

## **Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Food Safety Authority regarding the "Handling of Annual and Specific Declarations of Interest"**

Brussels, 5 June 2009 (Case 2008-737)

### **1. Proceedings**

On 2 December 2008, the European Data Protection Supervisor (EDPS) received by email from the Data Protection Officer (DPO) of the European Food Safety Authority (EFSA) a notification for prior checking relating to the processing of personal data in connection to the handling of annual and specific declarations of interest (DoI).

The prior checking notification contained the following documents:

- User Guide for Declaration of Interests IT Tool (EFSA Information Technology Unit, last updated 8 April 2008)
- EFSA Policy on Declaration of Interests
- Implementing Act to the Policy on Declaration of Interests (Guidance Document on Declarations of Interest of 22 October 2008) with four annexes: 1) Declaration of commitment, 2) Annual Declaration of Interests, 3) Specific Declaration of Interests and 4) Declaration concerning confidentiality
- Implementing Act to the Policy on Declaration of Interests (Procedure for Identifying and Handling Potential Conflicts of Interest of 22 October 2008
- Notification to the DPO under Article 25 of Regulation (EC) No 45/2001 (filled in for "Handling of Annual and Specific Declarations of Interest").

On 10 December 2008, the EDPS staff members visiting EFSA in another context had an opportunity to pose further questions regarding this processing operation, which was recorded in the "Memorandum" of that on the spot check.

On 19 December 2008, the EDPS requested further information via the DPO of EFSA to which he received the answers on 13 January 2009.

On 2 February 2009, the EDPS made a further request for information, to which he received the responses on 26 February 2009.

On 9 March 2009, the EDPS extended the deadline to issue his opinion due to the complexity of the matter.

On 1 April 2009, the EDPS received an updated version of the Implementing Act to the Policy on Declaration of Interests - Guidance Document on Declarations of Interest (dated of 26 March 2009) and new pieces of information. The EDPS extended the deadline for one more month consecutively.

On 12 May 2009, the EDPS sent the draft opinion for comments to the DPO of EFSA, and he received the comments on 4 June 2009.

## 2. The facts

**Introduction:** The European Food Safety Authority (EFSA) pursues a policy of screening potential conflict of interests. To this end an annual and specific declaration of interests is requested.

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA), states that members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee and Panels and the Executive Director shall undertake to act independently.

For this purpose Article 37 of Regulation 178/2002 (hereafter: "EFSA Founding Regulation") imposes the obligation on them to make a) a declaration of commitment; b) an annual declaration of interests "*indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence*". Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a *prima facie* breach of trust towards the EFSA.

Further to that, in accordance with Article 37 (3) of the EFSA Founding Regulation, the persons identified above and any external expert shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

The Executive Director of EFSA has extended this obligation to declare interests to the Deputy Executive Director and administrator staff of EFSA or staff on an equivalent level.

EFSA noted that the **publication** of some type of the Declarations of Interests is an obligation imposed on EFSA by Article 38 of Regulation 178/2002, which reads as follow: "*The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay: (...) (d) the annual declarations of interest made by members of the **Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels**, as well as the declarations of interest made in relation to items on the agendas and meetings*". This provision **does not refer** to other scientific experts for publication of their DoI. EFSA therefore asks for the consent of **Working Group experts** for publishing their DoI. According to EFSA's policy, publication is mandatory, unless the expert concerned could substantiate their refusal with extremely good reasons. In any case, the working group experts can indicate whether they give their consent by flagging or not flagging a box on the on-line system.

**The data controller** of the processing operation is the Executive Director of EFSA, and the following **organisational bodies of EFSA are entrusted with the processing operation:**

- Heads of units, Directors and the Executive Director of EFSA according to their respective responsibilities in charge of coordination and support to the EFSA Advisory Forum
- the EFSA Scientific Committee, EFSA Scientific Panels and Working Groups in their capacity of line manager for the staff in their units
- the Chairperson of EFSA Management Board in charge of coordinating the work of the EFSA Management Board and the EFSA Executive Director.

**The purpose of the personal data processing** is to ensure compliance with the above described legal obligations laid down in Article 37 of Regulation (EC) No 178/2002.

**Categories of data subjects:** A number of persons are obliged to submit either annual or specific declaration of interests:

- Members of the Management Board
- Members of the Advisory Forum
- Members of the Scientific Committee or panels
- Executive Director
- All EFSA staff of AD level or equivalent (also CA, FG IV, ENDS) (hereinafter as: "EFSA staff")
- External experts
- Experts of Member States
- Other EFSA experts who are not working in a Working Group of the Scientific Committee or Scientific Panel or who are not external experts are encouraged to fill in an Annual Declaration of Interest.

