European Ombudsman proposal in case 176/2015/JF on the alleged failure of the European Food Safety Authority to reply adequately to questions about an authorisation application for genetically modified maize

Solution - 06/05/2015
Case 176/2015/JF - **Opened on** 05/05/2015 - **Decision on** 13/12/2017 - **Institutions concerned** European Food Safety Authority (Settled by the institution) | European Food Safety Authority (Solution achieved) |

Made in accordance with Article 3(5) of the Statute of the European Ombudsman [1]

The Ombudsman finds that the European Food Safety Authority (EFSA) has not responded adequately to a number of questions put to it by the complainant. The questions were posed in the context of EFSA's role in the authorisation of food and feed and related in particular to the renewal of the authorisation for Monsanto's MON 810 genetically modified maize. The Ombudsman proposes that the authority now directly addresses the complainant's query, that is, whether a company seeking authorisation for a genetically modified product submitted all relevant data and, if it did not, whether EFSA's acceptance of this is in line with best scientific practice. This proposal does not question EFSA's assessment of the product's safety but rather whether it considers it appropriate that EFSA itself – and not the company seeking authorisation – is solely responsible for the securing of all data relevant to the assessment of a product's safety. While EFSA is accountable for product authorisation, the question arises of what should be the appropriate response to an alleged deliberate failure by a company, seeking product authorisation, to provide all appropriate information about the safety of that product.

The Ombudsman also proposes that EFSA should respond to concerns expressed by the complainant regarding reliance on a particular test allegedly proposed by experts known to be close to the applicant company.

The background to the complaint

1. The complaint, from the French association *G.I.E.T. - Groupe International d'Études Transdisciplinaires* is about how the European Food Safety Authority (EFSA) evaluates the safety of genetically modified organisms (GMOs) prior to their authorisation for use in the EU. Specifically, it concerns EFSA's handling of an authorisation application for genetically modified maize.

2. In October 2013, a member of the European Parliament (the 'MEP'), asked a number of

questions to the European Commission on behalf of the complainant. The questions were based on the assertion that an EU study with a focus on an authorisation renewal for Monsanto's MON 810 genetically modified maize, had cast doubt on some of Monsanto's published results and on the methods it used to assess the safety of MON 810 and other genetically modified plants. The MEP said that the complainant claimed that **Monsanto provided only data that supported its desired conclusions** . The MEP asked the Commission if this was the case and if so if this was scientifically valid. The MEP also **asked if Monsanto had chosen relevant "comparators" [2]** , particularly given what he described as " *the disturbing case of the average histidine rate* " [3] . Finally, the MEP stated that the study **questioned the pepsin-resistance test used by Monsanto** to show how the "interest protein" in MON 810 is destroyed by digestion [4] . According to the complainant, a member of EFSA's GMO Panel had said that the interest protein in MON 810 is *not* destroyed in conditions close to that of real digestion. The MEP therefore asked the Commission to explain why, in the view of the complainant, EFSA had validated a test result that had been questioned by one of EFSA's own experts [5] .

3. The Commission asked EFSA to reply to the MEP.

4. EFSA replied to the MEP and also to the complainant and said that it had understood the MEP's first set of questions to concern (a) the allegedly selective use of data; and (b) the appropriateness of the "comparators" used.

As regards (a) - EFSA said that it had given the MEP a detailed description of the procedure followed by its GMO Panel for the risk assessment of maize MON 810. It said that the GMO Panel had used the applicant's data, the scientific comments of Member States, the environmental risk assessment report from the competent authorities of the relevant Member State, and other recent and relevant scientific data available in the literature. It added that the GMO Panel, under the relevant guidelines, had produced a summary description of the scientific principles applied and a list of all the data and information used. The GMO Panel had considered all such data, regardless of whether they were in favour of or against the applicant.

