



# Annex VII. Annual Report on the implementation of EFSA's policy on independence

## 1. Executive Summary

As independence is one of its key values, EFSA attaches great importance to ensuring an impartial scientific process devoid of conflicts of interest. This annual report provides a clear picture of the investments and efforts made by EFSA during the reporting period for the implementation of its Policy on Independence and the management of conflicts of interest (CoIs). In the reference period, EFSA:

- Screened a total of 2,796 annual Declarations of Interest (DoIs) submitted by its scientific experts and identified 31 CoIs;
- Processed 17 DoIs submitted by its Management Board members, 393 DoIs of staff members, where 1 CoI was prevented, and 46 DoIs of candidates pre-selected in the context of recruitment procedures, for whom ordinary risk mitigation measures were adopted;
- Screened 59 "Institutional DoIs" and 179 "individual DoIs" submitted by participants to procurement and grant awarding procedures, identifying and preventing 5 conflicts of interests;
- Carried out in the context of *ex-post* controls two compliance and veracity checks, which led to the identification 8 minor non-conformities, none of which required the adoption of remedial measures;
- Evaluated the applications of 14 former staff members wishing to engage in occupational activities, none of which was considered overlapping with EFSA's tasks;
- Delivered 2 training sessions to EFSA's staff, 11 awareness sessions to scientific panels and made available 2 e-trainings to experts and staff members;
- Updated the list of "public institutions" published online and classified 360 organisations.

In order to carry out the above activities and to further improve its Policy on Independence, EFSA invested a total of 3.03 full-time equivalents and EUR 196,158.08. A similar level of investment is expected to continue in 2020, as EFSA will also focus on improving its IT solution and further enhancing its internal regulatory framework.

The analysis of these findings shows that the regulatory system currently in place is efficient and adequately safeguards the independence of EFSA's scientific work.



## 2. Background

Regulation (EC) No 178/2002<sup>81</sup> laying down the general principles and requirements of food law and establishing the European Food Safety Authority, prescribes that EFSA shall be a point of reference for risk assessment in the food chain by virtue of the quality of its scientific outputs and of its independence. Independence and high standards of professional conduct are crucial to EFSA's work, for it is essential that interested parties and the public at large trust the process leading to the adoption of its scientific outputs.

Against this background, as acknowledged in the "EFSA Strategy 2020", EFSA's motto of delivering "Trusted science for safe food" requires adherence to robust ethics and integrity standards<sup>82</sup>. An impartial scientific process populated with datasets gathered or developed in an objective manner and processed by scientists devoid of conflicts of interest is of fundamental importance to achieve EFSA's objective of being truly accountable to EU citizens and its institutional partners.

Adequate management of Conflicts of Interest (CoI) is of key importance for EFSA. In June 2017, EFSA adopted a new Policy on Independence followed by an implementing decision on the management of competing interests applicable to all members of EFSA's Scientific Committee, scientific panels, working groups, participants in peer-review meetings, network members, members of EFSA's governance bodies, hearing experts, observers, participants to procurement and grant awarding procedures as well as staff of EU institutions, bodies or other agencies taking an active role in EFSA's meetings<sup>83</sup>.

In its Policy on Independence, EFSA committed to making publicly available an annual report on independence-related activities, thereby increasing the transparency of related processes<sup>84</sup>.

This annual report is the second on independence-related matters and aims at providing a clear picture of the investments and efforts made by the Authority to meet the expectations of EU citizens and its institutional partners. In the reference year, some independence-related activities besides screening of Declarations of Interest (DoI) have been deprioritised by EFSA due to the need to divert internal resources to the implementation of Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain<sup>85</sup> (hereinafter Transparency Regulation), which entered into force on 26 June 2019, and whose provisions will become applicable as of 27 March 2021.

## 3. Regulatory developments

Independence is one of EFSA's core values, together with openness, scientific excellence, innovation and cooperation. For this reason, in line with the idea of a lean evolution, the

---

<sup>81</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 031, 01/02/2002, 2-24 as last amended.

<sup>82</sup> EFSA, EFSA Strategy 2020. Trusted science for safe food. Protecting consumers' health with independent scientific advice on the food chain, available online at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/strategy2020.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf).

<sup>83</sup> EFSA, Decision of the Executive Director of EFSA on Competing Interest Management, EFSA/LA/DEC/19568050/2018, available online at <http://www.efsa.europa.eu/en/corporate/pub/independencepolicy17>.

<sup>84</sup> EFSA's Policy on Independence. How the European Food Safety Authority assures the impartiality of professionals contributing to its operations, mb170621-a2, available online at <http://www.efsa.europa.eu/en/corporate/pub/policyonindependence>.

