

# Decision of the Executive Director of the European Food Safety Authority on **Competing Interest Management**

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# Decision

<b>EFSA – European Food Safety Authority</b>	<b>Decision of the Executive Director on Competing Interest Management</b>	<b>Decision No.:</b> REF. EFSA/LA/DEC/19568050/2018
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<b>Approvals</b>	Signature	Name
Originator	Signature on the file	<i>Dirk Detken</i>
Executive Director	See Decision	<i>Bernhard Url</i>

<b>Introduction</b>	See citations and recitals of the annexed Decision
<b>Description</b>	This decision lays down the rules to be followed by EFSA in order to manage competing interests, with the aim of preventing the occurrence of conflicts of interest, among the professionals involved in its Management Board, Scientific Committee, Scientific Panels, Working Groups, peer review meetings, networks, Advisory Forum and outsourcing schemes.
<b>References</b>	<p>Treaty on the Functioning of the European Union</p> <p>Charter of Fundamental Rights of the European Union</p> <p>Regulation (EC) No 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</p> <p>Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union</p> <p>Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission</p> <p>Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012</p> <p>Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups, C(2016) 3301 final</p> <p>European Parliament resolution of 8 May 2008 on the development of the framework for the activities of interest representatives (lobbyists) in the European institutions</p> <p>EFSA's Policy on Independence adopted by the Management Board on 21 June 2017</p>

	<p>EFSA's Management Board Decision concerning the establishment and operation of the European Networks of scientific organisations operating in the fields within the Authority's mission</p> <p>Decision of the Executive Director of the European Food Safety Authority concerning Pesticides Risk Assessment Peer Review</p>
<b>Revision history</b>	<ul style="list-style-type: none"> <li>- Amendment of Article 5(9) and Article 5(12)</li> <li>- Update of entry into force (Article 26(1))</li> <li>- Correction of typos</li> </ul>

# Abbreviations

<b>Authority</b>	European Food Safety Authority
<b>ADols</b>	Annual Declarations of Interest
<b>ODols</b>	Oral Declarations of Interest
<b>ColS</b>	Conflicts of Interest
<b>Dols</b>	Declarations of Interest
<b>EU</b>	European Union
<b>IT tool</b>	Information Technology allowing the e-processing of Dols
<b>LA</b>	EFSA Legal and Assurance Services
<b>MoU</b>	Memorandum of Understanding
<b>PI</b>	Public Institution

# Decision of the Executive Director of the European Food Safety Authority on **Competing Interest Management**

The Executive Director of the European Food Safety Authority has  
adopted the following decision

# 1. Scope and definitions

## Article 1. Scope

1. This decision lays down the rules on the establishment and the implementation of a system for managing competing interests and ensuring the prevention of conflicts of interests within EFSA. It aims to contribute to EFSA's commitment to ensure that the scientific outputs produced by the Authority are trusted and compliant with the principles laid down in EFSA's policy on independence<sup>1</sup>.
2. The rules set out in the present decision are addressed to all Concerned individuals as defined in Article 2(1)(k) below, unless specifically provided otherwise.

## Article 2. Definitions

1. For the purposes of this decision:
  - a. **"Declaration of interest (DoI)"** means all structured information about engagements outside EFSA that potentially overlap with EFSA's assignments, and which is submitted by individuals subject to this decision in the context of its implementation and discharge or related duties.
  - b. **"Annual Declaration of Interest (ADoI)"** means the annual submission of written information by Concerned individuals using a format provided by EFSA.
  - c. **"Oral Declaration of Interest (ODOI)"** means the verbal declaration of relevant information to be made by Concerned individuals at the beginning of each meeting with respect to the items on the agenda of the meeting.
  - d. **"Interest"** means the objective relationship between a Concerned individual, or his or her Close Family Members, and a company, organisation, entity, product,

business or other body (such as having a right or title, a claim, a share, a business engagement, a membership, a paid or unpaid involvement, etc.). The types of Interests taken into consideration in this decision are outlined under paragraph 2 of this Article;

- e. **"Conflict of Interest (CoI)"** means any situation where a Concerned individual has an Interest that may compromise, or be reasonably perceived as compromising, his or her capacity to act independently and in the public interest in relation to the subject of the work performed at EFSA<sup>2</sup>;
- f. **"Experts"** means the members of EFSA's Scientific Committee, Scientific Panels, Working Groups, candidates having applied to the call for expression of interest published by EFSA pursuant to Article 28(5) of Regulation (EC) No 178/2002,<sup>3</sup> and participants in peer review meetings<sup>4</sup> also when appointed by, or representing, Member States' authorities, and excluding Hearing Experts and Observers, as defined in this Article 2(1)(i) and 2(1)(j);
- g. **"Network Members"** means members of EFSA's networks<sup>5</sup>, focal points or other networking activities carried out pursuant to Article 36 of Regulation (EC) No 178/2002 (see Article 12);

<sup>2</sup> Article 2(4) of Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups, C(2016) 3301 final.

<sup>3</sup> Regulation (EC) No 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 L 31, 1.2.2002, p. 1, as last amended.

<sup>4</sup> As defined in the Decision of the Executive Director of the European Food Safety Authority concerning Pesticides Risk Assessment Peer Review, No 14461368 of 18 September 2015.

<sup>5</sup> Pursuant to the EFSA's Management Board Decision concerning the establishment and operation of the European Networks of scientific organisations operating in the fields within the Authority's mission – mb180310 – item 7 doc 6.

<sup>1</sup> mb170621-a2 – EFSA's policy on independence adopted by the EFSA Management Board on 21 June 2017.



