

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

Our complaint is about a letter dated 19th July 2018 from Commissioner Andriukaitis (DG SANTE) (attached). This letter rejects a request from GeneWatch UK and TestBiotech to annul several authorisations for genetically modified (GM) crops, and notes that we may now bring this matter before the ombudsman. The relevant decisions for the purpose of this complaint are Commission Implementing Decisions 2015/686, 2015/696 and 2015/698 (Off. J. Eur. Union L 112), which relate to the import of three different nutritionally-altered GM soybeans, for use in food and feed (Monsanto's MON 87769 soybean; Monsanto's MON 87705 soybean; Pioneer soybean 305423). The letter includes an annex containing more details (also attached).

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

The Commission's letter (with Annex) fails to respond adequately to our complaint. In our view, the authorisations should still be annulled and specific Guidance for the risk assessment of nutrient-altered GM crops should be adopted before any authorisations of such crops.

The three nutritionally-altered products which have been approved for import as food and feed are all soybeans which have been genetically engineered to express different fatty acids which alter the oil composition of the final crop. They are not regarded as "substantially equivalent" to existing conventional crops and therefore pose new challenges for regulators.

Throughout the complaint process (see below) GeneWatch UK and TestBiotech have stated that the authorisations should not have been granted because:

1. EFSA has initiated but not completed a process of developing guidance for the assessment of GM crops with significantly altered nutritional content. As well as being incomplete, this process has not been independent or transparent. In the absence of this guidance, approvals should not have been granted for nutritionally-altered GM crops.
2. The lack of guidance has led to inconsistent and inadequate risk assessments for all three crops, which fail to meet the requirements of the legislation.
3. Labelling and post-marking monitoring proposals are also inadequate and inconsistent.
4. In addition, the impacts of pesticide residues have not been fully considered for the two herbicide-tolerant crops and the unintended effects of RNA interference have not been adequately assessed for MON 87705.

In contrast, the Commission claims (see Annex, p.2) that the lack of specific guidance for assessing nutritional consequences of a significantly altered nutrient content in GM crop is not a valid argument to disqualify EFSA's assessment of the three GM soybeans and the subsequent adoption by the Commission of the above mentioned decisions of authorisation based on this assessment.

Lack of Guidance

To support our view that specific Guidance should have been adopted prior to approving any such crops we note that EFSA is mandated to issue guidance on the manner in which it will assess applications for authorisations for genetically modified organisms (GMOs). In particular:

- Under Article 23(b) of Regulation 178/2002, one of EFSA's tasks is that it must "*promote and coordinate the development of uniform risk assessment methodologies in the fields falling*

within its mission”;

- Under Articles 5(8) and 17(8) of Regulation 1829/2003 on genetically modified food and feed, EFSA “*shall publish detailed guidance to assist the applicant in the preparation and presentation of the application*”.

EFSA recognises the importance of developing methodologies in Section 5.2 of its Policy on Independence and Scientific Decision-Making Processes (*Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, 2011*). Guidance is also important to ensure a “level playing field” so that all products in a similar category (such as nutrient-altered GM crops) are subject to the same standards of regulatory oversight and assessment. Without Guidance, it is difficult to ensure that regulation is applied in a non-discriminatory manner. All GM nutritionally-enhanced plants are different and each will pose different risks, depending on their intended and unintended products and side-products.

However, despite highlighting the importance of developing standard methodologies to ensure impartiality and coherence of its outputs, EFSA has not completed work that it initiated in 2012 to develop the necessary guidance for the assessment of nutritionally altered crops. In Mandate Number M-2012-0084, EFSA has itself recognised the need to develop and detail a strategy for the safety and nutritional assessment of nutritionally altered GM crops, and its (former) Director commissioned the first step in this work. However, neither EFSA nor any other EU institution has taken subsequent steps to progress or finalise this work to create the necessary detailed strategy for the assessment of nutritionally-altered crops.

Under Mandate Number M-2012-0084, in June 2012, EFSA acknowledged that the process for evaluation of this new category of crops (including nutritionally enhanced foods with qualitative and quantitative changes in oils/lipids) required further study and development and commissioned an expert report at a cost of 75,000 euros (Geslain-Lanéelle, 2012, attached). EFSA’s mandate letter cites EFSA’s new (2011) Guidance for risk assessment of food and feed from genetically modified plants, which states (page 34):

*“In cases where a comparative assessment is not applicable, a comprehensive food and feed safety and nutritional assessment of the GM plant and derived food and feed should be performed. This should include, among others, a detailed compositional analysis and specific toxicological/nutritional analyses, selected according to the agronomic and compositional properties of the food and feed under assessment. **Further development and detailing of this strategy is needed.**”* [emphasis added]. The mandate letter states: *“In practical terms, such strategy for a comprehensive food/feed safety assessment, although being addressed in the guidance documents of the EFSA Panel on Genetically Modified Organisms, **has so far not been fully described.** For the assessment of applications of GM plants developed to express new traits the EFSA GMO Panel is currently receiving ad-hoc support from Nutrition (NUTRI) Unit and members of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). **The definition of clear strategies for the assessment of these applications is becoming a relevant issue for the GMO Panel.**”* [emphasis added].