As regards (b) - EFSA said it had taken proper account of " *natural variability* ". According to the applicable procedure, GMOs are, as a first step, compared with a suitable "control product" to identify possible differences due to the genetic modification. Then, as a second step, any identified differences are risk-assessed with regard to safety, nutritional impact and environmental implications, in accordance with the GM Food and Feed Regulation [6] and the *Codex Alimentarius* [7] . The EFSA GMO Panel followed this approach in respect of MON 810 and assessed all available data, namely from the field trials carried out in the US in 1994 and 1995.

5. EFSA said it had understood the MEP's second set of questions to concern (c) the reasons why EFSA had accepted the applicant's data despite what the complainant considered to be an apparent contradiction between its results and others; and (d) its views on the scientific validity of a test conducted in non-physiological conditions.

As regards (c) - EFSA said that, in 2009, its GMO Panel assessed the *in vitro* degradation studies presented by the applicant as well as other available studies and concluded that the subject protein was rapidly degraded by pepsin under the conditions used. These conditions were similar to those described in *Codex Alimentarius* and " *EFSA* " [8] . In 2012, the EFSA GMO Panel conducted a further risk assessment of maize MON 810 by reviewing other publicly available studies on the relevant protein degradation by pepsin. Accordingly, EFSA said that its GMO Panel had used all available scientific evidence, both by applying the recommended conditions for testing, as well as by following alternative protocols. The *in vitro* degradation studies were a valid additional tool for the allergenicity assessment. The EFSA GMO Panel did not identify indications of allergenicity concerns for humans or animals.

As regards (d) - EFSA explained that this test was conducted in accordance with the recommendations of the *Codex Alimentarius* and " *EFSA* ". This test is not an *in vitro* digestibility test designed to mimic the physiological conditions of the gastric digestion.

6. In conclusion, EFSA said that it had addressed all of the MEP's questions and that it had thoroughly described the methodology used in the risk assessment of maize MON 810. It said that it had considered all available data and had followed the internationally agreed principle of identifying the differences between the GMO and its non-GM comparator, assessed in the context of natural variation and taking into account their relevance for safety, in accordance with the GM Food and Feed Regulation and the *Codex Alimentarius* . The pepsin resistance test provided by the applicant followed the conditions described by the *Codex Alimentarius* and " *EFSA* " and was, therefore, considered a valid study for the allergenicity assessment. In support of its position, EFSA referred to a number of scientific publications, which it listed in its reply.

7. The complainant was not satisfied with EFSA's reply and complained to the European Ombudsman in February 2015.

The inquiry

8. The Ombudsman opened an inquiry into the complaint and identified the following allegations and claims:

1) EFSA was late in replying to the complainant's letter and the reply was in English rather than in the complaint's French.

2) EFSA failed to reply properly to the specific questions concerning the procedure for authorisation of GM maize MON 810. In particular, EFSA failed clearly to explain:

(i) whether the applicant had submitted only those data that were favourable to its application;

(ii) whether, if that was the case, it is scientifically acceptable that an applicant submits only data that is favourable;

(iii) whether the comparators referred to by the applicant were relevant for the GMO in question;

(iv) how it was possible, according to the complainant, that the applicant's results in respect of

the histidine rate were inconsistent by providing for rates which were both above and below normal; and

(v) why it did not consider, when deciding on authorisation, the opinion of one of its GMO Panel experts that the interest protein of MON 810 is not destroyed in conditions close to those of the physiology of digestion. According to the complainant, the pepsin resistance test used to assess the digestibility *in vitro* of the interest protein of MON 810 was proposed by experts close to the applicant.

3) EFSA should

(i) apologise for having replied late and in English; and

(ii) reply properly to the questions set out in points (i) to (v) of allegation 2 above.

9. The Ombudsman's proposal takes into account the arguments of all parties.
Allegation relating to delay and language and the claim for an apology

Arguments presented to the Ombudsman

10. The complainant said that it took EFSA seven and a half months to reply. The reply letter was in English, whereas the complainant had written in French. The complainant asked EFSA to apologise.

11. EFSA said it had replied in English to a request made in English by the Commission but regretted the lapse in not replying in French and apologised.

