European Food Safety Authority

Management Board
17 March 2011
Parma

Subject :	Benchmarking of EFSA's Independence	
Document number:	mb 17 03 11 - item 8 doc 6b	
Submitted by :	Office of the Executive Director and the Management Board	
Document for :	X	Information
		Discussion
		Possible adoption

European Food Safety Authority

COVER NOTE

Précis of an Independent Consultant Report on Benchmarking of EFSA's Independence

1. As part of the continuous review of its systems and procedures aimed at ensuring the independence of scientific advice EFSA engaged an external consultants to compare EFSA's policies, structures and practices relating to independence by undertaking a comparative study with 10 other organisations responsible for delivering scientific advice. The study focuses on governance, policies for the development of scientific advice, transparency, the appointment of external scientific experts, declaration of interests and the management of potential conflicts of interest. The consultants gleaned information from the websites of the organisations concerned, interviewed staff from the organisations to check on accuracy and completeness.

2. From assessing EFSA against the other organisations, the report finds in summary that EFSA with its; unique governance structure, wide definition of conflicts of interests, procedures for declaration of interests, systems for managing conflicts, emphasis on transparency and the involvement of stakeholders, seems to have one of the most advanced and robust systems in place towards ensuring independence of scientific expertise and advice.

Nonetheless, among the other organisations reviewed, a few best practices were identified for EFSA to consider which are précised below :

3. ***More comprehensive definition of conflict of interest.*** Eg adding to its definition anything that could call into question the expert's or committee's independence.

4. ***Positive obligation to inform of any matter that could undermine independence.*** - a broad-ranging obligation to volunteer any information which should be considered to give rise to a potential conflict of interest.

5. ***Differentiated categories of acceptable risk of conflict of interest.*** The EMA has an established system of differentiated conflict of interest disclosure rules according to an expert's level of responsibility within the committee or organisation. EFSA has a similar system but may wish to consider if there are further lessons to be learned from EMA's experience in this regard.

6. ***Special dedicated committees to advise on issues related to conflicts of interest.*** Eg to provide support when confronted with ethical issues or conflicts of interest. EFSA may wish to formalize an internal group composed both by legal and senior scientific staff tasked to evaluate the potential and real interests of experts. Moreover, an ad-hoc group of external "wise men" who have experience in assessing the borderline of conflicts of interest so that there is an authoritative committee for the management of critical conflicts of interest.

7. ***Focus on scientific work carried out by own staff members.*** EFSA may wish to consider expanding the existing requirements for staff Annual Declarations of Interest, and re-examining the comprehensiveness of the existing code of administrative practice for EFSA staff including whether these are sufficient in relation to ethical issues. [1]

[1] EMA guidance on Confidentiality and Discretion (2005) – Annex 2 of the in EMA Code of Conduct available at

8. ***More input from the public on potential conflicts of interest.*** Have a publicly available register to track the interests of committee members, enable the public to easily look up the declared interests of all committee members or posting the members of a committee on-line and inviting the public to comment before the first meeting takes place.

9. ***Consequences if a conflict of interest is found.*** EFSA is one of the few organisations with a policy laying out the potential consequences if a conflict of interest comes to light. Where a conflict of interest exists but EFSA allows the expert to present their knowledge in a hearing, in order for the committee to benefit from his or her expertise EFSA could be clearer about the role of such experts and the limits of their involvement.

10. In addition to these best practices, two other elements – shortening of the retrospective period and more opportunities for stakeholder participation – were considered useful to bring to EFSA's attention.

11. ***Shortening of the retrospective period.*** One issue which came up during the interviews was whether EFSA's system of declaration of interests may be too demanding in particular the fact that EFSA requires a 5-year period retrospectively for declaring an expert's interests as this could be overly limiting in terms of reducing the pool of experts. It was noted that EMA places less weight on interests which occurred in the distant past compared to those which are more up to date.

12. ***Increased opportunities for stakeholder involvement.*** Several of the organisations studied, including UK-FSA, EMA and the Codex Alimentarius, have provided for increased involvement of stakeholders and other interested parties, such as advocate organizations, in certain processes such as the possibility to participate in meetings as observers or to provide comments to draft reports. This has been criticised by some as having the unwanted effect of making it difficult for members of scientific committees to air any differences of opinion openly and therefore serve to limit scientific debate. However, it also increases the transparency of decision-making, and can lead to greater visibility with stakeholders.

---

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf.
ECHA Code of good administrative behaviour for the staff of the European Chemicals Agency in their relation with the public. http://echa.europa.eu/doc/ECHADocuments/Code_of_Good_Administrative_Behaviour.pdf

Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organisations similar to EFSA

Revised Final Report

January 2011

milieu
ENVIRONMENTAL LAW & POLICY

This Dossier has been prepared by Milieu Ltd for the European Food Safety Authority under Service Contract number CT/EFSA/Strategy/2010/04. The authors were Carole Biot-Stuart, Katalin Csaszar, Gretta Goldenman, and Tony Zamparutti.

Milieu Ltd. (Belgium), rue Blanche 15, B-1050 Brussels, tel: +32 2 506 1000; fax: +32 2 514 3603; g.goldenman@milieu.be; katalin.csaszar@milieu.be; web address: www.milieu.be

Contents

List of abbreviations used

ACMFS	Advisory Committee on the Microbiological Safety of Food
ACNFP	Advisory Committee on Novel Foods and Processes
ANSES	Agency for Food, Environmental and Occupational Health Safety (France)
BfR	Federal Institute for Risk Assessment (Germany)
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection
CODEX	Codex Alimentarius Commission
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CLP	Classification, labelling and packaging
COMP	Committee for Orphan Medicinal Products
CVMP	Committee for Medicinal Products for Veterinary Use
DIAG	Declaration of Interest Assessment Group
DG SANCO	Directorate General for Health and Consumers
DoI	Declaration of Interests
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EC	European Community
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration (US)
FSA	Food Standards Agency (UK)
HPFB	Health Product and Food Branch (Canada)
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
NAS	National Academy of Science (US)
NGO	Non Governmental Organisation
NRC	National Research Council
PCWD	Patients and Consumers Working Party
PDCO	Paediatric Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety
SEAC	Spongiform Encephalopathy Advisory Committee
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
US	United States of America
UK	United Kingdom
WHA	World Health Assembly
WHO	World Health Organisation

1. Introduction

This comparative study was commissioned by the European Food Safety Authority (EFSA) as part of the continuous review of its systems and procedures aimed at ensuring the independence of scientific advice. It compares EFSA to other peer organisations, focusing in particular on policies for the appointment of external scientific experts, for declaration of interests and for the management of potential conflicts of interest. It is intended to assist EFSA in identifying options to improve and strengthen its overall systems in these areas.

The European Food Safety Authority was established in 2002 in the aftermath of the BSE and dioxin crises. Consumer confidence in the safety of food on the EU market had plummeted. Moreover, the EU institutions with competence in this area had been severely criticized for their handling of the BSE crisis. There was a widespread perception that certain food-related risk management decisions had been politically rather than science driven and therefore to improve confidence in the food safety system it was essential to set up a structure that could operate with the highest possible level of scientific expertise, free from any interference from governments or vested interests.

In order to rebuild consumer confidence, it was proposed to establish the EFSA as an independent agency charged with providing objective scientific advice on issues related to food and feed safety. Several elements were considered important in order to ensure the objectivity, independence and excellence of EFSA's scientific opinions:

- separation of risk assessment from the more political activity of risk management
- governance structures that would ensure independence from political and industrial or other interests
- procedures for selecting external experts and for identifying and addressing conflicts of interest
- dialogue and transparency with stakeholders on food safety and health issues

Accordingly, EFSA has established a number of systems and procedures aimed at avoiding conflicts of interest and maintaining a credible and open relationship with stakeholders. But it can be difficult to achieve and maintain the appropriate balance of independence, excellence and transparency.

The aim of this study is to provide EFSA with information about the systems, structures and procedures aimed at ensuring objective scientific advice in organisations similar to EFSA, so that it can reflect on whether any additional practices may warrant consideration. To this end, a number of national (both EU and non-EU), European and international level organisations were identified as appropriate for review.

List of selected organisations with scientific advisory functions

- European & international level bodies:
  - European Chemicals Agency (ECHA)
  - European Medicines Agency (EMA)
  - DG SANCO (European Commission)
  - Codex Alimentarius Commission (CAC) & the joint FAO/WHO committees
- National level bodies:
  - France: Agency for Food, Environmental & Occupational Health Safety (ANSES)
  - Germany: Federal Institute for Risk Assessment (BfR)
  - United Kingdom: Food Standards Agency (UK FSA)
  - Canada: Health Products and Food Branch (HPFB)
  - USA: Food and Drug Administration (US FDA)
  - USA: National Academy of Science (NAS)

The criteria used for selecting these organisations were as follows:

- Whether they had mandates to provide scientific advice to support risk management decisions;
- Whether they drew on external experts to assist with the development of scientific opinions; and
- Whether they operated with robust systems for ensuring independence of scientific opinions.

Information was gathered for each organisation selected for review on the basis of publicly available resources (e.g. internet, journals), including descriptions of the organisation's policies and procedures relevant to the purposes of the study. Structured interviews were then carried out with staff of each organisation, in order to capture more detailed information. Where possible, interviews were carried out with more than one official from the selected organisations, to enable a more comprehensive understanding of the policies and systems in place.

The comparative study begins with an overview of EFSA and the systems it has set in place in order to ensure objectivity of scientific advice. It then provides brief overviews of the other organisations selected for review. The third, fourth and fifth sections provide a comparative analysis organised according to several topics, including governance structures and mandates, systems for ensuring independence of scientific advisory options, and transparency. The study concludes with identification of some best practices in place in other organisations as well as suggestions for EFSA to consider in its overall effort to ensure the independence of its scientific advice.

