European Commission

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Dr Christoph Then
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Brussels, 09 January 2017
ARES(2016)

Dear Mr Then,

Subject: **Request for internal review of Commission Implementing Decisions authorising genetically engineered soybeans FG72, MON 87708 × MON 89788 and MON 87705 × MON 89788 and of the alleged failure to set specific maximum residue levels for residues from spraying with isoxaflutole on genetically modified soybeans, submitted under Article 10 of Regulation (EC) No 1367/2006 - Your letter of 5 September 2016 (Ares(2016)5050110)**

Thank you for your letter of 5 September 2016, whereby you lodged a request for internal review, under Article 10 of Regulation (EC) No 1367/2006 ("the Aarhus Regulation")[1], of Commission Implementing Decisions (EU) 2016/1215, (EU) 2016/1216 and (EU) 2016/1217, of 22 July 2016, authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybeans FG72, MON 87708 × MON 89788 and MON 87705 × MON 89788, respectively[2] ("the Commission Implementing Decisions"), and of the alleged failure to set specific maximum residue levels ("MRLs") for residues from spraying with isoxaflutole on genetically modified soybeans.

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[1] 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.

[2] Commission Implementing Decision (EU) 2016/1215, Commission Implementing Decision (EU) 2016/1216, Commission Implementing Decision (EU) 2016/2017 of 22 July 2016, OJ L 199, 26.7.2016, pp. 16, 22, 28

The Commission considers that your organisation complies with the criteria set out in Article 11 of the Aarhus Regulation and that it is therefore entitled to lodge a request for internal review. Your request has been lodged on the basis of Title IV of the Aarhus Regulation, within the specified time limit and with indication of the grounds of review in which you base your request, in accordance with Article 10(2) of the Regulation.

In your request, you claim a violation of Union law resulting from the alleged illegality of the Commission Implementing Decisions and of the alleged failure to set specific MRLs from spraying with isoxaflutole on genetically modified soybeans. In particular, your request is based on the following grounds:

- Ground A: failure to assess residues from spraying with complementary herbicides[3];
- Ground B and C: failure to set specific MRLs from spraying with isoxaflutole on genetically modified soybeans[4];
- Ground D: failure to assess the accumulated effects of residues from spraying with complementary herbicides[5].

The Commission has carefully assessed your allegations and considers that your request is unfounded as regards the Commission Implementing Decisions and inadmissible as regards the absence of specific MRLs from spraying with isoxaflutole on genetically modified soybeans.

1. The request for internal review of the Commission Implementing Decisions is unfounded

In your request you consider that the adoption of the Commission Implementing Decisions is a violation of EU food law, especially of the legislation on genetically modified food and feed and on pesticides, because of the alleged failures described in your grounds A to D, which relate to the assessment of the effects of residues of pesticides to which the soybeans are made tolerant by genetic modification.

[3] Page 17 of the technical background of your request.
[4] Page 19 of the technical background of your request.
[5] Page 20 of the technical background of your request.

The Commission cannot agree with this position since the grounds of your request fall outside the scope of EU legislation on genetically modified food and feed, which is the sole legal basis on which the Commission Implementing Decisions have to be based.

Indeed, the Commission Implementing Decisions were adopted pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed[6] and, accordingly, the risk assessment that preceded these authorisations was conducted under that legal framework.

The risk assessment performed under this legislation aims at the evaluation of the risks posed by the genetic modification of the product. In accordance with the applicable European Food Safety Authority ("EFSA") Guidance for risk assessment of the food and feed from genetically modified plants[7], the field trials for these genetically modified organisms ("GMOs") were conducted under normal conditions of cultivation for the third countries where they will be cultivated, including appropriate herbicide treatment. Both the GMOs treated with their intended herbicides and not treated with these herbicides were compared with their conventional counterparts, thus allowing an assessment of the potential effect of the intended herbicides on the genetic modification.

EFSA concluded that the three genetically modified soybeans are as safe as their conventional counterparts and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of these applications, which cover imports and processing for food and feed uses and exclude cultivation in the European Union.

In this context, it should be mentioned that the assessment of herbicide residues present on food and feed is not a condition for the authorisations of genetically modified food and feed under Regulation (EC) No 1829/2003.

In fact, the assessment of the effects of herbicide residues on human and animal health is not regulated by the Union legislation on genetically modified food and feed authorisations, but by

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[6] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

[7] EFSA Panel on Genetically Modified Organisms (GMO), 2011a. Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011;9(5): 2150, 37 pp. doi:10.2903/j.efsa.2011.2150.

Regulation (EC) No 396/2005 on MRLs of pesticides in or on food and feed of plant and animal origin ("the MRL Regulation")[8].

The MRL Regulation provides for the risk assessment of pesticide residues in food and feed and the setting of MRLs taking into account the opinion of EFSA, based on good agricultural practice and the lowest customer exposure necessary to protect vulnerable consumers.

The MRL Regulation is also applicable to the control of pesticide residues on food and feed imported from third countries. As any other food and feed, genetically modified products placed on the Union market have to comply with the corresponding MRLs.

It results from the above that the safety of genetically modified food and feed products imported from third countries with a possible presence of pesticide residues is guaranteed by the combined application of Regulation (EC) No 1829/2003 and the MRL Regulation: the assessment of the potential risks posed by the genetic modification in food and feed products is regulated under Regulation (EC) No 1829/2003 and the assessment of the effects of residues which are possibly present on these food and feed on human health is regulated by the MRL Regulation.

