

## Executive Summary

At its meeting held on 16 March 2016, EFSA's Management Board discussed a conceptual approach to the review of the Policy on independence and scientific decision making process it had adopted in December 2011.

In October 2016, the Management Board set-up a working group on the review of EFSA's independence policy. The Working Group met five times from November 2016 until January 2017 and reviewed the current EFSA Policy on Independence primarily in the areas of:

- Definition of conflict of interest;
- Financial or economic interests;
- Risk based approach for competing interest management;
- Cooperation with EFSA's partners;
- Cooling-off periods;
- Research funding and other scientific activities;
- Transparency; and
- Enforcement

The outcome of this review is reflected in the draft Policy on Independence on which EFSA is asking your feedback. The paper sets out EFSA's ambitions on how it will ensure the independence of all actors involved in its decision making processes. In EFSA's view it potentially represents a marked step forward compared to the policy and rules currently in force in key areas such as cooling off periods, economic interests, transparency and enforcement.

Its content is supported by an *ex post* analysis on EFSA's 2011 Policy on Independence and 2014 Rules on Declarations of Interest delivered by Deloitte Belgium.

After the public consultation, EFSA will take stock of the input received and submit to its Management Board a revised draft Policy together with a public consultation report outlining all comments received and the report produced by Deloitte Belgium. All documents will be made publicly available in the context of the Board meeting in June 2017.

# EFSA's policy on independence

How the European Food Safety Authority assures the impartiality of professionals contributing to its operations.

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DRAFT

# EFSA's policy on independence

*How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*

## 1. Independence at EFSA – What are we discussing?

In accordance with the European Union (EU) constitutional setting, the EU administration is required to operate in an impartial manner<sup>1</sup> so as to ensure the achievement of its objectives in line with good administration principles<sup>2</sup>. The principles of impartiality, equal treatment and non-discrimination represent a bulwark for institutions, agencies and bodies impacting on the daily lives and rights of hundreds of millions of citizens, taxpayers and business operators. This holds true also for the European Food Safety Authority ("EFSA" or "the Authority"). EU legislators put a particular emphasis on EFSA's independence.<sup>3</sup> However, independence is a multi-faceted concept, covering, *inter alia*, aspects such as legal independence, financial independence, regulatory autonomy, personal independence and perception thereof. In 2002, EFSA was set up as part of a broader legislative reform aimed at restoring the confidence of EU partners and citizens in the ability of the EU to

ensure safety of the food chain. The Authority was created with a strong focus on its legal autonomy from the EU institutions, Member State governments and stakeholders in the public or private sector. Also for these reasons, EFSA's compliance with its Founding Regulation<sup>4</sup> and other secondary legislation<sup>5</sup> ensures the attainment of legal, financial, and regulatory independence.

**"Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union" Article 41, Charter of Fundamental Rights of the European Union.**

At EFSA, independence is of such importance that it is acknowledged as one of the agency's main corporate values. The most recent strategic document issued by EFSA<sup>6</sup> at the time this policy was adopted confirms EFSA's

<sup>1</sup> Article 298 of the Treaty on the Functioning of the European Union.

<sup>2</sup> Article 41 of the Charter on Fundamental Rights of the European Union.

<sup>3</sup> See e.g. Articles 22 of 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, 1 - 24.

<sup>4</sup> See e.g. Articles 25, 26, 27, 28 and 43-45 of Regulation (EC) No 178/2002.

<sup>5</sup> E.g. Regulation (EC) no 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p.9 or Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, 1-22.

<sup>6</sup> European Food Safety Authority, EFSA Strategy 2020 Trusted science for safe food Protecting consumers' health with independent scientific advice on the food chain, 2016.

47 commitment to achieve “the  
48 independence of its experts, methods and  
49 data from any undue external influence”<sup>7</sup>.

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51

## 52 2. Aim of this policy – 53 Ensuring the impartiality 54 of EFSA’s actors 55

56 This policy ensures the impartiality of the  
57 persons participating in EFSA’s operations  
58 based on the reassurance provided by  
59 projects securing the neutrality of the  
60 methods and data the Authority uses.<sup>8</sup>  
61 Given the importance that experts’  
62 judgment has in EFSA’s work, this policy  
63 focuses on the Authority’s ability to  
64 ensure that professionals contributing to  
65 the work of EFSA perform their tasks in  
66 an impartial manner, without favour or  
67 discrimination. This presupposes, *among*  
68 *other things*, that these individuals are  
69 devoid of conflicts of interest (CoI)  
70 harmful to the Authority’s work.  
71 This policy also outlines how EFSA  
72 prevents the occurrence of CoI.