**Consequences of submitting declaration of interests or failure to do so:**

A) *Members of the Management Board and Advisory Forum* are either appointed by the Council or by the Member States. EFSA therefore does not have any<sup>1</sup> power to disregard them in their activities. The declarations are made more for transparency reasons.

B) *Members of the Scientific Committee, Scientific Panels and EFSA external experts* are appointed by the Management Board, and there is a clear screening of their activities which is done by the secretariat of each panel.<sup>2</sup> The latest version of the Implementing Act to the Policy on Declarations of Interests lays down the consequences *if Members of the Scientific Committee, Scientific Panels and EFSA external experts do not declare their interests*.

**In particular,**

- failure to submit the annual declaration of interests (AdoI): experts **will not be invited**
- failure to submit (specific declaration of interests) SdoI: experts **can not attend relevant meeting**, as appropriate.

**A policy is foreseen as to breaches and omissions** regarding the declarations by experts in the Implementing Act to the Policy on Declarations of Interests. A failure to declare in a timely and complete manner the interests at question, will be considered as *prima facie* breach of trust towards EFSA, where appropriate actions, including the **dismissal** of the concerned person might be taken by EFSA.

**An internal procedure is foreseen to establish whether the omission by an expert is to be considered as a breach *vis-a-vis* the Authority**, whether it is an intentional omission or gross negligence. The procedure involves the following phases:

1) the expert **is notified about the opening** of a procedure which may lead to a potential dismissal. **Upon request** the expert shall **have access to all documents** related to the procedure.

2) the expert is **invited for a hearing** to put forward his view on the facts in question. A hearing is always organised before a decision is taken. The expert has a possibility to express his/her view and comments and documents submitted are taken into account.

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<sup>1</sup>EDPS Inspection Memorandum 2008-575, p 14.

<sup>2</sup> EDPS Inspection Memorandum 2008-575, p14

- 3) The expert **is notified about the reasoned decision** on the submission to the Management Board in a specified time frame.
- 4) The expert may **submit a complaint** against the decision.
- 5) When EFSA has **concluded its position for a dismissal**, the decision on the submission to the Management Board and the complaint shall be submitted to the Management Board for the final decision.
- 6) The decision for dismissal is taken by the Management Board on the proposal of the Executive Director.

C) **Consequences related to EFSA staff:** Where the declarations of EFSA staff are screened by the line manager, the Executive Director can take certain measures. According to explanations from EFSA, the possible remedial measures on a case by case basis, in accordance with Article 11 and 11(a) of the Staff Regulations, could involve removal of a staff member from a certain function to the temporary replacement on a given dossier. These declarations are done at recruitment level after the person has taken up his/her duties.<sup>3</sup>

**Categories of personal data concerned:** The annual and specific DoIs concern the following *main categories of personal data*:

- data concerning the data subject's career
- data concerning the data subject's private interests
- data concerning the data subject's family, i.e. data concerning the data subject's partner, though without specification of the name of the partner or of the nature of the relationship.

• *In particular*, the following information is contained in the Declarations of Interest (DoI):

I. **Ownership or other investments, including shares**

-to be interpreted in the *annual DoI* as: any substantial financial interests in a company/entity operating in the food or feed business<sup>4</sup>, including holding of stocks and shares, equity, bonds, partnership interests<sup>5</sup> in the capital of a company, one of its subsidiaries or a company in which it has a holding. The holding of financial interests connected with a pension scheme would not be considered a financial interest, provided that the individual has no influence on its financial management.

- to be interpreted in the *specific DoI* as: meaning any substantial financial interests in a company/entity *whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in an activity included in EFSA's remit or in conjunction with the one being reviewed*, including holding of stocks and shares, equity, bonds, partnership interests in the capital of a company, one of its subsidiaries or a company of which it has a holding. The holding of financial interests connected with a pension scheme would not be considered as a financial interest provided that the individual has no influence on its financial management.

II. **Member of a Managing Body or equivalent structure:**

- to be interpreted in the *annual DoI* as: any participation in the internal decision-making of a company, trade association or equivalent entity (e.g. board membership,

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<sup>3</sup> EDPS Inspection Memorandum 2008-575, p 14

<sup>4</sup> By reference to the definitions set out in Article 3 of Regulation (EC) No 178/2002, food or feed business should be taken to mean any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food or feed.

<sup>5</sup> When declaring financial interests e.g. stock and shares, only the kind and the name of the company need to be stated.

directorship).

- to be interpreted in the *specific DoI as*: meaning any participation in the internal decision-making of a company, trade association or equivalent entity (e.g. board membership, directorship) *whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in an activity included in EFSA's remit or in conjunction with the one being reviewed or the one from a competitor.*

### III. **Member of a Scientific Advisory Body**

- to be interpreted in *the annual DoI as*: Present or past participation of the data subject in the works of a Scientific Advisory Body with a right to vote on the outputs of that entity.