<sup>85</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain, OJ L 231, 6.9.2019, p. 1-28.



Authority adopts a continuous improvement approach characterised by the “Plan-Do-Check-Act” cycle<sup>86</sup>. The next steps will be the review of the rules on Competing interest management foreseen for 2020, and an ex post evaluation of the Policy to be performed by 2022.

In the reference period, EFSA kept enhancing the internal regulatory framework necessary for the implementation of its 2017 Policy on Independence. The key features of the Decision on Competing Interest Management can be found on EFSA’s website<sup>87</sup>.

As a follow-up action to the internal audit performed by the European Commission’s Internal Audit Service in May 2018, EFSA started developing in 2019 a new set of internal instructions on the prevention of conflicts of interest of the Selection Board’s Members within the recruitment procedures of EFSA Statutory Staff.

In the reference period EFSA continued developing a regulatory framework for the implementation of articles 11 and 11a of the EU Staff Regulations on the prevention of conflicts of interest of EFSA employees and candidates to EFSA vacant positions<sup>88</sup>. In view of the fact that this forthcoming Decision is implementing the EU Staff Regulations, it must undergo the *ex-ante* agreement by the European Commission set out in Article 110 of the EU Staff Regulations. The aim is to propose the new rules for adoption by the EFSA Management Board by Q4 2020.

Finally, in July 2019, EFSA’s Advisory Forum endorsed a Declaration of Intent<sup>89</sup> on the principles governing the impartiality of risk assessment in the areas of food, feed, plant health and animal health & welfare, and proposed to establish a Task Force on independence aimed at facilitating the exchange of information and best practices. Implementation was postponed due to the need to prioritise activities related to the Transparency Regulation.

#### 4. Ex-ante controls - figures on DoI processing operations

In the reference period, EFSA screened a total of 2,976 Annual DoIs submitted by its scientific experts.

In the course of 2019, EFSA also processed 17 DoIs submitted by Management Board members in charge and made publicly available<sup>90</sup> 4 DoIs as part of the registry of activities of former Management Board members<sup>91</sup>.

<sup>86</sup> So called “Deming cycle”, as further reviewed by Imai and Ishikawa, contemplates a continuous improvement process based on four phases: Planning, where issues are identified, hypothesis developed and strategic decisions taken; Doing, where the solutions are tested and implemented on a small scale, and the results measures; Checking, where the results are evaluated and a decision is taken whether the hypothesis and related solution is concerned; and Acting, where the successful solution is implemented: Deming, W.E., 1950. *Elementary Principles of the Statistical Control of Quality*, JUSE; Ishikawa, K., 1985. *What is Total Quality Control? The Japanese Way*. Translated by David, J. Lu. Englewood Cliffs, NJ: Prentice-Hall, Inc, pages 56-61

<sup>87</sup> Trusted Science for safe food, available online at <https://www.efsa.europa.eu/en/howwework/independentscience>

<sup>88</sup> Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, OJ P 045 14.6.1962, p. 1385.

<sup>89</sup> Declaration of Intent of the EFSA Advisory Forum, 3 July 2019, available online at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/190703\\_independence\\_AF\\_declaration\\_of\\_intent.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/190703_independence_AF_declaration_of_intent.pdf)

<sup>90</sup> The registry of post mandate activities in which former MB members engage dis available online at <https://ess.efsa.europa.eu/doi/doiweb/wg/684430>.

<sup>91</sup> The disclosure of activities of former Board members for two years after termination of their mandate is a voluntary transparency measure proactively adopted by the Management Board in EFSA’s Policy on Independence.



DoIs have to be submitted also by all tenderers and participants to grant awarding procedures regarding the outsourcing of scientific tasks or projects. In the reference year, this resulted in 31 calls being launched for which DoIs were requested, which led to the screening of a total number of 59 “institutional DoI” as well as of 179 “individual DoIs”. In the context of these screening processes, 5 conflicts of interests were identified and prevented from occurring by rejecting the concerned experts.

Finally, the Authority also processed 393 DoIs of staff members, as well as 46 DoIs of candidates being pre-selected for engagement as contract agents, temporary agents, seconded national experts, or national experts in professional training. As far as the screening of DoIs of staff members is concerned, 1 conflict of interest was identified which was prevented by the adoption of ordinary risk mitigating measures, while for candidates, ordinary mitigating measures were adopted in a number of cases to ensure that no perception of conflicts of interest could be caused by certain past interests held by candidates selected for fill vacant positions of EFSA statutory staff, seconded national experts and national experts in professional training.