12. The complainant accepted this.

The Ombudsman's assessment

13. The Ombudsman welcomes EFSA's apology and considers the matter settled.

Claims related to the alleged inadequate reply of EFSA to the complainant's concerns about the authorisation of a GMO

General arguments presented to the Ombudsman

14. The complainant argued that the first set of questions asked by the MEP did not concern EFSA's procedures, but the specific application for GMO authorisation regarding MON 810. The second set of questions concerned EFSA's evaluation methods for analysing GMO applications.

15. In its reply EFSA said that its role [9] is to provide scientific advice and technical support for EU legislation and policies in all fields that have an impact on food and feed safety, and to deliver opinions based on sound and up-to-date scientific knowledge reflected in available data. More specifically, EFSA performs scientific evaluations of applications for authorisation of GM food and feed. Applicants prepare and send their applications for placing GMOs on the market to the competent authorities of a Member State. The national authority then sends the application and any available supplementary information to EFSA. Both EFSA and the national authorities may, where appropriate, request applicants " *to supplement the particulars accompanying the application.* " EFSA assesses the application and delivers a reasoned opinion on it [10] .

16. According to EFSA, it had been in frequent contact with the complainant. Issues raised by the complainant, namely the digestibility *in vitro* , were also discussed at a workshop on the allergenicity assessment of GM plants held on 17 June 2015 (after the complaint was made to the Ombudsman), attended by the complainant.

17. EFSA's technical and scientific work is highly complex, with topics at the forefront of regulatory science. Its opinions do not always achieve full public acceptance, particularly in relation to divisive issues such as GMOs. EFSA is aware that some people, including the complainant, may not fully agree with the GMO Panel conclusions. EFSA nevertheless believes that it carries out its duties in a transparent and accountable manner, fully in line with the principles of good administration.

The Ombudsman's general remarks

18. The Ombudsman's conclusion is that there is a misunderstanding by EFSA about the complainant's concerns.

19. The complainant is not questioning EFSA's assessment of the genetically modified maize MON 810 but rather *the information provided by the applicant -Monsanto - in its application* and EFSA's attitude towards its comprehensiveness.

20. It is clear that EFSA takes into account *all available* data, studies and scientific evidence when assessing GMOs, and not only the data and information provided by the applicant.

21. However, the Ombudsman understands that the complainant's concern is that if an application is biased or incomplete in terms of the data, studies and scientific evidence that it refers to, there is a greater risk that EFSA, despite its best efforts, will make an incorrect assessment.

22. The complainant's concerns thus relate to what responsibility, if any, EFSA has in determining and acknowledging biased or incomplete applications and in taking action in relation to such applications. The Ombudsman's proposal for a solution in this case will be

based on this general understanding of the matter as well as on the particular concerns assessed below.

23. The Ombudsman does not have the scientific expertise to question the scientific evaluation of specialised scientific services. The Ombudsman may, however, seek to assess whether the institution, body or agency responsible for the relevant scientific services, such as EFSA, has procedural safeguards in place which ensure that the scientific advice given is reliable and independent.

Analysis of data provided by the applicant

24. The complainant had asked EFSA (i) whether the applicant had submitted only data that was favourable to its application; and (ii) whether it is scientifically acceptable that an applicant submits only such favourable data.

25. EFSA said that, according to the relevant rules, applicants must submit information that allow the risk assessors, that is, EFSA and the competent national authorities, to determine whether the product is or is not safe. The scientific requirements are laid down in relevant guidance documents. According to EFSA, " *it is clear that applicants are required to include in the application also studies showing negative results, or safety concerns.* " Failure to share meaningful studies highlighting a safety risk would be in breach of the GM Food and Feed Regulation. However, EFSA does not form its risk assessment opinion solely on the basis of information submitted by the applicant. EFSA continuously monitors the scientific literature for new relevant data. EFSA keeps itself up-to-date with new developments and papers. Following a weight-of-evidence approach, the EFSA GMO Panel thoroughly analyses all available evidence. In its assessment of the MON 810 application, EFSA said that it took into account all available relevant data, including data of an unfavourable nature.