- to be interpreted in the *specific DoI as*: the person concerned is participating or has participated, with a right to vote on the outputs, in the works of a Scientific Advisory Body which has expressed an opinion, a statement or an advice *about the product or substance at issue or about a competing product or about products or substances used in conjunction with the one in question or the one from a competitor.*

### IV. **Employment:**

-to be interpreted in *the annual DoI as* all forms of employment, part-time and full-time, either paid or unpaid, in any organisation whose activities are linked to EFSA's remit.

-to be interpreted in the *specific DoI as*: covering all forms of employment, part-time and full-time, either paid or unpaid, in any organisation (private or public) *whose product or substance is being reviewed or which has been involved in any way in the development or assessment of the product or substance or in a company that is a competitor in this area or a company that manufactures or markets products or substances used in conjunction with the one being reviewed or the one from a competitor.*

### V. **Consultancy/Advice:**

-to be interpreted in *the annual DoI as*: any activity in which the data subject charges or does not charge a fee for providing consultancy/advisory services, including the names of the beneficiary organisations of the consultancy. However, to accommodate the justified concern data subjects may have with regard to the publication of names of organisations to which they have provided services, they can opt for not publishing this part of the information in their DoI on the EFSA website. The DoI electronic tool includes a special feature to accommodate this option of hiding the name of the organisation. Under this category should be specified also any past and on-going contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee, i.e. on the subject matter of the consultancy.

-to be interpreted in the *specific DoI as*: an activity where the concerned person charges or does not charge a fee for providing advice or services in a particular field such as 1) the development of the product or substance 2) *a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor.* Any contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee as identified above should be specified under this activity. The subject matter should only indicate the domain in which the consultancy is/has been active.

### VI. **Research Funding:**

-to be interpreted in *the annual DoI as*: Any funding for research in relation to matter or work financed by a private or public entity, including grants, rents, sponsorships and fellowships and received in a personal capacity. Research projects may be grouped together

without stating the title of each project provided that a relationship between them exists.

-to be interpreted in the *specific DoI as*: meaning any funding for research on the development of the product or substance or a competitor product or substance or a substance or product used *in conjunction either with the one being reviewed or the one from a competitor* if financed by a private or public entity, including grants, rents, sponsorships and fellowships and received in a personal capacity. Research projects can be grouped together without stating the title of each project provided that a relationship between them exists.

#### VII. **Intellectual property rights:**

-to be interpreted in the *annual DoI as*: Rights granted to creators and owners of works that are the result of human intellectual creativity and that pertain to a domain falling within EFSA's remit. These can be publications or can be in the industrial, scientific and artistic domain. They can be in the form of an invention, a manuscript, a suite of software, or a business name (e.g. copyrights, patents, trademarks et cetera).

-to be interpreted in the *specific DoI as*: meaning rights granted to creators and owners of works that are the result of human intellectual creativity. These can be publications or can be in the industrial, scientific and artistic domain. They can be in the form of an invention, a document, a suite of software, or a business name (e.g. copyrights, trademarks, patents on the product or substance or a *competitor product or substance or a substance or product used in conjunction with the one being reviewed or the one from a competitor*)

VIII. **Other membership or affiliation:** Any membership or affiliation other than the above, which can be perceived as an interest in EFSA's remit.

#### IX. **Interests of close family members:**

-to be interpreted in the *annual DoI as*: known interests held by family members and relatives belonging to the same household or under the care of the members of the household in a domain falling within EFSA's remit. In order to maintain privacy, their names should not be declared nor the type of relationship. On the electronic tool just the nature of the activity triggering the interest of the close family member should be indicated, by choosing from a 'drop-down list' in the system. A check-box needs to be ticked indicating "Interest of close family member", and there is no option to give further specification as to the nature of the relationship via the electronic tool.<sup>6</sup>

-to be interpreted in the *specific DoI as*: known interests held by family members and relatives belonging to the same household or under the care of the members of the household and that relate to the development of the product or substance or a competitor product or substance or a substance or product used *in conjunction either with the one being reviewed or the one from a competitor*. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) should not be specified.

X. **Others:** Any activities or interests other than the above, which can be perceived as an interest in an activity included in EFSA's remit.