- h. **“Members of EFSA Governance bodies”** means members of EFSA’s Management Board and members of EFSA’s Advisory Forum, (see Articles 13 and 14);
- i. **“Hearing Experts”** means individuals invited to provide their input to EFSA’s work without having a decision making role therein, as per Article 15 of the *“Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to assist EFSA with its scientific work”* (see Article 9);
- j. **“Observers”** means individuals who are neither Experts, Hearing Experts nor members of the EFSA Governance bodies, and who are permitted by EFSA to attend meetings and events organised by EFSA itself. Observers do not have the power to participate in the discussion nor to present their views or the data in their possession (see Article 10);
- k. **“Concerned individuals”** means Experts, Networks Members, members of EFSA’s Governance bodies, Hearing Experts, staff of European Union Institutions, bodies or other agencies participating in EFSA’s meetings in their private capacity and without prejudice to the Staff Regulations of the European Union, tenderers and participants to grant awarding procedures;
- l. **“Annual Earnings”** means all income (gross) that a Concerned individual earned in the fiscal year prior to the one in which the DoI is submitted, including, and not limited to, compensation, fees, honoraria, salaries, rents, sponsorships, fellowships, grants or other funding, pension rights, reimbursement of expenses, endowments and dividend yields. It does not include earnings paid to persons other than the Concerned individual or his or her Close Family Members dependent on him or her.
- m. **“Public Institutions (PI)”** means any organisation included in the list drawn up by EFSA’s Management Board according to Article 2 of Commission Regulation (EC) 2230/2004.<sup>6</sup> It also means any other international, national, regional, local or academic institution, public authority, research institute or other body which carries out tasks related to EFSA’s remit, pursues public interest objectives, and receives more than 50% of its budget from public entities.
- n. **“Close Family Member”** means:
- i. a spouse, meant as the person engaged in the marital relationship with the Concerned individual;
  - ii. a partner with whom a Concerned individual has contracted a registered partnership, on the basis of the legislation of the relevant legal system;
  - iii. the direct descendants and ascendants who are financially dependent on the Concerned individual.
- o. **“Procurement”** means the procedures followed by EFSA to purchase services, works or goods pursuant to its Financial Regulation and Title V of Regulation (EU, Euratom) No 966/2012<sup>7</sup> and its rules of application.<sup>8</sup>

<sup>6</sup> Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority’s mission, OJ L 379, 24.12.2004, p. 64–67.

<sup>7</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, OJ L 298, 26.10.2012, p. 1–96.

<sup>8</sup> Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, OJ L 362, 31.12.2012, p. 1.

- p. **“Grants”** means financial support granted by a PI in accordance with the applicable legal framework, or by EFSA in accordance with Article 36 of Regulation (EC) No 178/2002, Commission Regulation (EC) No 2230/2004 or pursuant to Title VI of Regulation (EU, Euratom) No 966/2012 and its rules of application.
- q. **“Regulated Products”** means products, processes, organisms or substances submitted for evaluation by EFSA.
- r. **“Public interest duty”** means a task, project, function or mission performed by a Concerned individual in the context of his or her engagement<sup>9</sup> with a PI, carried out for the benefit of the public and not for the benefit of a specific legal or natural person or association thereof.
- s. **“Mandate”** means the scientific mandate on which the Scientific Committee, Panels, Working Groups or peer review meeting is, or is expected to be, involved.
- t. **“EFSA’s remit”** means the powers delegated to EFSA as per recital 36 and Article 22 of Regulation (EC) No 178/2002, or relevant sectoral EU food law.
2. For the purpose of declaring Interests as defined under paragraph 1, letter d, of this Article:
- I. **“Financial Investment”** means any economic stake or share in an entity with a direct or indirect interest falling within EFSA’s remit, including its stocks, equities or bonds, or of one of the entity’s subsidiaries or of a company in which it has a holding. **“Industry Financial Investments”** means any form of the above held in business operators directly or indirectly concerned by EFSA’s outputs. Financial instruments on which the Concerned individual has no influence are not to be considered for the purposes of this decision.
- II. **“Managerial Role”** means any participation, paid or unpaid, in the internal decision-making process (such as board membership or directorship) of an entity with an interest falling within EFSA’s remit. Any managerial role which contributes more than 5% to the Concerned individual’s Annual Earnings, shall be considered as Occasional Consultancy. If it contributes more than 25%, it shall be considered as Employment.
- III. **“Membership of a scientific advisory entity”** means any participation in a scientific advisory entity, paid or unpaid, other than those set up by EFSA, with a direct or indirect interest falling within EFSA’s remit. Any membership of a scientific advisory activity which contributes more than 5% to the Concerned individual’s Annual Earnings, shall be considered as Occasional Consultancy. If it contributes more than 25%, it shall be considered as Employment.
- IV. **“Employment”** means any form of occupation or business, part-time or full-time, paid or unpaid, including self-employment, with an employer or client directly or indirectly concerned with EFSA’s remit, or any activity defined in paragraph 2(I-V) of this Article that contribute for more than 25% to the Concerned individual’s Annual Earnings. **“Industry Employment”** means any Employment with companies, business operators, industry associations, lobbying organisations<sup>10</sup> and other corporate funded organisations directly or indirectly concerned by EFSA’s scientific outputs.

<sup>9</sup> *I.e.* Managerial Role, Membership of a scientific advisory entity, Employment or Occasional Consultancy.

<sup>10</sup> European Parliament resolution of 8 May 2008 on the development of the framework for the activities of interest representatives (lobbyists) in the European institutions (2007/2115(INI)) 2009/C 271 E/06.

