

Request for Internal Review

EUROPEAN COMMISSION

John DALLI

Member of the European Commission, responsible for Health and Consumer Policy

DG Health and Consumers (DG SANCO)

B-1049 BRUSSELS

Belgium

Dear Mr. John DALLI,

Justice & Environment represented by the undersigned **dr. Csaba Kiss** as Chair hereby submits to the European Commission the following

r e q u e s t f o r i n t e r n a l r e v i e w

pursuant to Article 10 of the **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** against the following European Union legal acts:

- **2010/135/EU** – Commission Decision of 2 March 2010 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 (*notified under document C(2010) 1193*)(1)
- **2010/136/EU** – Commission Decision of 2 March 2010 authorizing the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*notified under document C(2010) 1196*)(1)

Justice & Environment believes that the two aforementioned Commission Decisions by infringing Article 4 (2) of Directive 2001/18/EC are unlawful.

Detailed reasoning to the request for internal review:

A)

The Applicant

Justice & Environment (hereafter J&E) is a network of public interest environmental law organizations based in the EU member states (see: www.justiceandenvironment.org).

J&E is legally registered as an “association with full legal capacity” according to the respective domestic law under the file number **34213713** by the Dutch Chamber of Commerce.

The statutory seat of J&E is in Amsterdam (the Netherlands) at Plantage Middenlaan 2D, 1018 DD Amsterdam, the Netherlands.

The center of operation of J&E is in Brno (Czech Republic) at Dvořákova 13, 602 00 Brno, Czech Republic.

The current members of J&E are:

- The Center for Environmental Public Advocacy (VIA IURIS, Slovakia)
- The Estonian Environmental Law Center (EELC, Estonia)
- The Environmental Law Service (EPS, Czech Republic)
- The Environmental Management and Law association (EMLA, Hungary)
- The Legal Information Centre (PIC, Slovenia)
- ÖKOBÜRO – Koordinationsstelle österreichischer Umweltorganisationen (ÖKOBÜRO, Austria)

The Association for Environmental Justice (AJA, Spain), the Centre for Legal Resources (CRJ, Romania), the Front 21/42 (Macedonia), the International Institute for Law and the Environment (IIDMA, Spain), the Milieukontakt International (MKI, the Netherlands) and the Zelena Akcija (ZA, Croatia) are associate members of J&E.

J&E aims to use law to protect people, the environment and nature. Its primary goal is to ensure the implementation and enforcement of the EU legislation through the use of European law and exchange of information.

The J&E Network is a non partisan independent NGO.

B)

Criteria set by the Regulation (EC) No. 1367/2006 of the European Parliament and of the Council

J&E meets the criteria set by the Regulation (EC) No. 1367/2006 of the European Parliament and of the Council required from a non-governmental organization to be able to submit a request for internal review. The aforementioned criteria are set in two articles:

Article 10 Paragraph 1

“any non-governmental organization”

J&E clearly and undoubtedly falls under the category of a non-governmental organization which is demonstrated by the fact that it is registered as an association by the Dutch Chamber of Commerce.

Article 11

“(a) it is an independent non-profit-making legal person in accordance with a Member State’s national law or practice;”

J&E is independent from both governmental and business interests which is demonstrated by the fact that its full and voting membership only includes non-profit non-governmental organizations registered in European Union Member States such as Austria, Czech Republic, Estonia, Hungary and Slovakia.

J&E is also a non-profit-making entity which is demonstrated by the respective provisions of its statute.

J&E is a legal person which is demonstrated by the fact that it is registered as an association by the Dutch Chamber of Commerce.

J&E is registered in accordance with the national law of the Netherlands, the latter being a Member State of the European Union (Community) since 1957.

“(b) it has the primary stated objective of promoting environmental protection in the context of environmental law;”

J&E aims to use law to protect people, the environment and nature. Its primary goal is to ensure the implementation and enforcement of the EU legislation through the use of European law and exchange of information.

