COMPLAINT ABOUT MALADMINISTRATION

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On behalf of Testbiotech e.V.,
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2. Against which European Union (EU) institution or body do you wish to complain?
European Commission, DG SANTE

3. What is the decision or matter about which you complain? When did you become aware of it?

In April 2015, Testbiotech and several other organisations filed a request for an internal review according to Article 10 of EU Regulation 1367/2006 against the decision of the EU Commission to allow import of herbicide-tolerant genetically modified oilseed rape MON 88302 (Commission Implementing Decision (EU) 2015/687 of 24 April 2015, published on 30 April 2015 in the Official Journal of the European Union). This request for an internal review was rejected on 3 February 2016.

4. What do you consider that the EU institution or body has done wrong?

(1) Unlawful market authorisation of MON88302

In regard to the safety and assessment of MON88302 as food and feed, EFSA, and the other EU institutions, are obliged to ensure that a high level of protection for both humans and the environment is maintained, with due regard to the precautionary principle. In order to ensure that such a high level of protection is provided, EFSA is required to investigate and assess all the potential implications of authorising the use of the genetically modified food and feed in the manner sought – and where there is doubt the precautionary principle must apply.

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Instead of fulfilling the legal requirements imposed by the EU legislation, EFSA has adopted a “don’t look – don’t find” approach – stating that there is nothing to suggest that MON88302 is unsafe rather than requiring Monsanto, in accordance with, in particular, GM Regulation to prove that this is the case. EFSA’s approach, adopted and endorsed by the EU Commission, was to overlook the fact that crucial scientific data and publications were not taken into account. Other crucial data had and still have not been obtained, and Monsanto should have been required to carry out further investigation and make available the necessary data. Consequently, EFSA’s opinion should have been rejected and the import of MON88302 should not have been authorised by the EU Commission.

EFSA also failed to recommend, and the Commission failed to impose, sufficient monitoring requirements.

Accordingly, the Decision of the EU Commission is unlawful because it is based on a flawed and unlawful assessment of the risks posed by MON88302.

(2) Violation of Regulation 1367/2006

The response of the Commission of 3 February 2016 is substantially flawed. In the context of this complaint, the following points are most relevant:

- the response was not received until well beyond the legally defined time limit. This is a violation of the EU regulation.

- in regard to environmental risks, the response from the EU Commission, which is largely based on the opinion of the European Food Safety Authority (EFSA), neglects new evidence and relevant scientific data. It cannot be accepted for the following reasons:

    (1) EFSA failed to properly assess new information regarding the potential invasiveness and persistence of oilseed rape in general.

    (2) EFSA failed to investigate the specific invasiveness and persistence of MON88302 in feral populations

    (3) EFSA did not assess the environmental risks as required by law and by EFSA´s own guidance.

- the monitoring plan now published by the EU Commission is not sufficient.

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5 What, in your view, should the institution or body do to put things right?

Testbiotech recommends the following actions:

- The Commission should reconsider and withdraw the decision to allow market authorisation based on the EFSA risk assessment.
- If Monsanto upholds its application, the Commission should request new and more detailed risk assessment by EFSA, also taking into account those findings that indicate a much higher risk if MON88302 is imported into the EU than assumed by EFSA so far.
- If viable kernels are allowed for import, the monitoring plan has to be changed to effectively prevent spillage of viable kernels and emergence of transgenic plants during and after the period of authorisation.
- The Commission should make sure that in future the deadlines for responding requests under Regulation 1367/2006 are no longer violated.

6 Have you already contacted the EU institution or body concerned in order to obtain redress?

Yes. See attached documents.

7 If the complaint concerns work relationships with the EU institutions and bodies: have you used all the possibilities for internal administrative requests and complaints provided for in the Staff Regulations? If so, have the time limits for replies by the institutions already expired?

Yes. See attached communication with the EU Commission.

8 Has the object of your complaint already been settled by a court or is it pending before a court?

No

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9 Please select one of the following two options after having read the information in the box below:

Please treat my complaint publicly

10 Do you agree that your complaint may be passed on to another institution or body (European or national), if the European Ombudsman decides that he is not entitled to deal with it?

No

Date and signature:

Munich, 18.3.2016, Christoph Then

Attachments:

Commission (2015 a) COMMISSION IMPLEMENTING DECISION (EU) 2015/687 of 24 April 2015, authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302 (MON-883Ø2-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council published on 30 of April 2015 in the Official Journal of the European Union.

Commission (2015 b) Environmental monitoring plan for MON 88302 oilseed rape.

Commission (2015 c) e-mail communication from November 2015.

Commission (2016 a) letter from EU Commissioner Vytenis Andriukaitis, 3 February 2016.

Commission (2016 b) General legal framework, Ref. Ares(2016)677018 – 08/02/2016.

Commission (2016 b) ANNEX II- GROUNDS OF THE COMPLAINT, Ref. Ares(2016)677018 – 08/02/2016.

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EFSA (2014a) Panel on Genetically Modified Organisms (GMO), Scientific Opinion on application (EFSAGMO-BE-2011-101) for the placing on the market of herbicide-tolerant genetically modified oilseed rape MON 88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2014;12(6):3701, 37 pp. doi:10.2903/j.efsa.2014.3701, Available online: www.efsa.europa.eu/efsajournal.

EFSA (2015) Scientific advice to the European Commission on the internal review submitted under Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention against the Commission Implementing Decision 2015/687 to authorise genetically modified oilseed rape MON88302 of EFSA on environmental risks, www.efsa.europa.eu/en/supporting/pub/864e.

Testbiotech (2015a) Technical background for a complaint under Article 10 of Regulation (EC) No.1367/2006 against the decision of the EU Commission to give market authorisation to herbicide-tolerant genetically engineered oilseed rape MON88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto, www.testbiotech.org/node/1283.

Testbiotech (2015b) TESTBIOTECH Background 7 - 09 – 2015, Comments to the “Scientific advice to the European Commission on the internal review submitted under Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention against the Commission Implementing Decision 2015/687 to authorise genetically modified oilseed rape MON88302 of EFSA on environmental risks” (EFSA, August 2015).

Testbiotech (2016) TESTBIOTECH Background 18 - 03 – 2016, Risk assessment of genetically engineered oilseed rape MON88302 for import into EU, conclusions on a process for request of internal review under EU Regulation 1367/20006, with Annex (tabled overview on some relevant topics and findings and answers from EU Commission).

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