



16 MAI 2013

REPORT

Date d'arrivée **ON THE EUROPEAN OMBUDSMAN'S INSPECTION OF DOCUMENTS**
IN COMPLAINT 622/2012/ANA

Name of complainant: Testbiotech e.V. represented by Mr Christophe Then
Institution involved: The European Food Safety Authority (EFSA)
Subject matter of the case: Alleged conflict of interest of the Chair of a Scientific Panel

The inspection

Object of the inspection:

To facilitate the Ombudsman's inquiry into the complainant's allegation that EFSA failed to address the conflict of interest concerning the Chair of one of its scientific panels (hereinafter, 'the Chair') and the claims that EFSA should 1) acknowledge that it failed to address the conflict of interest concerning the Chair and 2) implement effective measures to prevent similar conflicts of interest in the future.

To this end, the Ombudsman asked EFSA to allow his representatives to inspect the following documents:

- a) the Chair's Annual Declarations of Interest (ADoI), Specific Declarations of Interest (SDoI) and Oral Declarations of Interest (ODoI) from 2009 to 2012 and the documents relating to the manner in which EFSA applied its internal rules to the screening of the Chair's ADoIs, SDoIs, and ODoIs from 2009 to 2012;
- b) the same documents from 2003 to 2009 (to help the Ombudsman understand the manner in which EFSA applied its procedures previously, without prejudice to the temporal scope of the inquiry);
- c) documents concerning any official contacts between the Chair and ILSI from 2009 to 2012 (and from 2003 to 2009); and
- d) any internal document or record that may exist of EFSA's assessment of the Chair's alleged potential conflict of interest, in particular, following the publication of the complainant's Report in December 2010.

Date: 16 May 2013. The inspection started at 10.15 am and finished at 13.45 pm.

Location: EFSA's premises – Parma

Present: a) EFSA services:

Per BERGMAN, Director, Scientific Evaluation of Regulated Products

Dirk DETKEN, Head of the Legal and Regulatory Affairs Unit

Simone GABBI, Legal Officer

b) European Ombudsman services:

Antonios ANTONIADIS, Legal Officer, CIU4, Directorate B

Emanuele REBASTI, Legal Officer, CIU4, Directorate B

Introductory and procedural aspects

At the outset, the Ombudsman's representatives introduced themselves and set out the object and purpose of the present inspection within the context of the Ombudsman's inquiry into the complaint. The Ombudsman's representatives outlined the legal framework which applies to the Ombudsman's services when they carry out inspections and informed EFSA's representatives that if they indicate any documents to be confidential, the applicable rules provide that no access may be granted to those documents, neither to the complainant nor to any other person outside the Ombudsman's office¹.

The documents on the EFSA's file

EFSA's file for the inspection was divided into three folders:

- A) EFSA's own file of the complaint,
- B) The Panel Chair's DoIs and EFSA's screening of these DoIs from 2008 to 2012, and
- C) The Panel Chair's DoIs and EFSA's screening of these DoIs from 2003 to 2007.

In response to a question from the Ombudsman's representatives as to why 2008 was chosen as the dividing point in folders B) and C), it was explained that this was a result of a change in the applicable rules and procedures that came into force in 2008.

The Ombudsman's representatives thoroughly examined the folders and inspected the following files:

Folder A)

This folder contained a) the complaint, its annexes and the reports forwarded by the complainant, b) the Ombudsman's letter opening the inquiry, c) EFSA's opinion on the complaint, d) the complainant's observations, e) the Ombudsman's letter informing EFSA of the inspection, and e) EFSA's notes on the internal handling of the complaint.

Folder B)

¹ Articles 13(3) and 14(2) of the European Ombudsman's Implementing Provisions.

1) Exchange of mails of 19 March 2013 between the Head of the GMO Unit and the Chair in relation to the question in the Ombudsman's inspection request about the Chair's formal contacts with ILSI, 2 pages.

