

Statement on Independence

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Science is „interest-driven“

Specific interests will affect:

- which research questions are asked
- choice of study design
- interpretation of the results
- discussion on practical consequences of study outcome

Criteria for scientific independence

(defined by Prof. Dr. Armin Grundwald)

- **without any prejudice**
= complete openness for all outcomes/results
- **freedom from bias**
= perfectly objective method is used to gather results
- **autonomy**
= absence of an external authority that issues directives

Grundwald A. Scientific independence as a constitutive part of parliamentary technology assessment. *Science and Public Policy* 2006 33(2):103–113

Is it possible to guarantee 100% scientific independence ??

Risk assessment and conflicts of interests

- interests of manufacturers
- interests of competitors
- other financial interests
- interests of „dramatic presentation“
- interests of researchers (becoming well-known)
- interests of various scientific professions
- personal and career interests

Scientific risk assessments of public authorities –

Potential conflict of interests of experts from:

Industry

- financial interests
- confirming own hypothesis

Universities

- external funding
- confirming own hypothesis

Public Authorities

- directives from superiour authorities
(does not apply to BfR, DTU, ANSES & other agencies)
- confirming own hypothesis

Conclusion:

Public authorities are best suited to conduct objective risk assessment

Good scientific practice - in the area of risk assessment - should foster:

- independent discussion
- standardisation and harmonisation

Science and authorised research for political consultations must therefore be completely free of all biased interests

EFSA public consultation:

Policy of Independence and scientific decision making process of EFSA

207 9. Organisational culture

208 EFSA has gradually created, and continuously fosters, an organisational culture that does not tolerate conflicts of
209 interest. This is ensured in a number of ways, ranging from the implementation of the staff regulations, to the
210 systematic organisation of training courses on ethics and integrity for staff members and scientific experts, the
211 implementation of a sophisticated and stringent screening system of interests declared by key people, the publication
212 of all relevant documents regarding that system, the development of workflows, standard operating procedures and
213 the provision of systematic legal advice to ensure a coherent interpretation of the comprehensive system put in
214 place²⁰.

215 In order to implement the more general provision stipulated under Article 22(7) of EFSA's Founding Regulation,
216 Article 37 of that Regulation requires that members of the Management Board, Advisory Forum, Scientific Committee
217 and Panels, external experts taking part in the Working Groups of the Scientific Committee and Scientific Panels and
218 the Executive Director shall undertake to act independently. Article 37 of that Regulation imposes on them the
219 obligation to make a declaration of commitment and an annual declaration of interests "*indicating either the absence
220 of any interests which might be considered prejudicial to their independence or any direct or indirect interests which
221 might be considered prejudicial to their independence*".

222 EFSA's Management Board adopted a *Policy on Declarations of Interests (DOIs)*²¹ in 2007 which laid down specific
223 provisions for preventing conflicts of interest. To implement the policy, a set of comprehensive rules and procedures
224 were drawn up²², supported by a detailed *Guidance Document on Declarations of Interest*²³.

225 The Authority has made and continues to make significant investments in tools to facilitate the implementation,
226 monitoring and enforcement of the DoI screening system²⁴. The effective implementation of DoI procedures has been
227 validated by a number of both independent and internal reviews performed from 2008 to 2011 by contractors and
228 auditors.

EFSA public consultation:

Policy of Independence and scientific decision making process of EFSA

Footnote 22: „Implementing act to the policy on declaration of interests - Procedure for identifying and handling potential conflicts of interest“

III. Assessment of the potential conflicts of interest and decision on the nature of the participation

1. Some declared interests could clearly be such that they cannot be expected to
:

6. Conflicts of interest may be of a different nature. They may be of a financial nature when individuals have a financial stake because of their employment, investment in a company or intellectual property rights whose value may be influenced in either a negative or positive sense by an opinion or the assessment of the safety or a claim of an ingredient or a product. However, conflicts can also be of a scientific nature when the individual has been involved in research relating to the subject that is being scrutinised. Similarly earlier involvement in an opinion of a national authority that will be assessed by the Scientific Committee or Panel may cause a conflict of interest for the concerned person. Religion or

... in BfR view this is in opposition to:

- EFSA Founding regulation (EC) No 178/2002, preamble (51)

(51) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.

- EFSA Founding regulation (EC) No 178/2002, Art. 22(7)

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

BfR suggestions

- Recusing experts of national risk assessment bodies may impede mutual assistance in the field of food safety
- Aim towards mutual recognition of risk assessments conducted in MS
 - to reduce double work
 - efficient use of resources
- Differentiate between good and bad science

Vision

Conducting the best science based risk assessments to protect consumers in Europe

→ close cooperation between national and European risk assessment authorities needed - as postulated in EFSA's Founding Regulation

- Gathering knowledge and best practices in risk assessment
- Using harmonised methods and standardised procedures
- Considering the possibility to apply the approach of pesticide assessment to other fields of risk assessment → increasing the robustness and quality of the scientific assessment by an independent review process

Thank you for your attention

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