

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 manner¹ so as to ensure the achievement of its objectives in line with good administration principles². 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.³ 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 Regulation⁴ and other secondary legislation⁵ 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 EFSA⁶ at the time this policy was adopted confirms EFSA's

¹ Article 298 of the Treaty on the Functioning of the European Union.

² Article 41 of the Charter on Fundamental Rights of the European Union.

³ 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.

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

⁵ 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.

⁶ 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”⁷.

50
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.⁸

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 (Col)
70 harmful to the Authority’s work.

71 This policy also outlines how EFSA
72 prevents the occurrence of Col.

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 Col 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 Cols, 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 Col. 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 Col is of particular significance in order
99 not to harm legitimate professional
100 activities contributing to EFSA’s mission.

101
102 A Col is deemed to exist whenever the
103 Authority identifies: any situation where
104 an individual has an interest that may
105 compromise or be reasonably perceived
106 as compromising his or her capacity to
107 act independently and in the public
108 interest in relation to the subject of the
109 work performed at EFSA.⁹

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

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

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

⁷ Op. cit., supra, at 14.

⁸ 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>.

⁹ 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.¹⁰

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

¹⁰ 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 ceases¹¹.

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.¹² 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

¹¹ 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.

¹² 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.¹³ 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 2020¹⁴ 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 meetings¹⁵

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

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

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

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 meetings¹⁶ 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.¹⁷ As a

¹⁶ E.g. "EFSA focal points" in Member States.

¹⁷ 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 7¹⁸ 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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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.¹⁹

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
417
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.²⁰
424

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.

¹⁸ 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.

¹⁹ 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>.

²⁰ 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.

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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.