2. EFSA and its systems for ensuring objectivity of scientific advice

Mandate: The European Food Safety Authority (EFSA) was set up in January 2002 via Regulation (EC) No 178/2002.[1] Its mandate is to act as an objective point of scientific reference on food safety and to maintain the internal market by bolstering confidence in the EU food supply. EFSA provides scientific advice and technical support for EU legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It focuses on risk assessment and risk communication; the regulation and control of any risks identified remains with the European Commission, institutions and the Member States. The European Commission as well as national authorities in Member States and the European Parliament can request its scientific judgement. EFSA can also issue scientific opinions on its own initiative.

Governance: The effort to set up EFSA as an independent agency includes the arrangements for its governance structure. The main governing body of EFSA is its Management Board, which is responsible for guiding EFSA's activities and ensuring that its mission and tasks are carried out. It adopts EFSA's annual reports, its work programme and budget, internal rules and procedures and appoints the Executive Director and members of the scientific committee and panels. Whereas the boards of other EU agencies are composed of representatives of all Member States, EFSA's Management Board members are appointed on the basis of their experience and expertise and not their nationality. Fourteen members are appointed by the EU Council, in consultation with the European Parliament, from a list provided by the European Commission. They are to provide a blend of expertise, with four members having backgrounds "representing consumers and other interests in the food chain". There is a representative from the European Commission. EFSA is fully funded by the EU budget

The link between EFSA and the Member States is provided by its Advisory Forum which provides the basis for joint work initiatives, planning, exchanges on best practices, etc. by advising the Executive Director of EFSA on priorities and areas of concern. The Advisory Forum and thus the Member States have no voting rights, neither does it discuss or advise on specific scientific opinions.

Scientific bodies & selection of experts: The Scientific Committee, Panels and their working groups are the main scientific bodies of EFSA. The Scientific Panels are composed of external experts, who are selected through an open call for expression of interest and an open and transparent selection procedure which involves an evaluation of candidates by an internal EFSA team with the process being ultimately reviewed by external evaluators. The experts are appointed by the Management Board based on proposals from the Executive Director. Though the list of selected scientists is shared with the Member States, neither they nor the European Commission and other EU level risk managers have a role in the selection.

The Scientific Committee is composed of the chairs of the Scientific Panels together with six independent scientific experts. It provides overall guidance (e.g. on transparency) and also functions as a general coordination body. For example, the Scientific Committee provides advice when a question falls within the scope of more than one panel. It can also create a working group if an issue arises for which no panel is responsible.

[1] OJ L 31/1, 1.2.2002.

- Scientific Committee
- Scientific Panels
  - Animal health and welfare (AHAW)
  - Food additives and nutrient sources added to food (ANS)
  - Biological hazards (BIOHAZ)
  - Food contact materials, enzymes, flavourings and processing aids (CEF)
  - Contaminants in the food chain (CONTAM)
  - Additives and products or substances used in animal feed (FEEDAP)
  - Genetically modified organisms (GMO)
  - Dietetic products, nutrition and allergies (NDA)
  - Plant protection products and their residues (PPR)
  - Plant health (PLH)

Working groups, which can be set up by the scientific committee or panels, carry out preparatory work only and are not responsible for the adoption of opinions. They are composed of independent external experts, with membership from the associated Panel(s) plus additional experts identified by consulting EFSA's expert database. Scientists with relevant expertise can apply to be admitted to the database. For issues for which specific expertise is needed, EFSA may also call upon so-called "hearing experts" -- scientists or officials having relevant knowledge who are invited to EFSA meetings to give a presentation or providing data, often on a single occasion, with the limited role to answer specific questions and without participating in deliberations, voting, and drafting outputs Hearing experts may indeed have conflicts of interests regarding the particular topics they are called to present, but their input is delivered within this context and considered in this light and careful consideration is given to their Declaration of Interest. [2]

Through EFSA's Scientific cooperation activities with the Member States EFSA also establishes scientific networks on specific issues which support EFSA through the coordination of activities, the exchange of information, the development and implementation of joint projects and the exchange of expertise and best practices.

The scientific advice provided by the scientific bodies of EFSA can be in the form of a scientific opinion, report or statement as well as elaborated scientific approaches and guidance documents.

Procedures to ensure independence: In order to safeguard the independence of the development and conclusions of EFSA's scientific processes EFSA has developed a policy on declarations of interest and applies a set of internal mechanisms and working processes. Members of the Scientific Committee, Scientific Panels and working groups sign declarations of commitment and of confidentiality. More importantly they are also required – at three different points -- to declare any interests. Applicants for a committee or panel place have to fill out an initial declaration of interests which is assessed by EFSA staff during the selection process. Thereafter, members of panels and working groups are required to make annual declarations of interests. Finally, experts involved in panel or working group meetings linked to a specific subject matter are required to make any relevant specific declarations of interest. Members of EFSA's scientific networks also have to complete Annual and Specific Declarations of interest.

Declarations of interest are assessed by the head of the EFSA department supporting the particular panel or working group to assess whether the declared interest presents a possible conflict of interest. Where potential conflicts of interest are found, the participation of the expert in meetings and decisions will depend on e.g. the nature of the input required, the individual's role in the phase of the assessment, and the type of matter to be addressed. EFSA has in place a graduated system of risks whereby different types of declared interests are

[2] "Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and External Experts to assist EFSA with its scientific work". At: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

assessed and classified into categories depending on whether the declared interest warrants a conflict and the nature of that conflict, which dictates the experts' on-going involvement in scientific discussions. For example, Chairs and Vice Chairs must have the least potential for conflicts of interests and are also instructed to refrain from activities during their tenure which may call into question their independence.

If the conflict of interest is considered serious, the expert may be excluded from certain or all activities concerned. Where a declaration is made in relation to a specific meeting point, the decision taken on the declaration is recorded in the meeting minutes.

A waiver may be granted if the involvement of the person concerned is considered essential for the particular activity and no suitable alternative expert can be found and in this case the decision on that experts participation will be taken by the Directors of Risk Assessment and Scientific Cooperation and the Executive Director informed. Overall for all types of declared interests the operational assessment of the interests is internal to EFSA.

EFSA has also elaborated rules for those cases when a non-declared conflict of interest comes to light at a later point. Failure to fulfil the obligations outlined in the EFSA procedures concerning Declarations of Interest are considered as a *prima facie* breach of trust towards EFSA and are investigated as such. A procedure may be opened to investigate the facts which could ultimately lead to the expert being dismissed from further involvement in EFSA's work following a recommendation from the Executive Director to the Management Board

Additionally, the final outcomes of the discussions of the Panels or Committee are taken by all their members which means in most cases that 21 scientists are involved in adopting these outcomes. In this way the views of the others can dilute the influence of any one member.

If necessary, scientific opinions may be adopted by voting. The EFSA Regulation provides for inclusion of minority opinions in its scientific opinions, though in practice the committees and working groups tend to aim for consensus decisions and the option is seldom used. Experts serving on a scientific panel or working group receive some compensation in the form of a moderate daily fee and their expenses are covered.

In addition, neither the Member States nor the risk managers at EU level have the right to influence the scientific opinions of EFSA although a representative of the European Commission can attend the Scientific Committee and panel meetings. They may assist for the purposes of clarification or information, if called to do so; they must not however seek to influence discussions.[3]

Transparency: In line with its core principles and commitment to transparency and openness, EFSA publishes its processes, outcomes of the expert selection procedures and their declarations of interests. The agendas, minutes of meetings, reports and scientific opinions of the Scientific Committee and the Scientific Panels are also published on-line, as well as the reports from expert working groups and draft opinions or reports where open consultation has been specifically agreed.

Moreover, in line with its risk communication mandate, EFSA pro-actively disseminates the results of its risk assessment activities, with information tailored to meet the needs of its different partners, stakeholders and audiences, and using various media and communication tools.

[3] Article 28§8.

3. Summary descriptions of the other organisations reviewed

3.1 European Chemicals Agency (ECHA)

Mandate: The European Chemicals Agency was established in 2006 by Regulation (EC) 1907/2006.[4] ECHA is responsible for managing and coordinating REACH and CLP-related regulatory activities and for ensuring the implementation of REACH at EU level. It is charged with providing the Member States and the EU institutions with the best possible scientific and technical advice on questions relating to chemicals which fall within its mandate and which are referred to it in accordance with the REACH Regulation. Final decisions (legally binding on third parties) are taken by the European Commission, in accordance with comitology procedures.

Governance: ECHA is governed by a Management Board composed of one representative from each Member State and a maximum of six representatives appointed by the European Commission, including three individuals from interested parties without voting rights and an additional two independent persons appointed by the European Parliament. The Management Board adopts ECHA's annual report for the previous year, its work programme and budget for each coming year, and its internal rules and procedures. It also appoints the members of ECHA's committees and exercises authority over the Executive Director. The Executive Director is responsible for the daily administration of ECHA and for managing the resources necessary for carrying out its tasks. ECHA's budget is provided by the EU budget, fees from industry and Member State contributions.

The Forum for Exchange of Information and Enforcement coordinates a network of Member State authorities responsible for REACH enforcement. ECHA's Secretariat provides technical, scientific and administrative support for the Committees and the Forum. The staff of the Secretariat are subject to ECHA's internal Rules of Good Administrative Practice which require them to be 'with impartiality and independence from external influence'.[5] In addition, the Secretariat supports the work required of ECHA under the REACH Regulation, and a Board of Appeal decides on appeals against decisions taken by ECHA.

Scientific bodies & selection of experts: ECHA also includes a Committee for Risk Assessment (CRA) a Committee for Socio-economic Analysis (CSEA) and a Member State Committee (MSC). The CRA prepares opinions on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling, and any other questions relating to risks to human health or the environment related to REACH. The CSEA prepares opinions on applications for authorisation, proposals for restrictions, and any other questions concerning the socio-economic impact of possible regulatory action on substances. The MSC is tasked with resolving differences of opinion on draft decisions proposed by ECHA or Member States concerning evaluations of substances.

