Justice and Environment
European Network of Environmental Law Organisations

APPLICATION

lodged on behalf of the applicant

Name of Applicant:	**Justice and Environment** European Network of Environmental Law Organizations
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Representative of Applicant:	**mgr. jur. Pavel Cerny** attorney at law Šikola and Partners, Dvořákova 13, 602 00, Brno Czech Republic
Defendant:	**European Commission** DG Health and Consumers (DG SANCO) B-1049 BRUSSELS Belgium
Method of service:	The Applicant hereby declares pursuant to Article 44(2) of the Rules of Procedure that it chooses as a method of service acceptance by email to the following **single email address**: **drkiss@emla.hu**

Justice and Environment
European Network of Environmental Law Organisations

General Court of the European Union
Rue du Fort Niedergrünewald
Luxembourg
L-2925

The Honorable Court,

Justice and Environment – European Network of Environmental Law Organizations (hereafter: Applicant)

- according to **Article 263** of the Treaty on the Functioning of the European Union (hereafter: TFEU)

- pursuant to Article 12 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 (hereafter: Aarhus Regulation)

- in conformity with **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) (hereafter: Aarhus Regulation Implementing Decision)

- according to the **Rules of Procedure of the General Court** (2010/C 177/02)

hereby submits the following

APPLICATION FOR ANNULLMENT

against the European Commission (hereafter: Defendant) as follows.

I. Type of Action

1. The Applicant requests pursuant to Article 264 TFEU the Honorable General Court to declare the following concerned acts null and void:

2. **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)*

3. **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)*

4. Answer of the European Commission **C(2010) 4632** dated 6 July 2010

5. In the Applicant's understanding, the two aforementioned Commission Decisions and the response of the Commission are unlawful by infringing Article 4(2) of Directive 2001/18/EC.

II. Statement of Facts

1. The Defendant has published in the Official Journal of the European Union (hereafter: OJ) No. L 53 on 4th March 2010 the aforementioned Commission Decisions **2010/135/EU** and **2010/136/EU**. The two contested decisions permit the placing on the market of a GMO potato product and the placing on the market of feed produced from a GMO potato.

2. The Applicant, conforming to the requirements of the Aarhus Regulation as well as the Aarhus Regulation Implementing Decision, has submitted a **Request for Internal Review** pursuant to Article 10 of the Aarhus Regulation dated 14 April 2010 within the statutory deadline of six weeks.

3. The Defendant has considered the Request for Internal Review of the Applicant procedurally admissible and has examined the Request for Internal Review in its merits. The Defendant has considered the legality of the two contested decisions but refused the request of the Applicant to remedy the unlawfulness thereof either by their amendment or by their total withdrawal as stated in its response dated 6 July 2010.

III.Legal Background

1. Eligibility of the Applicant to submit a Request for Internal Review

The Applicant believes that it was eligible to submit a Request for Internal Review to the Defendant according to the following reasons:

1.1 The Applicant is a network of public interest environmental law organizations based in the EU member states. The Applicant 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 original statutory seat of the Applicant was in Amsterdam (the Netherlands) at Plantage Middenlaan 2D, 1018 DD Amsterdam, the Netherlands. The center of operation of the Applicant is now in Brno (Czech Republic) at Dvorakova 13, 602 00 Brno, Czech Republic.

1.2 The Applicant meets the criteria set by Article 10 and Article 11 of the Aarhus Regulation. The Applicant is a *"non-governmental organization"*. The Applicant is *"(a) [it is] an independent non-profit-making legal person in accordance with a Member State's national law or practice;"*. The Applicant *"(b) [it] has the primary stated objective of promoting environmental protection in the context of environmental law;"*. The Applicant *"(c) [it] has existed for more than two years and is actively pursuing the objective referred to under (b);"*. The Applicant deals with the matter of the application on a professional basis and *"(d) the subject matter in respect of which the request for internal review is made is covered by its objective and activities."*.

1.3 The Applicant – unless the Honorable Court considers it otherwise – finds it unnecessary in this phase of the procedure to give a detailed description of how

exactly it meets the respective criteria of the Aarhus Regulation, given that the Defendant – both in a previous procedure[1] and the current procedure – accepted the eligibility of the Applicant to submit a Request for Internal Review and has never contested this eligibility in any of the referred procedures.

2. Admissibility of the Request for Internal Review submitted in the case

The Applicant believes that the contested measures were such that made possible the submission of a Request for Internal Review by an eligible subject according to the following reasons.

2.1 Both contested measures are administrative acts according to Article 2 Paragraph 1 Point g of the Aarhus Regulation i.e. they meet the criteria of being *"any measure of individual scope under environmental law, taken by a Community institution or body, and having legally binding and external effects;"*. Moreover, both contested measures were made as part of the environmental *acquis* and fall under the scope of environmental law.

2.2 The Request for Internal Review was submitted pursuant to the Aarhus Regulation, i.e. it was lodged at *"the Community institution or body that has adopted an administrative act"*; the request was *"made in writing"*; it was posted *"within a time limit not exceeding six weeks after the administrative act was adopted, notified or published, whichever is the latest"*; and the request stated *"the grounds for the review."*

[1] The European Commission has previously acknowledged that the Applicant is entitled to make a Request for Internal Review in its response to the Applicant dated 26 May 2008 under **SANCO/E1/CV/al D(2008) 510302**, also available under the following link:
http://ec.europa.eu/environment/aarhus/pdf/title_iv/Reply%20to%20J_E.pdf

2.3 The Applicant finds it unnecessary – unless the Honorable Court considers it otherwise – in this pleading to repeat the reasoning relating to the admissibility of the request contained in the original Request for Internal Review. The reasons contained therein are fully upheld by the Applicant for the current procedure as well.

3. Legal standing of the Applicant before the General Court

The Applicant believes that it has legal standing before the Court of Justice of the European Union according to a combined interpretation of Article 263 TFEU and of the Aarhus Regulation, taking into account the prevailing case law of the Court of Justice of the European Union and the Aarhus Convention.

3.1 Articles 10 to 12 of the Aarhus Regulation (Title IV – *"Internal Review and Access to Justice"*) set out special rules for the review of legality of certain acts and omissions of EC institutions in the field of environmental law. As these provisions are intended to implement the requirements of Article 9 of the Aarhus Convention, it seems obvious that they should give the to-date non-privileged applicants – environmental NGOs as well as other members of the public – a far broader access to the Court of Justice of the EU in environmental matters, compared to Article 263 TFEU as interpreted by the doctrine of *"direct and individual concern"* also known as the Plaumann test.