In document 1), the Chair indicated that he would welcome the opportunity to explain to the Ombudsman the issues arising in the present case. In this connection, the Ombudsman's representatives asked whether EFSA had acted upon the Ombudsman's suggestion in his letter informing EFSA of his inquiry to ensure that its opinion on the complaint takes account of any views the Chair may wish to express regarding the complaint.

In response, EFSA's representatives presented an

2) E-mail from the Head of the GMO Unit of 19 July 2012 enclosing EFSA's draft opinion on the complaint and the Chair's reply of 23 July 2012 with comments, 10 pages.

The Ombudsman's representatives further examined the following:

3) EFSA's record of assessment of the Chair's ADOIs (Comments on Involvements and Interests by expert account) in 2012, 15 pages.

4) EFSA's record of assessment of the Chair's SDOIs (Comments on Agenda Item by expert account) in 2012, 15 pages.

5) EFSA's record of assessment of the Chair's ADOIs (Comments on Involvements and Interests by expert account) in 2011, 1 page.

6) EFSA's record of assessment of the Chair's SDOIs (Comments on Agenda Item by expert account) in 2011, 19 pages.

7) EFSA's record of assessment of the Chair's ADOIs (Comments on Involvements and Interests by expert account) in 2010, 10 pages.

8) EFSA's record of assessment of the Chair's SDOIs (Comments on Agenda Item by expert account) in 2010, 21 pages.

9) EFSA's record of assessment of the Chair's ADOIs (Comments on Involvements and Interests by expert account) in 2009, 14 pages.

10) EFSA's record of assessment of the Chair's SDOIs (Comments on Agenda Item by expert account) in 2009, 14 pages.

11) EFSA's record of assessment of the Chair's ADOIs (Comments on Involvements and Interests by expert account) in 2008, 2 pages.

12) The Chair's SDOIs for GMO Panel Plenary meetings from 2008 to 2011, 11 pages.

13) The Chair's ADOIs from 2003 to 2012, 58 pages.

Folder C)

14) A summary table and the Chair's SDoIs concerning new GMO applications from 2003 to 2008, 34 pages.

15) The Chair's SDoIs concerning the Working Group on Food and Feed in 2008, 5 pages.

16) The Chair's SDoIs concerning other Working Groups from 2008 to 2010, 17 pages.

17) Minutes of the Working Group on Statistics from 2005 to 2008, 4 pages.

18) Minutes of Working Group on Animal Feeding Trials from 2005 to 2007, 58 pages.

19) Excerpts from minutes of the GMO Panel Plenary meetings from 2003 to 2012, 184 pages.

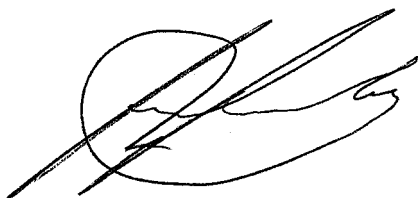
In response to the Ombudsman's representatives' question about the existence of any internal document on file of EFSA's assessment of the Chair's alleged potential conflict of interest, in particular, following the publication of the complainant's Report in December 2010, EFSA's representative explained that, in so far as this is not covered by the documents already inspected by the Ombudsman, EFSA's reaction to the complainant's Report is in the public domain.

Conclusion of the inspection

Following the inspection of the documents, the Ombudsman's representatives requested and received copies of the documents 1) to 16), totalling 248 pages.

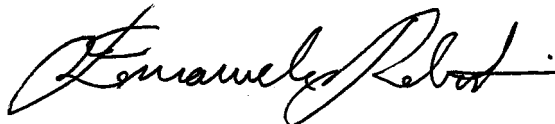
Documents 1) - 12) and 14) - 16) were identified by EFSA as confidential in accordance with Article 5.2 of the European Ombudsman's Implementing Provisions. These documents were marked 'CONFIDENTIAL' and initialled by an EFSA and an Ombudsman representative.

Brussels, 16 May 2013



Mr Antonios Antoniadis

Legal officer



Mr Emanuele Rebasti

Legal officer