In September 2013, EFSA published the expert report resulting from Mandate Number M-2012-0084, which considers in more detail the studies that would be necessary for regulatory approval of “novel” GM traits, including altered nutrient content (ADAS UK Ltd. & Rothamsted Research, 2013). In this report (page 3):

“A number of recommendations for further work are given, including the need for a wider review of risk assessment strategies to inform the approach to risk assessment for ‘novel’ traits, further work to develop guidance on post market monitoring, guidance on cases where field trial design for ‘novel’ traits may need to be amended, further work on the concept of history of safe use and guidance on the management of the risk assessment process.”

The report does not recommend a wholesale change to EFSA's risk assessment process but states: *"As such, it is recognised in the foreseeable scenario for risk assessments that approaches to risk assessment will be based on using a comparative approach as a starting point, with differences to the current EFSA guidance to make the process effective at assuring the safety of plants with 'novel' GM traits."* There is no record of any of the recommended further work being undertaken, nor of any further steps being undertaken by EFSA to develop guidance for the risk assessment of nutrient-altered GM crops. No final guidance has been published or adopted.

It is unclear whether EFSA informed the European Parliament, the Commission and the Member States of the existence of Mandate Number M-2012-0084 or this expert report, as it is required to do under Article 32 of Regulation 178/2002. No correspondence on the subject is recorded in EFSA's Register of Questions. Thus, whilst it is clear that EFSA was aware that its existing Guidance was not fit-for-purpose, it is unclear whether other EU bodies were informed of this before being requested to approve the authorisations granted in 2015. However, if the risk manager (DG SANCO, rather than EFSA) made the decision not to allow or require EFSA to proceed with developing specific Guidance before authorising nutrient-altered GM crops, this also undermines the scientific quality of the risk assessments (as outlined below) and the legal basis of the approvals.

The principle of transparency in EU food law (Article 9, Regulation 178/2002) also requires that there is open and transparent public consultation during the preparation, evaluation and revision of food law. No such consultation has taken place in relation to the development and detailing of a strategy for the assessment of nutritionally-altered GM crops.

Issues of conflicts-of-interest are raised by the fact that one of the research institutes commissioned to write the expert report under Mandate Number M-2012-0084, Rothamsted Research, is involved in developing nutrient-altered GM crops, notably GM sativa with enhanced omega-3 oils (<https://www.rothamsted.ac.uk/oceans-fields-and-back-again>). The one altered-oil crop included as a future scenario in the report (Section 8) is a GM oil seed plant producing enhanced levels of long-chain polyunsaturated fatty acids (omega-3) oils such as DHA and EPA i.e. a product being developed through Rothamsted's own R&D. Several of the authors of this report therefore have a clear conflict-of-interest as they are employed by the institution hoping to commercialise this research, which could benefit financially from weak regulation of nutritionally-altered crops and minimal data requirements. Furthermore, the main overview articles cited in relation to developing a risk assessment process for nutritionally-altered GM crops are all written by industry authors (Constable et al., 2007; Glenn, 2007, 2008; ILSI, 2007), although these industry-affiliations are not noted in the text. The authors highlight a number of areas of significant scientific disagreement in their report and acknowledge that:

"It also became apparent from preliminary searches of the literature that the types of records sourced would not contain extensive amounts of numerical data, rather dialogue, and to some extent opinion from the author or risk assessment body regarding strategies for risk assessment" (Section 2.1.1). In Section 7 (Foreseeable scenarios for risk assessment) they state: *"Please note that this section is based on the judgements and discussion of members of the project team..."*. The report states that it may not be considered as an output adopted by the Authority and it is clear that further steps should have been taken by EFSA to (i) complete the process it initiated to adopt new guidance; and (ii) ensure independence and transparency by, for example, commissioning further work from independent scientists, consulting with a wider range of stakeholders, conducting a public consultation, and keeping the relevant EU institutions fully informed.

In summary, EFSA has initiated but not completed a process of developing guidance for the assessment of GM crops with significantly altered nutritional content. As well as being incomplete,

this process has not been independent or transparent. In the absence of this guidance, approvals should not have been granted for nutritionally-altered GM crops.