3.2 In the current situation the Applicant believes that a broad interpretation of NGO legal standing before the Court of Justice of the EU should prevail since the date of entry into force of the Aarhus Regulation. The Applicant agrees with the Defendant that the entry into force of the Aarhus Regulation has created a fundamentally new and different situation where the boundaries of legal standing of those applicants called *"non-privileged"* to date have to be set anew. The

European Commission stated that *"there is no case-law on the application and interpretation of Title IV of Regulation No 1367/2006 as yet".*[2] As long as it is true, the lack of relevant case law opens a window of opportunity for environmental NGOs of Europe. If all prior ECJ rulings and judgments containing restrictive criteria and interpreting NGO standing in a prohibitive way are not the case law relating to the Aarhus Regulation *per se*, then there is literally a *tabula rasa* situation where the case law of the Aarhus Regulation has yet to be created. The Applicant believes that in such circumstances it possesses the necessary legal standing.

3.3 Article 12(1) of the Aarhus Regulation states that the NGO *"which made the request for internal review pursuant to Article 10 may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty"*. In the Applicant's understanding, the Aarhus Regulation gives standing before the Court of Justice of the EU to all NGOs meeting the criteria to file a Request for Internal Review and having done so (wholly or partly) unsuccessfully. There are a number of legal reasons and indications that the Aarhus Regulation indeed opens a way for NGOs to challenge acts of EC Institutions before the Court.

3.4 First of all, it seems to be the only plausible interpretation that Article 12(1) of the Aarhus Regulation shall apply in the situation when the NGO's request for internal review has been unsuccessful (i.e. dismissed as inadmissible for not meeting the above mentioned terms, or on merit). This is supported also by the wording of Article 10(2) of the Aarhus Regulation, which applies to the situation when the respective EC institution fails to deal with the Request for Internal Review in the appropriate time limits and entitles the NGO to institute the proceedings before the

2 Commission of the European Communities: Aarhus Convention Implementation Report – European Community, SEC(2008) 556, Brussels, 7 May 2008, p. 27

Court of Justice of the EU for the protection against such omission in this situation. Had legal standing before the Court of Justice of the EU not been available for such applicants (having received a negative or a delayed answer from any Community Institution) the cited provision of the Aarhus Regulation (*"may institute proceedings before the Court of Justice"*) would be absolutely and totally meaningless. In such situations if only the restrictive standing criteria of the Plaumann test would prevail there would be literally no applicant who could in practice institute proceedings before the Court of Justice of the EU which clearly cannot be the purpose of the Aarhus Regulation apart from being contrary to Article 9 Paragraph 3 of the Aarhus Convention.

3.5 Secondly, Article 12(1) of the Aarhus Regulation gives standing before the Court of Justice of the EU to NGOs which made (previously) the Request for Internal Review; this means that the Aarhus Regulation assumes that when an NGO is not satisfied with the results of the *"internal review procedure"*, it can ask the Court of Justice of the EU to review the legality of the administrative act in question. In the understanding of the Applicant, this entails the possibility of review of both the unsatisfactory response made by the Community Institution and of the underlying administrative act that gave rise to the internal review procedure. It would have no sense to have such provision in the Aarhus Regulation – unless the words *"in accordance with the relevant provisions of the Treaty"* would mean that in cases which fall under the scope of the Aarhus Regulation, the relevant provisions of the Treaty shall be interpreted in a way that NGOs meeting the criteria of the Aarhus Regulation have also standing before the Court of Justice of the EU (and that all other issues are regulated by the Treaty). Point 21 of the Aarhus Regulation Preamble has to be taken into account as well, which states that *"Where previous requests for internal review have been unsuccessful, the non-governmental*

organization concerned should be able to institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty").

3.6 Thirdly, this latter construction is supported by Article 6 of the Annex of the Commission Decision 2008/401/EC, Euratom called *"Remedies"*, that states: *"All replies informing the non-governmental organization that its request is either inadmissible, in full or part, or that the administrative act whose review is sought, or the alleged administrative omission, is not in breach of environmental law shall apprise the non-governmental organization of the remedies open to it, namely instituting court proceedings against the Commission, or making a complaint to the Ombudsman, or both, under the conditions laid down in Articles 230 and 195 of the EC Treaty, respectively."* This additional provision would again make no sense if the interpretation of Article 12(1) of the Aarhus Regulation continued as it prevails now in the current ECJ case law.

3.7 Fourthly, the NGO to which the written reply in the internal review procedure was or should have been addressed can argue that this reply as such shall be considered as *"a decision addressed to that person"* in the sense of Article 263 TFEU. It can be noted in this respect that a written reply under the Transparency Regulation[3] is deemed to be a decision that can be challenged by the NGO in the Court of Justice of the EU.[4] The response of the Commission is also an administrative act in the meaning of the Aarhus Regulation. In the Applicant's view, the response must be subject to review as well, according to Article 263 TFEU in combination with Article 10 Par. 1 of the Aarhus Regulation. At the same time, as the merit of the case concerns the legality of the Commission Decisions on GMOs, the illegality of

3 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145/43

4 Case T-264/04 WWF European Policy Programme v. Council of the European Union (supported by Commission of the European Communities, intervener), OJ C 96 of 28.04.2007, p. 32

the response necessary means that also the Commission Decisions as such are illegal - and thus, it would be highly impractical if the Court of Justice of the EU would interpret the Aarhus Regulation in a way that it cannot annul the underlying Commission Decisions directly. The Applicant considers that its right to have the response of the Commission reviewed indirectly implies its right to have the Commission Decisions reviewed since the response deals with the arguments concerning the Commission Decisions, and therefore – and for practical reasons – the Applicant shall also be considered to be directly and individually concerned by the Commission Decisions as well as by the response.