The declarations contain a final statement: *"I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Procedure for identifying and handling potential conflict of interests and that the above Declaration of Interests is complete."*

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<sup>6</sup> Point 4.2 of the user guide for "Declaration of interest IT Tool"

In addition, **other EFSA experts**<sup>7</sup>, staff of the European Commission or other Community agencies, etc **are invited at the beginning of each meeting to declare their interests**. In such cases, the minutes of panel meetings include their declaration. EFSA uses template sentences for that. Four possible scenarios can be differentiated:

- a) **No further interest**: it is a declaration that no further interest exists apart from those declared in the annual or specific declarations.
- b) **Interests but no conflict**: experts declare additional interests, but it does not represent a conflict of interest.
- c) **Conflict level C**: where the expert declares a conflict of interest, and as consequences he/she is excluded from participating in EFSA's activities concerned by the potential conflict in question.
- d) **Conflict level C with waiver**: where the declared interest of the expert represents a conflict but a waiver was granted, for example when the expert is unique in the field.<sup>8</sup>

**Information to be given to data subjects**: EFSA website<sup>9</sup> presents a number of documents in connection to the declaration of interests among the "Policy and guidance documents": EFSA policy on declarations of interests, Guidance document on declarations of interest (updated on 26 March 2009) and Procedure for identifying and handling potential conflicts of interest (updated on 24 Oct 2008).

Experts need to fill in and sign a "Declaration of Commitment", which informs them that they are obliged to make and sign a written ADoI and where required a SDoI in accordance with EFSA'S procedure.

The Guidance document on Declarations of Interest includes the following reference on the Data Protection Regulation: *“Without prejudice to Regulation (EC) No 178/2002, EFSA shall process Annual Declarations of Interest and Specific Declarations of Interest pursuant to Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data”*.

Although the DPO had proposed a more extensive data protection note<sup>10</sup> in accordance with Article 11 of Regulation 45/2001 for the Guidance document, the final text of the Guidance Document contains only a reference to Regulation 45/2001.

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<sup>7</sup> These other experts can be those who do not work in a Working Group of the Scientific Committee or Scientific Panel

<sup>8</sup> Example was given in EDPS inspection Memorandum 2008-575, p 14

<sup>9</sup> Available at: [http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/efsa\\_locale-1178620753812\\_DeclarationsInterest.htm](http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/efsa_locale-1178620753812_DeclarationsInterest.htm)

<sup>10</sup> The more extensive data protection note suggested by the DPO is the following: *“Without prejudice to Regulation (EC) No 178/2002, EFSA shall process Annual Declarations of Interest and Specific Declarations of Interest pursuant to Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The purpose of the processing is to safeguard the independency of EFSA and its constituent bodies. The EFSA Executive Director is identified as the controller of handling the declarations of interest. The nature of interests to declare and the obligation to do so as well as possible consequences of not declaring, are explained in the present document (read: the Guidance Document). The recipients of the Declarations of Interest are the persons and bodies identified in the document “Procedure for Identifying and Handling Potential Conflicts of Interest”, without prejudice to the publicity requirement regarding specifically Annual Declarations of Interest laid down in Article 38,1°(d) of Regulation (EC) No 178/2002. Furthermore, Declarations of Interest may be transferred to bodies in charge of monitoring or inspection task in conformity with Community Law, including the European Court of Auditors, the Internal Audit Service, OLAF, the European Data Protection Supervisor. EFSA will not keep Declarations of Interest for any period longer than 10 years. Data subjects have a right to access their Declaration of Interest and to update or*

A user guide regarding the use of the electronic tool is available explaining the basic functions such as the creation of a declaration, how to update it and how to edit interests.

**Procedures to grant rights of data subjects:** Recently, the DoIs are submitted by means of an electronic tool, which allows them to access, edit and re-submit their DoIs at any time.

**Recipients of personal data:** The personal data contained in the declaration of interests can be disclosed to internal recipients within EFSA, some can be accessed only upon request and EFSA maintains a publication policy for the declaration of interests.

- 1) The heads of units of EFSA, Directors, the EFSA Executive Director and the chairperson of the Management Board **are involved in the review process of DoIs.**
- 2) The **secretariat of each panel** is carrying out the screening of the activities of the Members of the Scientific Committee, Scientific Panels and EFSA external experts.
- 3) **Specific declarations of interest** will be made available upon request.

**Automated/manual processing:** Since July 2008, the processing operation is largely carried out by means of an IT tool. [...] The electronic tool allows the creation of a new annual declaration of interest by updating the existing one and the creation of specific declaration of interests.

The electronic tool also provides the outcome of the screening. The system allows both the spontaneous updating of the declaration of interests and includes an automatic notification feature alerting the experts to the fact that their annual declaration of interests should be updated. This email is sent 11 months after the submission of the previous update.

Previous annual declarations of interests submitted by EFSA staff are kept in paper format. From 2009 onwards, the IT tool will also be used to process DoIs of EFSA staff members. In this way EFSA is gradually moving to the electronic processing of all declarations of interests.