- V. "Occasional consultancy" means providing advice or services, paid or unpaid, to companies, trade associations or other private bodies with an interest falling directly or indirectly within EFSA's remit. In case the consultancy contributes more than 25% to the Concerned individual's Annual Earnings, it shall be considered as Employment.
- VI. "Research Funding" means financial support, including grants, rents and reimbursement of expenses, sponsorships and fellowships, for research or developmental work managed by, or benefiting, the Concerned individual, and being provided by public or private entities. For each research activity carried out, Concerned individuals indicate in their DoI whether the percentage of (co-)funding received from the private sector during the two years preceding the submission of the DoI exceeds 25% of the total research budget relevant for the matter under consideration.
- VII. "Intellectual property rights" means patents, trademarks, inventorship, copyrights and/or other intellectual property rights, irrespective of whether they grant a financial gain, that are recognised by the applicable law and that fall directly or indirectly within EFSA's remit. It does not include authorship or publications.
- VIII. "Other memberships or affiliations" means any membership or affiliation with entities with an interest falling within EFSA's remit, including professional organisations, which does not fall under the other categories defined above and which is relevant for the purposes of this decision.
- IX. "Other relevant Interests" means any Interest, involving or not a financial transaction, that does not fall under the categories defined above and which may be considered as a source of CoI pursuant to this decision.

### **Article 3. Requirements for a complete Declaration of Interest**

1. Concerned individuals are required to submit true, accurate and up to date DoIs, without prejudice to EFSA's right to perform audits and checks on the information received, also on a case-by-case basis.
2. Concerned individuals declare past or current activities. Past activities are declared if they have taken place within five years preceding the date of submission of the DoI.
3. Concerned individuals submitting DoIs provide all relevant details on the subject matter of each declared Interest. They indicate the sector in which the activity is or was carried out, clarify the exact Interest and role of the entity or organisation of relevance for each Interest and specify their precise role within that entity or organisation. Concerned individuals also provide other information relevant for performing the screening of the DoI, including the information to be submitted to calculate the impact of each interest on their Annual Earnings and clarifications that may be requested by EFSA in the context of the implementation of this decision.

### **Article 4. Annual Declaration of Interest**

1. Concerned individuals are requested to submit the ADol according to the rules set out in this decision and do so by submitting it through the dedicated IT tool or, in exceptional circumstances, by filling the form provided by EFSA.
2. Any Concerned individual updates his/her ADol without delay and in any case within 45 calendar days following any change in his/her Interests. With the exception of omissions resulting from force majeure, failure to do so is considered an omission pursuant to Article 19 below.
3. The ADol is used by EFSA to decide on the Concerned individual's eligibility with respect to his/her involvement regarding the relevant EFSA activity.

## Article 5. Oral Declaration of Interest

1. Concerned individuals declare orally at the beginning of each meeting any Interest not already declared which might be considered prejudicial to their independence with respect to the items on the agenda of the meeting.
2. The ODol is used to identify whether the Concerned individuals should or not be excluded from the discussion of a specific item on the agenda or from participating in a specific meeting.
3. Any ODol shall be recorded in the minutes of that meeting in the section dealing with the outcome of EFSA's screening of Interests.

# 2. Rules applicable to Experts

## Article 6. Annual Declaration of Interest

1. At least once every year, and in any case within 45 calendar days following any change in his/her Interests, Experts declare their Interests, as defined in Article 2, by submitting an ADol in accordance with Articles 3 and 4.
2. Without prejudice to the Staff Regulations of the European Union, staff of European Union institutions, bodies or agencies participating as members in the meetings of EFSA's scientific groups are subject to Dol related requirements as set out in this decision.
3. EFSA considers the review, assessment or rating by Experts of their own work as a Col incompatible with the Experts' participation to these activities. The concept of "work" should be meant as inclusive of publications, papers, data, studies, results or scientific opinions, with the exception of those adopted by EFSA's scientific groups.
4. Current Industry Employment or current Industry Financial Investments are considered incompatible with membership of EFSA's Scientific Committee, Scientific Panels, Working Groups or participation in peer review meetings.<sup>11</sup>

## Article 7. General principles of screening of Experts' Interests

1. The identification and prevention of Cols are based on the evaluation of the ADol and, where appropriate, of the ODol given by the Expert.
2. Without prejudice to the application of the general principle referred to in paragraph 4 of this Article, Interests are screened by EFSA by considering whether they are compatible with the tasks to be assigned to the expert, and with regards to the Mandate in which the relevant Scientific Panel, Working Group, Peer Review meeting or the Scientific Committee shall perform its activity.
5. The following activities are deemed incompatible with membership of the relevant Scientific Committee, Scientific Panel(s), Working Group(s) and peer review meeting(s) when they regard the Mandate of the scientific group: Managerial roles, Employment, Occasional Consultancy and membership of Scientific Advisory Bodies with non PIs. Research Funding from the private sector exceeding 25%<sup>12</sup> of the funding relevant for the scientific group also results in the incompatibility with membership of the relevant group.<sup>13</sup> These incompatibilities are applicable to the activities performed in favour of non-PIs, or with respect to

<sup>11</sup> Paragraph 3.1 of EFSA's policy on independence.

<sup>12</sup> Paragraph 3.4 of EFSA's policy on independence.

<sup>13</sup> See Annex 1 for details on calculation.

activities not performed by the Expert in the exercise of Public Interest Duties, or carried out in the performance of risk management functions, and last for two years after the competing activity has ended.<sup>14</sup>

6. Activities carried out within PIs as part of Public Interest Duties, including teaching or research, do not constitute a Col under this decision. An exception to the above concerns the risk management functions that are ongoing, or terminated in the two year prior to Dol submission, and that are performed with PIs on the same subject discussed in the EFSA scientific groups.
7. Activities with PIs that are unrelated to Public Interest Duties are assessed and validated as per the rules set out in this Article and presented in a tabular manner in Annex 1.
8. For the purpose of screening Dols and evaluating thresholds for employment, occasional consultancy, managerial activity or membership of a scientific advisory entity, all Annual Earnings coming from the same entity shall be considered as a single entry, also when registered under different forms or activities.
9. The screening of interests of Close Family Members is performed as for interests of the experts submitting the Dol, except for:
  - a. paragraph 3, which shall not apply to Close Family Members,
  - b. paragraph 4, which shall apply to Close Family members only when the activities overlap with the subject matter of the EFSA scientific group.
10. No EFSA assignment shall be declared or considered to be a source of Col.
11. Memberships, affiliations or other relevant Interests not specifically addressed in Annex 1, shall be screened on a case-by-case basis, taking into consideration the general principles set

out in this Article and the rationale behind EFSA's policy on independence.