3.8 Fifthly, in the Acores case[5] the Court of Justice of the EU has already expressed its position towards a possible standing of environmental NGOs, based on Article 12 of the Aarhus Regulation (though indirectly), when saying that *"although it is true that the conditions for admissibility laid down in [Article 230 of the Treaty] are strict, the fact remains that the Community legislature adopted, in order to facilitate access to the Community judicature in environmental matters [the Aarhus Regulation]*. ***Title IV (Articles 10 to 12) of that regulation lays down a procedure on completion of which certain non-governmental organizations may bring an action for annulment before the Community judicature under Article 230 EC.*** *Since the conditions laid down in Title IV of that regulation are manifestly not satisfied* ***in the present case****, it is not for the Court to substitute itself for the legislature and to accept, on the basis of the Aarhus Convention, the admissibility of an action which does not meet the conditions laid down in Article 230 EC."* This part of the decision can be interpreted in the way that the Court explicitly recognized that the Aarhus Regulation laid down a procedure which makes it possible for "certain environmental NGOs" to bring an action for

5 Case T-37/04 Regiao autonoma dos Açores v. Council, of 1st July 2008.

annulment of certain EC acts before the Court of Justice of the EU. The term *"annulment"* also indicates that it should be possible for the NGOs to challenge the act in question, i.e. the administrative act of the Community Institution in merit. It also means that this remedy shall not be restricted to the response of the Community Institution and to only procedural failures in dealing with the Request for Internal Review. At the same time, it shall be noticed that the Court found the Aarhus Regulation inapplicable in this case because the applicants did not follow the internal review procedure of the Aarhus Regulation's Title IV (it has not been in force yet at the relevant time), and because the contested measure was of legislative and not of administrative character. This again suggests an interpretation that had the rules of the Aarhus Regulation been complied with and had the contested measure been of an administrative character, the decision of the Court would have been different, i.e. would have granted access to the NGO in question. And because in the current case the Aarhus Regulation was in force, and the Applicant has complied with all procedural requirements of the internal review procedure and the contested measures fully meet the criteria of the Aarhus Regulation, the Applicant concludes that it has legal standing pursuant to the reasoning given by the Court of Justice of the EU in the Acores case.

3.9 Sixthly, it shall be added that the Court of Justice of the EU has not always applied the "individual concern" criteria so strictly in other branches of law, e.g. in trademark or competition and anti-dumping law cases. In these areas the Court seems to examine more flexibly if the particular situation of the plaintiff has some unique characteristics that may justify the action to be accepted. For example, the situations in which *"the plaintiff holds a unique right that is affected by the contested measure"* (Case C-309/89, *Codorniu SA v. Council*, [1994] ECR I-1853), *"the Commission owns a legislative duty to take account of the specific circumstances of the plaintiff before adopting a measure"* (Cases T-480 and

483/93, *Antillean Rice Mills NV v. Commission* [1995] ECR II-2305) or *"an investigation was initiated by the Commission on the basis of the plaintiff's complaint"* (Case C-26/76, *Metro-SB-Großmärkte GmbH & Co KG v. Commission* [1977] ECR 1875) were accepted by the Court of Justice of the EU as sufficient for granting to private persons standing to challenge the acts of the Commission. It is especially relevant to cite the findings of the ECJ in the Metro case[6] since the circumstances are almost identical with the current situation created by the Aarhus Regulation: *"The abovementioned facts establish that the contested decision was adopted in particular as the result of a complaint submitted by Metro and that it relates to the provisions of Saba's distribution system, on which Saba relied and continues to rely as against Metro in order to justify its refusal to sell to the latter or to appoint it as a wholesaler, and which the applicant had for this reason impugned in its complaint. It is in the interests of a satisfactory administration of justice and of the proper application of Articles 85 and 86 that natural or legal persons who are entitled, pursuant to Article 3(2)(b) of Regulation No. 17 , to request the commission to find an infringement of Articles 85 and 86 should be able, if their request is not complied with either wholly or in part, to institute proceedings in order to protect their legitimate interests. In those circumstances the applicant must be considered to be directly and individually concerned, within the meaning of the second paragraph of Article 173, by the contested decision and the application is accordingly admissible."*

[6] Judgment of the Court of 25 October 1977. - Metro SB-Großmärkte GmbH & Co. KG v Commission of the European Communities. - Selective distribution systems. - Case 26-76.

4. Substance of the claim – unlawfulness of the contested measures

Unlawfulness of the Commission Decision 2010/135/EU of 2 March 2010

4.1 The Commission Decision 2010/135/EU is unlawful because it infringes:

- rules of law relating to the application of the Treaties within the meaning of Article 263 (4), (2, enumeration 4) TFEU
- essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU
- the Treaties within the meaning of Article 263 (4), (2, enumeration 3) TFEU

4.2 The said claims were already submitted in the Request for Internal Review lodged by the Applicant on 14 April 2010. They could not be disproved by the expositions laid down in the response of the Commission of 7 July 2010 according to Regulation (EC) 1367/2006 thus also rendering this act of the Commission (the response) illegal.

4.3 The laws governing the employment of genetically modified organisms (GMOs) like the Directive 2001/18/EC are provisions relating to the application of the Treaties within the meaning of Article 263 (4), (2) TFEU. According to the recitals of the Commission Decision 2010/135/EU the legal basis for this Decision is the "deliberate release Directive" 2001/18/EC. Therefore Article 4 (2) sentences 3/4 of this Directive have to be observed. The text of Article 4 (2) sentences 3/4 reads 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 authorized 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 Commission Decision 2010/135/EU the GMO-product (starch potato) whose cultivation is authorized constitutes a GMO for placing on the market pursuant to part C Directive 2001/18/EC. Under Article 2 No. 1 of the Commission Decision 2010/135/EU the authorized GMO-product contains an nptII-type kanamycin resistance gene as antibiotic resistant marker (hereafter: ARM). According to a European Food Safety Authority (hereafter: EFSA) Opinion adopted on 2 April 2004 concerning the use of ARMs in genetically modified plants[7] (hereafter: the 2004 Opinion), EFSA stated that – apart from kanamycin – nptII also affect the antibiotics neomycin and geneticin[8]. On 26 February 2007, in the light of a report published by the World Health Organization (hereafter: 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 (hereafter: EMEA) issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine[9]. Thus both WHO and EMEA consider a GMO containing an

[7] http://www.efsa.europa.eu/en/scdocs/doc/48.pdf

[8] See page 7 of the 2004 Opinion.

[9] See recital 10 sentence 1 of the preamble of the Commission Decision 2010/135/EU.

nptII-type kanamycin and neomycin resistance gene to have adverse effects on human health and the environment.

4.4 **First appearance appraisal of the facts**

According to Article 4 (2) Sentence 4 in connection with Sentence 3 Directive 2001/18/EC the placing on the market of GMOs 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. Article 4 (2) Sentence 3 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 authorized product constitutes a twofold violation of the Directive 2001/18/EC.