- Committee for Risk Assessment (CRA)
- Committee for Socio-economic Analysis (CSEA)
- Member State Committee (MSC)

The Committee for Risk Assessment, the Committee for Socio-economic Analysis and the Member States Committee may establish working groups to carry out certain delegated tasks.

[4] OJ L 396, 30.12.2006.

[5] As laid down in the Code of Good Administrative Behavior for the staff of the ECHA in their relation with the public: http://www.echa.europa.eu/doc/ECHADocuments/Code_of_Good_Administrative_Behaviour.pdf, page 4.

Each Member State may nominate candidates for the CRA and CSEA[6] the list of nominees is then prepared by the Executive Director and published on ECHA's website. Before appointment by the Management Board, the Secretariat verifies in particular the affiliation of the nominees and seeks clarification if need be. The Management Board appoints committee members from the list, including at least one but not more than two members for each Member State that has nominated candidates. To ensure a broad range of expertise, each Committee may co-opt an additional five members chosen for their specific competence. Management Board members may not be committee members. The MSC is composed of one member appointed by each Member State and up to five co-opted members chosen on the basis of their specific competence.

Once an expert is selected for a committee or working group, ECHA enters into a written contract with the expert. The expert concerned (or his employer) is remunerated by ECHA in accordance with a scale of fees established by the Management Board.

When a Committee is preparing an opinion, it appoints one of its members as a rapporteur (a co-rapporteur may also be appointed). Committee chairs are employees of the Agency assigned by the Executive Director.

Procedures to ensure independence: The REACH Regulation requires members of the Management Board, the Executive Director, and members of the Committees and the Forum to make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered prejudicial to their independence. These declarations are made in writing annually. These declarations are registered and publicly available on the Agency's website. There is a strong requirement for these to be done. If an appointed member of the Committee for Socioeconomic Analysis or the Committee for Risk Assessment does not sign the declarations of commitment, interests and confidentiality within three months after the decision of the appointing body, the appointment is revoked.

Each Committee is to use its best endeavours to reach a consensus. Member States are required to refrain from giving committee members or their advisers any instructions which may be incompatible with ECHA's tasks, responsibilities, and independence. As with EFSA, if consensus cannot be reached, the opinion is to consist of the majority position, including the grounds for that position; minority position(s), including their grounds and this information is also to be published.

In addition, before each meeting, members are obliged to declare (oral declaration) any interests that could be considered prejudicial with respect to any points on the agenda; in such cases, the member may not vote on that agenda item. These declarations are included in the meeting minutes.

Rapporteurs are requested to declare any interests which might prejudice their independence in writing. Any direct or indirect interests, both current and past (back to five years) with a financial, professional and personal nature (including household members' interests) are required to be declared in the Annual Declaration of Interests form. Annual declarations are assessed by the secretariat, whereas specific declarations of interests are handled by the chair. In case of conflicting interests, the secretariat may ask the member for further clarification. Depending on the decision of the chair, the member may be able to participate in the voting on the relevant agenda item.

Transparency: ECHA ensures that regulatory, scientific and technical information as well as appointments are made available publicly. ECHA provides for increased involvement of its applicants and industry stakeholders and other interested parties, such as case-owners and representatives of third countries and international organisations, in certain processes such as the possibility to participate in meetings as observers. Stakeholders (e.g. industry representatives) invited to meetings have no voting rights.

In principle, Members, their advisers, invited experts and observers of the Committee and its working groups shall not disclose any information acquired as a result of their work. They are required to make a written declaration of confidentiality.

[6] The Management Board has established guiding principles concerning independency which Member States are to take into account when nominating candidates.

3.2 European Medicines Agency (EMA)

Mandate: The European Medicines Agency was established by Regulation (EC) 2309/93, which was subsequently repealed and replaced by Regulation (EC) 726/2004.[7] EMA is charged with responsibility for coordinating the evaluation, supervision and pharmacovigilance of medicinal products, using the existing scientific resources put at its disposal by the Member States. Its remit is to provide the Member States and the EU institutions with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy in accordance with EU legislation on medicinal products.

In particular, EMA is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines. Under this centralised procedure, companies submit a single marketing authorisation application to EMA. Once granted, a centralised marketing authorisation is valid in all EU and EFTA states. Decisions to authorise particular medicinal products must be in compliance with legally binding substantive decision criteria; the authorisations are then adopted on a proposal from the Commission by the Member States through comitology.

EMA also gives scientific advice and other assistance to companies for the development of new medicines. The process of evaluating and approving applications for a product authorisation integrates risk/benefit assessment as well as different types of judgements concerning such aspects as labelling and distribution. EMA is thus involved in risk assessment but also reaches into areas which could be considered to be risk management.

Governance: EMA is comprised of a Management Board, an Executive Director, a Secretariat, and six scientific committees. The Management Board is responsible *inter alia* for approving the annual work programme, adopting procedures for the performance of scientific services, appointing the Executive Director and adopting the budget. The Board is composed of 35 members: a representative appointed by each of the Member States, two representatives appointed by the Commission, two representatives appointed by the European Parliament, two from patients' organisations, one from doctors' organisations and one from veterinarians' organisations. The four 'civil society' representatives are appointed by the Council after consulting the European Parliament, on the basis of a list drawn up by the Commission.[8] Members are appointed on the basis of their relevant expertise. Unlike EFSA but more in line with ECHA, the EMA Board has a strong representation of the Member States and the European institutions.

The Executive Director is responsible for the staff and the day-to-day management of the Agency, including the management of the Agency's financial resources. The Agency is financed by the EU budget as well as by fees paid by the private sector for market access evaluations as well as other services.

Scientific bodies & selection of experts: EMA operates through six scientific bodies; the composition of these varies considerable from those of EFSA with the Member States taking a strong part in the overall appointment of members. Members of the scientific committees are in fact appointed by the Member States. Each Member State, after consultation with the Management Board, appoints one member and one alternate to the Committee for Medicinal Products for Human Use as well as a member and alternate to the Committee for Medicinal Products for Veterinary Use. These members and alternates are chosen for their role and experience in evaluating medicinal products. They in fact represent the competent national authorities. The CHMP and the CVMP may co-opt an additional five members on the basis of their specific scientific competence. In addition, the CHMP and the CVMP may also establish scientific advisory groups in connection with the evaluation of specific types of medicinal products.

[7] OJ L 136, 30.4.2004.

[8] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000098.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c2f.

- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee on Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Committee for Advanced Therapies (CAT)
- Paediatric Committee (PDCO)

In addition to members nominated by Member States, members of the Committee on Orphan Medicinal Products (COMP) the Paediatric Committee (PDCO) and the Committee on Advanced Therapies (CAT) are also composed of members who represent 'civil society' organisations, such as patients' organisations, clinicians, or healthcare professionals.

Early in the selection of nominated experts and prior to any formal nomination by the Competent Authority, conflicts of interest are considered through an obligatory screening by the Agency of the declared conflicts of interests of Scientific Committee members. The Agency will provide feedback to the Nominating Authority on the outcome of the pre-screening for subsequent consideration by the Nominating Authority when launching the formal nomination process. Likewise, the possibility of pre-screening of any expert prior to involvement in the Agency's activities is offered to the Nominating Authority.

Each of the committees may establish standing and temporary working parties, including standing working parties with the sole remit of providing scientific advice to undertakings, particularly regarding the development of new therapies.

Experts with proven experience in the evaluation of medicinal products who would be available to serve on working parties or scientific advisory groups of the CHMP, the CVMP or the HMPC are identified by Member States and placed on a list that is kept up to date by the EMA; the EMA can also identify accredited experts for this list. Once an expert is selected for a committee or working group, EMA enters into a written contract with the Rapporteurs (and Co-Rapporteurs of the Committee) and the experts[9]. The expert concerned (or his employer) is remunerated in accordance with a scale of fees established by the Management Board.

The committees adopt scientific opinions by consensus wherever possible. In case a consensus cannot be reached, minority opinions with their supportive arguments are included in the scientific opinions.

Procedures to ensure independence: EMA's procedures for ensuring the independence and impartiality of its committees include four sets of declarations of interests: (1) upon nomination all European experts need to be registered in the EMEA's database (initial declaration of interests), (2) potential conflict of interests should be declared before each meeting (specific declaration of interests), (3) conflict of interests which appear during the meetings shall also be declared (spontaneous declaration of interests), (4) financial and other interests, including relations with pharmaceutical companies, shall be indicated in the annual declaration of interests.

In October 2010 EMA's Management Board adopted a new, more robust policy on declaration of interests which will be applied as of 2011. The policy aims to ensure that decisions are solely guided by public and animal health considerations. Under this new policy, external experts (expert witness)[10] may be invited to meetings of scientific committees in order to share opinions. Through this process EMA seeks to find the

[9] Procedural Advice on CHMP/CAT rapporteur/co-rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) 726/2004. At, http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004163.pdf, page 4.

[10] An expert witness is considered an expert whose role is limited to specialist advice on a specific issue by providing information and replying to questions. This is similar to EFSA's policy on "hearing experts" who have the same role of EMA witness experts. http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

right balance between the core principles of independence and the highest possible level of scientific expertise.

According to EMA's policy, independence of a panel member and his or her ability to perform specific tasks can be given different risk levels. Their policy aims at ensuring the highest possible independence of their scientific evaluation processes. In this respect, EMA has defined different risk levels depending on any direct or indirect involvement or association an expert may have with the pharmaceutical industry. The different risk levels are used to determine the level of involvement an expert may have in working on a scientific evaluation.

Conflicts of interests are classified into 3 categories, i.e. direct versus indirect versus no interests declared. Direct interests are assigned the highest risk level (level 3), indirect interests an intermediate risk level (level 2), and in case no interests are declared a risk level 1 is assigned.