EFSA’s compliance with its Founding Regulation and secondary legislation ensures **legal, financial, and regulatory independence**.

73  
74 EFSA’s approach to impartiality rests on:  
75 (i) the commitment that persons having  
76 an impact on the Authority’s operations  
77 are not allowed to operate in situations  
78 where a CoI exists according to EFSA’s  
79 policy and its implementing rules; and (ii)  
80 the transparency assured by its extensive  
81 rules and procedures regulating the  
82 prevention of CoIs, other ethics and

83 integrity issues, and its scientific  
84 operations.

85  
86

## 87 3. A risk-based approach to 88 prevent the occurrence of 89 conflicts of interest 90

91 It is widely acknowledged that having  
92 interests does not necessarily mean there  
93 is a CoI. On the contrary, it is precisely  
94 interests, experiences and activities held  
95 that qualify an individual as an expert in  
96 a certain matter. This means that the  
97 definition of what the Authority considers  
98 a CoI is of particular significance in order  
99 not to harm legitimate professional  
100 activities contributing to EFSA’s mission.  
101 A CoI is deemed to exist whenever the  
102 Authority identifies: any situation where  
103 an individual has an interest that may  
104 compromise or be reasonably perceived  
105 as compromising his or her capacity to  
106 act independently and in the public  
107 interest in relation to the subject of the  
108 work performed at EFSA.<sup>9</sup>

109  
110 However, the actual impact of this  
111 definition on EFSA’s independence related  
112 processes mainly depends on the way the  
113 Authority defines the sources of potential  
114 CoI.

115  
116 EFSA recognises the main patterns of CoI  
117 affecting actors contributing to its  
118 operations in activities concerning:

119

- 120
- 121 ■ their “economic or financial”  
122 sphere (e.g. deriving from  
123 research funding, financial  
124 investments, professional fees,  
125 salary, reimbursement of  
126 expenses, gifts, prizes or  
127 donations);

128

<sup>7</sup> Op. cit., supra, at 14.

<sup>8</sup> E.g. Expertise Management Programme, MAXTRIX project and Prometheus project: see EFSA, Annual Activity Report 2016. Available online: <http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm>.

<sup>9</sup> Based on the definition of “conflict of interest” set out in 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.

- 129     ▪ creations of the mind (such as
- 130     authoring, inventing or providing
- 131     sworn statements); and
- 132
- 133     ▪ affiliations or other involvements
- 134     (such as involvement in business
- 135     operators, industry associations,
- 136     non-governmental organisations,
- 137     universities and their spin-offs,
- 138     research bodies, ministries and
- 139     risk management bodies, risk
- 140     assessment bodies or
- 141     intergovernmental organisations).
- 142

143 To prevent all potential CoIs, the  
 144 Authority requires concerned actors to  
 145 declare all interests held by them, their  
 146 partners or dependent family members,  
 147 in a timeframe covering the five years  
 148 preceding the declaration, falling under  
 149 EFSA's remit and belonging to the  
 150 following fields: financial investments,  
 151 managerial roles, scientific advisory roles,

**EFSA defines a conflict of interest as** “any situation where an individual has an interest that may compromise or be reasonably perceived to compromise his or her capacity to act independently and in the public interest in relation to the subject of the work performed at EFSA”.

152 employment or self-employment, full or  
 153 occasional consultancy, research funding,  
 154 intellectual property rights, sworn  
 155 statements, memberships of professional  
 156 or learned societies, and interests not  
 157 captured by the above.