4.5 **Ban on ARM use is breached by the Commission Decision 2010/135/EU**

First the Commission Decision 2010/135/EU violates the obligation of the Commission pursuant to Article 4 (2) Sentence 3 Directive 2001/18/EC to consider the obligation - which is already in force since 2001 - of phasing out such ARMs. But even if one would allege that Sentence 3 provides for some kind 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 authorization 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 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 Commission Decision 2010/135/EU leads to a clear violation of wording and spirit of Article 4 (2) Directive 2001/18/EC. As the obligation of phasing out ARMs clearly is an issue of the precautionary principle the breach of this obligation as a corollary also

represents an infringement of the precautionary principle set out in Article 191 Paragraph 2 Sentence 2 TFEU. Those first appearance findings are corroborated by the following further in-depth examinations:

4.6 **Risk assessment of EFSA legally flawed**

The Commission Decision 2010/135/EU violates 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. According to EFSA this is 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 uses[10]. That reasoning of EFSA carries grave procedural errors. It was EFSA itself that earlier 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"*[11]. In the Commission Decision 2010/135/EU EFSA openly contradicts to its own earlier observation and tenet in conducting risk assessment. By resorting to the *"extremely low probability*

[10] See recital 10 of the preamble Commission Decision 2010/135/EU.

[11] The EFSA Journal (2004) 48, 1-18, http://www.efsa.europa.eu/en/scdocs/doc/48.pdf

of gene transfer from plants to bacteria and its subsequent expression"[12] EFSA is doing precisely the opposite as its own tenet requires: considering the realistic value of the threat to antibiotics whereas according to EFSAs 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 Commission Decision 2010/135/EU EFSA does not give any reason for departing from its own tenets for risk assessment. It merely 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 Commission Decision 2010/135/EU that the risk a gene transfer from plant to bacteria is not – as EFSA indicates – extremely low, but low to high[13]. So even the scientific backing of this already illegal approach is poor. So it appears that the Commission Decision 2010/135/EU 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 and as the laws of logics are the bed-rock of every legal review of facts and consideration of evidence thus being an

[12] See recital 10 Sentence 3 of the preamble of Commission Decision 2010/135/EU.

[13] EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593, http://www.efsa.europa.eu/en/scdocs/doc/1108.pdf

intrinsic element of the general principles of European law such errors as compelling corollary must render this assessment invalid, the response of the Commission unsubstantiated which in turn renders the Commission Decision 2010/135/EU based on this assessment and defended by this response illegal. Contradictory consideration of evidence and lack of giving requisite reasoning constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU. Apart from that it also infringes the TFEU within the meaning of Article 263 (4), (2, enumeration 2) TFEU. Infringements of the laws of logic never can constitute sound science. Such defective opinions like the aforementioned EFSA opinions hence do not represent the *"available and scientific data"* according to Article 191 paragraph 3 indent 1 TFEU.

4.7 **Incorrect interpretation of Article 4(2) Directive 2001/18/EC**

EFSA and the EU Commission try to justify their stance by interpreting Article 4(2) Directive 2001/18/EC narrowly thus allowing them to authorize GMO products although they contain ARM genes which may have adverse effects on human health. To this end EFSA and the Commission assume that there are two ways in which Article 4(2) could be read:

(i) as providing for the phasing out of ARM genes because, considered by reference to their intrinsic properties or characteristics, they *"may have adverse effects on human health and the environment"* (absolute ban) 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"* (relative ban).

EFSA and the Commission resort to the second interpretation of Article 4(2). This would enable them to authorize a product containing ARM genes that, although its intrinsic properties or characteristics actually have an adverse effect on human

health and the environment, nevertheless does not have to be phased out because subject to certain conditions those adverse effects can be reduced. The conditions EFSA mentions in this respect are the alleged[14] 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 environment[15]. But the second interpretation of Article 4(2) 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 authorization granted. 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 Directive[16], the Commission stated unambiguously:

"The Commission is of the opinion that antibiotic resistance marker 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 pose a threat because of a particular use to be made of them or if no relevant conditions were included in an

[14] Two members of the GMO Panel do not share this view; see EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593.

[15] See recital 10 Sentence 3 of the preamble of Commission Decision 2010/135/EU.

[16] COM(2000) 293 final, under Amendment 48, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0293:FIN:EN:PDF

authorization: if either situation was the problem, the solution would be to refuse authorization 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 those ARM genes from actually having that effect. Only this conclusion is consistent with the precautionary principle[17] thus resulting that only the above mentioned (i) interpretation (absolute ban) of Article 4 (2) Directive 2001/18/EC is possible and legal.

4.8 EFSA classification system for ARMs unlawful

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

As showed above, the starting point for the compliance of the Commission Decision 2010/135/EU with Article 4(2) 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 principle[18]. In the 2004 Opinion, EFSA classified ARMs into three groups on the basis of two

[17] 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.

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

criteria[19]:

(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 had concluded that:

(i) the frequency of horizontal gene transfer from GM plants to other organisms is *"very low for all ARMs considered"*[20] and

(ii) each of the groups identified by EFSA includes ARMs that are, or are likely to be, widespread in the environment[21]

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 categorized in detail 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 – are still allowed both in authorization for placing on the market (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

[19] See paragraph 6 of the above mentioned 2004 opinion.

[20] See the third paragraph of the "Summary" section of the 2004 Opinion and point 1 on page 13.

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

(ii) *"confer resistance to antibiotics which are used for therapy in defined areas of human and veterinary medicine"*[22].

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 market[23].

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"*[24] 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"*[25]. 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 antibodies in question, the importance of the antibiotics in question outweighed those other considerations and justified its recommendation to be phased out. By establishing this classification system contrary to the binding obligation of Article 4(2) Directive 2001/18 EFSA has taken the view that, in order to answer the question whether or not an ARM 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

[22] See paragraph 6.2 of the 2004 Opinion.

[23] See the penultimate paragraph of the 2004 Opinion.

[24] Paragraph 6.3 of the 2004 Opinion.

[25] See the last paragraph of the 2004 Opinion.

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. The provision in the Directive rules out any further differentiation once an ARM (like nptII[26]) 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 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 based on such a classification system – by classifying it in an allegedly non hazardous Group 1 – is contrary to the Directive thus illegal.