**Storage media of data:** [...]

**Retention policy for personal data:** EFSA will keep the DoIs for a period no longer than 10 years. The 10 years period corresponds to the period of validity of authorisations by EFSA scientific panels in core business areas such as genetically modified organisms, feed additives and smoke flavourings.

At the request of the EDPS, the data controller explained that the above 10 years period proposed by EFSA applies to all types of Declarations of Interests, including DoIs of EFSA staff members.

**Security measures:** [...]

### 3. Legal analysis

#### 3.1. Prior checking

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*correct it. They are also entitled to have recourse at any time to the European Data Protection Supervisor: <http://www.edps.europa.eu>."*



Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (hereinafter referred to as "the Regulation") applies to data processing activities by Community institutions and bodies. The Regulation applies to the data processing activities by the European Food Safety Authority in the context of Handling of Annual and Specific Declarations of Interest for the reasons enumerated below.

**Personal data are defined** as any information relating to an identified or identifiable natural person. An identifiable person is the one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity. In the frame of handling declaration of interests, as explained in the facts part above, various personal data related to a particular individual are processed. Article 2(a) of the Regulation thus applies.

The processing of personal data is carried out by the European Food Safety Authority in its activity which clearly falls under Community law. Article 3(1) of the Regulation therefore applies.

Annual declarations and their updates are handled by an electronic tool (**automatic means**), specific declaration of interests of experts and DoI of EFSA staff are processed **manually**. Paper files are intended to form part of a filing system, a structured set of data are processed which is accessible according to given criteria. The processing operation falls under Article 3(2) of the Regulation, as it is mainly automatic and also as the results of manual processing are intended to form part of a filing system.

Article 27 (1) of Regulation (EC) 45/2001 **subjects to prior checking** by the EDPS all "processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes". Article 27 (2) of the Regulation contains a list of processing operations that are likely to present such risks, among which those processing operations intended to evaluate personal aspects relating to the data subject, including his/her ability, efficiency and conduct (Article 27(2)(b)). The procedure of screening and detecting conflict of interests falls under this provision, as it relates to the assessment of the conduct of experts and of EFSA's staff members. It is equally true for the internal procedure envisaged by the new Guidance Document on DoIs, which clearly aims at evaluating whether the omission by an expert need to be considered as a breach of trust *vis-à-vis* the Authority.

Since prior checking is designed to address situations that are likely to present certain risks, the opinion of the EDPS should be given prior to the start of the processing operation. The data processing operations are already established in the frame of the declaration of interests. EFSA nevertheless should still implement the recommendations of the EDPS expounded in the current opinion.

The notification of the DPO was received on 2 December 2008. According to Article 27(4) the present opinion must be delivered within a period of two months that is no later than 3 February 2009. The prior checking procedure has been suspended for a period of 25+16 days+ 23 days for comment on the draft opinion. The procedure was extended for two months due to the complexity of the matter. Thus, the Opinion should be rendered not later than 8 June 2009.

### 3.2. Lawfulness of the processing

Personal data may only be processed by EFSA if the processing operation falls under Article 5 of Regulation 45/2001. EFSA bases it on Articles 5(a) and 5(d) of the Regulation.

**Article 5(a) of the Regulation** permits the processing of personal data if it is "*necessary* for performance of a task carried out in *the public interest* on *the basis* of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof". The provision has three main elements: the principle of necessity, the goal of the processing should be a public interest and it also specifies the nature of the legal basis for the processing.

The processing of the above described personal data to ensure that the concerned individuals have no conflict of interests which could interfere with their activities carried out for EFSA, clearly serves a **public interest**. The personal data requested by EFSA in the declarations can be seen, *in abstracto*, as necessary for EFSA's task.

**Legal basis:** The following legal basis for the respective three activities can be found in the specified instruments. **Three main activities** can be differentiated in the present processing operation:

- 1) submission of declaration of interests and screening them
- 2) publication on the website
- 3) internal procedure in case of incompleteness or no declaration.

#### **1) Submission and screening of declaration of interests of the various categories of data subjects:**

##### **Annual declaration of interests:**

a) Annual declaration of interests for the **members of the Management Board, the members of the Advisory Forum and the Executive Director:** Articles 37(1) of Regulation (EC) No 178/2002<sup>11</sup> provides for: "*The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing*".

b) Annual declaration of interests **for the members of the Scientific Committee and the Scientific Panels:** Article 37(2) of Regulation 178/2002 specifies that: "*The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing*".