J&E works on the EU and national levels. Internationally, J&E focuses on implementation and transposition of horizontal as well as sectoral legal issues. The strong grass roots contacts of its members encourages J&E to concentrate on horizontal problems with the Aarhus Convention and related legislation, Environmental Impact Assessment, Environmental Liability, Pollution, Waste, GMO, Natura 2000, Transport and organizational capacity.

J&E cooperates with the Green 10. As a legal specialist, J&E fills a niche in providing hard legal evidence for the lobbying efforts of EU level environmental NGOs. Organizations such as the EEB, Bankwatch, ClientEarth, T&E, FoE and Birdlife International cooperate with J&E in their actions. The information flow is two-ways: J&E also receives information from the Green 10 on the current issues in EU policy development and lawmaking, enabling it to keep up with the state of the play. J&E then re-distributes this information to its network members.

What does J&E do in detail?

- National Transposition Legal Analyses
- Collecting Case Studies
- Compiling Position Papers
- Submitting Strategic Complaints
- Discussion and Education
- Outreach
- Needs Analysis

“(c) it has existed for more than two years and is actively pursuing the objective referred to under (b);”

J&E has been established informally in 2003 and subsequently officially incorporated in September 2004.

J&E has been registered by the Dutch Chamber of Commerce on 30 September, 2004.

J&E has been operational since its incorporation.

J&E has been granted operational funding by the Commission under the LIFE+ NGO grant scheme between 2006 and 2009.

“(d) the subject matter in respect of which the request for internal review is made is covered by its objective and activities.”

The subject matter of the Commission Decisions in respect of which the present request for internal review is made concerns the regulation of Genetically Modified Organisms (GMOs). J&E has dealt with GMOs in the previous years in numerous aspects, such as

- GMO regulation needs analysis during the preparation for the Workplan 2007
- protection of biodiversity in the implementation of the Workplan 2006 and Workplan 2007 of J&E
- cooperation with Green 10 environmental NGOs in particular with Greenpeace International and Greenpeace Austria and Greenpeace Hungary
- submission of a request for internal review to DG Health and Consumer Protection in December 2007 against the following European Community legal acts:
 - o 2007/701/EC – Commission Decision of 24 October 2007 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*notified under document number C(2007) 5140*)
 - o 2007/702/EC – Commission Decision of 24 October 2007 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*notified under document number C(2007) 5141*)
 - o 2007/703/EC – Commission Decision of 24 October 2007 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*notified under document number C(2007) 5142*)

C)

Criteria set by the Commission Decision of 13 December 2007 laying down detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts (2008/50/EC)

J&E meets the criteria set by the aforementioned Commission Decision especially those defined in the Annex thereof as follows:

- statute or by-laws, etc.: J&E has submitted the required documents in December 2007 when submitting its request for internal review mentioned on page 5
- annual activity reports: J&E has submitted annual activity reports to the Commission within the annual narrative reporting process on the use of the LIFE+ NGO operational grant scheme between 2006 and 2009
- copy of the legal registration: J&E has submitted the required documents in December 2007 when submitting its request for internal review mentioned on page 5
- documentation that the non-governmental organization has previously been acknowledged by a Community institution or body as being entitled to make a request for internal review: see the response of the Commission dated 26 May 2008 under **SANCO/E1/CV/al D(2008) 510302** available under the following link: http://ec.europa.eu/environment/aarhus/pdf/title_iv/Reply%20to%20J_E.pdf

D)

Requirements of the request for internal review

Article 10 Paragraph 1 of the Regulation (EC) No. 1367/2006 of the European Parliament and of the Council sets formal as well as material requirements for the request for internal review in order to be eligible for consideration by the respective European Union institution or body. These are

“to the Community institution or body that has adopted an administrative act”

The present request for internal review is addressed to the Commission of the European Union. Both Commission Decisions that are requested to be reviewed were adopted by the Commission and were signed by Mr. John DALLI as Member of the European Commission, responsible for Health and Consumer Policy.