26. The complainant said that the question was about the MON 810 *application* . The complainant has access to a non-confidential version of that application which, in its view, contains only favourable data and says that this cannot be scientifically acceptable. It claims that EFSA's failure to provide the answer sought raises questions as to whether EFSA knowingly allows unsatisfactory applications to be made.

The Ombudsman's preliminary assessment

27. EFSA and the complainant appear to be referring to different things in relation to this issue: EFSA refers in general terms to its rigorous analysis while the complainant refers to its concerns about the completeness of the information provided by the applicant in the particular application regarding MON 810.

28. In addition to explaining that it has taken into account all available data, studies and scientific evidence - whether provided by the applicant or not - EFSA has said that " *it is clear*

that applicants are required to include in the application also studies showing negative results, or safety concerns " and that a failure to share meaningful studies highlighting a safety risk would be in breach of the GM Food and Feed Regulation. It is therefore clear from EFSA's statement that it is not scientifically acceptable to submit only favourable data when unfavourable data are also available. EFSA's position is that an applicant has to submit *all* relevant data to EFSA. However, EFSA has not answered the complainant's question as to the completeness of the data provided in the particular case. Nor has it explained why it has not answered the complainant's question. The complainant has a valid concern that applicants should provide **all** relevant scientific data and EFSA should therefore provide a clear and unequivocal answer to the question as to whether the applicant in the present case provided **all relevant data** . If EFSA considered that the applicant had not provided all relevant data, it should have asked the applicant to submit the missing data and analysed it. It should also have made all the relevant scientific data public. In the event that EFSA did not proceed in this way, it should clearly explain why.

29.

The Ombudsman notes that GMO approvals may provoke strong public concerns. In order to gain and maintain the trust of EU citizens in this area, it is not only important to have trustworthy procedures for scientific evaluation, but also that any reasonable questions about this procedure, from citizens and other stakeholders (such as NGOs), are answered as clearly as possible. The Ombudsman fully understands why the complainant considers EFSA's response to the question to be evasive. This perception is damaging not only to EFSA's reputation but also to that of the EU. Accordingly, the Ombudsman makes the proposal below in accordance with Article 3(5) of the Statute of the European Ombudsman.

The relevance of the chosen "comparators"

30. The complainant said that EFSA did not explain whether the "comparators" referred to by the applicant were relevant for the GMO in question [11] . The complainant said that applicants often select inadequate comparators, which give inconsistent results. The complainant wants EFSA to explain whether the comparators used by the applicant were correct.

31. EFSA said that it had considered all available evidence while analysing the GMO. It said it had applied a comparative approach on the assumption that traditionally-cultivated conventional crops have a history of safe use. This approach enables EFSA to assess whether the properties of the GM plant alter the level of risk. The GM plant's toxicological, allergenic and nutritional properties are investigated to assess the relevance of the observed changes to human and animal health. EFSA explained that it applied a two-step approach: first, EFSA identifies possible differences between the GM plant and the " *appropriately selected comparator* " (the

'proof of difference'); then, it assesses whether the characteristics of the GM plant fall within the range of natural variability as derived from literature data or estimated from concurrently non-GM reference varieties with a history of safe use (the 'proof of equivalence'). Efforts are made to identify any statistically significant differences which may point at biological changes caused by genetic modification. Should a statistically significant difference be observed, but which is within the range of natural variability known for the plant, then it can be considered biologically insignificant. Otherwise it will constitute a change that requires consideration in the risk assessment. The risk assessment would involve determining if and to what extent the change is or is not meaningful as regards harm to humans, animals or the environment.

32. As regards the histidine rate of MON 810, EFSA stated that the GMO Panel took into account data collected during field trials in the USA and in France. EFSA concluded that the observed difference in the histidine level was of no biological relevance and did not raise any concerns in terms of food safety. To state the opposite would be tantamount to arguing that varieties of conventional non-GM maize would also raise concerns in terms of food safety.

33. The complainant said that EFSA's reply implicitly meant that EFSA did approve the comparators selected by the applicant. The complainant did not question whether there was any risk resulting from the differences in the histidine rate but rather criticised the methodology. The complainant said that the comparators were incompatible with EFSA's own standards as the applicant failed to provide all necessary evidence of their adequacy [12] . The chosen comparators were thus, in the complainant’s view, inappropriate.