These ordinary mitigating measures consist in the exclusion of the concerned individual from processes and projects regarding their previous employer in the private sector, such as those regarding the evaluation of application dossiers submitted to EFSA by applicants, participation in the evaluation of tenders by previous employers, or the review of the candidate’s own work<sup>92</sup>.

#### 4.1 Competing Interests prevented by sector

In the reference period, in the context of *ex ante controls* performed on the DoIs submitted by its experts, EFSA identified and prevented 31 conflicts of interest at ADoI level. This systematically resulted in the exclusion of the expert either from membership, or from participation in the discussion at the relevant meeting of the scientific group if the CoI regarded an intellectual property right or the expert’s previous work.

The breakdown by sector of the conflicts prevented is provided in Table 1.

**Table 59:** Competing interests prevented by sector

Sector	Number of conflicts of interest prevented
Animal Health and Welfare	3
Biological Hazards	5
Communications, Engagement and Cooperation	1
Contaminants	1
Food Additives and Flavourings	2
Pesticides	17
Scientific Committee	2
<b>Total</b>	<b>31</b>

<sup>92</sup> For a definition of this concept, see SOP 039 on management of competing interests, available on EFSA’s website at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/SOP-039\\_A.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-039_A.pdf).



## 5. Ex post controls

### 5.1 Background and aggregated results

Pursuant to the Decision of the Executive Director on Competing Interest Management, twice a year EFSA performs a check of the compliance and veracity of a sample of screening processes of DoIs submitted by experts who participated in meetings of the Scientific Committee, scientific panels, working groups (WGs), peer review meetings as well as of DoIs submitted in the context of outsourcing procedures.

For each reporting period, relevant documents related to 15 experts and 15 tenderers and grant beneficiaries are randomly selected and are checked for compliance with the regulatory framework in force at the time the DoI was screened and for the veracity of the information contained. Tenderers and grant beneficiaries who are part of the teams being awarded contracts and grants in the scientific domain as well as experts participating as Chairs or members in scientific meetings are included in the list for random selection. Experts participating as hearing experts or observers, as well as experts participating in meetings of the Management Board, (scientific) Networks, Advisory Forum or Focal Points, those participating in scientific preparatory or follow-up meeting and in scientific conferences and/or workshops on EFSA's behalf are not part of the exercise as they are not implicated in developing or adopting EFSA's scientific outputs.

Overall, in 2019 these checks identified eight findings, none of which consisted in a non-conformity requiring the adoption of remedial measures.

In 2019, following up from a finding identified in the 2018 compliance and veracity checks and reported in the first Annual Report on Independence,<sup>93</sup> EFSA's Legal and Assurance services confirmed that based on the supporting documents held by the Authority there is no indication of an undue influence by the concerned expert in the preparation of a draft opinion. Furthermore, an extra level of reassurance is given by the fact that the expert whose input was reviewed by the Legal and Assurance Services contributed to the preparatory work delivered by a working group, while the final scientific opinion was adopted by the EFSA Scientific Panel on Novel Foods and Food Allergens, whose members discussed, reviewed and endorsed the draft opinion submitted to their attention, thereby ensuring an additional level of scrutiny on the original proposal from the working group. In the reference year, this was complemented by an action taken in response to a breach of the applicable rules.

### 5.2 Findings of compliance and veracity check of 2019

The compliance checks of 2019 demonstrated that, for 30 out of 30 experts checked, the Decision of Executive Director on Competing Interest Management had been followed correctly.

The 2019 veracity checks revealed that the ADoIs of 25 experts out of 30 were complete, while for 5 experts the ADoIs revealed the following omissions, that upon declaration were evaluated as not leading to a conflict of interest:

- A consultancy activity to aid the United States Department of Agricultural Animal and plant health Inspection Service (USDA APHIS) and a different ending date of a research activity funded by Defra.

<sup>93</sup> European Food Safety Authority, Annual Report on the implementation of EFSA's policy on independence, Reporting period: 1 January – 31 December 2018, available on EFSA's website at [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/EFSA\\_report\\_on\\_independence\\_2018.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/EFSA_report_on_independence_2018.pdf).



- Habilitation as Assistant Professor at a public University.
- Chairmanship in a Commission at the German Central Committee of Agriculture.
- An on-going research activity concerning the protection of ground water against pesticides. No follow-up action was required since the expert is currently acting as Hearing expert.
- Four research activities falling within EFSA's remit by the same expert.
- A patent on chimeric gene coding for a transcription factor and expression in plants.