“an administrative act”

Both Commission Decisions that are requested to be reviewed qualify as administrative acts according to Article 2 Paragraph 1 Point g of the Regulation (EC) No. 1367/2006 of the European Parliament and of the Council: “any measure of individual scope under environmental law, taken by a Community institution or body, and having legally binding and external effects;”

The Commission Decisions are measures having an individual scope and not having a legislative effect which is demonstrated by the fact that both are addressed to specific legal entities such as

- the Kingdom of Sweden (2010/135/EU)
- BASF Plant Science GmbH, Carl– Bosch–Straße 38, 67056 Ludwigshafen, Germany (2010/136/EU)

The Commission Decisions are adopted under environmental law – see below.

The Commission Decisions are taken by a European Union institution or body – see above.

The Commission Decisions are having legally binding and external effect.

(2010/135/EU)

The Commission Decision

- contains conditions for placing on the market and labeling (Article 3) and on monitoring and reporting (Article 4)
- uses a legal language that is used for having a mandatory effect (e.g. “the consent holder shall ensure that”), therefore it is undoubtedly legally binding
- contains provisions that relate to a private legal entity not being European Union institutions or bodies, therefore it is clearly having an external effect

(2010/136/EU)

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- contains provisions that relate to a private legal entity not being European Union institutions or bodies, therefore it is clearly having an external effect

“under environmental law”

Both Commission Decisions that are requested to be reviewed fall under environmental law according to Article 2 Paragraph 1 Point f of the Regulation (EC) No. 1367/2006 of the European Parliament and of the Council: “Community legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Community policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilization of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems;”

The regulation of GMOs falls under the scope of European Union environmental law according to the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, according to – inter alia – the following provisions:

Preamble

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).

(6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken.

Art. 1

In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

- . carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,
- . placing on the market genetically modified organisms as or in products within the Community.

Art. 4

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

The regulation of GMOs falls under the scope of European Union environmental law also according to the following sources:

- Ludwig Kramer: EC Environmental Law, Sweet & Maxwell, London, 2003, page 224
- Ludwig Kramer: Casebook on EU Environmental Law, Hart Publishing, Oxford–Portland Oregon, 2002, Page 233
- Jan H. Jans: European Environmental Law, Europa Law Publishing, Groningen, 2000, page 382
- Wybe Th. Douma: European Environmental Case Law, TMC Asses Press, the Hague, 2002, page 484

Moreover, the construction that regulation of GMOs fall under the scope of European Union environmental law is reinforced by the judgment of the European Court of Justice in the case Association Greenpeace France and Others v. French State, GM Maize (C-6/99).

“request must be made in writing”

The present request is made in writing and addressed to the European Commission.

“within a time limit not exceeding six weeks after the administrative act was adopted, notified or published, whichever is the latest”

Both Commission Decision were adopted on 2 March 2010 and published in the Official Journal of the European Union on 4 March 2010 (L 53). The six-week deadline of submission expires on 15 April 2010 before which date the present request is submitted to the European Commission.

“The request shall state the grounds for the review.”

See below.

E)

Grounds for the review

Commission Decision 2010/135/EU is unlawful because it infringes Article 4 (2) of Directive 2001/18/EC.

Commission Decision 2010/136/EU is unlawful because it infringes Article 4 (2) Directive 2001/18/EC

1. Preliminary remarks

According to the recitals of the 2010/135/EU Decision the legal basis for this Decision is the so-called “deliberate release directive” (2001/18/EC). So Article 4 (2) sentences 3/4 of this Directive has to be observed.

According to Article 2 of the 2010/136/EU Decision the legal basis for this Decision is the so-called “food and feed regulation” (1829/2003/EC). Under – among other provisions – Article 2 (4), Article 6 (4) and Article 18 (4) the Regulation 1829/2003/EC refers for the determination whether the submitted food or feed product bears adverse effects on human health or the environment to the risk assessment provisions of the Directive 2001/18/EC.

As Article 4 of this Directive represents one of the cornerstones of this risk assessment it also refers to this Article. So Article 4 (2) sentences 3/4 of this Directive have to be observed here as well.

The text of Article 4 (2) sentences 3/4 read as follows:

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.

