European Commission

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ARES(2015)

, GeneWatch UK, 60 Lightwood Rd,
Buxton SK1 7BB – United Kingdom

Testbiotech, Frohschammerstrasse 14
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Dear Dear

Re: Request for internal review of three Implementing Decisions authorising genetically engineered soybeans MON 87769, MON 87705, and 305423 submitted under Article 10 of Regulation (EC) No 1367/2006 - Your letter of 29 May 2015

Thank you for your letter of 29 May 2015 whereby you lodged a request for internal review of three Commission Implementing Decisions of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from the soybeans MON 87769, MON 87705, and 305423[1] under Article 10 of Regulation (EC) No 1367/2006 (the Aarhus Regulation)[2].

In your request, you ask the Commission to "withdraw the market authorisations for the import and use in food and feed of the nutritionally-altered genetically modified products", on the basis of the following allegations:

1. lack of EFSA guidance for health impacts of GM crops with significantly altered nutritional content;

2. inadequate and inconsistent nutritional risk assessment;

[1] Commission Implementing Decision (EU) 2015/686, Commission Implementing Decision (EU) 2015/696, Commission Implementing Decision (EU) 2015/698 of 24 April 2015, OJ L 112, 30.04.2015, p. 16, 60 and 71.

[2] Regulation 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, OJ L 264, 25.9.2006, p. 13.

3. inadequate and inconsistent labelling for GM food with altered nutritional composition;

4. inadequate and inconsistent post-market monitoring proposals for GM food with altered nutritional composition;

5. herbicide residues are not considered in the health impacts of the GM food and feed consumption;

6. inadequate assessment of the unintended effects of Ribonucleic acid (RNA) interference.

The Commission has carefully assessed your allegations and considers that most of them (allegations 1 to 5 and one part of allegation 6) relate to the risk assessment of human and animal consumption of the GM soybeans, which does not fall within the scope of review under Article 10 of the Aarhus Regulation for the reasons provided under points 1.1. and 1.2. below.

Concerning one part of allegation 6, which relates to the environmental risk assessment and falls within the scope of the Aarhus Regulation, you will find under point 1.3. the result of the Commission's review in accordance with Article 10(2) of the Aarhus Regulation.

Notwithstanding the above, I would like to inform you that the Commission has asked EFSA to analyse all scientific elements of your request for internal review, including those out of the scope of the Aarhus Regulation, as it routinely does for any new scientific report received containing information questioning the safety of a GM product. In reply to this request, EFSA published a Technical Report on 30/07/2015[3], which concludes that you have not put forward new information that would invalidate the previous risk assessment conclusions made by its GMO Panel for the three GM soybeans 305423, MON 87705 and MON 87769.

EFSA considers therefore that the previous risk assessment conclusions on these three soybeans remain valid.

1. Assessment of the allegations invoked in your request for internal review

1. 1 Scope of the review under Article 10 of the Aarhus Regulation

The objective of the Aarhus Regulation, as specified in its Article 1(1), is to contribute to the implementation of the Aarhus Convention[4] by providing for, *inter alia*, "*the right of public access*

[3] http://www.efsa.europa.eu/en/supporting/pub/862e

[4] UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in

to environmental information"[5], "*public participation concerning plans and programmes relating to the environment*"[6], and "*access to justice in environmental matters*"[7].

The Commission considers that a request for administrative review made under Article 10 of the Aarhus Regulation cannot cover the elements of the decisions of authorisation on GM food and feed addressing the health impacts of the consumption of the products.

Article 10 of the Aarhus Regulation needs to be read in light of Article 2 f) and recitals 10, 16 and 18 of the Regulation which define environmental law as "Community legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Community policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources and promoting measures at international level to deal with regional or worldwide environmental problem".

In addition, as the Regulation contributes to the implemention of the Aarhus Convention, it is worth recalling that pursuant to Article 1 of the Aarhus Convention its objective is to "contribute to the protection of every person of present and future generations to live in an environment adequate to his or her health and well being" [8] through access to justice (regulated under Article 9.3 of the Convention).

As indicated in recital 18 of the Aarhus Regulation, provisions on access to justice (Article 9.3 of the Aarhus Convention) should be consistent with the Treaty. The terms "human health" mentioned in Article 191 of the TFEU referred to by Article 2 f) of the Regulation cannot therefore be interpreted as covering health issues other than those related to the state of the environment.

Under the Treaty, a specific provision is dedicated to the protection of public health (Article 168 of the TFEU). This Article contains a legal basis to cover veterinary and phytosanitary measures having as direct objective the protection of public health[9], which was precisely used as legal basis of Regulation (EC) No 1829/2003 on genetically modified food and feed to cover the health aspects not related to Article 191 of the TFEU. An interpretation of Article 191 of the TFEU as covering

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Environmental Matters of 25 June 1998.