12. By way of derogation from paragraph 5, past activities classified as employment, managerial roles, scientific advisory roles, consultancy with, or Research Funding exceeding 25% from, non-PIs held by participants in peer review meetings are compatible with membership of these meeting(s) if the expert has an ongoing employment with a PI. The same derogation from paragraph 5 shall apply to interests held by Close Family Members of participants in peer review meetings. Paragraph 5 shall instead apply to participants in peer review meetings holding interests related to dossiers submitted by legal or natural persons with whom they, or their Close Family Members: a. were employed; b. held managerial or scientific advisory positions or; c. to whom they tendered advice, in the two years prior to Dol submission.

## **Article 8. Screening process of Experts' Dols**

1. The officer identified as responsible by the relevant working instructions performs the assessment of the ADols according to the criteria set out in Article 7 and presented in a tabular format under Annex 1, and sends them to LA along with the result of the assessment. LA carries out the validation of the assessment of the ADols according to the same set of criteria.
2. Before starting the discussion of any of the items on the agenda of the meeting, the officer identified as responsible by the relevant working instructions performs the screening of the ODols in accordance with the criteria laid down in Annex 1, and in the light of the principles set out in Article 7 above.

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<sup>14</sup> Paragraph 3.2 of EFSA's policy on independence.

# 3. Rules applicable to Hearing Experts and Observers

## Article 9. Hearing Experts

1. Hearing Experts submit an ADol in advance of a meeting to which they are invited. No Dol screening, assessment or validation is performed for ADols submitted by Hearing Experts.
2. Participation to the meeting in the previous paragraph is permitted only if the Hearing Experts has submitted an ADol.
3. Hearing Experts do not perform tasks which are the responsibility of the members of the EFSA scientific group. They may present topics and answer questions, and may not draft or be

involved in the discussion or the adoption of a scientific output.

## Article 10. Observers

1. Observers are not required to submit Dols.

## Article 11. Staff of Union institutions, bodies or agencies

1. Without prejudice to the Staff Regulations of the European Union, staff of EU institutions, bodies or agencies attending the meetings of EFSA's scientific groups as Observers or Hearing Experts are not required to submit Dols.

# 4. Rules applicable to Network Members

## Article 12. Network Members

1. Network Members shall declare their Interests as defined in Article 2(1)(d) by submitting an ADol in accordance with Article 4 above. No screening, assessment or validation is performed by EFSA.
2. MoUs between EFSA and PIs specify applicable standards.

3. EFSA follows-up on serious and well documented cases of Col substantially affecting the work of the EFSA's network or EFSA's reputation that are brought to its attention. In this event, the Executive Director shall submit the issue to the Management Board which may ask the competent Member State to replace the Concerned individual.

# 5. Rules applicable to members of EFSA's Governance Bodies

## Article 13. Members of the Management Board

1. Members of the EFSA Management Board shall declare their Interests as defined in Article 2(1)(d) by submitting an ADol in accordance with Article 4 above.
2. The Management Board members shall declare orally at the beginning of each meeting any newly emerging Interest or a modification of an already declared one.
3. EFSA shall provide an assessment of the declared Interests to the Management Board, taking due account of the decisions of the Council appointing its members and of the notarial function the Board enjoys with respect to EFSA's scientific processes.
4. Before commencing the discussion of the items on the agenda, the Management Board shall reach a conclusion with regard to the assessment provided by EFSA and, where appropriate, recommend a follow-up, including the exclusion of the concerned member from the discussion of specific items on the agenda.
5. If an identified Col which may substantially affect the work of the Board or EFSA's reputation is not resolved by the concerned member or by the recommended follow-up action, the Board may ask for the replacement of the concerned member pursuant to Article 15 of its Rules of Procedure.<sup>15</sup>

6. For two years after their mandate as members of the Management Board has expired, the former Board members shall inform EFSA of any professional engagement overlapping with EFSA's mission or tasks.

## Article 14. Members of the EFSA Advisory Forum

1. Members of the EFSA Advisory Forum shall declare their Interests as defined in Article 2(1)(d) by submitting an ADol in accordance with Article 4 above.
2. EFSA follows up on serious and well documented cases of Col substantially affecting the work of the EFSA's Advisory Forum or EFSA's reputation that are brought to its attention. In this event, the Executive Director shall submit the issue to the Management Board, which may ask the competent Member State to replace the concerned individual.

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<sup>15</sup> mb270613 – Management Board Rules of Procedure – adopted by the EFSA Management Board on 27 June 2013.

## 6. Procurement and grant awarding procedures

### Article 15. Declaration of Interest of tenderers and participants in EFSA's procurement and Grant awarding procedures

1. Legal or natural persons taking part in EFSA's public procurement procedures concerning EFSA's scientific activities are required to submit a true, accurate and up to date Dol using the Form provided by EFSA and by declaring their Interests as defined in Article 2(1)(d) in accordance with Article 4 above. They update the Dol every time a new interest emerges or an already declared one changes.
2. A Dol is submitted by each of the members of the team the tenderer or Grant applicant is proposing to work on the project connected to the public procurement procedure or Grant. They do so by declaring their Interests as defined in Article 2(1)(d) and by submitting a Dol in accordance with Article 4 above.