4.9 **Classification of nptII in Group I contradicts EFSAs own Opinions and the EMEA**

Even if one would assume that the aforementioned classification system of EFSA would be legal, EFSA infringed this concept, because it classified the litigious product containing nptII in Group I[27]. This is for the following reasons:

In the Opinion adopted on 7 December 2005[28], EFSA stated that the nptII was *"unlikely to have an adverse effect on human health or the environment in the context of its proposed uses"*. For backing this up EFSA evaluated nptII from a number of different perspectives. To this end EFSA relied upon its 2004 Opinion,

[26] See above.

[27] See paragraph 6.1 of the 2004 Opinion.

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

which had described kanamycin, neomycin and geneticin as of no or only minor relevance for therapeutic purposes thus being able to classify nptII in Group I[29]. EFSA's view was, as noted above, based upon its obviously illegal balancing of the level of risk against the anticipated consequences if the risk eventuated. But in February 2007, EMEA issued an opinion[30] on the importance of the antibiotics affected by nptII (hereafter: 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"*[31]. In other words, those ARMs cannot be classified in Group I[32]. 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 gene"*[33]. 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 two significant comments made by EMEA:

(i) the importance of the antibiotics affected by the nptII gene;

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

[30] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500054091.pdf

[31] See point 5 of the annex to the EMEA Opinion

[32] First paragraph under the heading "Overall conclusions from Human and Veterinary [Committees]".

[33] 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 Commission Decision 2010/135/EU .

(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 authorized 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. Contradictory consideration of evidence, lack of giving requisite reasoning and ignoring scientific assessments like the one of EMEA constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2,

enumeration 2) TFEU thus making both the Commission Decision and the response of the Commission unlawful.

4.10 **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"[34]. 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)"*[35] 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. This lack of giving requisite reasoning by the Commission respectively ignoring scientific assessments like the one of EMEA again constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU.

4.11 **Response of the EC Commission (letter of 7 July 2010)**

All the above mentioned argumentations were submitted to the EC Commission in

[34] See point 2 of the annex to the EMEA Opinion

[35] Ibidem.

the Request for Internal Review lodged by the Applicant on 14 April 2010. The EC Commission replied to the request with a letter dated 7 July 2010. The reasoning given by the EC Commission in the aforementioned letter does not refute the above mentioned argumentation. First of all it has to be stated that the litigious letter does not undertake any in depth examinations of the argumentation submitted by the Request for Internal Review: whilst the Request for Internal Review provides detailed material argumentation on 11 pages the EC Commission restricts itself to a superficial response containing no more than scarcely two pages. This "optical" and *prima facie* impression is underpinned by the reasoning itself given in that letter. Neither do they deal thoroughly with the arguments submitted by the Request for Internal Review or even only try to rebut them nor do they present any new aspects, which not already had been addressed in the Request for Internal Review. In detail:

4.12 Contradictory opinions of EFSA not addressed

The centerpiece of the expositions given in the response of the Commission is the claim, that according to EFSA the use of ARMs only would be interdicted, if the circumstances pose a certain probability of adverse effects (page 3 of the response) and this probability is a realistic threat (also page 3 of the response). By using this tenet EFSA in an evident way contradicts its own opinion it has delivered for assessing adverse effects of ARMs on the occasion of the (then) newly adopted Directive 2001/18/EC, respectively Article 4 (2) thereof. In this 2004 Opinion EFSA asserted exactly the opposite: ARMs with adverse effects have to be banned *„irrespective of considerations about the realistic value of the threat"*[36]. The Commission in its response does not explain or clarify this obvious contradiction of EFSA assessment standards regarding ARMs. It just ignores this evident breach

[36] The EFSA Journal (2004) 48, 1-18.

of the law of logics. Hence the Commission did not bring anything forward to rebuff the argumentation laid down in section 3 of the Request for Internal Review.

4.13 **Amended law ignored**

The Commission also ignores the new law regarding the use of ARMs. Before the amendment of the European genetic engineering law (i.e. before the introduction of Article 4(2) Directive 2001/18/EC) the ARM issue was not explicitly addressed. As the predecessor Directive 90/220/EEC did not contain any specific rules dealing with ARMs the assessment of ARMs had to be conducted within the framework of the general risk assessment. This enabled the Commission to balance out the pros and cons of the employment of ARMs in the respective case and consider the respective circumstances. Under this – old – law indeed it was possible to decide on a case-by-case basis whether to approve or reject the application depending on the realistic value of the threat and/or the probability of adverse effects. It was the very purpose of the newly inserted Article 4(2) Directive 2001/18/EC to put an end to this approach. From now on the assessment of ARMs should not confer any more leeway for scientific discretion within the general impact assessment. To this end special provisions (sentences 2 and 3 of Article 4(2) Directive 2001/18/EC) were introduced into the paragraph dealing with the risk assessment. Those new provisions exempt ARMs from the general risk assessment and prescribe special exigencies when it comes to ARMs: the unequivocal phasing out of ARMs with adverse effects as employed in the litigious consent by 31 December 2004. This obligation only can be met by a special ARMs related evaluation of potential adverse effects based on their intrinsic properties. By (still) admitting a consideration of the respective circumstances, the Commission employs an assessment method which – as far as ARMs are concerned – is prohibited since 31 December 2004.

4.14 **Continuance of errors**

Based on the above mentioned ill-founded assumptions the response of the Commission is not only unable to refute the claims established in the Request for Internal Review but shows additional legal flaws.

4.15 **False conclusions**

On page 2 of its response the Commission explicates that EFSA – quote: *"recognized the therapeutic relevance of kanamycin and neomcyin"*. It has to be noted that the WHO even classifies kanamycin and neomycin as *"critically important antibacterials"*. Nevertheless EFSA *"reiterated its favorable opinion on Amflora"*. As ARMs with therapeutic relevance obviously do have the potential of adverse effects, the Commission cannot infer from the explications it used in its own response (page 2) that they do not have the potential of adverse effects.

4.16 **Further incomplete consideration of evidence**

The Commission in its response tried to justify its stance by resorting to the alleged fact that the litigious antibiotic resistant gene already would be widespread in bacteria in the environment i.e. that bacteria carrying resistance against neomycin and kanamycin already were widespread in the EU. Even if such a consideration of circumstances and probabilities would be deemed to be legal[37] the Commission in employing this approach committed an additional procedural error. In the Request for Internal Review[38] it was shown that the assumption of EFSA, that bacteria carrying resistance against neomycin and kanamycin were already widespread in the EU, is not true. On the contrary EMEA considered that *"occurrence of resistance to neomycin and kanamycin varies substantially*

[37] In fact it is not, as this would re-introduce considerations other than the potential adverse effects by the intrinsic properties, see above section 4 and section 8.3.