The Ombudsman's preliminary assessment

34. EFSA refers to its rigorous procedures and analysis, whereas the complainant's concern is about the applicant possibly having provided insufficient information in its application regarding MON 810.

35. EFSA's response to the validity of the comparators can be seen as opaque. Its failure to state unambiguously whether all relevant information was provided by the authorisation applicant also raises questions of trust.

36. The Ombudsman therefore makes a proposal below in accordance with Article 3(5) of the Statute of the European Ombudsman.

The GMO Panel expert

37. The complainant says that EFSA failed to explain why it did not take into consideration the opinion of one of its GMO Panel experts, which was that the interest protein of MON 810 **is not destroyed** by digestion. The complainant says that the pepsin resistance test used to assess the digestibility *in vitro* of the interest protein of MON 810, was proposed by experts with links to the applicant.

38. The complainant says that the conditions in the human stomach are different from those of the pepsin used in the pepsin resistance test. The interest protein of MON 810 degrades relatively quickly in the pepsin test, which the complainant says is convenient for the applicant. However, the complainant says that the EFSA allergenic expert claims that the interest protein of MON 810 **does not degrade** in conditions that reflect the real life conditions in the human body. The complainant noted EFSA's statement that the digestibility test *in vitro* was recommended by the *Codex Alimentarius* and by " *EFSA* ", that is, itself. EFSA further referred to a scientific article co-authored by 26 people. The complainant claims that 22 of those authors had links to the applicant and to its affiliated companies. In its view, the pepsin test is being applied in the industry's interest rather than in the interest of science and public health. The complainant claims that this testing method cannot be considered as adequate for the assessment of GM maize safety.

39. EFSA states that the expert in question was a member of the relevant GMO panel. It said that the GMO panel adopted its opinion on MON 810 unanimously, that is, without any minority opinions. EFSA added that the expert was also a member of its standing Working Group dealing with the safety assessment of GM food and feed, which includes the assessment of changes in allergenic potential of a GMO. The expert was also Chair of the Working Group which, in 2010, developed the scientific opinion on the allergenicity of GM plants and derived food and feed, which made additional recommendations for the allergenicity assessment. EFSA therefore said that the views of that particular expert had been taken into account in the scientific opinion on the renewal of the authorisation for maize MON 810, as well as in the context of assessing allergenicity of GM plants and derived food and feed.

40. As regards the pepsin test, EFSA acknowledged that there is no single test that, on its own, can predict the allergenic properties of proteins. EFSA follows an approach that brings together experimental data and other information to define the potential allergenic profile of newly expressed proteins. The protein resistance test is only one of the elements of information considered. The currently recommended conditions for the pepsin resistance test are those described by the *Codex Alimentarius* and by EFSA. The pepsin resistance test is not, EFSA stated, designed to mimic the physiological conditions of gastric digestion. It therefore cannot be considered as an *in vitro* "digestibility test". It is rather a test to determine the biochemical character of the subject protein and its stability to pepsin degradation at pH 1.2 (since stability to pepsin digestion has been established in those conditions for some allergenic proteins in food).

41. EFSA described the relevant assessment of the MON 810 application: in 2009, its GMO Panel analysed the *in vitro* degradation studies presented by the applicant, as well as other studies publicly available at the time, and concluded that the subject protein was degraded by pepsin under conditions similar to those proposed by the *Codex Alimentarius* and EFSA. It found, therefore, the applicant's studies to be a valid **additional tool** for the allergenicity assessment. In late 2012, the EFSA GMO Panel reviewed additional publicly available studies on the interest protein degradation by pepsin, namely one from 2010 providing for the interest protein degradation **using different experimental conditions** . Hence, the EFSA GMO Panel used **all available scientific evidence** when assessing the allergenicity of maize MON 810,

that is, scientific evidence obtained by applying **currently recommended conditions** and **scientific evidence following alternative protocols** .