### Article 16. Screening of the Dols in the context of EFSA procurement and Grant awarding procedures

1. EFSA screens Dols submitted in the context of procurement and Grant awarding procedures according to the criteria presented in a tabular format in Annex 2. The Dol is validated by the Authorising officer identified as responsible by the relevant working instructions.
2. If the responsible Authorising officer considers that a Col would occur if a contract or Grant is awarded, he/she shall ask the tenderer/Grant applicant to put in place, within a set deadline, appropriate measures to prevent the Col.
3. The responsible Authorising officer shall assess the measures taken by the tenderer/applicant to ensure that the Col no longer exists. If the tenderer/applicant is not able to adopt appropriate measures, EFSA shall exclude them from the procedure.

## 7. Implementation and enforcement

### Article 17. Coordination and implementation

1. The internal assignment of tasks and responsibilities for the implementation of this decision is set out in standard operating procedures and working instructions implementing the principles

of centralized handling and coordination and of functional separation of responsibilities between the provision of scientific advice and decision making power in competing interest management.



### **Article 18. Review of the decisions**

1. If a specific complaint is filed against a decision taken under the rules set out in this decision, or if reconsideration of a decision is deemed appropriate to address an error, the Executive Director may review that decision.
2. The decisions taken under these rules may be brought to the attention of the European Ombudsman for alleged maladministration pursuant to article 228 of the Treaty on the Functioning of the European Union (TFEU) or may be challenged before the General Court of the European Union at the conditions set out in Article 263 TFEU.

### **Article 19. Compliance and veracity checks and omissions by Experts**

1. Twice a year, EFSA shall check the compliance and the veracity of a random sample of Dols submitted in the context of this decision by Experts, tenderers and grant beneficiaries, and make the outcome of this exercise publicly available.
2. In the framework of this check, EFSA may require from any Concerned individual his/her declaration of personal income for tax purposes, as well as relevant documentation supporting the details provided in the relevant Dol in order to check the veracity of the information declared therein.
3. If EFSA becomes or is made aware of information that is not consistent with, or that is missing from, the Dol of a Concerned individual, and if a preliminary assessment of this information suggests that it concerns an Interest that should have been declared pursuant to Articles 1 to 7 of this decision, EFSA shall seek additional information from the Concerned individual and ask him or her to update his or her Dol and to include the missing information.
4. Once the Concerned individual has completed this update, EFSA shall screen the Dol in accordance with this decision.

### **Article 20. Process regarding breaches of EFSA's rules on CIM by Experts**

1. The omission of information that would have resulted in a Col is considered a breach of these rules.
2. In the event of an ascertained breach of the rules, the Management Board for members of the Scientific Committee or Scientific Panel, or the Executive Director for members of Working Groups or of participants to peer review meetings, applies one of the following measures:
  - a. Reprimand letter;
  - b. Suspension from participation in any EFSA activity, with corresponding suspension of any compensation therefrom, for a period of 6 months up to a maximum period of 1 year, without dismissal from the relevant body or scientific group;
  - c. Dismissal from the relevant body or scientific group, which may or may not be combined with a prohibition on participating in further EFSA activities for a period of 1 year up to a maximum period of 10 years.
3. To identify the measure to be applied, the Management Board or the Executive Director, respectively, shall take into account the following criteria:
  - a. Subjective element of the conduct (wilful misconduct vs. negligence);
  - b. Importance of the Interest as a source of influence on the Expert's scientific positions;
  - c. Financial impact on the Annual Earnings of the non-declared Interest pursuant to Article 2(1)(litt. l) of this decision;
  - d. Role of the relevant Expert within the scientific group;
  - e. Timing of the omission (Interest already existing at the time of the Dol vs. Interest arising later and not promptly declared) and delay in declaring.

4. If a measure under letters b. and c. of paragraph 2 of this Article is applied, EFSA shall perform a review of the scientific output(s) to which the Expert in question contributed. EFSA shall clarify whether, and the extent to which, that Expert influenced the outputs adopted by the EFSA group(s) in which he or she participated.
  5. EFSA shall report the audit findings to the Executive Director, and to the Audit Committee of the Management Board. The Executive Director shall take all measures that are deemed fit to address these findings.
  6. At least once a year, EFSA shall report to the Audit Committee of its Management Board on the findings identified in application of this Article, and on other relevant cases resulting from the implementation of this decision.
- draft output, when no suitable alternative Expert could be identified, and when the Expert's contribution could not be handled through his or her participation as Hearing Expert.
  4. No waivers shall be granted to Experts with a current Industry Employment or with a current Financial Investment in an entity impacted by EFSA's outputs.
  5. Waivers are recorded in the minutes of the meeting(s) and in the ensuing scientific output.
  6. If a waiver is granted, the concerned Expert is invited to take part in the discussions and in the drafting phase of the scientific output. Experts to whom a waiver has been granted are not eligible for chairmanship, vice-chairmanship and may not be appointed as rapporteur.

## Article 21. Granting of waivers

1. This Article only applies to members of EFSA's Working Groups<sup>16</sup> and peer review meetings.<sup>17</sup>
2. When EFSA identifies a Col concerning an Expert wanting to participate in a Working Group, the secretariat of the Working Group shall carry out a search for an alternative Expert. Exceptionally, where no suitable alternative Expert is found, the officer responsible for the DoI assessment may request the issuing a waiver in respect of the Expert with the identified Col, by submitting to the Executive Director a detailed report outlining the reasons supporting the request.
3. Such a waiver may only be granted by the Executive Director when the contribution of the concerned Expert is found to be essential for the completeness of the

<sup>16</sup> mb170322-a4 - Decision of the Management Board of the European Food Safety Authority concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups adopted by the Management Board on 22 March 2017.