A two-step procedure applies to assessing the input of an expert to a scientific opinion. Following a review by the Agency's Secretariat of the declaration of interest form, a risk level is assigned according to the above classification. The subsequent level of participation in the Agency's activities is determined taking into account the assigned risk level and the restrictions which apply to participation in the various activities of the Agency.

In defining whether an interest is direct or indirect, weight is given to the potential impact on the individual's behaviour, and may also reach to the expert's household members. Direct interests in the pharmaceutical industry include: (1) employment with the company, (2) consultancy for a company, (3) strategic advisory role for a company, (4) financial interests, (5) ownership of a patent. Indirect interests in the pharmaceutical industry are: (1) principal investigator, (2) investigator, (3) individual's institution receives a grant or other funding. All current and past (back to 5 years) financial, personal and institutional interests must be declared. EMA also has a policy on gifts and invitations.

Declared interests are assessed by EMA staff. EMA has established a virtual Declaration of Interests Assessment Group (DIAG[11]) comprising EMA staff to consider cases where a declared interest could constitute a conflict and, if so, whether the involvement of the member in EMA's activities is acceptable. The DIAG works formally to check the source of the potential conflict of interest in the involvement of the experts in EMA activities. DIAG evaluates the best alternative to experts who have been categorized at risk level 3. In addition if there are no alternatives to an expert at risk level 3 the DIAG will consider whether a waiver can be granted and the expert allowed to contribute to discussions in a limited manner.[12] As with EFSA and ECHA, EMA may be looking for specific scientific expertise from a very limited pool and has built in a possibility to use an expert where no alternative is available. It has also sought to restrict the influence that expert may have on the outcome of the discussions while at the same time being transparent about the role that person has played in these discussions.

Transparency: In order to create a platform for permanent dialogues with stakeholders, the Agency established the Patients and Consumers Working Party (PCWD). As stakeholders are full members of some Scientific Committees (COMP, PDCO, and CAT), they are fully involved in the scientific decision-making process. CVMP or CHMP might invite stakeholder representatives to their meetings for further clarification.

In line with its draft transparency policy, EMA aims to publish product related documents, such as agendas, meeting minutes of scientific committee meetings as well as additional information elaborating on the benefit/risk of medicinal products for human use.[13] The new policy on Declarations of Interests has also opened these up for greater public scrutiny.

[11] See http://www.emea.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500005213.pdf.
[12] http://www.emea.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500005213.pdf .
[13] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500005269.pdf.

3.3 DG SANCO's Scientific Committees

Mandate: The European Commission's Directorate-General on Health and Consumers (DG SANCO) has the role of ensuring that food and consumer goods sold in the EU are safe, that the EU's internal market works for the benefit of consumers and that Europe helps protect and improve its citizens' health. In order to succeed in its mission, DG SANCO works with other EU Institutions, national governments and agencies, consumer organisations, health interest groups, business groups, scientists, researchers and experts.

Governance: DG SANCO is a department of the European Commission, the EU's executive body. The Commission is charged with representing and upholding the interests of Europe as a whole as determined through the EU Treaties and mandates. It drafts proposals for new European laws and manages the day-to-day business of implementing EU policies and spending EU funds. The College of Commissioners, which includes the Commissioner on Health and Consumer Policy, defines policy and takes decisions: it carries political responsibility for the actions undertaken by the Commission. Operational implementation is delegated to the Directors-General; accordingly, DG SANCO is headed by a Director General. It is therefore appropriate to note that the Commission is primarily responsible for risk management although it also has risk assessment responsibilities in some areas.

Scientific bodies & selection of experts: The work of DG SANCO is supported by three Scientific Committees established by Commission Decision 2004/210/EC (subsequently repealed and replaced by Commission Decision 2008/721/EC). The mission of the Scientific Committees is to respond to Commission requests for opinions in cases where so required under EU law. In addition, the Commission may request opinions on questions of particularly relevance to consumer safety, public health or the environment and that do not fall within the mandate of other EU bodies, as well as rapid advice on the state of scientific knowledge concerning specific risks in case of urgent needs. The Scientific Committees may also act on their own initiative. They may also set up thematic workshops on particular risks or broad risk assessment issues, and they may draw the Commission's attention to a specific or emerging problem falling within their remit that may pose an actual or potential risk to consumer safety, public health or the environment. Although under the same umbrella as the risk managers, their specific and legal mandates are in the area of risk assessment, rather than risk management. The secretariat to the Committees is ultimately under the same management structure as the risk managers.

The three committees, which were examined in this study and which deal only with non-food-related issues, and their working groups are:

- Scientific Committee on Health and Environmental Risks (SCHER)
- Scientific Committee on Consumer Safety (SCCS)
- Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

In addition, Decision 2008/721/EC sets up a Pool of Scientific Advisors on Risk Assessment (the "Pool") to support the activities of the three committees.

Each Scientific Committee is composed of a maximum of 17 members. Members are appointed by the Commission from a list of suitable candidates established following an open call for expressions of interest. This is followed by a rigorous selection procedure by Commission officials with experience in the field and with assistance from outside experts. The Commission appoints members from amongst the proposed candidates. The Committees may associate, at their own initiative, up to five scientific advisors from the Pool to contribute to the Committee's work on specific issues or disciplines. Each committee appoints a chair and two vice-chairs from amongst its members. For coordination purposes, an Inter-Committee Coordination Group has been set up, composed of the chairs and vice-chairs of each committee. The committees may also invite other experts (from expert databases or the Pool) for assistance in the preparation of specific scientific opinions.

In line with Commission Decision 2008/721/EC and the 'Rules of Procedure of the Scientific Committees', members of scientific committees, Pool members and external experts are selected on the basis of their expertise and are required to act independently. Similar to the members of the EFSA Panels and Committee, these experts are not nominated by Member States and are therefore unlike the members of the ECHA and EMA scientific bodies.

Procedures to ensure independence: Experts selected for a DG SANCO scientific body need to make declarations of commitment and declarations of interests, the latter being in one of four forms: spontaneous, initial, specific and annual declaration of interests. Interests include current and past interests of a financial, personal and intellectual nature. Family members' interests are declared as well. Annual and specific declarations of interests are published on DG SANCO's website, while other declarations of interests are included in meeting minutes.

Moreover, Committee members and external experts are under a continuing duty to declare any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, in order to allow the Scientific Committee and/or the Commission to identify those interests that might be considered prejudicial to the independence of the member, advisor or external expert. Therefore a continuing positive onus is on the members to put forward declarations that might be considered a conflict.

The assessment of whether there is a potential conflict is performed by the peers (i.e. the chair and the other members of the Scientific Committee) and the secretariat. The secretariats draw attention to interests which could undermine the independence of the scientific committees, as well as measures to be taken where conflicts may exist. In such cases, the committee chair decides, in consultation with the committee and in agreement with the Commission, the relevant conclusions and necessary action in order to ensure the effective application of the independence requirements.

Scientific opinions are adopted by a majority of the total number of Committee members combined with the number of associated members. To the extent there are minority opinions, these and related supporting arguments are included in the final scientific opinion and published on the EC website.

Transparency: In line with the principle of transparency, most of the documents relating to the activities of Scientific Committees are published on the Commission's website (without prejudicing confidentiality). Stakeholders are not directly involved in the work of the committees. NGOs and industry representatives may provide information when a committee so requests.

3.4 Codex Alimentarius Commission (Codex)

Mandate: The Codex Alimentarius Commission is an intergovernmental body created by a Food and Agricultural Organisation (FAO) Conference in 1961 and a World Health Assembly resolution (WHA 16.42) in 1963. The main objective of the CAC is to protect consumer health and fair trade practices to facilitate food trade by setting international food standards (the Codex Alimentarius), guidelines and other related texts, such as codes of practice.

Governance: The supreme decision-making body is the Commission itself, which has 174 member countries and one regional organisation (the EU). The Commission normally meets every two years but it can also meet more frequently in special sessions. National delegations are led by senior government officials and may also include representatives of industry, consumers' organisations and academic institutes. A number of international governmental organizations and international NGOs can also attend as observers. The Executive Committee is the executive organ of the commission between its meetings. The Secretary of the Commission is appointed jointly by FAO and WHO after an open search for qualified candidates. The Secretary is supported by a small professional staff based at FAO headquarters in Rome.

The CAC has several kinds of subsidiary bodies: Coordinating Committees, Codex Committees, and ad hoc Intergovernmental Task Forces. The six Coordinating Committees (Africa, Asia, Europe, Latin America and

the Caribbean, Near East, and North America and South West Pacific) are the vehicle for regions or groups of countries to coordinate food standards activities in the region. This enables the CAC to ensure that its work is responsive to regional interests and to the concerns of developing countries.

The task of developing international standards for commodity and general subject areas is spread across the 15 technical Codex Committees. The ten General Subject Committees are "horizontal" committees that develop general concepts and principles, endorse or review relevant provisions in Codex commodity standards and develop major recommendations concerning consumers' health and safety. They include committees on General Principles, Food Labelling, Methods of Analysis and Sampling, Food Hygiene, Pesticide Residues, Food Additives, Contaminants in Foods, Import and Export Inspection and Certification Systems, Nutrition and Foods for Special Dietary Use, and Residues of Veterinary Drugs in Food.

The five Commodity Committees are responsible for developing international standards for specific foods or classes of foods and are often referred to as "vertical" committees. They include the committees on Fats and Oils, Fish and Fishery Products, Milk and Milk Products, Fresh Fruits and Vegetables, and Processed Fruits and Vegetables. In addition, five ad hoc Intergovernmental Task Forces have been established by the CAC to date to work for fixed time periods on particular areas of scientific interest, such as antimicrobial resistance or foods derived from biotechnology.