As this article is part of the general provisions of the Directive 2001/18/EC it applies both to the deliberate release of GMOs to be placed on the market according to part C of the Directive and the release of GMOs for other reasons than placing on the market according to part B of the Directive.

According to Article 1 of the 2010/135/EU Decision the GMO product (starch potato) whose cultivation is authorised constitutes a GMO for placing on the market pursuant to part C of Directive 2001/18/EC. Under Article 2 No. 1.a of the 2010/135/EU Decision and according to Annex b) last paragraph of the 2010/136/EU Decision the authorised GMO product contains an nptII-type kanamycin resistance gene as antibiotic resistant marker (ARM). According to an EFSA Opinion adopted on 2 April 2004 concerning the use of ARMs in genetically modified plants (“the 2004 Opinion”), EFSA stated that – apart from kanamycin – nptII also affect the antibiotics neomycin and geneticin¹.

On 26 February 2007, in the light of a report published by the World Health Organisation (WHO) 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 (EMA) issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine². Thus both WHO and EMA consider a GMO containing an nptII-type kanamycin and neomycin resistance gene to have adverse effects on human health and the environment.

2. First appearance appraisal of the facts

According to Article 4 (2) sentence 4 in connection with sentence 3 of Directive 2001/18/EC the placing on the market of GMOs and genetically modified food or feed expressing resistance to antibiotics in use for medical or veterinary treatment which may have adverse effects on human health and the environment is prohibited after 31 December 2004. In fact this is the ultimate date for ending the use of such ARMs as Article 4 (2) sentence 3 of Directive 2001/18/EC – already since the effectiveness of this Directive which is 2001 – calls for phasing out those ARMs. So the – uncontested – use of the above mentioned ARM in the authorised products constitutes a twofold violation of the Directive 2001/18/EC.

First it violates the obligation of the Commission pursuant to Article 4 (2) sentence 3 of Directive 2001/18/EC to consider the obligation – which is already in place since 2001 – of phasing out such ARMs. But even if one would allege that sentence 3 provides for some kind

¹ See page 7 of the 2004 Opinion.

² See recital 10 Sentence 1 of the preamble of the 2010/135/EU Decision.

of leeway and balancing out the pros and cons of the ARM use in the period between 2001 and 2004, there is no doubt, that any authorisation of GMOs containing the abovementioned ARM after the date of 31 December 2004 is prohibited. As opposed to sentence 3, which might afford a certain degree of leeway, sentence 4 is mandatory law without any discretion because it sets by 31 December 2004 an ultimate deadline for phasing out those ARMs at the latest.

So it appears that a simple subsumption of the facts underlying the contested Decisions leads to a clear violation of wording and spirit of Article 4 (2) Directive 2001/18/EC.

Those first appearance findings are corroborated by the following further in-depth examinations:

3. Risk assessment of EFSA legally flawed

The contested Decisions violate general principles of EU law as the underlying risk assessment is contradictory – thus infringing the law of logics which has to be observed in consideration of evidence – and does not give requisite reasoning – thus running against due process requirements. This is for the following reasons:

On 13 April 2007, taking into account the above mentioned statements of WHO and EMEA, EFSA indicated that the therapeutic effect of the antibiotics at stake will not be compromised by the presence of the nptII gene in GM plants. This is according to EFSA allegedly due to the extremely low probability of gene transfer from plants to bacteria and its subsequent expression and to the fact that this antibiotic resistant gene in bacteria is already widespread in the environment. EFSA thus in spite of the warnings of EMEA and WHO confirmed its previous assessment of the allegedly safe use of the antibiotic resistance marker gene nptII in genetically modified organisms and their derived products for food and feed uses³.

That reasoning of EFSA carries grave procedural errors. It was EFSA itself that indicated that marker genes conferring resistance to antibiotics highly relevant for human therapy like the nptII gene should be banned „irrespective of considerations about the realistic value of the threat“⁴. In the contested Decisions EFSA openly contradicts to its own observation and tenets in conducting risk assessments. By resorting to the “extremely low probability of gene transfer from plants to bacteria and its subsequent expression”⁵ EFSA is doing precisely the

³ See recital 10 of the preamble of the 2010/135/EU Decision.