<sup>17</sup> Decision of the Executive Director of the European Food Safety Authority concerning Pesticides Risk Assessment Peer Review, No 14461368 of 18 September 2015.

# 8. Common rules

## Article 22. Advisory Committee

1. At any point, EFSA may consult or refer a matter to an internal Committee with the responsibility of reviewing and advising on assurance and independence related matters.
2. The Committee shall meet at least twice a year and shall be in charge of:
  - a. validating the findings of compliance performed pursuant to Article 19 of this decision;
  - b. advising on key operational decisions regarding the implementation of the independence related regulatory framework.

## Article 23. Training

1. EFSA shall ensure that all staff members implementing this decision, and the Concerned individuals receive induction training on how to comply with this decision. In particular, EFSA shall ensure that all responsible officers, identified by the relevant working instructions as responsible for the screening of Dols are properly trained on the content of EFSA policy on independence, of this decision and of all the relevant working instructions.
2. For this purpose, EFSA shall implement training for all responsible officers and members of its Scientific Committee and Scientific Panels, document and keep track of attendance, and keep on hand at all times an advisor to answer questions or clarify doubts from the Concerned individuals about how the rules should be implemented. EFSA shall also make available working instructions and supporting materials to Working Group members and participants to peer review meetings.

## Article 24. Transparency

1. In accordance with EFSA's policy on independence, EFSA shall make publicly available on its institutional website *inter alia*:
  - a. ADols of: (i) members of EFSA's Management Board; (iii) members of EFSA's Advisory Forum; (iv) members of Operational Management Team composed as indicated on EFSA's website; (v) members of its Scientific Committee or Scientific Panels, Working Groups, participants in peer review meetings, including when appointed by, or representing, Member States' authorities, or members of its networks;
  - b. The Consolidated Annual Report, which shall include information about independence-related activities of EFSA (including number of Dols screened, ColS prevented, breaches of the rules confirmed, the relevant measures applied under Article 20 and the outcome of the compliance and veracity checks performed as per Article 19);
  - c. MoUs signed by EFSA with Pls;
  - d. The list of Pls;
  - e. Following the positive conclusion of technical and feasibility considerations, all conclusions reached by EFSA in the assessment and validation process of its Experts' ADols;
  - f. A register of activities undertaken by former members of EFSA's Management Board for two years after their term of office has ended.

## Article 25. Protection of personal data

1. EFSA processes all Dols pursuant to Regulation (EC) No 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.<sup>18</sup>
2. The purpose of the data processing is to safeguard the independence of EFSA and its various bodies.
3. The legal basis for Dol processing is provided in:
  - a. Articles 22, 37 and 38 of Regulation (EC) No 178/2002;
  - b. For Dols of participants in procurement and grant awarding procedures, Article 107 of Regulation (EU) No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union as well as Article 142 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU) No 966/2012.
4. The EFSA's Executive Director is the controller for handling of the Dols.
5. The recipients of the Dols are the persons and bodies identified in this decision, without prejudice to the publicity requirement specifically regarding ADols laid down in Article 38(1) litt. (d) of Regulation (EC) No 178/2002. Furthermore, Dols may be transferred to bodies in charge of monitoring or inspection in conformity with EU Law, including the European Court of Auditors, the Internal Audit Service, the European Anti-Fraud Office, the European

<sup>18</sup> This decision was drafted also against the legislative proposal updating the aforementioned Regulation, in the light of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.

Ombudsman and the European Data Protection Supervisor.

6. The conservation period for Dols per category of data subjects is 10 years from the date of submission of the relevant Dol.
7. Concerned individuals have the right to access their Dol and to update or correct it at any time. To meet this requirement, the Dol IT tool, available upon username/password authentication, is permanently accessible to Concerned individuals. If EFSA is aware of information that is not consistent with the declared interest, or of the failure to submit a Dol, the Concerned individual shall be contacted with the purpose of updating the Dol with the missing information. If an internal breach of the rules procedure is opened, the Concerned individuals shall be notified without delay.
8. Concerned individuals are also entitled to have recourse at any time to the European Data Protection Supervisor: <http://www.edps.europa.eu>.

## Article 26. Entry into force

1. The present decision shall enter into force on 30 June 2018, thereby repealing and replacing Decision EFSA/LA/DEC/18571869/2017 and shall be applicable as of 1 July 2018.
2. As of 1 July 2018, the present decision repeals the Decision of the Executive Director of the European Food Safety Authority on the Committee on Conflicts of Interest of 29 February 2016<sup>19</sup>, Article 8 of the Decision of the Executive Director of the European Food Safety Authority concerning Pesticides Risk Assessment Peer Review and the provisions of the Decision of the Executive Director of the European Food Safety Authority on Declaration of Interest of 31 July 2014<sup>20</sup>, with the exception of Articles 19 and 20 thereof.

<sup>19</sup> EFSA/2015/15303659/LRA.

<sup>20</sup> EFSA/LRA/DEC/02/2014.

3. The Executive Director shall review this decision by 1 December 2020, and at least every two years thereafter. As part of each review, the Executive Director shall determine whether any adjustment to

this decision is appropriate. The Executive Director shall communicate to the Management Board the rationale and results of such review, and the justification for any such adjustment.

Done in Parma on 29 June 2018

*Signed*

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Bernhard Url  
Executive Director

**Annexes:**

Annex 1: General principles and Screening Criteria for Experts' ADols and ODols.

Annex 2: Screening Criteria of the Dols in the context of EFSA's public procurement and Grant awarding procedures



# ANNEX 1

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## General Principles and Screening Criteria for Experts' ADols and ODols.