Scientific bodies & selection of experts: Independent scientific expert advice is provided to the Commission and its specialist Committees through the three Joint FAO/WHO Expert Committees (JECFA, JEMRA and JMPR). While not part of the Codex Alimentarius Commission structure, the three joint committees nonetheless work closely with the CAC committees to provide the scientific expertise needed for the CAC's work. For example, in the course of preparing a draft standard to be submitted to the Commission for adoption, a Codex Committee may request one of the joint FAO/WHO expert committees to perform the required risk assessment. Upon receipt of the joint expert committee report, the Codex Committee will consider this along with other factors legitimate to the matter at hand and propose to the Codex Commission a text for final decision. The joint committees also assist the FAO and the WHO in overcoming difficulties related to their specific fields of expertise and in achieving a greater level of consumer protection for food in international trade.

Joint FAO/WHO Expert Committees

- Joint Expert Committee on Food Additives (JECFA)
- Joint Meetings on Microbiological Risk Assessment (JEMRA)
- Joint Meetings on Pesticide Residues (JMPR)

Members of the joint FAO/WHO expert committees are invited to be considered for selection through a "call for experts". A selection board assesses the applications; the rules applied depend on which organization chooses the expert. Appointments are for a period of 5 years; experts are placed on a roster with the secretariats of the organizations calling experts off the roster depending on the expertise required to address a specific scientific matter. FAO rules apply to those experts chosen by the FAO and WHO rules apply to those experts chosen by WHO. Care is taken to select experts considered as pre-eminent in their area, with the highest level of expertise and as impartial and objective in their judgment. Experts are appointed in their own personal right, and not as representatives of a government or organisation.

Procedures to ensure independence: Experts of the joint FAO/WHO expert committees are required to declare any interests which could unduly influence the expert's position. Declarable interests cover real, potential and apparent conflicts of interests, which can be both financial and other manner of interests. The interest can be personal or the interest of individuals in close proximity to the expert. Experts are asked to complete an initial 'declaration of interest' form during the selection process. Interests declared are scrutinized by the selection panel (initial declaration of interests) and the Joint Secretariat of WHO and FAO. Candidates with conflict of interests are not selected. Experts with specific conflicts of interest with respect to a certain issue may not participate in meetings or take part in a decision process relevant to that issue.

Declarations of interests are not disclosed, apart from cases when the objectivity of the meeting was questioned. The onus to declare is placed on the expert and requires a positive affirmation that they do not have any conflict of interest which may prejudice the scientists' independence to address a matter.

Transparency: In line with the principle of transparency, CAC ensures that all interested parties understand the process for the development of scientific advice and have access to reports, safety assessments, evaluations and other basic information. Stakeholders cannot participate in the development of scientific opinions. Electronic summaries of the main findings and conclusions of each meeting of the expert groups are published by the Joint Secretariat shortly after each meeting on the websites of FAO and WHO.

The concise description of the key data used in the assessments, the evaluation of these data and the conclusions of the committee are published by WHO in the Technical Report Series. These reflect the view of the committee as a whole; the positions of any dissenting expert(s) and the reason for the disagreement will be recorded in the report.

The CAC also encourages other scientifically based intergovernmental organisations to contribute to its work through providing advice and support.

3.5 France: Agency for Food, Environmental & Occupational Health Safety (ANSES)

The Agency for Food, Environmental and Occupation Health Safety is the newest of the organisations selected for this review. It is a public administrative body that reports to the French Ministries of Health, Agriculture, Environment, Labour and Consumer Affairs. It was created in the beginning of 2010 by a Ministerial Order combining two pre-existing agencies: the French Food Safety Agency (AFSSA) and the French Agency for Environmental and Occupational Health Safety (AFSSET).

Mandate: ANSES's mandate is to contribute to the improvement of human health in the areas of the environment, the workplace and food. It also aims to protect animal and plant health and welfare, and to evaluate the nutritional and functional characteristics of food. The primary function of ANSES is to carry out risk assessments. However, it also carries out very limited risk management activities, e.g., permits for veterinary drugs.

The founding charter of ANSES establishes as one of its basic principles the reliance on collective expert assessment for evaluating health risks. Expertise must be provided collectively at all stages, from the initial presentation of data, through successive discussion and debate, until the final conclusion. The goal of requiring collective expert assessment is to ensure that the broadest range possible of knowledge and data on a particular issue are taken into account in order to be able to issue an independent opinion, after considering all hypotheses. ANSES has compiled a best practices guide in collective expert assessment. This requirement provides ANSES with a responsibility to be open to consider the widest range of information in a pluralistic manner, a requirement which is not specifically foreseen for the other organisations assessed.

Governance: ANSES is headed by the Director General who is nominated by a decree of the French government. The Board of Administration establishes the general policy of ANSES as well as its multi-year strategy for development, and approves the annual budget (which is provided by the French national budget). The Board is comprised of a Chair (also nominated by government decree) and five *colleges*: (1) 8 public authority representatives (Ministries of Health, Environment, Labour, Finance, Agriculture, Consumer Affairs, Research and Industry); (2) 5 labour union and 3 employer organisation representatives; (3) 7 NGOs or non-profit associations; (4) 6 representatives of relevant professional bodies; and (5) 3 elected officials. The Board may also establish thematic steering committees. Four such committees have already been created related to (i) environmental health, (ii) occupational health, (iii) food safety and nutritional quality and (iv) animal health and food.

The role of ANSES's Scientific Advisory Committee is to ensure impartial scientific expertise. It takes part in the screening of applications for scientific panels, reviews disclosures of conflicts of interest, and gives advice on the composition of the scientific panels. The Scientific Advisory Committee is composed exclusively of scientists, including 3 peer-nominated scientists from ANSES itself, 24 scientists appointed by Ministerial Order, and the President of the Scientific Council of the French Agency for Health Safety of Health Products along with the President of the Scientific Council of the Institute for Health Monitoring.

The Committee for Ethical Standards and Prevention of Conflicts of Interests has been created to ensure that ANSES adheres to stringent ethical standards and, in addition to this wide ranging requirement, that it also avoids conflict of interests. It comprises five to eight members who are fully independent from the Agency and recognized for their expertise in ethical matters. This committee can act on a request by the Director General, the Board of Administration, the SAC, one of the scientific panels, or an ANSES employee. After carrying out an investigation, the CESPCI sends its opinion and recommendations to the petitioning body, the Board of Administration, the Director General and the supervising Ministries.

Scientific bodies & selection of experts: As a result of the fusion of AFSSA and AFSSET, ANSES operates with two sets of scientific panels specialised either in (i) environment and occupational health safety or (ii) food, animal health and nutrition and plants. Members of the scientific panels are external experts specialised in the particular field, appointed by the Director General. Prior to their appointment, ANSES organises an open selection procedure. Suitable candidates are screened by the Scientific Advisory Committee, which also advises on the setting up of each scientific panel. Scientific panel experts are appointed for a three-year mandate and may include scientists from other countries. The experts are compensated only for basic expenses.

Panels meet to draw up a response to a particular issue in the form of an opinion. Each request is analysed in order to select the most suitable expert assessment methods to deal with each issue raised, and in particular the competent *rapporteurs* to be appointed, or the setting-up of a working group, responsible for providing the initial report to the scientific panel. In case of emergency, a group of emergency collective expertise (*Groupe d'Expertise Collective d'Urgence or GECU*) is set up to provide an opinion to the Director General.

Procedures to ensure independence: During the selection procedure potential experts are requested to draft and sign a public disclosure of interests form, which is scrutinized prior to appointment. In addition, panel experts are to declare if they have interests in any of the agenda items coming before the panel. This form of declaration of interest (covering only financial interests) is assessed by the president of the panel. In the case of a conflict of interest, the panel member might be excluded from the panel meeting or the decision-making process.

ANSES has a rigorous policy for dealing with failure to conflicts of interest or other major faults related to an expert's ethical obligations. In such cases, ANSES could bring a judicial action against the expert, which could result in the imposition of a fine. Under the French Public Health Code, certain unethical behaviour, such as accepting advantages from a company, might even constitute a criminal offence. Violation of ANSES's conflict of interest policy could lead to nullification of the Committee's opinion. Declarations of interests and decisions of the CESPCI are available for public view.

Scientific outputs in the form of opinions and recommendations are taken by majority vote when a quorum of panel members is present. The panel's Chair plays an essential role in determining the pluralism and collegiality of the debates and in defending the rights of members to express any divergent views – provided they are scientifically well-founded; the aim is to strive for scientific objectivity rather than consensus. Minority opinions with their supporting arguments are recorded both in the meeting minutes and the final decision.

The quality and independence of ANSES's expertise is supported by an audit mechanism and by the Committee for Ethical Standards and Prevention of Conflicts of Interests, which can be called upon to deal with particularly complex situation and evaluate decisions which have been brought into question or have raised doubts.

Transparency: Stakeholders through their capacity of Board members are involved in decisions related to the general policy of ANSES. However, stakeholders are not represented in scientific panel meetings.

3.6 Germany: Federal Institute for Risk Assessment (BfR)

The Federal Institute for Risk Assessment (BfR) was established in November 2002 by means of the Law on the Establishment of the BfR (BfRG). It is a federal agency which offers scientific advice to the Federal Ministry of Food, Agriculture and Consumer Protection and, in a lesser extent, to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, and the Federal Ministry of Transport, Building and Urban Affairs. Like EFSA, it was established in reaction to the BSE and other crises, and for the same reasons its independence is of particular importance. With the objective to keep risk assessment functionally separated from risk management actions, the parallel institute of the Federal Office for Consumer Protection and Food Safety (BVL) was established in 2002.

Mandate: The aim of the BfR is to promote and strengthen consumer health protection by ensuring the safety of food, products and chemicals. The BfR carries out risk assessments, communicates risks to the public, offers policy advice and participates in national and international activities. It provides scientific advice for authorisation procedures and other regulatory actions: in some cases it is invited to present a non-binding statement for the regulatory approval of a substance, mixture or product; in other cases, it must give its legal binding consent as part of the regulatory action. The BfR also advises other government bodies in the form of non-legally binding reports and statements. Responsibility for risk management lies with the competent ministries, the BVL and the *Länder*.

