European Ombudsman

Handling of a set of questions concerning an application for authorisation of a genetically-modified ('GM') maize

Case opened
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) |

Allegation(s)

1) EFSA replied belatedly to the complainant's letter of 30 June 2014 and in a language (English) different to that used by the complainant in its letter.

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 submitted only that data that was favourable to its application;

(ii) whether it is scientifically acceptable that an applicant submits favourable data only;

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

(iv) how it was possible that the applicant's results in respect of the histidine rate were inconsistent in that they provided for rates which were both above and below normal; and

(v) why it did not take into due consideration, when deciding on the application for authorisation, the opinion of one of its GMO Panel experts, which was 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 pepsine resistance test (also known as the Astwood test) used to assess the digestibility *in vitro* of the interest protein of MON 810 was proposed by experts close to the applicant.

Claim(s)

EFSA should

1) Apologise for having replied belatedly and in English; and

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