[38] See above 6. This reasoning in an identical way was submitted by the Request for Internal Review lodged on 14 April 2010.

between countries and bacterial species"[39]. This means that in some areas of the EU bacteria resistant against neomycin and kanamycin are **not** widespread. This in turn means that regarding those countries the claim of the Commission, that due to special circumstances (already widespread resistance to the nptII), the nptII gene could not have adverse effects, **cannot be upheld**. In such a situation, where the EMEA, which by far disposes of more knowledge, expertise, experience and competence than EFSA, openly contradicts to the findings of EFSA, the EC Commission cannot just ignore this renowned agency and in a blind way – without even trying to sort out the differences – follow suit the view of EFSA. This is even more true as in the EU it falls by statutes within the scope of EMEA and not EFSA to assess the risks of resistances to antibiotics. The Commission in the least was required to give reason why it followed EFSA and not EMEA. In the omission of dealing with this blatant ignorance of EMEA findings by EFSA the EC Commission again (like EFSA itself in its litigious opinion) committed a grave procedural error in form of incomplete consideration of evidence and denying of giving reasons. Apart from that the denial of reasons leads to an incomprehensive and intransparent response of the EC Commission. The statements above only deals with those items taken up by the Commission. 80% of the argumentation in the Request for Internal Review was not addressed at all in the response of the Commission. The only remark the Commission makes regarding all those reasoning is that EFSA Opinion of 2009 was a "consolidated opinion" (page 3 of the response). It has to be noted that for the question of lawfulness of EU Decisions it is irrelevant whether scientific opinions backing up a Decision are consolidated or not.

[39] See point 5 of the annex to the EMEA Opinion

Unlawfulness of the Commission Decision 2010/136/EU of 2 March 2010

4.17 The aforementioned Decision is unlawful because it infringes:

- rules of law relating to the application of the Treaties within the meaning of Article 263 (4), (2, enumeration 4) TFEU
- essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU
- the Treaties within the meaning of Article 263 (4), (2, enumeration 3) TFEU

4.18 The said claims already were submitted in the Request for Internal Review lodged by the Applicant on 14 April 2010. They could not be disproved by the expositions laid down in the response of the EC Commission of 7 July 2010 according to Regulation (EC) 1367/2006) thus also rendering this act of the Commission illegal.

4.19 **Preliminary remarks**

The laws governing the employment of genetically modified organisms (GMOs) like the Directive 2001/18/EC and the Regulation 1829/2003/EC are provisions relating to the application of the Treaties within the meaning of Article 263 (4), (2) TFEU. According to Article 2 of the Commission Decision 2010/136/EU the legal basis for this Decision is the "food and feed regulation" 1829/2003/EC. Under – among other provisions – Article 2 No. 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 has to be observed. The text of Article 4(2) sentences 3/4 reads 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 authorized 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 Commission Decision 2010/136/EU the GMO-product (starch potato) whose use is authorized constitutes a GMO for placing on the market pursuant to part C Directive 2001/18/EC. Under the Annex point (b) of the Commission Decision 2010/136/EU the authorized 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 affects the antibiotics neomycin and geneticin[40]. On 26 February 2007, in the light of a report published by the World Health Organization (WHO) listing kanamycin and neomycin as *"critically important antibacterial agents for human medicine and for risk management strategies of*

[40] See page 7 of the 2004 Opinion.

non-human use", the European Medicines Agency (EMEA) issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine[41]. Thus both WHO and EMEA consider a GMO containing an nptII-type kanamycin and neomycin resistance gene to have adverse effects on human health and the environment.

4.20 **First appearance appraisal of the facts**

According to Article 4(2) Sentence 4 in connection with Sentence 3 Directive 2001/18/EC[42] the placing on the market of GMOs 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. Article 4 (2) Sentence 3 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 authorized product 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 Directive 2001/18/EC to consider the obligation - which is already in force since 2001 - of phasing out such ARMs. But even if one would allege that Sentence 3 provides for some kind 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 authorization 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 without any discretion because it sets by 31 December 2004 an ultimate deadline for phasing out those ARMs at the latest. So

[41] See Recital 6 of the preamble of the Commission Decision 2010/136/EU.

[42] By reference of the above mentioned Articles of Regulation 1829/2003/EC.

it appears that a simple subsumption of the facts underlying the Commission Decision 2010/136/EU leads to a clear violation of wording and spirit of Article 4 (2) Directive 2001/18/EC. As the obligation of phasing out ARMs clearly is an issue of the precautionary principle the breach of this obligation as a corollary also represents an infringement of the precautionary principle set out in Article 191 Paragraph 2 Sentence 2 TFEU. Those first appearance findings are corroborated by the following further in-depth examinations:

4.21 **Risk assessment of EFSA legally flawed**

The Commission Decision 2010/136/EU violates 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 according to EFSA is 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 uses[43]. 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*

[43] See Recital 10 of Commission Decision 2010/135/EU and Recital 4 of Commission Decision 2010/136/EU.

considerations about the realistic value of the threat"[44]. In the Commission Decision 2010/136/EU EFSA openly contradicts to its own observation and tenet in conducting risk assessment. By resorting to the *"extremely low probability of gene transfer from plants to bacteria and its subsequent expression"*[45] EFSA is doing precisely the opposite its own tenet requires: considering the realistic value of the threat to antibiotics whereas according to EFSAs 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 a number of recitals (e.g. 3, 6 and 8) of the preamble of the Commission Decision 2010/136/EU 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 (contradictory 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 Commission Decision 2010/136/EU that the risk a gene transfer from plant to bacteria is not – as EFSA indicates – extremely low, but low to high[46]. So even the scientific backing of this itself already illegal approach is poor. So it appears that the Commission Decision 2010/136/EU 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

[44] The EFSA Journal (2004) 48, 1-18.

[45] See Recital 10 of Commission Decision 2010/135/EU and Recital 6 of the Commission Decision 2010/136/EU.

[46] EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593.