Governance: The president of the BfR is responsible for the overall management and representation of the institute; he decides on its main work and research areas. The president is also responsible for taking final decisions concerning the BfR's scientific opinions. He and the vice-president are appointed by the BMELV after an open competitive job announcement. They are civil servants as are the other approximately 700 employees of the BfR. The executive office and the policy matters and strategic planning unit support the president with his day-to-day work, including assistance in decision-making, while the research coordination unit coordinates the research work of the BfR both internally and externally.

The BfR is financed by the Federal budget and also by third-party contributions. Each year the BfR must prepare a budget plan including expected income and anticipated expenditures that is then authorised by the BMELV. At the end of the year the BfR presents a final budget for the BMELV's review.

Scientific bodies & selection of experts: The Scientific Research Council supports the BfR by identifying main research areas as well as through networking and cooperation with other national and international research institutes. It consists of 12 scientists from universities and non-university research institutions acting on an honorary basis.

The BfR's main scientific opinions are based on the internal research and risk assessments carried out by the staff members of its scientific departments. The fact that its decisions are based mainly on the work and analysis of its staff enables the BfR to react quickly to new situations and to develop the expertise of its scientists internally. This is considered to bolster its independence.

The BfR also operates with scientific committees composed of external experts selected through an open procedure, based on their expertise and considering gender equality. Following a call for expression of interests, the members of the BfR committees are appointed by a selection panel.These committees provide specialised expertise; a major function is to provide external quality assurance. They only have advisory functions and do not participate in the internal decision-making processes.

Procedures to ensure independence: The BfR considers that conflicts of interests are not likely to occur with members of the scientific departments, since they are employees, than in cases where bodies rely on external expertise. The internal work instructions of the BfR require every staff member to conduct research and render decisions independently. These instructions have been certified in accordance with ISO 9001. The certified qualified management system covers all of its work areas, including its entire risk assessment and risk communication processes.

For its scientific committees involving external experts, it has provided for mechanisms in the selection procedure and in the conduct of meetings mechanisms to avoid conflicts of interest. During the selection process, experts are required to commit themselves to act independently.

According to a new BfR conflict of interest policy, members of the scientific committees are asked at the beginning of each meeting if they have potential conflict of interests relating to one of the agenda items or topics discussed. An expert who gives notice about an existing potential conflict of interests needs to leave the room. Then, the committee collectively decides on the participation of the committee member concerned in further discussions. Potential conflicts of interests that might occur during a meeting are noted, corresponding statements published over the internet, and the results included in the meeting minutes.

Transparency: Stakeholders are not involved in the research and scientific opinion process, as BfR's risk assessment is mainly based on its own scientific work. The Risk Communication Department of the BfR nonetheless organizes regular dialogues with stakeholders from science, trade and industry, political circles, the media, associations, non-governmental organisations and consumers.

All reports and recommendations based on BfR's assessments are published over the internet, as well as the list of experts for each committee.

3.7 United Kingdom: Food Standards Agency (FSA)

Mandate: The UK government established the Food Standards Agency in 2000 on the basis of the 1999 Food Standards Act. The FSA is charged with protecting consumer interests in relation to food safety. It is involved in all aspects of risk analysis. It carries out scientific risk assessments and decides on measures for managing food-related risks. For example, the FSA drafts and implements most UK food and animal feed law, provides guidance to food businesses on how to comply with the law, and works with local authorities and other food law enforcement bodies to help them take effective and timely action to protect consumers.[14]

Governance: The Food Standards Agency is a non-Ministerial Government Department led by a Board rather than directly by Ministers. The Board comprises a Chair, Deputy Chair and between eight and twelve ordinary members of whom one is appointed by the Welsh Health Minister, one by the Northern Ireland Health Minister, two by the Scottish Health Minister and the remainder by the Secretary of State for Health. Board members are expected to represent a variety of skills and experience; they are required to act in the interest of the public without representing any sectoral interests.

The Board of FSA is responsible for setting its strategic direction and for ensuring that scientific advice, consumer interests and other factors are taken into account in its activities. [15]

The General Advisory Committee on Science (GACS) provides independent advice on the Agency's activities, provides support in such matters as horizon scanning, scientific governance, good practices and scientific priorities and acts as a coordinating body.[16] It comprises an independent Chair, four independent

[14] http://www.food.gov.uk/multimedia/pdfs/publication/aboutusguide0907.pdf .
[15] 1999 Food Standards Act, Article 2(1).
[16] This work includes: (1) horizon scanning, (2) science governance, (3) developing good practices, (4) and informing science priorities.

experts, two lay members and the chairs of the eight scientific advisory committees that provide independent expert advice to the Agency in specific areas.[17]

The FSA is also supported by three Food Advisory Committees (FACs) for Northern Ireland, Scotland and Wales. These committees were set up to provide greater focus on specific geographical interests and their advice is also taken into account by the FSA in carrying out its functions with the Chairs of the FACs also being members of the FSA Board.

Scientific bodies & selection of experts: The FSA's risk assessment activities are carried out with the support of its nine Scientific Advisory Committees:

- Advisory Committee on Microbiological Safety of Food
- Advisory Committee on Novel Foods and Processes
- Advisory Committee on Animal Feeding stuffs
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
- Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
- Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
- Spongiform Encephalopathy Advisory Committee
- General Advisory Committee on Science
- Social Science Research Committee
-

The nine Scientific Advisory Committees may establish working groups for the consideration of scientific topics or to prepare brief assessments. In addition to the SACs, the Agency's website lists 28 working groups, task forces and other bodies.[18]

The FSA provides the secretariat to these scientific advisory committees (in some cases jointly with other Departments that also receive advice from the Committees). In addition to this administrative support, FSA staff also support the scientific advisory committees with scientific expertise, including comprehensive background information and briefing papers.

Members of the Scientific Advisory Committees are appointed through open competition in a selection procedure that identifies experts who fulfil the 'personal specifications'. Each Committee has at least one lay member in order to ensure that all aspects relevant for the public are discussed and that decisions are written in language that is easily understood.

Procedures to ensure independence: The UK government has in place a number of procedural codes of practice for the operation of all its scientific advisory committees which include overall requirements for scientists to act in the public interest, to work independently, to work in an open and transparent manner and unless specifically requested to do so – to focus on risk assessment and not risk management. Scientists are requested to always take the broadest view of evidence, to have a broad mind, acknowledging where differences or alternative hypotheses exist and to transparently explain how these have been considered in any scientific opinions or reports. The cross government code also describes and guides the values and responsibilities of scientists engaged in public work with the aim to foster ethical research, to encourage active reflection among scientists on the wider implications and impacts of their work, and to support constructive communication between scientists and the public on complex and challenging issues.

The SACs that advise the FSA also have in place an overall Code of Practice which reflects the cross government advice. This outlines, *inter alia*, the roles of the secretariat, the chairs, and the experts on the panels, clarifying how discussions should be conducted, and how varied and alternative views addressed and recorded. In particular, the Code considers and defines what should be declared by scientific experts as well

[17] http://www.food.gov.uk/science/ouradvisors/gacs/ .
[18] http://www.food.gov.uk/aboutus/committees/.

as the procedures for doing this, to ensure that scientific advice provided to the Agency is impartial and not compromised by other influences. This includes not only guidance on declarations of interests but also on acceptance of gifts and invitations. Members of the Scientific Advisory Committees are expected to declare any personal and business interests which might influence or be perceived to influence their judgement at two points: (1) Registration of interests with the Secretariat; (2) Declaration of interests at each meeting of the respective committee.

In addition, the FSA Board, Chief Executive, and members of the Food and Scientific Advisory Committees are expected to comply with the so-called "Nolan principles" which are a cross government requirement for those in public office elaborated by the UK Committee on Standards in Public Life for people who hold public positions. [19] These are specifically referred to in the FSA's Code of Practice.

If a member has a potential conflict of interest with a matter that is on the agenda of the committee, the committee Chair decides on the extent to which the person can participate in further discussions concerning a scientific opinion. For example, the Chair may decide that the person should leave the meeting but first be allowed to make a statement on the issue, in order for the committee to benefit from his or her expertise.

Where possible, the Scientific Advisory Committees take their decisions by consensus and the different views considered in coming to a conclusion are included in the record. Where a consensus is not possible differing views are to be recorded as an addendum to the main report and this is specifically emphasised in the FSA's guidance. The reports of the meetings, minutes and agendas are published on the website. Where relevant, the Chair of the appropriate SAC is invited to participate in open FSA Board meetings where their Committee's risk assessment advice is pertinent to an item on the agenda. This ensures that the Board has direct and public access to the risk assessment advice when discoing risk management options.

Transparency: The FSA has a central value to be open and transparent and, like EFSA, undertakes specific activities in public: e.g., the FSA's Board meetings are open to the public. The FSA has established Stakeholders' Forums to enable main stakeholders to raise matters of concern with the Agency through regular consultations (e.g., in the form of annual stakeholder meetings). The secretariat of the SACs is guided to ensure that stakeholders' concerns are addressed. In addition, stakeholders are to be consulted at appropriate points in the committee's considerations and, wherever possible, SAC discussions are held in public. Committees also include at least one lay member.

The FSA has organised listings of committee members' outside interests into a publicly available register which is updated when an interest changes. Not only does this provide a way to track the interests of committee members, but it also enables the public to easily look up the declared interests of all committee members. As an ultimate sanction members of the scientific advisory committee may have their appointments terminated due to misconduct.