158  
 159 In order not to go beyond what is  
 160 necessary to ensure the actors’  
 161 impartiality, the Authority identifies CoIs  
 162 related to activities that overlap with  
 163 matters discussed in the relevant EFSA  
 164 group(s) where the individual is serving  
 165 or is expected to serve. In this way, the  
 166 Authority ensures that this policy does

167 not hinder the availability of expertise  
 168 needed to accomplish EFSA's duties in  
 169 line with the principle of scientific  
 170 excellence.  
 171  
 172 In line with the concept of proportionate  
 173 administrative action, more stringent  
 174 rules and procedures are applied to areas  
 175 where CoIs with commercial interests are  
 176 likely to occur. The same applies in cases  
 177 where multiple items are discussed in the  
 178 same forum.<sup>10</sup>

179  
 180 EFSA identifies cash flows from entities  
 181 with an interest in EFSA's activities to be  
 182 a main driver for potential lack of  
 183 impartiality and for CoIs. EFSA therefore  
 184 asks all its actors to declare the  
 185 proportion of their annual earnings (at  
 186 the time of submission) that originate  
 187 from such entities. This information is  
 188 made public and assessed by EFSA to  
 189 determine whether conflicts of interest  
 190 exist.

191  
 192 Since as per its Founding Regulation  
 193 EFSA also outsources part of its scientific  
 194 work to contractors and national  
 195 competent authorities, tenderers  
 196 responsible for the provision of services  
 197 in the area of regulated products are  
 198 subject to the same requirements  
 199 applicable to members of EFSA's  
 200 Scientific Committee and Scientific  
 201 Panels.

202  
 203 Due to their ambassadorial role,  
 204 members of EFSA's Management Board  
 205 are subject, among others, to  
 206 transparency requirements obliging them  
 207 to submit a declaration of interest at least  
 208 once a year, and to update it as soon as  
 209 new interests emerge. The scrutiny of  
 210 declared interests is exercised by the  
 211 Board, upon advice from the Executive  
 212 Director, and may result in the adoption

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<sup>10</sup> E.g. BSE TSE validation tests, Feed Additives, Feed Materials, Food Contact Materials, Food Additives, Food Enzymes, Infant foods, Food supplements, Genetically Modified Organisms, Novel Foods, Nutrition and Health claims, Recycling Processes, Pesticides Active Substances or Maximum Residue Levels thereon,

213 of preventive measures by the  
214 Management Board.

**EFSA's actors declare all interests** overlapping with EFSA's remit in the previous five years and belonging to the following fields: financial investments, managerial roles, scientific advisory roles, employment or self-employment, consultancy, research funding, intellectual property rights, sworn statements, memberships in professional or learned societies, and interests not captured by the above.

215 EFSA employees, including the Executive  
216 Director, are subject to CoI checks prior  
217 to receiving a job offer under Article 11 of  
218 the Staff Regulations and to Annual  
219 Declaration of Interest (ADoI) and  
220 screening requirements. In addition, they  
221 are required to obtain preliminary  
222 clearance for all "outside activities"  
223 during their time at EFSA, and for all  
224 gainful activities in which they intend to  
225 engage for two years after their  
226 employment with EFSA ceases<sup>11</sup>.

227  
228 The following paragraphs outline the key  
229 features of EFSA's policy to prevent CoIs  
230 among the actors who contribute to its  
231 work. More detailed provisions and  
232 procedures will be set out in forthcoming  
233 implementing rules.

### 234 235 **3.1 Financial investments or** 236 **employment in regulated** 237 **companies – A red line** 238

239 EFSA considers financial investments with  
240 business actors directly or indirectly

241 impacted by EFSA's operations as a  
242 source of potential CoI irrespective of  
243 their magnitude.<sup>12</sup> The same holds true  
244 for current employment engagements.

**Financial investments** in, and **employment** with, business operators directly or indirectly impacted by EFSA's outputs are **incompatible with** Scientific Committee, Scientific Panels or Working Groups **membership**.

245 The Authority adopts a zero tolerance  
246 approach to these two interests, resulting  
247 in a total ban on financial investments in,  
248 or employment by, industries that EFSA  
249 helps to regulate. This exclusion applies  
250 to any professional wishing to become a  
251 member of EFSA's Scientific Committee,  
252 Scientific Panels, Working Groups or peer  
253 review meetings. Employment with  
254 regulated companies is "banned"  
255 irrespective of whether or not it concerns  
256 the mandate of the relevant EFSA  
257 scientific group.