42. In 2012, EFSA found that the pepsin resistance test, and the " *in vitro digestibility tests* ", deserved further discussion. The subsequent literature review on *in vitro* digestibility tests for allergenicity assessment highlighted the need for a better standardisation and harmonisation of the conditions used. As a result, a working group was established in 2014 with the aim of developing supplementary guidance. A **report was expected by the end of 2016.**

43. The complainant stated that it found the GMO Panel's scientific opinion incoherent, considering the position of one of its members. The complainant acknowledged that there is no test available to predict the allergenic properties of a protein. It questioned, however, the justification for EFSA's approach in such circumstances. The complainant said that competent EU institutions should be able to require applicants to provide more appropriate tests than the pepsin test proposed in the *Codex Alimentarius* . If the pepsin test is not a digestibility test, then the GMO Panel could not have concluded, as it did in its scientific opinion, that the reference protein rapidly degraded at **"** *simulated gastric conditions* **"** . The complainant says that EFSA has used the pepsin test as a "digestibility test". It says that the correlation between the results of the pepsin test and alleregenicity has been contested by the expert mentioned by the MEP [13] . In addition, the complainant said that EFSA had not responded to its concern that the pepsin resistance test had been proposed by experts linked to the applicant. The complainant provided a copy of an article on stability of food allergens to digestion *in vitro* where explicit reference is made to the applicant as the employer of some of the authors of that article [14] .

The Ombudsman's preliminary assessment of this aspect of the complaint

44. The Ombudsman notes that the EFSA GMO Panel adopted its opinion on MON 810 unanimously, which means that no panel member had submitted a minority opinions during the process. The Ombudsman thus finds that the views of all of the experts on the GMO panel were duly taken into consideration [15] .

45. The Ombudsman also notes that, in an e-mail to the complainant dated 1 October 2012, EFSA stated that " *there is not a standardised protocol for performing in vitro digestibility test in more physiological conditions than those conditions used in the pepsin resistance test. EFSA launched a procurement call in April 2012 with the objective of performing a literature review on "in vitro digestibility tests for allergenicity assessment"* ". EFSA has said that the subsequent literature review showed a need for a better standardisation and harmonisation of the conditions used, that a working group was established in 2014 for that purpose, and that a report is expected **for the end of 2016** . The Ombudsman finds EFSA's approach and the procedural steps taken to be **reasonable** : EFSA is clearly **aware of the limits of the pepsin test.** There is no readily available alternative test that EFSA can require applicants to use - the complainant itself notes (see paragraph 43 above) that **there is currently no test available to predict the allergenic properties of a protein.** EFSA is taking steps to find a way to improve the testing

methods - and it has put in place a working group on new testing methods. The Ombudsman therefore considers that EFSA has addressed the issue in an appropriate manner. Her preliminary view is that there has been no maladministration by EFSA as regards this aspect of the complaint. However, if the complainant gives EFSA what it considers to be a more appropriate test, EFSA would have to assess it.

46. The Ombudsman notes that EFSA has not replied to the complainant's concern that the pepsin resistance test had been proposed by experts linked to the applicant company. It is important that EFSA should reply to this concern and say whether or not it has procedures in place to ensure the integrity of tests being relied upon by an applicant. This matter, therefore, will be included in the Ombudsman's proposal for a solution.

Ombudsman proposal

The Ombudsman proposes that EFSA should give clear and full answers to the questions raised by the complainant. Specifically, EFSA should

(i) explain to what extent it is responsible for determining whether scientific data in applications are biased or incomplete and for taking action in relation thereto;

(ii) explain, on the basis of its response to point (i), whether the applicant for MON 810 submitted all relevant data in its possession and, if it did not, whether EFSA requested the applicant to provide additional data and subsequently made all the relevant data public;

(iii) explain, on the basis of its response to point (i), whether the "comparators" which had been selected by the applicant for MON 810 were relevant or not; and

(iv) respond to the concerns expressed by the complainant regarding a possible link between experts linked to the applicant and the reliance on the pepsin test.