Safety implications

We also note that there are safety issues due to the lack of risk assessment guidance for these crops. In this complaint, we do not make a comprehensive review of the scientific disagreements. We only ask the ombudsman to decide whether Guidance for the assessment of GM crops with significantly altered nutritional content should have been provided prior to the approval of these crops. To support our argument, we provide a few examples highlighted in the Commission's letter, which show that, due to the lack of Guidance, risk assessments for these crops were inadequate.

Example 1: Failure to assess the risk of prostate cancer due to enhanced EPA and DHA

For MON87769, the intended physiological consequence of consuming the soybeans is enhanced synthesis of the fatty acids EPA and DHA. The Commission notes (see p.6 Annex to its letter) that publications by Brasky et al. (2011 and 2013), and Chua et al. (2013) reported meta-analysis of associations between blood biomarkers of EPA and DHA and increased risk of prostate cancer. However, it states that the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) appraised these studies and found no evidence for a role of EPA and/or DHA intake in the development of prostate cancer. To support this claim, the Annex cites a publication (EFSA Journal 2014;12(10):3843, 17 pp. doi:10.2903/j.efsa.2014.3843), which is a Scientific Opinion on (non-GM) DHA and EPA-rich algal oil, containing a 3-page discussion of this risk. However, in our view, the failure to cite or assess this risk for the GM soybean MON87769 is still a major omission from EFSA's risk assessment of this GM crop. GeneWatch UK and TestBiotech are not asking the ombudsman to assess the science in the discussion, only whether an assessment of this risk should have been included when the risks of consuming the soybean were considered (just as it was included in the assessment of risk of the non-GM algae).

Example 2: Failure to consider potentially vulnerable subgroups

Article 14(4) of Regulation 178/2002 states:

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers." [Emphasis added]

In the Annex to its letter, the Commission acknowledges that, in the three cases, dietary intake estimates were made for adults (19-64 years old) and, in only one case (305423 soybean), also for other age groups (< 19 years old), and in no case for pregnant and lactating women and the elderly. However, it states that no such assessment is necessary for these specific categories of consumers (p.9 of Annex) (whilst at the same time accepting that they are intended to consume it). This is a clear breach of Article 14(4) of Regulation 178/2002.

Regarding concerns about the decrease in linoleic acid in MON 87705, the Commission states that reduction below the adequate intake of 4 E% was observed for toddlers, children and teenagers (3.2-3.8 E%), but then states that the EFSA GMO Panel is of the opinion that this is not a matter of concern, as linoleic acid deficiency symptoms have not been observed at intakes > 1 E% (p. 10 of Annex). In our view, this means that rather than paying particular attention to the needs of

vulnerable subgroups, the method of comparison with adequate intakes has been discarded when it might have led to refusal of the application. This is again a clear breach of Article 14(4) of Regulation 178/2002.

Regarding the subjects with chronic diseases and compromised immune system, which constitute potentially vulnerable population subgroups, the Commission (Annex p. 10) states it must be noted that they would be under medical care and presumably supervision of their diets. In our view, this is an inadequate explanation for the failure to include this specific category of consumers in the risk assessment, as required by Article 14(4) of Regulation 178/2002. In addition, the proposed labelling is inadequate to allow informed medical decisions (see below).

Further, the Commission states (Annex, p.10) that consumption data on individuals with specific dietary preferences (e.g. vegans) are not available and consequently, separate exposure assessments for these groups could not be made. This is a further breach of Article 14(4) of Regulation 178/2002.

Example 3: Inadequate feed safety assessment

The Commission accepts that the deliberate introduction of modified soybean oil into animal diet with intention of changing the fatty acid profile of animal products is possible, but states that to date there has been no commercial uptake and consequently, at present no human exposure assessment of the impact of the GM soybean oil on the nutritional content of animal products, such as meat, milk or eggs can be made (Annex, p. 11). However, this is inadequate because, if no such safety assessment could be made, the use of the modified soybean oil in feed should have been prevented through the use of a restriction on the authorisation.

Example 5: Inadequate labelling

Article 14(3) of Regulation 178/2002 states:

“3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.” [emphasis added].

Article 13(2 and 3) of Regulation 1829/2003 state:

“2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

3. In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.”

Article 14 highlights that detailed rules for implementing this Section, amongst other things

regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2). However, no such detailed rules have been adopted for nutrient-altered GM crops.