### 258 259 **3.2 Cooling off periods: An effective** 260 **way of preventing conflicts of** 261 **interest** 262

263 EFSA values prior experience gained by  
264 professionals contributing to its work in  
265 the sectors it helps to regulate. However,  
266 EFSA considers that when certain types of  
267 professional involvement with the food  
268 industry become part of an expert's  
269 professional life, there is a perception of  
270 regulatory "capture" that has to be  
271 addressed. For this reason, and to avoid  
272 CoIs, the Authority enforces thorough  
273 cooling off periods on certain activities.

274  
275 This is why having worked as a self-  
276 employed professional or as an employee

<sup>11</sup> Articles 11 and 11a of 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 45, 14.6.1962, as last amended.

<sup>12</sup> With the exclusion of financial instruments on which the individual has no control.

277 for a legal entity pursuing private or  
278 commercial interests in EFSA's sphere is  
279 deemed incompatible with membership of  
280 the Scientific Committee, Scientific Panels  
281 and Working Groups for two years *after*  
282 the conflicting activity has ended.<sup>13</sup> This

EFSA enforces a **two years cooling off period on managerial, employment and consultancy activities undertaken by its experts with food industry.**

283 cooling off period applies to all  
284 managerial roles, employment and  
285 consultancies, even of an occasional  
286 nature, on matters falling under the  
287 mandate of the relevant EFSA scientific  
288 group. It does *not* apply to scientific  
289 advisory activities the individual provided  
290 in the past as member of a collegial body  
291 (e.g. scientific group, committee, task  
292 force or working group).

### 294 3.3 Cooperation with national and 295 international authorities, 296 universities or research 297 institutes

298  
299 Two of the main objectives of EFSA's  
300 Strategy 2020<sup>14</sup> are: cooperation with  
301 national or international academies,  
302 academic institutions, public authorities,  
303 research institutes and other bodies  
304 subject to public control or funding and  
305 pursuing public interest objectives; and  
306 the strengthening of the risk assessment  
307 community. Therefore, the Authority  
308 takes pride in recruiting to its Scientific  
309 Committee, Scientific Panels, Working  
310 Groups and peer review meetings<sup>15</sup>

311 professionals cooperating with, advising  
312 or employed by these partners, and is  
313 grateful for the possibility granted by  
314 their employers to cooperate with the EU  
315 food risk assessment project. This  
316 notwithstanding, EFSA will implement a  
317 thorough screening of activities unrelated  
318 to public interest duties.

319  
320 However, the independence of experts

With the exception of risk management functions, **expert's activities with national and international authorities, teaching or research are compatible** with all roles in EFSA's scientific groups.

321 representing the views of Member States  
322 or international organisations in EFSA's  
323 network or networking meetings<sup>16</sup> is to  
324 be ensured by each appointing authority  
325 in accordance with the applicable  
326 legislative and regulatory framework.  
327 Although the Authority relies on the  
328 ability of these bodies' legal systems to  
329 achieve impartiality of their respective  
330 representatives, EFSA will follow-up on  
331 serious and well documented cases  
332 brought to its attention.

### 334 3.4 Managing conflicting interest in 335 research funding. A balanced 336 approach

337  
338 Research is the fundamental activity of  
339 scientists. Therefore, EFSA encourages  
340 professionals contributing to its work to  
341 pursue projects with the global research  
342 community in order for them to be at the  
343 forefront of scientific developments and  
344 innovation. EU-wide policies and policy  
345 papers encourage private-public  
346 partnership and collaboration.<sup>17</sup> As a

<sup>13</sup> Irrespective of whether the legal entity is of a commercial nature or an association of activists pursuing a common interest or objective.

<sup>14</sup> See e.g. the first operational objective of the third strategic objective of the Strategy: *op.cit.*, p. 17.

<sup>15</sup> E.g. peer review meetings organised by EFSA in accordance with Regulation (EC) No 1107/2009.

<sup>16</sup> E.g. "EFSA focal points" in Member States.

<sup>17</sup> See e.g. Europe 2020 Strategy, COM(2010) 2020 and Communication from the Commission to the European

347 decentralised agency of the EU  
348 responsible for assessing food safety  
349 risks, EFSA acknowledges the importance  
350 of close cooperation between these two  
351 spheres.