Following an exchange of information, EFSA confirmed to the EDPS that the legal basis to request annual declaration of interests from **Working Group and other experts** is based on Article 13(3) of Decision of the Executive Director concerning the Selection of Members of

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<sup>11</sup> OJ L 31, 1.2.2002, p. 1–24

the Scientific Committee, Scientific Panels and External Experts to Assist EFSA with its Scientific Work<sup>12</sup>. The database of EFSA experts covers also "the networks as well as other working groups of EFSA"<sup>13</sup>. Article 13(3) reads as follow: *"To be included into the Database of Scientific Experts<sup>14</sup>, the expert will need to satisfy all of the following eligibility criteria, which will be assessed from the information provided with a valid application: (...) "a completed Annual Declaration of Interests"*.

In addition, the Implementing Act to the Policy on Declaration of Interests-Guidance Document on Declarations of Interest (dated 26 March 2009) extends the obligation to also cover the **Working Group and other EFSA experts**.

**c) Specific declaration of interests for categories a) and b) above and for external experts:** Article 37(3) specifies that *"The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda"*.

**d) Annual declaration of interests of EFSA staff:** Part D point II of the Implementing Act to the Policy on Declaration of Interests Procedure for Identifying and Handling Potential Conflicts of Interest adopted by the Executive Director on 22 October 2008 extends the obligation to submit annual declaration of interests to all AD-grade staff of the Authority. *"This is in line with the spirit of the founding Regulation under which all the individuals in a position to influence EFSA's output, particularly in the core business areas of science and communications should act with independence and integrity and should be subject to the same standards of professional conduct as members of EFSA bodies and other EFSA experts, using a similar system for the verification thereof. These declarations will be screened by the respective line manager allowing the Executive Director to take appropriate measures"*.

EFSA also referred to Articles 11 and 11(a) of the Staff Regulations providing for legal basis: *"An official shall carry out his duties and conduct himself solely with the interests of the Communities in mind; he shall neither seek nor take instructions from any government, authority, organisation or person outside his institution. He shall carry out the duties assigned to him objectively, impartially and in keeping with his duty of loyalty to the Communities. An official shall not without the permission of the appointing authority accept from any government or from any other source outside the institution to which he belongs any honour, decoration, favour, gift or payment of any kind whatever, except for services rendered either before his appointment or during special leave for military or other national service and in respect of such service"* and *"An official shall not, in the performance of his duties and save as hereinafter provided, deal with a matter in which, directly or indirectly, he has any personal interest such as to impair his independence, and, in particular, family and financial interests."*

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<sup>12</sup> Available at:

[http://www.efsa.europa.eu/cs/BlobServer/resource\\_EFSA/about/core/selectionofexperts\\_decision\\_signed.pdf?sbinary=true](http://www.efsa.europa.eu/cs/BlobServer/resource_EFSA/about/core/selectionofexperts_decision_signed.pdf?sbinary=true)

<sup>13</sup> Article 12(2) of Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee, Scientific Panels and External Experts to Assist EFSA with its Scientific Work.

<sup>14</sup> EFSA's Expert database was prior checked by the EDPS. See Opinion on the notification for prior checking received from the Data Protection Officer ("DPO") of the European Food Safety Authority ("EFSA") regarding EFSA's Expert Database. Available at: [www.edps.europa.eu](http://www.edps.europa.eu)

2. Any official to whom it falls, in the performance of his duties, to deal with a matter referred to above shall immediately inform the Appointing Authority. The Appointing Authority shall take any appropriate measure, and may in particular relieve the official from responsibility in this matter.

3. An official may neither keep nor acquire, directly or indirectly, in undertakings which are subject to the authority of the institution to which he belongs or which have dealings with that institution, any interest of such kind or magnitude as might impair his independence in the performance of his duties".

**2) Publication on the website:** Article 38(1)(d) of Regulation 178/2002 specifies that: "*The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay (...) "the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings".*

Article 38(1)(d) of Regulation 178/2002, requiring a high level of transparency, refers to both annual and specific DoIs. EFSA nevertheless decided to meet these transparency requirements by publishing on EFSA's website only the annual DoIs. Specific DoI's made in the beginning of a meeting are disclosed only upon request.

The present opinion explains in more detail how EFSA's transparency policy could be improved to meet the requirements of Regulation 45/2001 regarding the present data processing operation, in particular to the data security (part 3.8) and information supplied to the experts (part 3.7).

The language of Article 38(1)(d) does not cover the publication of annual declaration of interests of **other EFSA experts**, such as the Working Group experts. Thus, EFSA requests their consent under Article 5(d) of Regulation 45/2001 for publishing their declaration of interests. Although in principle the expert could decline to give his/her consent to the web publication, EFSA stated that publication is mandatory, unless the expert could substantiate his/her refusal with extremely good reasons.