[5] Article 1 (1) (a) of Regulation (EC) No 1367/2006.

[6] Article 1 (1) (c) of Regulation (EC) No 1367/2006.

[7] Article 1 (1) (d) of Regulation (EC) No 1367/2006.

[8] Underlined by us.

[9] Article 168(4)(b) of the TFEU mentions "*measures in the veterinary and phytosanitary fields which have as direct objective the protection of public health*".

any measures related to the protection of human health would devoid of substance Article 168 (4) of the TFEU and would not be in line with the Aarhus Regulation which specifies that for access to justice in environmental matters the Treaty has to be respected.

A systematic reading of Regulation (EC) No 1367/2006 corroborates the above interpretation.

Article 2(1)(d)(vi) on the definition of environmental information states that it means any information (omissis) on *"the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures in as much as they are* ***or may be affected by the state of the elements of the environment referred to in point(i)***[10] *or, through those elements, by any of the matters referred to in points(ii) and (iii)"*[11].

The definition of "environmental information" in Article 2(1)(d) is also relevant, even if not at stake here, as to the boundaries of the notion of "environmental law":

Firstly, it should be noted that genetically modified organisms (GMOs) are covered in (i) amongst the different types of environmental information as components of "biological biodiversity", which is described as an "element of the environment", but not by reference to their properties as food or as feed.

Secondly, amongst the measures mentioned in (iii) as "environmental information", only measures affecting the elements of the environment or the factors likely to affect these elements are encompassed. In other words, measures which are not linked to the protection of the environment, such as the nutritional characteristics of a food and a feed, are not considered as "environmental information".

In addition, Article 11(2)(b) of the Aarhus Regulation specifies that one of the criteria for entitlement to make a request for internal review is for the non-governmental organisation to have *"the primary stated objective of promoting environmental protection in the context of environmental law"*. A non-governmental organisation having for primary objective consumer or public health protection, for example, could not be entitled to make a request for internal review under Article 10(1) of the Aarhus Regulation.

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[10] According to Article 2(1)(d)(i), environmental information means any information (omissis) on the *"state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements"*.

[11] Italics and bold by us.

Turning to GMOs, it is to be noted that Regulation (EC) 1829/2003 does not have as specific legal basis Article 191 TFEU, but can be said to contribute to the pursuit of the objectives of Community policy on the environment as set out in the Treaty so that some decisions adopted under its basis, or some elements of the decisions, could fall within the scope of the Aarhus Regulation.

GMOs are explicitly mentioned as "elements of the environment" in Article 2(1)(d)(i) of the Aarhus Regulation to which Article 2(1)(d)(vi) refers for the purpose of access to environmental information under Aarhus Regulation, but due to a systematic interpretation and in light of the objective of the Regulation and of the Aarhus Convention, Article 10 is to be interpreted in the sense that only the allegations of the requests for internal review of decisions adopted under Regulation (EC) 1829/2003 under the Aarhus Regulation which cover the environmental and health impacts due to the release of GMOs in the environment are to be reexamined, but not the health impacts of the consumption of GM food and feed.

It stems from all the above considerations, that not all the elements of the decisions adopted under Regulation (EC) 1829/2003 can be reviewed under Article 10 of the Aarhus Regulation, but a case-by-case analysis of the decisions is necessary to identify whether a request for internal review refers to the environmental risk assessment, to the health impacts due to the release of GMOs in the environment, or to the health impacts of the consumption of GM food and feed which are deemed not be covered by the Regulation.

1.2 Consequences on the applicability of Article 10 of the Aarhus Regulation to Commission Decisions authorising genetically modified food and feed

In light of the objective and provisions of the Aarhus Regulation, as described before, the Commission considers that, under Article 10, the allegations related to parts of the decisions which refer to the health impacts of the consumption of GMOs cannot be reviewed under Article 10 of the Aarhus Regulation.

In the present case, the three Commission implementing Decisions adopted pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed authorise the import and food and feed uses of GM soybeans MON 87769, MON 87705, and 305423, but exclude the use of the products for cultivation. A risk assessment of the consumption of the GM soybeans and an environmental risk assessment of potential release in the environment of the three GM soybeans consisting of or containing GMOs were carried out by the European Food Safety Authority (EFSA), as required by Regulation (EC) No 1829/2003.

We would like to underline that, in the case of GM food and feed, the safety assessment of the GM food and feed and the environmental risk assessment of GMOs must be distinguished.

