EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Brussels, 6.7.2010
C(2010) 4632

Dear

Subject: Request for internal review of the two Decisions authorising the cultivation and the placing on the market as food and feed of a genetically modified potato product

Thank you for your letter dated 14 April 2010 whereby you requested, on behalf of your organisation, the Commission to review its Decisions 2010/135/EU[1] and 2010/136/EU[2] both dated 2 March 2010, authorising the placing on the market of a potato product genetically modified (genetically modified potato EH92-527-1) for enhanced content of the amylopectin component of starch and for the placing on the market of feed produced from this genetically modified potato and the adventitious presence of the potato in food and other feed products under Directive 2001/18/EC of the European parliament and of the Council[3] and Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed[4] respectively.

Your request for internal review has been lodged on the basis of Title IV of Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies[5].

You argue that these Commission Decisions are unlawful because they infringe Article 4 (2) of Directive 2001/18/EC.

Justice & Environment
Dvorakova 13
602 00 Brno
CZECH REPUBLIC

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[1] OJ L 53, 04.03.2010, p. 11.
[2] OJ L 53, 04.03.2010, p. 15.
[3] OJ L 106, 17.04.2001, p. 1.
[4] OJ L 268, 18.10.2003, p. 1.
[5] OJ L 264, 25.9.2006, p. 13.

Article 4 (2) of Directive 2001/18/EC reads as follows:

"Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs 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 antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B".

You consider that the two authorisation Decisions and the use of ARM in the authorised products constitutes a violation of Directive 2001/18/EC because the above-mentioned 2004 and 2008 phasing out obligations of ARMs were, allegedly, not respected (point 2 of your request).

Additionally, in your request (point 4), you give an interpretation of Article 4(2) of Directive 2001/18/EC according to which a distinction should be made between an evaluation of potential adverse effects of ARM genes based on their intrinsic properties and an evaluation based on the particular circumstances or the particular use of such genes. According to your view, the Commission erroneously took the contested Decision in light of the second interpretation.

The Commission however cannot follow this interpretation of the above mentioned Directive.

According to the Commission, Article 4 of the said Directive explicitly mentions that the phasing out obligation concerns antibiotic resistance markers which might have adverse effects on human health and the environment.

In this regard the Commission would like to emphasise that it follows from the said provision that the criteria to take into account when deciding to phase out GMOs containing antibiotic resistance markers, are their potential adverse effects on human health and environment following the environmental risk assessment.

In 2009 EFSA published a scientific opinion made with the assistance of experts from the European Medicine Agency (EMA) and from the European Centre for Disease Prevention and Control (ECDC). It recognised the therapeutic relevance of kanamycin and neomycin and concluded by reiterating its previous favourable opinion on Amflora potato based on the low probability of gene transfer from plants to bacteria and to the fact that this antibiotic resistant gene in bacteria is already widespread in the environment. EFSA has always issued favourable opinions for GM plants containing the ARM gene present in the Amflora potato.

Indeed, as you mention in your request EFSA published in 2009 its consolidated opinion in this regard according to which such adverse effects, as a result of the use of these genes, are unlikely.

Therefore we do not share your prima facie analysis that there is a violation of the wording and spirit of Article 4(2) of Directive 2001/18/EC as the conditions for the application of this Article *i.e.* possibility of adverse effects, were not met based on the EFSA opinion on this issue.

In light of the above-mentioned, we therefore do not consider either that Article 4(2) of Directive 2001/18/EC requires that the Commission decides to phase out a GMO containing genes expressing resistance to antibiotics "by reason of its intrinsic properties or characteristics," independently of the probability of its adverse effect to be realised.

Furthermore, you consider that the risk assessment of EFSA is legally flawed because of the fact that it took into account the realistic value of the threat to antibiotics and thus committed a procedural error (point 3 of your request). The Commission considers that taking into account the realistic value of a threat, in the framework of the procedures to be followed for its assessment under both Directive 2001/18/EC and Regulation (EC) No 1829/2003 does by no means infringe any procedural obligation EFSA might have under the specific legal framework for the assessment of GMOs. On the contrary, EFSA is under the obligation to take into consideration for its evaluation all realistic threats that the substance might pose to human health and the environment and not doing so would be infringing the law of logics.

Finally as concerns your allegations on the EFSA classification system, the fact that the classification of nptll in Group I contradicts EFSA's and EMA's opinions and your concerns on gentamicin (points 5, 6 and 7 of your request) the Commission considers that the 2009 EFSA opinion is a consolidated opinion which took into consideration the previous EFSA, EMA as well as ECDC opinions on this issue.

On the basis of the aforementioned observations, the Commission considers that there is no contradiction between the above mentioned Decisions and Directive 2001/18/EC.

As a consequence, Decisions 2010/135/EU and 2010/136/EU are in line with provisions of law regarding to the environment and do not need to be amended by the Commission.

Should you not agree with the present reply, you may bring the matter before the Ombudsman or before the General Court if you have a complaint which falls within the conditions laid down in Articles 228 and 263 respectively of the Treaty on the Functioning of the European Union.

Yours sincerely,

John Dalli
Member of the Commission