The measure, followed currently by EFSA, to publish ADoIs of working group and other experts on the basis of their freely given consent, should be combined with a policy providing sufficient information regarding EFSA's transparency policy and its consequences on the experts (see later in part 3.7)

**3) Internal procedure:** The recently revised version of the Implementing Act to the Policy on Declaration of Interests-Guidance Document on Declaration of Interest dated of 26 March 2009 specifies further the procedures which may follow after the declaration of interests. Passages on the "Consequences of not declaring" and the "Process regarding omissions and breaches to EFSA's Policy on DoI" specifies in more detail the potential meaning of breach of trust *vis-à-vis* the Authority (see above in "Facts" part).

**Conclusion to part 3.2.:** The EDPS notes the above described legal basis for the processing operation and advises EFSA to follow a strong policy to supply information about EFSA's transparency requirements.

### 3.3. Data Quality

Personal data must be *adequate, relevant and non excessive in relation to the purposes* for which collected and/or further processed (Article 4 (1) (c) of the Regulation).

Having examined the data fields requested by EFSA in the annual and specific declaration forms and also regarding the template sentences in the minutes of meetings, the EDPS considers that in principle the requested information is adequate, relevant and not excessive for the purposes to see whether any conflict of interests which potentially could interfere with the work of the data subjects could appear. The EDPS nevertheless would like to stress that whenever in the beginning of a meeting declarations of interest are recorded, consideration should always be given to ensure that the registered information is adequate, relevant and not excessive for the purposes, as public access request to access such declarations may always be made.

The EDPS finds appropriate under Article 4(1) (c) of the Regulation that the concerned individuals have to declare only the nature of activity of close family members from a drop-down list, but they do not need to declare either the name of family members and relatives or the type of relation. The arrangement put in place by EFSA also prevents processing "sensitive" data under Article 10 of the Regulation (i.e. as the relationship is not declared, no information is registered on sexual orientation, for example).

Personal data must be *accurate and where necessary kept up to date* (Article 4(1) (d) of the Regulation). The direct access to the electronic tool by the data subjects ensures that the processed personal data are updated by the concerned data subject himself/herself annually which ensures the accuracy of their own data.

Personal data must be processed fairly and lawfully (Article 4(1) (a) of the Regulation). The lawfulness was addressed in part 3.2., fairness relates to the information supplied to the data subjects (see below in part 3.7).

The data subject has the right to access and the right to rectify data ex Articles 13 and 14 of the Regulation, so that the file can be as complete as possible. This also makes it possible to ensure the quality of data (see in point 3.7 below).

### **3.4. Conservation of data**

Personal data should be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data are collected or for which they are further processed (Article 4(1) (e) of the Regulation).

EFSA's retention policy is set as a maximum of 10 years in line with the period of validity of authorisations by EFSA scientific panels in core business areas. The same retention period would apply to keeping the declarations of EFSA staff.

The purpose of the present processing operation is to ensure compliance with Article 37 of the EFSA founding Regulation to follow up the independence of the concerned persons and make sure that conflicting interests do not prejudice one's independence in carrying out his/her task for EFSA.

The 10 year retention period is not established in line with the purpose of the processing operation, but rather relates to the functioning of the panels. Moreover, this remote link does not exist regarding EFSA staff members, who otherwise also need to declare their interests.

The EDPS requests the data controller to reconsider the necessity to keep the personal data of EFSA staff and experts for such a long period and inform the EDPS accordingly.

### **3.5. Transfer of data**

Article 7(1) of the Regulation specifies that personal data shall only be transferred within or to other Community institutions or bodies if the data are necessary for the legitimate performance of tasks covered by the competence of the recipient.

The personal data contained in the specific declaration of interests can be **accessed upon request**; and the data in the declarations can be disclosed to internal recipients within EFSA as it was described above in the facts part, notably:

- 1) The heads of units of EFSA, Directors, the EFSA Executive Director and the chairperson of the Management Board **are involved in the review process of DoIs for EFSA staff.**
- 2) The **secretariat of each panel** carries out the screening of the activities regarding the Members of the Scientific Committee, Scientific Panels and EFSA external experts.

The EDPS considers that in principle the transfer of personal data in the framework of declaring interests to the listed recipients within EFSA meets the requirement of Article 7 of the Regulation.

In order to meet the obligation in Article 7(3) of the Regulation, the EDPS requests that arrangements are put in place to remind internal recipients that the information can be processed only for the purposes for which they are transmitted.