This position was confirmed by the General Court in points 233 and 289 of case T-177/13[9]. In particular, the General Court held that the tests and adjustments made to establish MRLs for genetically modified soybeans under the provisions of Regulation No 396/2005, in order to take account of herbicide-tolerant soybeans, should be done as part of an examination under that Regulation and not under Regulation (EC) No 1829/2003.

In these circumstances your claim that, in the absence of specific MRLs being set for residues from spraying with isoxaflutole in genetically modified food and feed, the Commission would not have been in a position to adopt the Commission Implementing Decisions, should also be rejected.

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[8] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[9] Case T-177/13, Testbiotech and Others v Commission, Judgment of the General Court (Fifth Chamber) of 15 December 2016. Not yet published. Paragraphs 233 and 289.

As mentioned above, the setting of a MRL (including for genetically modified food and feed imported from third countries) is a matter which falls under the scope of the MRL legislation, and is not a condition for the approval of GMOs under the GMO legislation. The Commission considers therefore that this ground cannot be used to challenge the legality of the Commission Implementing Decisions which are based on the GMO legislation, even in the case where no MRL would have been set for this substance.

For the sake of completeness, the Commission would like to recall that MRLs for the substance isoxaflutole have been set through the adoption of Commission Regulations in 2008[10], 2014[11] and 2015[12], in compliance with Recital 10 and Article 18(1) of the MRL Regulation. Depending on the product, the MRLs are currently set at 0.1, 0.05 or 0.02 mg/kg. Thus, food and feed to be placed on the market within the Union, including genetically modified food and feed, must comply with those MRLs, as well as with those set for other substances within the scope of the MRL Regulation.

The MRL Regulation does not require setting MRLs for genetically modified soybeans different from those set for conventional soybeans. (Annex I of the MRL Regulation does not distinguish genetically modified food or feed products from conventional food and feed).

Against this background, the Commission considers that the products authorised by the three Commission Implementing Decisions are safe as regards both the risks posed by the genetic modification of the products and the possible effects of pesticides residues on health and the environment.

However, the setting of MRLs for pesticide residues and the assessment of the effects of pesticides residues on health and the environment are aspects which fall outside the scope of Regulation (EC) No 1829/2003 and therefore cannot be used as valid grounds to challenge the legality of these Decisions.

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[10] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto. OJ L 58, 1.3.2008, p. 1–398.

[11] Commission Regulation (EU) No 703/2014 of 19 June 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S methyl, ethoxyquin, flusilazole, isoxaflutole, molinate, propoxycarbazone, pyraflufen-ethyl, quinoclamine and warfarin in or on certain products Text with EEA relevance. OJ L 186, 26.6.2014, p. 1–48.

[12] Commission Regulation (EU) 2015/845 of 27 May 2015 amending Annexes II and III to Regulation (EC) No 96/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac in or on certain products. OJ L 138, 4.6.2015, p. 1–69.

In follows that the Commission considers that your request for internal review of the three Commission Implementing Decisions on the basis of the claims lodged in the grounds A to D of your request is unfounded insofar as it does not raise elements which should be taken into account in the context of Regulation (EC) No 1829/2003, which is the legal basis of these Decisions.

2. The request for internal review of the absence of a specific maximum residue level from spraying with isoxaflutole on genetically modified soybeans is inadmissible

Pursuant to Article 10(1) of the Aarhus Regulation only acts which fall within the definitions of 'administrative act' and 'administrative omission' as defined in the Regulation may be subject to an internal review. The notion of administrative act is defined in Article 2(1)(g) as referring to "any measure of individual scope under environmental law, taken by a Community institution or body, and having legally binding and external effects." In turn, Article 2(1)(h) defines an administrative omission as "any failure of a Community institution or body to adopt an administrative act as defined in (g)".

In this regard, according to Article 2(1) of the MRL Regulation, such Regulation is applicable to all operators manufacturing or placing on the market products of plant and animal origin to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.

MRLs set under the MRL Regulation are therefore applicable to all operators placing food and feed products on the market, who are obliged to comply with those MRLs as a necessary condition to carry out their activity. Thus, in line with the well settled case-law of the Court of Justice[13], the establishment of MRLs must be regarded as an act of general application and not as an administrative act within the meaning of Article 2(l)(g) of the Aarhus Regulation, since it applies to objectively determined situations and produces legal effects for categories of persons envisaged generally and in the abstract.

It results from the above that a failure to set MRLs would not be subject to review under the Aarhus Regulation as long as it cannot be considered as an administrative omission within the meaning of Article 2(1)(h) of the Regulation.

[13] Joined cases C-404/12 P and C-405/12 P, Council and Commission v Stichting Natuur en Milieu and Pesticide Action Network Europe, Judgment of the Court (Grand Chamber) of 13 January 2015. Published in the electronic Reports of Cases (Court Reports - General). Paragraphs 57-61.

Consequently, your request for internal review of the absence of a specific MRL from spraying with isoxaflutole on genetically modified soybeans is not admissible under Article 10(1) of the Aarhus Regulation.

3. Conclusion

The Commission considers that your request for internal review of Commission Implementing Decision (EU) 2016/1215, Commission Implementing Decision (EU) 2016/1216 and Commission Implementing Decision (EU) 2016/2017 must be declared as unfounded insofar as all your grounds for review are concerned (grounds A, B, C and D) and as inadmissible insofar as your grounds B and C are concerned.

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,