⁴ The EFSA Journal (2004) 48, p. 1–18.

⁵ See recital 10 Sentence 3 of the preamble of the 2010/135/EU Decision.

opposite its own tenet requires: considering the realistic value of the threat to antibiotics whereas according to EFSA's own observations antibiotics highly relevant for human therapy like nptII gene should be banned irrespective of considerations about the realistic value of the threat.

This error is aggravated by the fact that according to Recital 10 Sentence 3 of the preamble of the contested Decisions EFSA does not give any reason for the departing from its own tenets for risk assessment. It just ignores its earlier observation that such genes have to be banned irrespective of their realistic threat, then (contrary to its own stance) examines the realistic threats resulting in an approval based on the absence of realistic threats.

It also has to be noted that the assumption of no realistic threats was contested by members of its own GMO panel: two members held in the opinion for the contested Decisions that the risk a gene transfer from plant to bacteria is not – as EFSA indicates – extremely low, but low to high⁶. So even the scientific backing of this itself already illegal approach is poor.

So it appears that the contested Decisions is one of the very seldom cases, where the courts cannot accept the scientific opinion of an official scientific panel. Whilst it is true that such panels like the GMO panel of EFSA usually are afforded – by their scientific competence – certain discretion in the assessment of scientific issues which cannot be controlled by judges not disposing of this knowledge, this case is different: an assessment of scientists which contradicts itself is not an assessment based on sound science. It infringes the laws of logics. As the laws of logic are the bed-rock of every legal review of facts and consideration of evidence thus being an intrinsic element of the general principles of European law such errors as compelling corollary must render this assessment invalid, which in turn renders the contested Decisions based on this assessment illegal.

4. Incorrect Interpretation of Article 4 (2) of Directive 2001/18/EC

EFSA and the European Commission try to justify their stance by interpreting Article 4 (2) of Directive 2001/18/EC narrowly thus allowing them to authorise GMO products although they contain ARM genes which may have adverse effects on human health.

To this end EFSA and the Commission pretend that there were two ways in which Article 4 (2) could be read:

(i) as providing for the phasing out of ARM genes that, considered by reference to their

⁶ EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593.

intrinsic properties or characteristics “may have adverse effects on human health and the environment” or

(ii) as providing for the phasing out of such ARM genes only if and to the extent that, because of particular circumstances or the particular use made of them, they “may have adverse effects on human health and the environment”.

EFSA and the Commission resort to the second interpretation of Article 4 (2). This would enable them to authorise a product containing ARM genes that, although its intrinsic properties or characteristics do actually have an adverse effect on human health and the environment, nevertheless do not have to be phased out because subject to certain conditions those adverse effects can be reduced. The conditions EFSA mention in this respect are the alleged⁷ extremely low probability of gene transfer from plants to bacteria and its subsequent expression and the alleged fact that this antibiotic resistant gene in bacteria is already widespread in the environment⁸.

But the second interpretation of Article 4 (2) of Directive 2001/18/EC is ill-founded. Both the wording of Article 4 (2) and the legislative history indicate that the intention was to phase out ARM genes that, by reference to their intrinsic properties or characteristics, “may have adverse effects on human health and the environment” irrespective of their intended use or the conditions that might be placed upon any authorisation granted⁹. For example, in the Opinion of the Commission on the European Parliament’s amendments to the Council’s Common Position during the legislation process of the Directive¹⁰, the Commission stated unambiguously:

“The Commission is of the opinion that antibiotic resistance market genes need to be phased out and be replaced with alternatives as soon as practically possible. A phasing out is foreseen in the Common Position”.

Further, the wording “phasing out” in Article 4 (2) would be inappropriate if the concern arose only in relation to ARM genes that posed a threat because of a particular use to be made of them or if no relevant conditions were included in an authorisation: if either

⁷ Two Members of the GMO Panel do not share this view; see EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593.

⁸ See recital 10 Sentence 3 of the preamble of the 2010/135/EU Decision.

