context of its proposed uses.

Following the positive assessment by EFSA, a draft Commission decision to place the product on the market was presented to the Regulatory Committee for a vote on 4 December 2006. The Committee failed to deliver, by qualified majority, an opinion on the draft submitted by the Commission.

In 2007, EFSA agreed with EMEA that the preservation of the therapeutic relevance of the antibiotics kanamycin and neomycin is important (the World Health Organisation (WHO) considers them as "highly important antimicrobials"). Notwithstanding these considerations, EFSA confirmed the safety of nptII by indicating that the use of this gene in GM plant will not affect the therapeutic effect of these antibiotics.

Consequently, the Commission was required to submit to the Council a proposal relating to the measures to be taken; the Council having three months in which to act by a qualified majority. The proposal was considered by the Agriculture and Fisheries Council on 16 July 2007. No qualified majority was reached at the Council.

On 11 June 2009, EFSA published a statement on the use of ARM genes in GM plants which concludes that the previous assessment of EFSA on genetically modified potato EH92-527-1 is in line with the risk assessment strategy described in the statement, and that no new evidence has become available that would prompt EFSA to change its previous opinion.

Are there still additional procedural steps needed to allow the cultivation? When will the cultivation start?

The decision of authorisation for cultivation adopted under directive 2001/18 is addressed to Sweden that carried out the original assessment. In accordance with this procedure, Swedish authorities have 30 days to issue the final consent to the company.

The GM starch potato will be sold by the company BASF on the basis of contracts signed with the operators (farmers and starch processors).

The company BASF plans the commercial cultivation in Czech Republic and Germany for this year (the planting season starts in April). For the coming years, the company indicated that it had already an agreement for the additional commercial cultivation in The Netherlands and Sweden.

Is this decision an indication of what the Commission will be doing with the GMOs in the coming months?

In his political guidelines presented in September 2009, President Barroso states that it should be possible to combine a Community authorisation system, based on

science, with the freedom of Member States to decide whether or not they wish to cultivate GMOs in their territory.

In the case of the Amflora potato, the four Member States (Germany, the Czech Republic, Sweden and The Netherlands) in which cultivation of the Amflora potato is anticipated by the Company BASF in the coming years expressed themselves in favour of the authorisation.

The Commission is currently reflecting on the most efficient way to implement these guidelines.

Why is the Commission also authorising today three GM maize products?

The three GM maize products that were authorised today for food and feed uses with the exception of cultivation are the following: MON863xNK603, MON863xMON810 and MON863xMON810xNK603. These maize products are resulting from the combination, by conventional breeding, of genetic modifications that are already authorised.

Since the genetic modification of the MON863 maize harbours the same marker gene as the Amflora potato, the final decision of authorisation was also to be taken after the last EFSA opinion on antibiotic resistance marker genes.

Are some GMO's already cultivated in the EU?

Yes. There is one GM maize -"MON 810"- that is commercially cultivated in the EU. Its genetic modification aims to protect against the European corn borer.

It was authorised in 1998 and as of today there are more than 140 different varieties of this GM maize that are registered in the EU common catalogue of varieties.

In 2009, MON810 was cultivated in 5 Member States: Spain, the Czech Republic, Romania, Portugal, and Slovakia. Spain cultivates around 80 % of the total EU area used for the cultivation of MON810 (circa 100 000 ha).

The procedure to renew the EU authorisation is currently ongoing. EFSA adopted a favourable opinion in August 2009 and the Commission is considering the next steps in accordance with the comitology procedure.

In this context, it is also worth to note that six Member States (Austria, Hungary, France, Greece, Germany, and Luxembourg) adopted safeguard clauses and prohibit the cultivation of GM maize on their territories. In addition, Poland has legislation in place forbidding cultivation of all GMOs.

These safeguard measures on the cultivation of MON 810 will be viewed within the light of the solution to be proposed by the Commission by the summer.

Are there any other GMO's on which the Commission could take decision in the near future?

The MON810 excluded, the Commission will also have to take decisions on three other GM maize products that have received favourable EFSA opinions.

The first two are GM Bt maize which confer protection to the plant against insects. These two maize are Bt maize Bt 11 (from the company Syngenta) and Bt Maize 1507 (from the company Pioneer). They are in the middle of the Comitology procedure since proposals of authorisations did not receive the necessary support of the Regulatory Committee. The Commission should now decide whether it is appropriate to transmit to the Council proposals for authorisation.

The third one is maize NK 603 (from the Company Monsanto) that is tolerant to the herbicide RoundUp. The favourable EFSA opinion was adopted in June 2009 and the Commission should take a decision regarding the submission of a draft decision to SCoFCAH (first step of the comitology procedure).

For more information please see:

http://ec.europa.eu/environment/biotechnology/index_en.htm

http://ec.europa.eu/food/food/biotechnology/index_en.htm