### ASSESSMENT APPROACH

Unconditional restrictions Interests are considered incompatible with the involvement in any EFSA scientific activity (not applicable to interests held by Close Family Members)	Qualified restrictions Interests are screened by EFSA by considering whether they are compatible with the tasks to be assigned to the Expert, with regard to the mandate of the relevant group/panel
<ul style="list-style-type: none"><li>■ Current financial investments in "Industry" concerned with EFSA's outputs</li><li>■ Industry employment as described in Article 2(2)(IV) of this decision</li></ul>	<ul style="list-style-type: none"><li>■ Managerial Roles</li><li>■ Membership of scientific advisory entities</li><li>■ Employment in organisations other than food/feed industries</li><li>■ Occasional Consultancy</li><li>■ Research funding</li><li>■ Intellectual property rights</li><li>■ Other membership or affiliations</li><li>■ Other relevant interests</li></ul>

## REVIEW OF SCIENTIFIC WORK

		ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODoI Scientific Committee, Panels, Working Groups and peer review meetings	
		Eligibility Chair & Vice-chair	Eligibility Member	Participation in meeting when review of Expert's work is not in agenda	Participation in meeting when review of expert's work is in agenda
<b>Assessment, rating or review of Expert's own work</b>	which constitutes a part of the publications, opinions, paper, study, test or protocol which the mandate requires to review	YES	YES	YES	NO
	which is the only one to be reviewed or constitute the main subject of the mandate	NO	NO	NO	NO



## EXPERTS' DoI SCREENING CRITERIA

Declared interest		Time since declared interest ended (in years)	ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODOIS Scientific Committee, Panels, Working Groups and peer review meetings	
			Eligibility Chair & Vice-chair	Eligibility Member	Participation, when interest not overlapping with agenda item(s)	Participation, when interest overlapping with agenda item(s)
FINANCIAL INVESTMENTS in food or feed Industry		Current interest	NO	NO	NO	NO
		Past from 0 to 2 years	YES	YES	YES	YES
		Past from 2 to 5 years	YES	YES	YES	YES
MANAGERIAL ROLE MEMBERSHIP of a SCIENTIFIC ADVISORY ENTITY, OCCASIONAL CONSULTANCY with entities other than PI	Not overlapping with mandate of the scientific group	Current interest	YES	YES	YES	NO
		Past from 0 to 2 years	YES	YES	YES	YES
		Past from 2 to 5 years	YES	YES	YES	YES
	Overlapping with mandate of the scientific group	Current interest	NO	NO	NO	NO

Declared interest		Time since declared interest ended (in years)	ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODoIS Scientific Committee, Panels, Working Groups and peer review meetings	
			Eligibility Chair & Vice-chair	Eligibility Member	Participation, when interest not overlapping with agenda item(s)	Participation, when interest overlapping with agenda item(s)
		Past from 0 to 2 years <sup>21</sup>	NO	NO	NO	NO
		Past from 2 to 5 years <sup>20</sup>	YES	YES	YES	YES
EMPLOYMENT with food or feed Industry or other lobbying organisations directly or indirectly concerned by EFSA's scientific outputs		Current interest	NO	NO	NO	NO
		Past from 0 to 2 years <sup>20</sup>	NO	NO	NO	NO
		Past from 2 to 5 years <sup>20</sup>	NO	YES	YES	YES
EMPLOYMENT with entities other than food/feed Industry and PI	Not overlapping with mandate of the scientific group	Current interest	YES	YES	YES	NO
		Past from 0 to 2 years	YES	YES	YES	YES

<sup>21</sup> By way of derogation from paragraph 5, past activities classified as employment, managerial roles, scientific advisory roles, consultancy with, or Research Funding exceeding 25% from, non-PIs held by participants in peer review meetings are compatible with membership of these meeting(s) if the expert has an ongoing employment with a PI. The same derogation from paragraph 5 shall apply to interests held by Close Family Members of participants in peer review meetings. Paragraph 5 shall instead apply to participants in peer review meetings holding interests related to dossiers submitted by legal or natural persons with whom they, or their Close Family Members: a. were employed; b. held managerial or scientific advisory positions or; c. to whom they tendered advice, in the two years prior to DoI submission.

Declared interest		Time since declared interest ended (in years)	ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODoIS Scientific Committee, Panels, Working Groups and peer review meetings	
			Eligibility Chair & Vice-chair	Eligibility Member	Participation, when interest not overlapping with agenda item(s)	Participation, when interest overlapping with agenda item(s)
		Past from 2 to 5 years	YES	YES	YES	YES
	Overlapping with mandate of the scientific group	Current interest	NO	NO	NO	NO
		Past from 0 to 2 years <sup>20</sup>	NO	NO	NO	NO
		Past from 2 to 5 years <sup>20</sup>	NO	YES	YES	YES
MANAGERIAL ROLE, SCIENTIFIC, MEMBERSHIP of a SCIENTIFIC ADVISORY ENTITY, OCCASIONAL CONSULTANCY, EMPLOYMENT with PI	Public interest duty (no Risk Management tasks)	Current interest	YES	YES	YES	YES
		Past from 0 to 2 years	YES	YES	YES	YES
		Past from 2 to 5 years	YES	YES	YES	YES
	Public interest duty	Not overlapping	Current interest	YES	YES	YES