⁹ So the conditions for placing on the market laid down in Article 3 of the contested Decisions are as meaningless as the monitoring requirements laid down in Article 4.

¹⁰ COM(2000) 293 final, under Amendment 48.

situation was the problem, the solution would be to refuse authorisation for the use in question or impose appropriate conditions on a case by case basis. Phasing out is precisely the opposite of this approach: ARM genes are prohibited irrespective of a case by case assessment, which was employed by EFSA.

Accordingly, an ARM gene like nptII that is intrinsically capable of adversely affecting human health and the environment cannot be excluded from the class of ARM genes to be phased out under Article 4 (2) merely because, in a particular case, it might be thought that steps could be taken to prevent that ARM genes from actually having that effect. Only this conclusion is consistent with the precautionary principle¹¹ thus resulting that only the above mentioned (i) interpretation of Article 4 (2) of Directive 2001/18/EC is possible.

5. EFSA classification system for ARMs unlawful

EFSA and the Commission also try to justify their decisions by establishing a system of certain groups of ARMs, of which some groups still are allowed and others not. For the following reasons this approach is illegal too:

As showed above under subchapter 4, the starting point for the compliance of the contested Decisions with Article 4 (2) of Directive 2001/18/EC is whether or not, by reason of its intrinsic properties or characteristics, the nptII gene “may have adverse effects on human health and the environment”. To determine that it is necessary to exercise a factual assessment based upon up-to-date scientific information and it is also necessary to bear in mind the precautionary principle¹².

In an Opinion adopted on 2 April 2004 concerning the use of ARM genes in genetically modified plants generally (“the 2004 Opinion”), EFSA classified ARMs into three groups on the basis of two criteria¹³:

- (i) the presence of ARMs in soil, plant, water and enteric bacteria and
- (ii) the importance of specific antibiotics in therapeutic use

When considering EFSA’s classification, it must be borne in mind that EFSA

¹¹ The precautionary principle is to be applied to the interpretation and application of the Directive: cf. recital (8) of the preamble of the Directive 2001/18/EC.

¹² See recital 8 of the preamble to the Directive 2001/18/EC.

¹³ See para. 6 of the above mentioned 2004 opinion.

had concluded that:

- (i) the frequency of horizontal gene transfer from GM plants to other organisms is “very low for all ARMs considered”¹⁴ and
- (ii) each of the groups identified by EFSA includes ARMs that are, or are likely to be, widespread in the environment¹⁵

Accordingly, the material difference between the ARMs falling into the different groups lies in the therapeutic importance of the antibiotics to which they confer resistance, which rises from “no or only minor therapeutic importance and restricted use” in Group I to “highly relevant” in Group III. Unfolding this concept of assessment further EFSA in detail categorised the three groups as follows:

Group I covers ARMs that are:

- (i) already widely distributed among soil and enteric bacteria and
- (ii) confer resistance to antibiotics having no or only minor therapeutic relevance and restricted use.

ARMs of this group – according to this EFSA methodology – still are allowed both in authorization for placing on the market (Regulation 1829/2003/EC and part C of the Directive) and experimental releases (part B of the Directive).

Group II covers ARMs that are:

- (i) widely distributed in micro-organisms in the environment and
- (ii) “confer resistance to antibiotics which are used for therapy in defined areas of human and veterinary medicine¹⁶”.

EFSA considered that ARMs in Group II should be used only for field trial purposes and should not be present in GM plants to be placed on the market¹⁷.

¹⁴ See the third paragraph of the “Summary” section of the 2004 Opinion and point 1 on page 13.

¹⁵ See point 2 on page 13 and, in relation to Group III, paragraph 5.7 of the 2004 Opinion.

¹⁶ See paragraph 6.2 of the 2004 Opinion.

¹⁷ See the penultimate paragraph of the 2004 Opinion.

Group III covers ARMs that:

“confer resistance to antibiotics highly relevant for human therapy”.