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 logics 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 Decision and the response of the Commission defending the Decision based on this assessment illegal. Contradictory consideration of evidence and lack of giving requisite reasoning constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU. Apart from that it also infringes the TFEU within the meaning of Article 263 (4), (2, enumeration 2) TFEU. Infringements of the laws of logic never can constitute sound science. Such defective opinions like the aforementioned EFSA opinions hence do not represent the "available and scientific data" according to Article 191 Paragraph 3 indent 1 TFEU.

4.22 **Incorrect interpretation of Article 4 (2) Directive 2001/18/EC**

EFSA and the EU Commission try to justify their stance by interpreting Article 4 (2) Directive 2001/18/EC narrowly thus allowing them to authorize GMO products although they contain ARM genes which may have adverse effects on human health. To this end EFSA and the Commission assume that there are 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 intrinsic properties or characteristics, *"may have adverse effects on human health and the environment"* (absolute ban) 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"* (relative ban).

EFSA and the Commission resort to the second interpretation of Article 4(2). This enables them to authorize a product containing ARM genes that, although its intrinsic properties or characteristics actually have an adverse effect on human health and the environment, nevertheless does not have to be phased out because subject to certain conditions those adverse effects can be reduced. The conditions EFSA mentions in this respect are the alleged[47] 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 environment[48]. But the second interpretation of Article 4(2) 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 totally because, by reference to their intrinsic properties or characteristics, they *"may have adverse effects on human health and the environment"* irrespective of their intended use or the conditions that might be placed upon any authorization granted. 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 Directive[49], the Commission stated unambiguously:

"The Commission is of the opinion that antibiotic resistance marker 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".

[47] Two members of the GMO Panel do not share this view, see EFSA, EFSA-Q-2009-00589, EFSA-Q-2009-00593.

[48] See recital 10 Sentence 3 of the preamble of Commission Decision 2010/135/EU and Recital 6 of the Commission Decision 2010/136/EU.

[49] COM(2000) 293 final, under Amendment 48, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0293:FIN:EN:PDF

Further, the wording *"phasing out"* in Article 4(2) would be inappropriate if the concern arose only in relation to ARM genes that pose a threat because of a particular use to be made of them or if no relevant conditions were included in an authorization: if either situation was the problem, the solution would be to refuse authorization 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 those ARM genes from actually having that effect. Only this conclusion is consistent with the precautionary principle[50] thus resulting that only the above mentioned (i) interpretation (absolute ban) of Article 4(2) Directive 2001/18/EC is possible and legal.

4.23 **EFSA classification system for ARMs unlawful**

EFSA and the Commission also try to justify their decision by establishing a system of certain groups of ARMs, of which some groups are still allowed but others not. For the following reasons this approach is illegal too. As showed above, the starting point for the compliance of the Commission Decision 2010/136/EU with Article 4(2) 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

[50] 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.

exercise a factual assessment based upon up-to-date scientific information and it is also necessary to bear in mind the precautionary principle[51]. 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 criteria[52]:

(i) the presence of ARMs in soil, plant, water and enteric bacteria and

(i) the importance of specific antibiotics in therapeutic use

When considering EFSA's classification, it must be borne in mind that EFSA had concluded that: the frequency of horizontal gene transfer from GM plants to other organisms is *"very low for all ARMs considered"*[53] and each of the groups identified by EFSA includes ARMs that are, or are likely to be, widespread in the environment[54]. 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 categorized in detail the three groups as following:

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 - are still allowed both in authorization for placing on the market (part C of the Directive) and

[51] See recital 8 of the preamble to the Directive 2001/18/EC.

[52] See paragraph 6 of the above mentioned 2004 opinion.

[53] See the third paragraph of the "Summary" section of the 2004 Opinion and point 1 on page 13.

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

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 medicine[55]".

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 market[56].

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"*[57] 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"*[58]. 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 antibodies 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) Directive 2001/18 EFSA has taken the view that, in order to answer the question whether or not an ARM 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

[55] See paragraph 6.2 of the 2004 Opinion.

[56] See the penultimate paragraph of the 2004 Opinion.

[57] Paragraph 6.3 of the 2004 Opinion.

[58] See the last paragraph of the 2004 Opinion.

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 of the Directive rules out any further differentiation once an ARM (like nptII[59]) 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 based on such a classification system – by classifying it in an allegedly non hazardous Group 1 – is illegal.

4.24 **Classification of nptII in Group I contradicts EFSAs own Opinions and EMEA**

Even if one would assume that the above mentioned classification system of EFSA would be legal, EFSA infringed this concept, because it classified the litigious product containing nptII in Group I[60]. This is for the following reasons: In the Opinion adopted on 7 December 2005[61], EFSA stated that the nptII was *"unlikely*

[59] See above.

[60] See paragraph 6.1 of the 2004 Opinion.

[61] It is the Opinion referred to in recital 8 of the preamble to Commission Decision 2010/136/EU, which states that it was published on 24 February 2006 – for that reason referred to here as "the 2006 Opinion".

to have an adverse effect on human health or the environment in the context of its proposed uses". For backing this up EFSA evaluated nptII 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 nptII in Group I[62]. EFSA's view was, as noted above, based upon its (illegal, see above) 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 nptII (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"*[63]. In other words, those ARMs cannot be classified in Group I[64]. 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 gene"*[65]. 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 two significant comments made by

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

[63] See point 5 of the annex to the EMEA Opinion

[64] First paragraph under the heading "Overall conclusions from Human and Veterinary [Committees]".

[65] 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 Commission Decision 2010/136/EU.

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 authorized 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. Contradictory consideration of evidence, lack of giving requisite reasoning and

ignoring scientific assessments like the one of EMEA constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU.

4.25 **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"[66]. 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)"*[67] 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. This lack of giving requisite reasoning respectively ignoring scientific assessments like the one of EMEA again constitute infringements of essential procedural requirements within the meaning of Article 263 (4), (2, enumeration 2) TFEU.

[66] See point 2 of the annex to the EMEA Opinion

[67] Ibidem.