- Articles 5 and 17 of Regulation (EC) No 1829/2003 on GM food and feed require applicants to submit data demonstrating the safety of the GM food and feed when they are consumed, including data on toxicity, allergenicity, and nutrition.
- Articles 5(5)(a) and 17(5)(a) of Regulation (EC) No 1829/2003 impose an environmental risk assessment to be carried out in case of food and feed containing or consisting of GMOs (which consist of or contain "live" GMOs) and refer to Annexes II and III to Directive 2001/18/EC on the deliberate release of GMOs in the environment[12]. This applies to the potential releases in the environment of imported GM grains and to GMOs for cultivation.

In view of the above, the Commission considers that, in this specific case, allegations 1 to 5 and part of allegation 6 invoked in your request for internal review[13] do not fall within the scope of Regulation (EC) 1367/2006 for the following reasons:

1. The alleged lack of EFSA guidance for "safety and nutritional assessment of nutritionally altered GM crops"[14] mentioned in your request is clearly related to health impacts of the GM food and feed through consumption;

2. The nutritional assessment is one of the areas of risks considered when assessing the health impacts of the consumption of GM food and feed, not the environmental risk assessment of potential release in the environment;

3. The labelling of the composition of the GM food relates to the characteristics of the GM food delivered to the final consumers for consumption and has no link with the environmental risk assessment carried out for the three GM soybeans;

4. The post-market monitoring aims at ensuring the collection of data on the consumption of imported GM food in all Member States and has no link with the environmental risk assessment;

5. As regards herbicide residues present on GM food and feed, you allege that they have not been considered in the safety assessment, which is also an issue relating to the health impacts of the

[12] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
[13] Pages 1 and 2 of this letter.
[14] Page 2 of your request for internal review.

consumption of GM food and feed. In addition, I would like to stress that the assessment of the herbicide residues on human and animal health is not regulated by the EU legislation on GMOs, but under Regulation (EC) No 396/2005 on maximum residue levels in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC[15];

6. The Heinemann *et al.* (2013) publication[16] relates to the impact of possible unintended effects of the consumption of RNA interference-plants on human and animal health and has no link with the environmental risk assessment.

The Commission therefore considers that these allegations cannot be reviewed under Article 10 of the Aarhus Regulation.

1.3. Review of the allegation falling within the scope of Article 10 of the Aarhus Regulation

The Commission considers that only a part of allegation 6 falls within the scope of Regulation (EC) No 1367/2006, which is restricted to the protection of the environment. However, we consider that, on the substance, your claim is flawed and should be rejected.

In your request for internal review, you indicate that *"In MON 87705, the genetic modification results in an inhibition of the expression of the FAD2-1A and FATB1-A genes by RNAi interference (RNAi). The use of RNA interference can give rise to unintended off-target effects but this possibility has not been adequately investigated"*. The analysis of this allegation on its merit shows that you did not provide elements specifying the type of off-target effects due to the use of RNA interference[17], except the reference to two scientific publications (Lundgren *et al.* (2013) and Heinemann *et al.* (2013)). As explained above, the scientific publication Heinemann *et al.* (2013) has no link with the environmental risk assessment.

The Lundgren *et al.* (2013) publication[18] refers to the environmental risk assessment of the cultivation of RNA interference-based plants and more specifically the effects on target and non-target organisms of insecticide RNA interference-based plants during cultivation. However, the Commission Implementing Decision (EU) 2015/696 on MON 87705 excludes the cultivation of this

[15] OJEU of 16.3.2005, L 70/1.

[16] Heinemann JA, Agapito-Tenfen SZ, Carman JA (2013) A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environment International, 55:43–55.

[17] The use of RNAi is a new technique of genetic modification resulting in an inhibition of the expression of the given genes.

[18] Lundgren JG, Duan JJ (2013) RNAi-Based Insecticidal Crops: Potential Effects on Nontarget Species. BioScience. 63(8):657–665.

soybean in the EU and potential interactions with non-target organisms in case of imports of GMOs are not considered to be a relevant issue by EFSA in its scientific opinion on the genetically modified soybean MON 87705[19]. Therefore, your allegation in this respect is not pertinent and should be refuted.

2. Conclusion

The Commission would like to provide the following answer to your request for internal review made under Article 10 of the Aarhus Regulation of Commission Implementing Decision (EU) 2015/686, Commission Implementing Decision (EU) 2015/696 and Commission Implementing Decision (EU) 2015/698:

- Allegations 1 to 5 and part of allegation 6 are rejected as falling outside the scope of Article 10 of the Aarhus Regulation;
- Part of allegation 6 related to the environmental risk assessment does not justify the need to amend Commission Implementing Decision (EU) 2015/696 as a consequence of the Commission's review.

Should you disagree with this reply, you may bring the matter before the Ombudsman or before the General Court if you have a complaint which falls within the conditions laid down in Article 228 or 263 respectively of the Treaty on the Functioning of the European Union.

Yours sincerely,

[19] http://www.efsa.europa.eu/en/efsajournal/pub/2909