Declared interest			Time since declared interest ended (in years)	ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODoIS Scientific Committee, Panels, Working Groups and peer review meetings	
				Eligibility Chair & Vice-chair	Eligibility Member	Participation, when interest not overlapping with agenda item(s)	Participation, when interest overlapping with agenda item(s)
	(Risk Management tasks) <u>or</u> Non-public interest duty	with mandate of the scientific group	Past from 0 to 2 years	YES	YES	YES	YES
			Past from 2 to 5 years	YES	YES	YES	YES
		Overlapping with mandate of the scientific group	Current interest	NO	NO	NO	NO
			Past from 0 to 2 years	NO	NO	NO	NO
			Past from 2 to 5 years	YES	YES	YES	YES
		RESEARCH FUNDING not linked to the mandate of the scientific group			Current interest	YES	YES
Past from 0 to 2 years	YES				YES	YES	YES
Past from 2 to 5 years	YES				YES	YES	YES
RESEARCH FUNDING linked to the mandate of the scientific group		Private funds < or = 25%	Current interest	YES	YES	YES	YES
			Past from 0 to 2 years	YES	YES	YES	YES
			Past from 2 to 5 years	YES	YES	YES	YES
		Private funds > 25%	Current interest	NO	NO	NO	NO
			Past from 0 to 2 years <sup>20</sup>	NO	NO	NO	NO
			Past from 2 to 5 years	YES	YES	YES	YES
INTELLECTUAL PROPERTY RIGHTS linked to the mandate		which is being reviewed as part of a broader scientific	Current interest	NO	YES	YES	NO
			Past from 0 to 2 years	YES	YES	YES	YES

Declared interest		Time since declared interest ended (in years)	ADoI Scientific Committee, Panels, Working Groups and peer review meetings		ODoIS Scientific Committee, Panels, Working Groups and peer review meetings	
			Eligibility Chair & Vice-chair	Eligibility Member	Participation, when interest not overlapping with agenda item(s)	Participation, when interest overlapping with agenda item(s)
of the scientific group	mandate or as part of a large body of evidence	Past from 2 to 5 years	YES	YES	YES	YES
		Current interest	NO	NO	NO	NO
	which is the only or main subject of the mandate	Past from 0 to 2 years	NO	NO	NO	NO
		Past from 2 to 5 years	YES	YES	YES	YES
INTELLECTUAL PROPERTY RIGHTS not linked to the mandate of the scientific group		Current interest	YES	YES	YES	NO
		Past from 0 to 2 years	YES	YES	YES	YES
		Past from 2 to 5 years	YES	YES	YES	YES

## Calculation of private research funds (to be performed by the Expert)

<p>Step 1: determination of the Expert's overall research portfolio in €</p>	<p>Research funds directly received and managed by the Expert during the two years preceding the submission of the Dol (Ex: 200,000 Euro)</p> <p style="text-align: center;">+</p> <p>Research funds benefiting the Expert during the two years preceding the submission of the Dol, and received or managed by his/her organisation of affiliation (Ex: 500,000 Euro)</p> <p style="text-align: center;">+</p> <p>Research funds directly received and managed by the Expert's Close Family Member during the two years preceding the submission of the Dol (Ex: 50,000 Euro)</p> <p style="text-align: center;">+</p> <p>Research funds benefiting the Expert's Close Family member during the two year preceding the submission of the Dol, and received or managed by his/her organisation of affiliation (Ex: 250,000 Euro)</p>	<p>Step 2: determination of the amount representing basis for calculation of % of private and public funds</p>	<p>IN THE MANDATE</p> <p>Research funds invested in scientific area(s) pertaining to the mandate of the relevant Panel/Working Group/peer review meeting</p> <p>(Ex: 200.000 Euro)</p>	<p>Step 3: determination of the % of research funds from private sector</p>	<p>CONFLICT if &gt; 25%</p> <p>Ex: 60.000 Euro of the 200.000 Euro invested in researches pertaining to the mandate of the Panel/Working Group/peer review meeting originate from private sources = 30%</p>
	<p>OUT OF THE MANDATE</p> <p>Research funds invested in scientific area(s) other than that/those pertaining to the mandate of the relevant Panel/Working Group/peer review meeting</p> <p>(Ex: 800.000 Euro)</p>		<p>NO CONFLICT if = OR &lt; 25%</p> <p>Ex: 40.000 Euro of the 200.000 Euro invested in researches pertaining to the mandate of the Panel/Working Group/peer review meeting originate from private sources = 20%</p>		

## ANNEX 2

### Screening Criteria of the Dols in the context of EFSA's public procurement and Grant awarding procedures

Declared interest		Time since declared interest ended	Participation in the tender or project / awarding of Grant	
Industry Employment or Industry Financial Investment	Overlapping with the subject of the project	Current	NO	
		Past 0 to 5 years	YES	
	Not overlapping with the subject of the project	Current or past 0 to 5 years	YES	
EMPLOYMENT with non-PIs (non-food or feed industry)	Overlapping with the subject of the project	Current	NO	
		Past 0 to 5 years	YES	
	Not overlapping with the subject of the project	Current or past 0 to 5 years	YES	
MANAGERIAL ROLE , MEMBERSHIP of aSCIENTIFIC ADVISORY ENTITY, OCCASIONAL CONSULTANCY with non PIs	Overlapping with the subject of the project	Current	NO	
		Past 0 to 5 years	YES	
	Not overlapping with the subject of the project	Current or past 0 to 5 years	YES	
MANAGERIAL ROLE, MEMBERSHIP of aSCIENTIFIC ADVISORY ENTITY, OCCASIONALCONSULTANCY or EMPLOYMENT with PI	Risk management functions	Overlapping with the subject of the project	Current	NO
			Past 0 to 5 years	YES
		Not overlapping with the subject of the project	Current or past	YES
	Risk assessment functions	Overlapping or not overlapping	Current or Past	YES
RESEARCH FUNDING with private funds < or = 25%	Linked to the subject of the project	Current or past	YES	
	Not linked to the subject of the project	Current	NO	
		Past 0 to 5 years	YES	

RESEARCH FUNDING with private funds >25%	Linked to the subject of the project	Current or past	YES
	Not linked to the subject of the project	Current	NO
		Past 0 to 5 years	YES
Intellectual Property Rights	Overlapping with the subject of the project	Current	NO
	Not overlapping with the subject of the project	Past 0 to 5 years	YES