3.8 Canada: Health Products and Food Branch (HPFB)

Mandate: The Health Products and Food Branch is Canada's authority for regulating health products and foods. The mandate of HPFB is to take an integrated approach to managing the health-related risks and benefits of health products and food by: (1) minimizing health risk factors to Canadians while maximizing

[19] Standards for Public Life' http://www.public-standards.gov.uk/: The Committee on Standards in Public Life elaborated principles (the Nolan principles) that people who hold public positions should respect. The principle of 'selflessness' emphasizes that holders of public office should take decisions solely in public interests without being compromised by financial or other material benefits for themselves, their family or their friends. According to the principle of 'integrity', public officers cannot place themselves under any financial or other obligations which might influence them in their judgement and fulfilment of their duties. The principle of 'objectivity' emphasizes that public officers should make decisions on their merit. Public officers are also required to be 'honest' in a sense that they need to declare any private interests which might relate to their public duties and they should take the necessary steps to resolve these conflicts.

the safety provided by the regulatory system for health products and food; and, (2) promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Governance: HPFB is a branch of Health Canada, the Canadian Federal Department of Health. It is headed by an Assistant Deputy Minister who works under the responsibility of Canada's Minister of Health. HPFB is organised into 12 directorates such as the Marketed Health Products Directorate and the Biologics and Genetic Therapies Directorate, which in some cases include a risk management component (under Canada's multi-jurisdictional legislative framework, risk management is usually a shared responsibility of the federal and provincial or territorial governments, together with industry, municipal, and public health partners). Health Canada (like other federal departments) is subject to the Cabinet Directive on Streamlining Regulations, which defines the risk assessment-risk management cycle.

Scientific bodies & selection of experts: At HPFB, scientific expertise is mainly provided by employees of the branch who are nominated by the Assistant Deputy Minister and who work in the directorates. In addition, HPFB has established Advisory Bodies to provide scientific health and food-related advice to the HPFB's directorates, e.g., when issues are very technical and require additional expertise.

External experts with the required expertise or experience related to the particular Advisory Body's mandate are sought out through an open call for tenders. They may include scientists, researchers, academics, health professionals, consumers, patients, caregivers and industry stakeholders. The HPFB may consult with Health Canada, the chair and members already on the Advisory Body or other government organization when considering whom to select. It also may ask the public for suggestions, e.g., by inviting them to an Advisory Body meeting to share their personal experience as a patient.

Examples of HPFB Advisory Bodies

- Expert Advisory Committee on Antimicrobial Resistance Risk Assessment
- Infant Feeding Expert Advisory Group
- Working Group on Dietary Sodium Reduction
- Food Regulatory Advisory Committee

The Advisory Bodies issue advice in the form of minutes, records of proceedings or formal reports. Such advice is usually reached by consensus. Dissenting opinions will be recorded in the Advisory Body report. Directorates use the advice given by advisory bodies to prepare a final report for transmission to the Director General of the relevant Directorate, who may adopt risk management measures on the basis of the advice. Meetings of Advisory Bodies are confidential and not open to the public or to other stakeholders.

Procedures to ensure independence: HPFB relies mainly on employees for its scientific advice and only uses external experts on highly specialized issues that cannot be treated by internal scientists. The limited involvement of external experts in the decision-making process is aimed at reducing the emergence of conflicts of interest that could influence its decisions.

According to the HPFB Guidance on Advisory Bodies, external experts are required to complete a declaration of affiliations and interests during the selection process and before their appointment. In addition, at the beginning of every meeting, the chair may ask members to make a verbal declaration of their affiliation and interests. External experts also have to adhere and comply with confidentiality clauses provided in the Guidance on Advisory Bodies.

If an expert has a direct financial interest, defined as a situation where the expert or one of his or her close relatives has a direct financial interest in the outcome of the final recommendations or report of an Advisory Body, he or she cannot become a member of that particular Advisory Body. However, a member with a direct financial interest may have a limited participation in an Advisory Body with a broad mandate encompassing matters of policy, management or program development. However, the member will not be

able to participate in any formulation of advice or recommendation of that Advisory Body. Similarly, individuals with particular expertise might be invited to provide input on a specific topic or agenda item. However, these contracted experts may not participate in the formulation of advice or recommendations to the Branch.

If a member of an Advisory Body fails to act in an independent manner or according to the Advisory Body's term of reference, the HPFB will terminates his or her contract. The HPFB will advise him or her in writing, stating the reason for the termination and the effective date.

Health Canada recently announced a new policy on scientific integrity, which attempts to align best scientific practices (eg. non-falsification, respect for research subjects, etc.) between Health Canada and other regulatory bodies, universities, etc. This new policy should be adopted in the course of 2011. The same rules will then apply to both internal and external scientists.

Transparency: The HPFB publishes summaries of the Affiliation and Interests Declaration Form for Advisory Body Members and provides information about Advisory Body meetings in the form of minutes, records of proceedings or formal reports. Summaries of expertise, experiences and affiliations and interests of all Advisory Body members are published on the Branch website. Moreover, this constitutes a condition of appointment.

Although Advisory Body meetings are generally held in private, individuals, organizations or members of the general public may be allowed to observe meetings of Advisory Bodies: this is to be decided by the Branch and the chair in consultation.

3.9 USA: Food and Drug Administration (FDA)

Mandate: The US Food and Drug Administration is responsible for protecting and advancing public health. It was established by the 1906 Food and Drug Act. Within its competence, FDA (1) assures the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics and products that emit radiation; (2) assists innovation projects to make medicines and food safer, more effective and affordable; (3) regulates the production, marketing and distribution of tobacco products; and (4) provides the public with scientifically reliable information on medicines, food and tobacco use. FDA shares responsibility with other regulatory bodies on certain products, such as pesticides, and on water. The remit of FDA does not cover advertising, alcohol beverages and consumer products (such as paint baby toys), illegal drugs, health insurance, meat and poultry, restaurants and grocery stores.

Governance: The US FDA is an agency of the US Department of Health and Human Services. It is headed by the Commissioner of Food and Drugs, who is appointed directly by the US President, with consent of the US Senate. The FDA consists of six product centers (Biologics Evaluation and Research, Devices and Radiological Health, Drug Evaluation and Research, Food Safety and Applied Nutrition, Tobacco Products, Veterinary Medicine), one research center (National Center for Toxicological Research), and two offices (Office of Regulatory Affairs, Office of the Commissioner).

Scientific bodies & selection of experts: The Food and Drug Administration has 49 advisory committees and panels which provide FDA with independent advice from experts on issues related to human and veterinary drugs, vaccines and other biological products, medical devices, and food. The mandates of these committees and panels are determined either by statute or by decisions of the Department on Health and Human Services. The FDA may take legally binding final decisions on the basis of the recommendations of these bodies.

Selected FDA advisory committees

- Food Advisory Committee
- Blood, Vaccines and Other Biologics Committee
- Drugs Committee
- Medical Devices Committee
- Paediatric Advisory Committee
- Risk Communication Advisory Committee
- Science Board to the Food and Drug Administration
- Toxicological Products Scientific Advisory Committee
- Veterinary Medicine Advisory Committee
- Tobacco Products Scientific Advisory Committee

In general, advisory committees include a chair, several members, plus a consumer, industry, and a patient representative. Additional experts with special knowledge may be added for individual committee meetings as needed. Stakeholders are widely involved in the work of the FDA (e.g. Patient Representatives and Consultants Programmes) and in particular in scientific committees.

The FDA publishes open calls for experts on the web and in the Federal Register. Professional groups, industry, consumer organisations, advocacy groups and other interested parties may nominate candidates for advisory committee membership. Candidates are expected to provide the FDA with detailed information on their interests (including financial situation, employment, research activities). Before appointing members of the scientific committees, the FDA reviews the qualifications of the nominees and their financial interests (initial declaration of interest), and appoints committee members on the basis of their expertise. Advisory committee members are appointed as either Special Government employees (external experts, receiving a salary for each meeting) or Regular Government employees[20] (e.g. when FDA request employees of U.S. Departments to provide special expertise). Committee members usually belong to research and University centres[21] and typically represent ethnic, gender, geographic diversity, wide-range of expertise in a specific field.

The FDA requests scientific opinions in form of questions. The Chair of the advisory committee is encouraged to generate discussions on the subject matter, as well as to summarise and catch all views of the committee members. Depending on the nature of the question, committees might take decisions by voting. Following an oral vote, the advisory committee adopts a recommendation or an advice, which is then submitted to the FDA. After voting, the Chair can provide the members with the opportunity to explain the reasons for their vote. These opinions are included in the meeting minutes.

Procedures to ensure independence: To ensure its independence and in particular the independence of the scientific decision-making process, the FDA has introduced rules and procedures for dealing with conflicts of interests. The US FDA has also established an ethics programme which provides employees with advice and assistance on ethic related laws and regulation, in order to facilitate the understanding of rules applied to experts and to help ensure that the decisions taken by employees are not prejudiced by conflict of interests or by an appearance of conflict of interests.

According to FDA rules, conflicts of interest have a financial nature. Members of scientific committees need to declare their personal, their immediate family members' and other imputed interests. Conflict of interest may appear if a member has a financial interest relating to a specific topic of a meeting (specific declaration of interest). Experts who are regular government employees are required to declare any financial interests annually.

[20] Guidance on Procedures for Determining Conflict of Interests and Eligibility for Participation in FDA Advisory Committees p. 5. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf.

[21] Experts working at federal agencies are often engaged in the work of other advisory committees of other departments.

As a consequence of conflict of interest, the member may not participate in the Committee's decision-making process. However, the FDA might decide to grant a waiver, which would allow the member to participate in the advisory committee meeting but with no voting rights. A waiver is granted if the member has an essential expertise, the member's financial interests do not exceed the nominal value of $50,000, and the FDA has not exceeded the maximum number of waivers that it can grant per year.

Transparency: In line with the principle of transparency, the FDA discloses on its website the financial interests of advisory committee members who were granted a waiver. The Agency is also required to disclose materials received from the industry two days before the meeting takes place. According to the Federal Advisory Committee Act, reports, transcripts,[22] appendixes, working papers, drafts and other documents which were prepared for or by the advisory committees need to be available for public either at the location of the scientific committees' offices or at the agency.