It needs to be noted that web publications of declaration of interests are not to be considered transfers of personal data following the judgement of the Court of Justice in the Bodil Lindqvist case.<sup>15</sup> Consequently, Article 9 of the Regulation does not apply to website publication of the declaration of interests. Nevertheless, the other requirement of Regulation 45/2001 needs to be respected. In this regard the information provided to the concerned persons deserve special attention (see below in part 3.7)

### **3.6. Right of access and rectification**

Article 13 of the Regulation provides for a right of access and arrangements for exercising it upon request by the data subject. Data subjects have a right to rectify their inaccurate or incomplete personal data under Article 14 of the Regulation without delay.

The electronic tool makes it possible for the data subjects to access, re-edit and re-submit their declaration of interests. This automatic means ensures respect for Articles 13 and 14 of the Regulation.

A procedure should be put in place to ensure the right of access and rectification for those declarations of interests which are not done via the electronic tool.

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<sup>15</sup> See, EDPS position expounded in case 2006-403.

Letter of 13 February 2007 concerning the publication of personal data on the Internet and the applicability or not of Article 9 of the Regulation. Available at: <http://www.edps.europa.eu/EDPSWEB/edps/site/mySite/pid/77> and see also another EDPS prior checking opinion for similar position: Opinion on a notification for prior checking received from the Data Protection Officer of the European Commission on verification of lack of conflict of interest of special advisers and its publication on Europa website (2007-294).

The EDPS recalls that the right of access and rectification should be ensured throughout all procedures which deal with the consequences of incomplete declarations. In this regard, the internal procedure foreseen in the new Guidance Document issued on 26 March 2009 envisages that upon request the experts will have access to all documents and they can express their views on the hearing and submit documents which will be taken into regard. This procedure ensures that personal information involved in the procedure can be updated and as complete as possible.

### **3.7. Information to the data subject**

Article 11 of the Regulation provides for a list of mandatory items of which data subjects should be informed at the time of collecting the data, except where the data subjects already have the information. Article 12 of the Regulation prescribes the information to be supplied to the persons concerned, where the data was not obtained from the data subject.

In the current case, the persons concerned declare all the interests listed in the respective in EFSA's implementing rules themselves. Article 11 should thus be respected. The internal procedure which is foreseen in cases of breaches and omissions by experts is carried out not only on the basis of information obtained from the data subjects but possibly also on information obtained from other sources. Article 12 therefore also applies to the processing operation.

The EDPS noted that information is provided on EFSA website as to the legal basis: the updated version of the Guidance Document on Declarations of Interests (26 March 2009) and the Procedure for Identifying and Handling potential conflict of interests and EFSA's founding Regulation.

As the data processing involves web-publication, for fairness towards the data subjects, the EDPS supports the suggestion of the DPO that a more extensive data protection note should be provided to the persons concerned. In addition, the text of the data protection notice should be updated in the light of the present opinion as to the legal basis (see part 3.2. above) and reconsidered retention period. Information should also be supplied with more explanation about the fact that annual declarations of interests are published on the website and of the internal procedures which may follow regarding incomplete declarations or failure to declare one's interests.

As to the placement and timing of the data protection note: apart from annexing the data protection notice to the "Guidance Document," the EDPS advises to display the data protection notice in the first letter contacting the experts. The data protection notice should thus clearly inform the experts in an individualised way about the transparency requirements and policy followed by EFSA, including web publications and potential request to access the declarations by a third party which in turn would also clearly lay down the consequences of failure to submit the declarations or to submit it with incomplete content.

### **3.8. Security measures**

According to Articles 22 of Regulation (EC) No 45/2001, the controller must implement the appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected. These security measures must in particular prevent any unauthorised disclosure or access,

accidental or unlawful destruction or accidental loss, or alteration and prevent all other forms of unlawful processing.

EFSA provided to the EDPS information regarding the security measures put in place in order to ensure the confidentiality, integrity, accountability and availability of the data included in the system.

The EDPS notes the security measures put in place, but at the same time considers that [...]

### **Conclusion:**

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001 providing that the above expounded considerations are fully taken into account. In particular, EFSA should:

- always consider that whenever information regarding interests is recorded in the minutes of a meeting, it should be adequate, relevant and not excessive for the purposes,
- reconsider the data retention period by linking it to the purposes of the processing operation,
- remind internal recipients that they should process the personal data only for the purposes for which they are transmitted,
- the right of access and rectification should be ensured also regarding the paper files, and the internal procedure regarding the consequences of failure to submit declaration or in case of incomplete declaration,
- display the data protection notice not only in the Guidance Document but also in the first letter communicating with the expert. The text of the data protection notice suggested by the DPO should be revised taking into account the EDPS recommendations made in this opinion,
- improve its security policy along the following lines:[...].

Done at Brussels, 5 June 2009

(signed)

Giovanni BUTTARELLI  
Assitant European Data Protection Supervisor