4.26 **Response of the EC Commission (letter of 7 July 2010)**

All the above mentioned argumentations were submitted to the EC Commission in the Request for Internal Review under the Aarhus Regulation lodged by the Applicant on 14 April 2010. The EC Commission replied to the request with a letter dated 7 July 2010. The reasoning given by the EC Commission in the aforementioned letter does not refute the above mentioned argumentation. First of all it has to be stated that the litigious letter does not undertake any in depth examinations of the argumentation submitted by the Request for Internal Review: Whilst the Request for Internal Review provides detailed material argumentation on 11 pages the EC Commission restricts itself to a superficial response containing no more than scarcely two pages. This "optical" and *prima facie* impression is underpinned by the reasoning itself given in that letter. Neither do they deal thoroughly with the arguments submitted by the Request for Internal Review or even only try to rebut them nor do they present any new aspects, which not already had been addressed in the Request for Internal Review. In detail:

4.27 **Contradictory opinions of EFSA not addressed**

The centerpiece of the expositions given in the response of the Commission is the claim, that according to EFSA the use of ARMs only would be interdicted, if the circumstances pose a certain probability of adverse effects (page 3 of the response) and this probability is a realistic threat (also page 3 of the response). By using this tenet EFSA in an evident way contradicts to its own opinion it has delivered for assessing adverse effects of ARMs on the occasion of the (then) newly adopted Directive 2001/18/EC, respectively Article 4 (2) thereof. In this 2004 opinion EFSA asserted exactly the opposite: ARMs with adverse effects have to be banned *„irrespective of considerations about the realistic value of the threat"*[68]. The

[68] The EFSA Journal (2004) 48, 1-18.

Commission in its response does not explain or clarify this obvious contradiction of EFSA assessment standards regarding ARMs. It just ignores this evident breach of the law of logics. Hence the Commission did not bring anything forward to rebuff the argumentation laid down in section 3 of the Request for Internal Review.

4.28 **Amended law ignored**

The Commission also ignores the new law regarding the use of ARMs. Before the amendment of the European genetic engineering law (i.e. before the introduction of Article 4 (2) Directive 2001/18/EC) the ARM issue was not explicitly addressed. As the predecessor Directive 90/220/EEC did not contain any specific rules dealing with ARMs the assessment of ARMs had to be conducted within the framework of the general risk assessment. This enabled the Commission to balance out the pros and cons of the employment of ARMs in the respective case and consider the respective circumstances. Under this – old – law indeed it was possible to decide on a case by case basis whether to approve or reject the application depending on the realistic value of the threat and/or the probability of adverse effects. It was the very purpose of the newly inserted Article 4 (2) Directive 2001/18/EC to put an end to this approach. From now on the assessment of ARMs should not confer any more leeway for scientific discretion within the general impact assessment. To this end special provisions (sentences 2 und 3 of Article 4 (2) Directive 2001/18/EC) were introduced into the paragraph dealing with the risk assessment. Those new provisions exempt ARMs from the general risk assessment and prescribe special exigencies when it comes to ARMs: the unequivocal phasing out of ARMs with adverse effects as employed in the litigious consent by 31 December 2004. This obligation only can be met by a special ARMs related evaluation of potential adverse effects based on their intrinsic properties. By (still) admitting a consideration of the respective

circumstances, the Commission employs an assessment method which – as far as ARMs are concerned – is prohibited since 31 December 2004.

4.29 **Continuance of errors**

Based on the above mentioned ill-founded assumptions the response of the Commission is not only unable to refute the claims established in the Request for Internal Review but shows additional legal flaws.

4.30 **False conclusions**

On page 2 of its response the Commission explicates that EFSA – quote: *"recognized the therapeutic relevance of kanamycin and neomcyin"*. It has to be noted that the WHO even classifies kanamycin and neomycin as *"critically important antibacterials"*. Nevertheless EFSA *"reiterated its favorable opinion on Amflora"*. As ARMs with therapeutic relevance obviously do have the potential of adverse effects, the Commission cannot infer from the explications it used in its own response (page 2) that they do not have the potential of adverse effects.

4.31 **Further incomplete consideration of evidence**

The Commission in its response tried to justify its stance by resorting to the alleged fact that the litigious antibiotic resistant gene already would be widespread in bacteria in the environment i.e. that bacteria carrying resistance against neomycin and kanamycin already were widespread in the EU. Even if such a consideration of circumstances and probabilities would be deemed to be legal[69] the Commission in employing this approach committed an additional procedural error. In the Request for Internal Review[70] it was shown that the assumption of EFSA, that bacteria carrying resistance against neomycin and kanamycin were already widespread in the EU, is **not true**. On the contrary EMEA considered that

[69] In fact it is not, as this would re-introduce considerations other than the potential adverse effects by the intrinsic properties, see above section 4 and section 8.3.

[70] See above 6. This reasoning in an identical way was submitted by the RIR lodged on 14 April 2010.

"occurrence of resistance to neomycin and kanamycin varies substantially between countries and bacterial species"[71]. This means that in some areas of the EU bacteria resistant against neomycin and kanamycin are not widespread. This in turn means that regarding those countries the claim of the Commission, that due to special circumstances (already widespread resistance to the nptII), the nptII gene could not have adverse effects, **cannot be upheld**. In such a situation, where the EMEA, which by far disposes of more knowledge, expertise, experience and competence than EFSA openly contradicts the findings of EFSA, the EC Commission cannot just ignore this renowned agency and in a blind way – without even trying to sort out the differences – follow suit the view of EFSA. This is even more true as in the EU it falls by statutes within the scope of EMEA and not EFSA to assess the risks of resistances to antibiotics. The Commission in the least was required to give reason why it followed EFSA and not EMEA. In the omission of dealing with this blatant ignorance of EMEA findings by EFSA the EC Commission again (like EFSA itself in its litigious opinion) committed a grave procedural error in form of incomplete consideration of evidence and denying of giving reasons. Apart from that the denial of reasons leads to an incomprehensive and intransparent response of the EC Commission. The statements above only deal with those items taken up by the Commission. 80% of the argumentation in the Request for Internal Review was not addressed at all in the response of the Commission. The only remark the Commission makes regarding all those reasoning is that EFSA opinion of 2009 was a "consolidated opinion" (page 3 of the response). It has to be noted that for the question of lawfulness of EU Decisions it is irrelevant whether scientific opinions backing up a Decision are consolidated or not.

[71] See point 5 of the annex to the EMEA Opinion.

IV. Summary of the claim, date and signature by attorney

The Applicant requests the Honorable General Court to declare the contested measures (Commission Decisions 2010/135/EU and 2010/136/EU and the Response of the Commission C(2010) 4632) made by the Defendant null and void.

Done in Brno, Czech Republic on 10 September 2010, on behalf of the Applicant, signed by mgr. jur. Pavel Cerny licensed attorney at law.

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mgr. jur. Pavel Cerny
on behalf of the Applicant