Since the applicants accept the three soybeans are different from their conventional counterparts, labels have been proposed for all three products. The Commission Decisions state that for 305423 and MON 87705 soybeans, the label must contain the words "with increased monounsaturated fat and reduced polyunsaturated fat", whereas for MON 87769 the words "with stearidonic acid" must appear on the label (Annex, p14). However, these labels do not describe in detail all the nutritional changes in these products, which feature significant and complex changes in nutrient content, some of which are unintentional, namely:

- The newly expressed desaturases in soybean MON 87769 seeds result in an alteration of the fatty acid profile, leading to the appearance of four new fatty acids (stearidonic acid (SDA), also known as octadecatetraenoic acid; alpha-linolenic acid (ALA); and two trans-fatty acids, 9c,12c,15t trans-ALA (18:3) and 6c,9c,12c,15t trans-SDA (C18:4)) and a reduction in linoleic acid (LA). The compositional analysis also revealed increased protein and differences in the levels of amino acids. For the processed oil, statistically increased levels of palmitic acid, stearic acid, trans-ALA and vitamin E were observed, whereas the level of lignoceric acid was reduced. The level of LA was also extensively reduced (from 54.8–55.9 % in the conventional counterpart to 20.7–30.9 % of the fatty acids in soybean MON 87769). In addition to these changes, three of the new fatty acids identified in the whole seed were also seen in the refined oil from MON 87769 (SDA, GLA and trans-SDA). Small quantities of trans-ALA were present in all types of refined, bleached and deodorised soybean oil. LA in protein isolate from soybean MON 87769 was reduced, and trans-ALA and ALA increased. The fat phase of the protein isolate produced from soybean MON 87769 also contained SDA, GLA and trans-SDA. The crude lecithin derived from soybean MON 87769 contained SDA, GLA and trans-SDA, which are usually not detected in lecithin from conventional soybeans, and the level of linoleic acid (C18:2) was significantly reduced.
- MON 87705 differs from the conventional counterpart in the fatty acid profile (proportion of (C18:1) oleic acid increased and proportions of (C18:2) linoleic acid and (C16:0) palmitic acid decreased) in seeds and the presence of the CP4 EPSPS protein. Smaller although significant decreases in stearic acid, linolenic acid, arachidic acid and behenic acid and an increase in eicosenoic acid were also observed. The intended effects of the genetic modification and the effects on the fatty acid pattern seen in the analysis of unprocessed soybean seeds were also reflected in the composition of derived oil and additional differences were seen in heptadecenoic acid (C17:1 9c) and octadecadienoic acid (C18:2 6c, 9c).
- In soybean 305423, the conversion of oleic acid to linoleic acid is inhibited and the oleic acid level is elevated. Since linolenic acid is produced from linoleic acid, linolenic acid content is also decreased in soybean 305423. Some of the observed differences of the fatty acid profile are consistent with the intended effect of the genetic modification, i.e. an increase in oleic acid at the expense of PUFA, but changes in the levels of odd chain fatty acids are an unintended effect probably caused by the introduction of the ALS enzyme. Other parameters (calcium, zinc and glycitin and related total glycitein equivalents) also showed non-equivalence. Data was not provided for the compositional content of derived oil, despite this being the main product destined for human consumption.

Inadequate labelling also impacts on vulnerable subgroups, since sufficient information is not available to consumers and the medical profession to make informed decisions about the possible inclusion of these products in these people's diets. This is a breach of the requirement in Article 13(2) of Regulation 1829/2003 that the label should mention "*(iv) implications for the health of certain sections of the population*".

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

The Commission should annul Implementing Decisions 2015/686, 2015/696 and 2015/698 (Off. J. Eur. Union L 112), which relate to the import of the three different nutritionally-altered GM soybeans, for use in food and feed (Monsanto's MON 87769 soybean; Monsanto's MON 87705 soybean; Pioneer soybean 305423).

The Commission should require that EFSA develops Guidance for the risk assessment of GM crops with intentionally-altered nutritional content, and should ensure such Guidance is adopted before any authorisations for such crops are considered. This Guidance, which should be subject to public consultation, should include (but not be limited to) all of the matters outlined above, to ensure a comprehensive, high quality risk assessment.

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

Yes.

On 24th April 2015, the European Commission issued market authorisations for the import and use in food and feed of several nutritionally-altered genetically modified (GM) soybeans with altered oil content (European Commission, 2015. Commission Implementing Decisions 2015/686, 2015/696 and 2015/698. Off. J. Eur. Union L 112).

On 29th May 2015, GeneWatch UK and TestBiotech sent a formal request for internal review of these GM crop authorisations under Article 10 of Regulation (EC) No. 1367-2006 ('the Aarhus Regulation') (attached).

On 16th November 2015, the European Commission replied stating that the complaint was largely inadmissible, since the objections relating to the health effects of consumption of the soybeans, were (in its view) outside the scope of Article 10 of the Aarhus Regulation (letter attached). As a result of legal action brought by TestBiotech, the General Court annulled this letter from the Commission, finding that all the matters raised in the complaint did in fact fall within the Scope of Article 10 (case T-33/16).

The letter sent by the Commission to GeneWatch UK and TestBiotech on 19th July 2018, which is the subject of this complaint, contains the Commission's subsequent review of the substance of the original allegations.