Having regard to the importance of such antibiotics in clinical usage, EFSA took the view that ARMs falling within Group III should be avoided in the genome of transgenic plants “irrespective of considerations about the realistic value of the threat”¹⁸ and recommended that they should not be “present in GM plants to be placed on the market or in plants used for experimental field trials”¹⁹.

As far as Group III is concerned, it is clear from the 2004 Opinion that EFSA took the view that, even though the frequency of horizontal gene transfer was very low and even though there was (or was likely to be) widespread naturally occurring resistance to the antibiotics in question, the importance of the antibiotics in question outweighed those other considerations and justified its recommendation to phase out.

By establishing this classification system contrary to the binding obligation of Article 4 (2) of Directive 2001/18/EC EFSA has taken the view that, in order to answer the question whether or not ARMs may have adverse effects, it is not sufficient to look at the intrinsic properties or characteristics of the ARM. Rather – according to EFSA – it is also necessary to consider the chances that the presence of the ARM in a GMO will have adverse effects on human health and the environment. In doing so EFSA was not able to exclude the possibility of any of the ARMs that it was considering having some adverse effect on human health and the environment. Instead its approach is based upon the idea that the degree of risk should be balanced against the anticipated consequences if the risk eventuated. This idea contravenes the exigencies laid down in Article 4 (2) sentences 3/4 of Directive 2001/18/EC. This provision rules out any further differentiation once an ARM (like nptII²⁰) has been identified as affecting antibiotics in use for medical and veterinary treatment which may have adverse effects on human health and environment. The only relevant consideration is whether or not the ARMs “may have adverse effects on human health and the environment”. It is neither necessary nor admissible to consider anything else by setting up a classification system. Hence an exemption of any ARMs having (even only some) adverse effects like nptII from the phasing out obligation laid down in Article 4 (2) sentences 3/4 of Directive 2001/18/EC

¹⁸ Paragraph 6.3 of the 2004 Opinion.

¹⁹ See the last paragraph of the 2004 Opinion.

²⁰ See above.

based on such a classification system – by classifying it in an allegedly non hazardous Group I – is illegal.

6. Classification of nptll in Group I contradicts EFSA's own Opinions and EMEA

Even if one would assume that the above (subchapter 5) mentioned classification system of EFSA would be legal, EFSA infringed this concept, because it classified the litigious product containing nptll in Group I²¹. This is for the following reasons:

In the Opinion adopted on 7 December 2005²², EFSA stated that the nptll was “unlikely to have an adverse effect on human health or the environment in the context of its proposed uses”²³. For backing this up EFSA evaluated nptll from a number of different perspectives. To this end EFSA relied upon its 2004 Opinion, which had described kanamycin, neomycin and geneticin as of no or only minor relevance for therapeutic purposes thus being able to classify nptll in Group I²⁴. EFSA’s view was, as noted above, based upon its (illegal, see above subchapter 5) balancing of the level of risk against the anticipated consequences if the risk eventuated.

But in February 2007, EMEA issued an opinion on the importance of the antibiotics affected by nptll (“the EMEA Opinion”) in response to a request from the Commission that was, in turn, prompted by a WHO report that did classify kanamycin and neomycin (amongst others) as “critically important antibacterials”. EMEA stated that kanamycin and neomycin “are of importance for veterinary and human use and that their current and potential future use cannot be classified as of no or only minor therapeutic relevance”. Moreover EMEA considered that “occurrence of resistance to neomycin and kanamycin varies substantially between countries and bacterial species”²⁵. In other words, those ARMs cannot be classified in Group I²⁶.

²¹ See paragraph 6.1 of the 2004 Opinion.

²² It is the Opinion referred to in recital 8 of the preamble to the 2010/135/EU Decision, which states that it was published on 24 February 2006 – for that reason referred to here as “the 2006 Opinion”.

²³ See the last paragraph of the “Summary” section.

²⁴ See, for example, paragraphs 4.2.3.2 and 5.2.2(a) of the 2006 Opinion.

²⁵ See point 5 of the annex to the EMEA Opinion.

²⁶ First paragraph under the heading “Overall conclusions from Human and Veterinary [Committees]”.