Emily O'Reilly

European Ombudsman

Strasbourg, 17/01/2017

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] The Ombudsman consulted the article "Safety assessment of genetically modified plants with deliberately altered composition" by Halford, Nigel G. *et al.* (last consulted on 14

November 2016 at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265246/ [Link]) where it is explained that "[t] *he food and feed risk assessment strategy for genetically modified (GM) crops in Europe, as applied by the European Food Safety Authority (EFSA) GMO Panel, compares GM plants and their derived food and feed with a conventional non-GM comparator, the comparator being a plant with a history of safe use as food (the principle of substantial equivalence).* "

[3] According to Encyclopaedia Britannica (https://www.britannica.com/science/histidine [Link]): " *Histidine is an amino acid obtainable by hydrolysis of many proteins . A particularly rich source, hemoglobin (the oxygen -carrying pigment of red blood cells) yields about 8.5 percent by weight of histidine. First isolated in 1896 from various proteins, histidine is one of several so-called essential amino acids for human beings; they cannot synthesize it and require dietary sources. In microorganisms histidine is synthesized from the sugar ribose and the nucleotide adenosine triphosphate .* "

[4] According to Encyclopaedia Britannica (https://www.britannica.com/science/pepsin [Link]): " *Pepsin is the powerful enzyme in gastric juice that digests proteins such as those in meat, eggs, seeds, or dairy products.* "

[5] The full text of the MEP's questions is available here: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2013-012049+0+DOC+XML+V0//EN [Link] and here http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2013-012048+0+DOC+XML+V0//EN [Link]

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

[7] According to the website www.codexalimentarius.org [Link], "[i] *nternational food standards, guidelines and codes of practice contribute to the safety, quality and fairness of this international food trade. Consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications. Public concerns about food safety issues are often placing Codex at the centre of global debates. Biotechnology, pesticides, food additives and contaminants are some of the issues discussed in Codex meetings. Codex standards are based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO. While being recommendations for voluntary application by members, Codex standards serve in many cases as a basis for national legislation. The reference made to Codex food safety standards in the World Trade Organizations' Agreement on Sanitary and Phytosanitary measures (SPS Agreement) means that Codex has far reaching implications for resolving trade disputes. WTO members that wish to apply stricter food safety measures than those set by Codex may be required to justify these measures scientifically. Codex members cover 99% of the world's population. More and more developing countries are taking an active part in the Codex process - in many cases assisted by the Codex Trust Fund, which strives to finance - and train - participants from such countries to enable efficient participation. Being an*

active member of Codex helps countries to compete in sophisticated world markets - and to improve food safety for their own population. At the same time exporters know what importers demand, and importers are protected from substandard shipments. International governmental and non-governmental organizations can become accredited Codex observers to provide expert information, advice and assistance to the Commission. Since its beginnings in 1963, the Codex system has evolved in an open, transparent and inclusive way to meet emerging challenges. International food trade is a 200 billion dollar a year industry, with billions of tonnes of food produced, marketed and transported... "

[8] EFSA did not explain what it meant by this reference. Presumably, " *EFSA* " would refer to, broadly-speaking, EFSA's publications setting out the conditions for testing food safety which are accepted by EFSA.

[9] In accordance with Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p.1), available here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF

[10] In accordance with the GM Food and Feed Regulation.

[11] See footnote 2.

[12] According to the complainant, while EFSA had stated, in an e-mail to it of 5 March 2014, that "[a] *pplicants and risk assessors must ensure that an evaluation has sufficient power to provide reasonable evidence of equivalence* ", in the present case, the applicant has not provided any calculation of power with its application MON 810 and no equivalence test has ever been submitted with any application for a GMO authorisation in Europe.

[13] The complainant enclosed with its comments a sound recording of, according to the complainant, a presentation by the expert mentioned by the MEP, made at a scientific conference on the pepsin test.

[14] The list of authors of the article does not include the expert mentioned by the MEP.

[15] For this reason, the Ombudsman does not consider it necessary to forward to EFSA the sound recording provided by the complainant with its comments.