In terms of the outcome of the compliance checks, 7 out of 7 Institutional DoIs and 23 out of 23 Individual DoIs checked in the context of procurement and grant procedures were found to be fully compliant. The compliance check run during the first reporting period revealed that in two cases the DoI assessment by the Evaluation Committee prior to the screening by the Authorising Officer was found to be missing. This did not impact the DoI screening outcome, which was correctly finalised by the Authorising Officer.

In terms of veracity, it was found that 21 out of the 23 Individual DoIs checked were complete, while the following omissions, not leading to a conflict of interest, were identified with respect to the DoIs of two tenderers:

- Membership in the Food and Agriculture Organisation working group on assessment and comparison of available influenza Risk Models. Upon clarification provided by the team member, EFSA concluded that this is a past involvement and that therefore there was no need to declare it.
- Discrepancy between the starting date of the current employment declared in the Individual DoI and in the CV.

## 6. Assurance Working Group on Independence

Pursuant to Article 22 of the Decision on Competing Interest Management, EFSA's Legal and Assurance Services are advised by the Assurance Working Group on Independence (AWGI). The AWGI reports to EFSA's Assurance Council, which in turn informs the Audit Committee of EFSA's Management Board.

Five AWGI meetings took place in 2019 and focused mainly on the interpretative approaches of EFSA's regulatory framework on independence and competing interest management.

## 7. Activities undertaken by former EFSA staff members

### 7.1 Background

In accordance with Article 16 of EU Staff Regulations<sup>94</sup>, an official, temporary agent or contract agent intending to engage in an occupational activity, whether gainful or not, shall inform EFSA within two years of leaving the service. If the activity is related to the work carried out by the official, temporary agent or contract agent during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the authority empowered to conclude contracts may, having regard to the interests of the service, either forbid him/her from undertaking it or give its approval subject to any conditions it thinks fit.

<sup>94</sup> Regulation (EU, Euratom) No 1023/2013 of the European Parliament and of the Council of 22 October 2013 amending the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union, OJ L 287, 29.10.2013, p. 15–62.





In the case of former senior officials as defined in implementing measures of the EU Staff Regulations, the authority empowered to conclude contract shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy *vis-à-vis* staff of their former institution for their business, clients or employers on matters for which they were responsible during the last three years in the service. Each institution shall publish annually information on its implementation, including a list of the cases assessed, in compliance with Regulation (EC) 2018/1725 of the European Parliament and of the Council<sup>95</sup>.

## 7.2 Overview

In the reference period, no former senior official or agent left EFSA nor informed the Authority of their intention to engage in outside activities. Furthermore, in the reference year, EFSA processed the applications of 14 staff members having left the Authority. Of these, five opted for the public sector, and nine for the private sector (see table 2). None of the activities were deemed to be overlapping with EFSA’s tasks and consequently no restriction was applied.

**Table 60:** Overview of dossiers submitted under Article 16 of the Staff Regulations.

Reference year	Total number of cases	Of which to the private sector	Of which overlapping with EFSA’s tasks	Restrictions applied
2019	14	9*	0	0

\*IT private firm, companies providing consultancies services, private firm specialised in the development and marketing of innovative medicines, private firms providing recruitment services, private firm providing workforce project management and consulting solutions, private Engineering and Validation services company.

## 8. Awareness raising and training

EFSA attaches great importance to the need of establishing a corporate culture aware of the importance of ethics and integrity matters, and to the fact that the Authority comes across as a workplace intolerant of situations conducive to conflicts of interest.

Against this background, in 2019, two training sessions were delivered to EFSA staff in order to keep raising awareness about the key features of the Decision on Competing Interest Management. Furthermore, individual awareness sessions were delivered to each scientific panel. E-training sessions were also made available both to experts and staff members, including an e-learning module on “Conflicts of Interest” framed in a wider set of modules aimed at addressing issues related to “ethics @ work” for EFSA statutory staff (see table 3).

<sup>95</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.



**Table 61:** Training activities

Training activities	
Sessions for scientific panels	11
Sessions for DoI assessors	1
Session for EFSA procurement team in the Finance unit	1
E-training sessions	2

## 9. IT developments

In 2019, EFSA kept improving the component of its IT solution permitting the automated processing of DoIs of staff members, members of its Management Board and experts, thereby ensuring the sustainability of the DoI tool operated by EFSA and improving its availability and efficacy. The tool relies on a proprietary interface combined with a commercial off-the-shelf software.

In the reference period, EFSA also finalised the proof of concept of the so-called “complete solution”, aimed at replacing the legacy part of the current IT solution in line with the criteria set out in the EFSA IT strategy. The implementation of the complete solution has been outsourced on the basis of a common platform provided by the Oracle Corporation.