Because of those statements of EMEA and WHO the Commission then requested EFSA “to consider the information provided by the EMEA and to indicate the possible consequences of the EMEA’s conclusions on the safety assessment of the nptII gene²⁷”. On the assumption that the Commission framed its request to EFSA in the way indicated in the passage quoted above from the 2007 Statement, EFSA had to address at least 2 significant comments made by EMEA:

- (i) the importance of the antibiotics affected by the nptII gene
- (ii) the variability of natural resistance to neomycin and kanamycin

EFSA’s response is contained in the 2007 Statement. In the first paragraph of the section entitled “Conclusions”, EFSA stated: “The GMO Panel agrees with the EMEA that the preservation of the therapeutic potential of the aminoglycoside group of antibiotics is important” (that is the group that includes gentamicin, kanamycin and neomycin). On the basis of the classification adopted by EFSA in the 2004 Opinion that would therefore move nptII into Group III – leading to the conclusion that the litigious GMO product could not be authorised because of the presence of nptII. At the very least, it would have led to the classification of nptII in Group II, leading to the restriction of the use of the GMO to field trials thus ruling out any use in products to be placed on the market. However, in the 2007 Statement, EFSA did not draw those conclusions, although it never disavowed the 2004 Opinion or the reliance placed upon it in the 2006 Opinion.

The 2007 Statement of EFSA also does not address EMEA’s concern about the variability of natural resistance. The 2007 Statement appears on the face of it to be undermined by the point raised by EMEA (which EFSA has not rejected or, apparently, considered or evaluated), namely, the variability of the natural occurrence of resistance. If natural resistance is variable, the impact of nptII would also be variable. EFSA does not state that EMEA’s concern is ill-founded. It simply does not mention it.

There is no indication that EFSA has even addressed its mind to EMEA’s concern, let alone tried to evaluate it. This constitutes incomplete consideration of evidence. The 2007 Statement is therefore inconsistent with the approach followed by EFSA in the 2004 and 2006 Opinions and does not address concerns raised by EMEA that, on the face of it, call for consideration.

²⁷ See the last paragraph of the “Background” section of EFSA’s subsequent Statement adopted on 22–23 March 2007 – “the 2007 Statement”, mentioned in recital 10 of the contested Decision.

7. Incomplete consideration of evidence concerning gentamicin

In the first paragraph of the above mentioned EMEA Opinion, it is stated that nptII codes for an enzyme that generally confers resistance to several antibiotics other than the ones referred to by EFSA in its 2004 Opinion, including gentamicin. EMEA regarded the importance of gentamicin as “undisputed” and the omission of gentamicin from EFSA’s evaluation as “crucial”²⁸.

But nevertheless EMEA based its views upon only “the assumption that the substrate specificity of the product of the nptII gene used as marker in the potato in question is really restricted to neomycin and kanamycin (and geneticin)”²⁹ and therefore restricted itself to a consideration only of those antibiotics.

The 2007 Statement of EFSA does not address expressly the concern expressed by EMEA about gentamicin. Accordingly, it is not clear if EMEA’s assumption (that the substrate specificity of the product of the nptII gene used as marker in the GMO is really restricted to neomycin, kanamycin and geneticin and does not extent to gentamicin) is correct.

If gentamicin indeed would be affected, that would reinforce the classification of nptII in Group III. By not addressing this point but simply ignoring it the consideration of evidence is incomplete.

²⁸ See point 2 of the annex to the EMEA Opinion.

²⁹ Ibidem.

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Claim

For this reason, J&E respectfully asks the Commission to

- consider the legality of the two contested Commission Decisions as cited above
- remedy the unlawfulness of the two Commission Decisions if found in breach of the respective European Union environmental law as cited above
- inform J&E about its decision in the aforementioned matter.

Done at Budapest, 14 April 2010

For Justice & Environment
dr. Csaba Kiss
Chair of the Association
www.justiceandenvironment.org

Postal Address:

dr. Csaba Kiss
EMLA
Garay u. 29-31.
Budapest
1076