352  
353 In line with the EU approach to research  
354 funding, EFSA considers that for actors  
355 contributing to its operations, the  
356 acceptable level of research directly  
357 funded by the private sector is 25% of  
358 the total budget of the expert's research  
359 team, for the sector of relevance. Private  
360 contributions to projects funded by public  
361 actors, such as those financed under EU  
362 Framework Programme 7<sup>18</sup> or Horizon  
363 2020, do not count for this purpose.

**Research funding from the private sector benefiting EFSA's experts should not exceed 25% of the total research budget.**

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366  
367  
368  
369  
370

#### 4. Transparency and communication on competing interests management

371 Communications and transparency are  
372 important elements in building and  
373 maintaining trust in EFSA's independence  
374 policy and any actions the Authority takes  
375 to enforce it.

376  
377 Since its establishment, EFSA has  
378 ensured a high level of transparency  
379 across all its activities. This is also the

380 case for independence-related processes.  
381 Indeed, the Authority publishes all ADols  
382 of the members of its Management Board  
383 and Advisory Forum, members of its  
384 Scientific Committee, Scientific Panels  
385 and their Working Groups, its Executive  
386 Director and members of its Operational  
387 Management Team.<sup>19</sup>

388  
389 Every year, EFSA reports on  
390 comprehensive information about  
391 independence-related activities in its  
392 Annual Report, including numbers of Dols  
393 screened, potential CoIs prevented, and  
394 breaches of trust procedures initiated.  
395  
396 Furthermore, with this policy, EFSA  
397 commits to make publicly available:

- 398
- 399 ■ Decisions on the cooperative  
400 approach outlined in section 3.3.;
- 401
- 402 ■ A register of activities undertaken  
403 by former members of its  
404 Management Board for two years  
405 after their term of office has  
406 ended.
- 407

408 Finally, EFSA will systematically create  
409 engagement opportunities for interested  
410 parties to explain how it manages  
411 experts' interests and to address specific  
412 concerns.

413  
414

#### 5. Policy implementation and enforcement

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416  
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418 Even the most ambitious policy  
419 commitment is hollow unless it is  
420 properly implemented, its compliance  
421 checked, mistakes acknowledged and  
422 addressed and breaches or omissions  
423 sanctioned.<sup>20</sup>  
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Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Public-private partnerships in Horizon 2020: a powerful tool to deliver on innovation and growth in Europe, COM/2013/0494 final.

<sup>18</sup> Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), OJ L 412, 30.12.2006, p. 1–43.

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<sup>19</sup> Do you want to know more about EFSA's experts' interests? Check online EFSA's database of declarations of interest at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

<sup>20</sup> If you are interested in facts and figures related to the implementation of this policy, have a look at EFSA's Annual Reports at <http://www.efsa.europa.eu/en/publications/corporate>.

425 Compliance with this policy and its  
426 implementing rules is a shared  
427 responsibility between the concerned  
428 actors, for the submission of a complete  
429 and truthful declaration, and EFSA, for  
430 the identification and prevention of  
431 potential CoIs and enforcing its decisions.  
432 Within the sphere of attributed powers  
433 delegated to EFSA by EU legislators, the  
434 Authority has put in place a system of  
435 compliance checks coupled with  
436 proportionate, effective and dissuasive  
437 sanctions for actions or omissions in  
438 breach of this policy and of its  
439 implementing procedures and rules.

The Authority enforces this policy with a system of compliance checks coupled with **proportionate, effective and dissuasive sanctions** for actions or omissions ranging from a **reprimand letter to dismissal** from the relevant body or scientific group or **follow up with law enforcement bodies**.

440 These range from a reprimand letter  
441 issued by the Authority to the dismissal  
442 from the relevant body or scientific group  
443 by the Board.  
444 In the most serious cases, where the  
445 active conduct of the concerned  
446 individual(s) assumes the contours of  
447 wilful criminal action, EFSA will cooperate  
448 with EU or national competent authorities  
449 to ensure the most appropriate  
450 enforcement and follow up.

451  
452

## 453 6. Entry into force and review 454

455 This policy comes into effect as of the  
456 adoption of the implementing decision  
457 and procedure on competing interest  
458 management. As of then, it shall repeal  
459 and replace the Policy on Independence  
460 and Scientific Decision-Making Processes

461 of the European Food Safety Authority of  
462 15 December 2011.  
463 This policy shall be subject to an *ex post*  
464 evaluation five years after its entry into  
465 force.