## 10. Transparency

Building on already highly transparent standards, in 2019 EFSA continued making independence-related processes accessible to citizens and interested parties.

In accordance with EFSA’s Policy on Independence adopted by its Management Board in June 2017, in Q3 2019, EFSA updated and made publicly available on its website the list of “public institutions”<sup>96</sup>. This list is instrumental in the screening of DoIs submitted by concerned individuals, in accordance with EFSA’s Policy on independence and its Decision on Competing Interest Management. In general terms, the inclusion of an entity in this list certifies that the institutional activities performed by its employees in the public interest do not create a risk of conflict with EFSA’s interest.

The list is regularly updated by EFSA with new entries based on the DoIs it receives, and the inclusion of an entity presupposes compliance with the criteria set out in Article 2(1), point “m” of the Decision on Competing Interest Management. In 2019, 360 organisations have been classified by EFSA.

In line with its Policy on Independence, in 2019 EFSA kept publishing on its website the DoIs of the members of its operational management team, comprising EFSA’s Heads of Departments as well as Heads of Unit<sup>97</sup>.

Finally, EFSA’s Management Board discussed in March 2019 an external report assessing the feasibility of publishing individual decisions taken by the Authority in the context of the screening of ADoIs submitted by scientific experts. The Management Board decided

<sup>96</sup> The list is publicly available on EFSA’s website at this address: <https://www.efsa.europa.eu/en/howwework/independentscience>.

<sup>97</sup> The DoIs of the Heads of units and of the Heads of departments are publicly available at this address: <https://www.efsa.europa.eu/en/people/operationalmanagement>.





not to make these individual acts publicly available as they were deemed not fit for purpose.

## 11. Engagement

In 2019, EFSA kept participating to the interagency task force managed by the European Commission's DG SANTE, comprising also representatives of the European Chemicals Agency, European Medicines Agency, Community Plant Variety Office and European Centre for Disease Prevention and Control. This forum is instrumental in optimising the use of resources deployed by these actors to prevent competing interests, as well as benchmarking and identifying best practices.

Moreover, in the spirit of interagency cooperation, EFSA's Head of Legal and Assurance Services served as alternate Chair of the European Chemical's Agency Independence Advisory Committee.

In the reporting period, EFSA also provided constant support to internal and external stakeholders. In 2019, EFSA also engaged 22 times with members of the European Parliament, citizens, media professionals and external parties inquiring about EFSA's independence policy and competing interest management practices by providing the requested clarifications or support.

## 12. Conclusions

In the reference year, EFSA devoted its investments in this sector to the further implementation and improvement of its Policy on Independence. To deliver the activities described in the previous paragraphs, EFSA invested a total of 3.03 full-time equivalents and EUR 196,158.08

A comparable level of investment is expected to continue in 2020 with ongoing work on competing interest management for staff members, investigation of a complete IT solution as well as transparency.

Furthermore, margins for improvement identified in terms of implementation and compliance in the context of the *ex-ante* and *ex-post* controls are to be addressed in a manner adequate to the risk they represent.

Out of 3.670 DoIs screened by EFSA in the context of the *ex-ante* controls, 37 cases of conflicts of interest were identified and prevented. The *ex post* controls resulted in eight findings, and none consisted in a non-compliance requiring the adoption of remedial measures. (see table 4)

The qualitative analysis of the detailed findings of these operations supports the efficacy of the regulatory system currently in place and improvements in the awareness-raising and IT sectors.



**Table 62:** Overview of 2019 facts and figures on independence

Ex Ante Control								Ex Post Control	Awareness-raising	Resources	
No of ADoIs screened	No of conflicts of interest prevented	No of waivers granted	No of Hearing experts	DoIs screened for tenderers and participants in grant-awarding procedures	No of Staff ADoIs screened	No of staff members leaving EFSA	No of organisations classified	Non-compliance findings and actions	No of training activities	M€	FTEs
Experts: 2,976 Management Board members: 17 Total: 2.993 ADoIs	31: ADoIs	16	319	59: Institutional DoIs 179: Individual DoIs 5: conflict of interest prevented	393: statutory staff 1: conflict of interest prevented 46: candidate staff 0: conflict of interest prevented	Total: 14 Private sector: 9* Restrictions:0	360	8 non-compliances; none which leading to a conflict of interest 1 sanction	2: e-training tool for experts 1: session for DoI assessors 1: session for EFSA procurement team in the Finance unit 11 sessions for Scientific Committee and Panels	0.2	3.03

\* IT private firm, companies providing consultancies services, private firm specialised in the development and marketing of innovative medicines, private firms providing recruitment services, private firm providing workforce project management and consulting solutions, private Engineering and Validation services company.