In principle, meetings are open for public and meeting minutes are published. Scientific outputs also need to be available for public. In June 2009, the FDA launched a Transparency Initiative and formed an internal task force to develop recommendations for making useful and understandable information about FDA activities and decision-making more readily available to the public, in a timely manner and in a user-friendly format.

3.10 USA: National Academy of Science (NAS)

Mandate: The National Academy of Science is a private non-profit institution which provides independent science, technology and health policy advice to the US Federal Government, including risk assessments. It was established by an Act of Congress of March 1, 1863. The federal charter provides that the NAS "[o]n request of the United States Government, [...] shall investigate, examine, experiment, and report on any subject of science or art."[23]

The NAS is composed of approximately 2,100 members and 380 foreign associates who are elected in recognition of their continuing achievements in original research. Each of the members is affiliated with one of the 31 disciplinary sections, which are themselves organised into six "classes" of membership "Committees" (Physical and Mathematical Sciences; Biological Sciences; Engineering and Applied Sciences; Biomedical Sciences; Behavioural and Social Sciences; Applied Biological, Agricultural and Environmental Sciences). .

Governance: The Academy is governed by a President and by the Council of the Academy, which also has an Executive Committee. The Academy has a Home Secretary, a Foreign Secretary and a Treasurer. The NAS does not receive a direct appropriate from the government; it is financed by donations, devises, gifts and bequests; the scientists, engineers, health professionals, and other experts who are NAS members volunteer their time for the study of specific issues.

The NAS and its sister organizations, the National Academy of Engineering (NAE), the Institute of Medicine (IOM), and the National Research Council (NRC) are collectively referred to as the National Academies. The NRC is the operational arm of the National Academies and has the final authority over committee appointments.

Scientific bodies & selection of experts: As per its mandate to provide independent science, technology and health policy advice to the US Federal Government, the NAS convenes specialist scientific committees to carry out studies on particular issues. All committee members serve as individual experts, and not as representatives of organisations or interest groups. The process for selecting committee members starts with a search by NAS staff for potential members, using a wide range of sources for suggestions. The staff then recommend a list of nominees. The nominees are reviewed and approved at several levels within NAS, until

[22] Transcripts are also published after the meeting, Summary of transcripts are published on the website of FDA.
[23] Federal Charter of the National Academy of Sciences 36 U.S.C. 150303.

a provisional slate is approved by the President of NAS. As exceptions, sponsors with an interest in the underlying subject matter of a particular study may suggest potential Committee members with knowledge and expertise in the relevant matter. Nonetheless, the final choice of Committee members will rest solely with the Academy.

The provisional list is posted for public comments on the NAS website. Provisional committee members are required to complete a conflict of interests disclosure form and a background information sheet. Following the investigation of these documents, the Committee is formally approved. Committee members continue to be screened for conflict of interest throughout the life of the committee.

Procedures to ensure independence: According to the Policy on Committee Composition and Balance and Conflicts of Interest and the Federal Advisory Committee Act, the NAS guarantees that no individual is appointed to a committee who has conflicts of interests, that the committee membership is fairly balanced and that the final decisions of the Academy are based on independent judgment. The NAS differentiates between bias and conflict of interests. Bias (lack of objectivity) does not disqualify someone, but is taken into account in the overall composition of the Committee. However, conflicts of interest could potentially undermine the reputation of NAS, and therefore they are more carefully handled.

Conflicts of interest apply to current financial interests and interests of others, who have substantial common financial interests with the member (*e.g*. spouse, minor children, business partner). The policy operates with a category of other potential conflicts of interests, which includes access to confidential information, reviewing one's own work, public statements and positions. During the selection process, nominees are required to inform the Committee about potential conflict of interests ('Background information and Confidential Conflict of Interest Disclosure'). If a conflict of interest is unavoidable, the person cannot be appointed. In case of change in a potential conflict of interests, such information needs to be reported. An alternate conflict of interests systems has also been set up for projects. It is crucial for the Academy to operate in a transparent manner, as according to the Federal Committee Act, the Academy's advice can only be used by the Government if committees comply with certain requirements relating to providing public access to meetings and completed reports. However, declarations of interests are not disclosed.

As an extra guarantee for ensuring transparency, the US Government may not use any advice or recommendation provided by NAS, unless it has complied with various requirements regarding public access to written materials, such as summaries or completed reports provided by sponsors.

Transparency: NAS focuses on providing independent scientific advice; therefore stakeholders are not involved in the decision-making process. It is worth noting, however, that the final step of the selection procedure for committee experts is the posting of the names and brief biographies of committee members on the NAS website, with an invitation for the public to comment on it before the first meeting takes place.

4. Mandates and governance structures

Each of the organisations reviewed has a regulatory function related to the protection of human health and/or the environment, with the exception of the NAS which is a joint public/private body with a broader remit of providing scientific advice in many other areas as well. Their roles in support of regulatory decision-making are typically grounded on risk analysis and its three components -- risk assessment (scientific advice and information analysis), risk management (regulation and control) and risk communication. Given that risk analysis is also the foundation for the EU's food safety policy, [24] the comparative review considered whether the mandate of the organisation covered risk assessment, risk management or both. The comparative review also considered the relationship between the organisations' governance structures and their provision of scientific advice.

4.1 Risk assessment and risk management

The issue of whether or not to separate risk assessment and risk management is a much-debated issue, both among the organisations reviewed and also among academics.[25] The functional and organisational separation of risk assessment from risk management is considered important by some in order to minimise the role of policy or politics in the scientific phase of risk assessment, to ensure the scientific integrity of the risk assessment process and reduce any conflict between risk assessment and risk management.[26]

Not all observers and policy makers agree, however; it is sometimes argued that this separation between risk assessment and risk management does not automatically ensure the independence and objectivity of the science on which a regulatory decision may be based. It is also argued that 'risk analysis is an iterative process and interaction between risk managers and risk assessors is essential' and therefore an organisational separation can result in a fragmentation of the overall process.[27]

Prior to the creation of the EFSA, there were numerous discussions concerning the pros and cons of separating the two functions. In the end, the separation of risk assessment from risk management became one of the main principles applied to ensure the independence of EFSA's scientific advisory opinions. Other organisations studied also focus exclusively on scientific risk assessment include Germany's BfR and the US NAS. A few, such as ANSES[28] and ECHA[29], provide predominantly risk assessment functions but also carry out albeit very limited risk management.

However, even in those cases where the parent or client organisation also has a significant risk management role (Codex and its expert committees, UK FSA, HPFB, US FDA), risk assessment is almost always *functionally* separated from risk management. For these organisations, the scientific advisory bodies are an important vehicle for ensuring a functional separation between the two elements of risk assessment and risk management. Particularly noteworthy are the Joint FAO/WHO expert committees that are not formally part of the Codex Alimentarius but which provide scientific risk assessment for the political process of setting the Codex standards.

In almost all of these bodies, a clear separation between the two functions within the organisation is usually in place to guarantee the scientific integrity of the risk assessment process. The degree to which the scientific advisory bodies managed with a secretariat answerable to the same parent organisation as the risk managers depends to what extent the functional separation can be maintained and be seen to be maintained. The full

[24] 2000 White Paper on Food Safety, p.9, at: http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.
[25] See The Red Book prepared by the National Research Council.
[26] Catherine Button,*The power to protect: trade, health and uncertainty in the WTO,* Hart Publishing (2004), p. 100.
[27] FAO/WHO framework for provision of Scientific Advice on Food Safety and Nutrition (p.5). Available at: ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf.
[28] Risk management of ANSES is only with respect to veterinary medicines (marketing authorization).
[29] Evaluation and authorisation of substances by ECHA are considered risk management measures in the context of this review.

organisational separation of the two activities with the development of different cultures and values could be argued to offer a more obvious model provided adequate governance mechanisms exist.

4.2 Governance structures

The governance structures of each organisation and its links to the parent or client organisation differ depending on the type of organisation, its role and mandate, and the rationale underlying its creation. Almost all of the organisations reviewed are governed by some form of management board. In general, these bodies are responsible for the strategic direction of the organisation and for management and budgetary oversight. They can have considerable influence on an organisation's overall programme of activities and how limited resources are allocated. In some cases, management boards also play a significant role in the selection of the experts who serve on the scientific advisory committees. Thus the relationship between an organisation's governance structure and its scientific committees can potentially have an indirect influence on the composition and thus objectivity of their scientific advisory panels.

During the establishment of EFSA, particular attention was given to ensuring that its governance structure ensured its independence from its primary "clients" – the EU institutions and the Member State food regulatory agencies and other competent authorities. EFSA's Management Board is therefore by design comprised of individuals selected for their particular expertise (almost all Management Board candidates need to go through a selection procedure prior to appointment)[30] and serving in their personal capacities. Board members also must declare interests for public scrutiny even though they are not themselves involved in the development of specific scientific opinions. EFSA is also funded exclusively through the EU budget and does not rely on private or other sources of potential interest.

In contrast, the management boards of both ECHA and EMA are comprised predominantly of representatives nominated by the Member States. In the case of both agencies, each Member State has the right to directly appoint a representative. With this model, while bringing the Member States closely into the overall management of the agencies' work, there could also be a possible degradation of independence or the perception of independence, should national interests and pressure be brought to bear.

The national organisations under review tend to have governance systems with strong links with their parent governments. However, two of the national-level food regulatory agencies formed by Member States following the BSE and other food safety crises have management structures aimed at ensuring a certain independence from their parent governments. In France, the Board of Administration for ANSES is designed to include stakeholder representation, while in Germany the BfR was set up without a management board as such; instead the organisation is governed by a president who is assisted by a vice-president and directors of the scientific departments. The UK FSA was established as a non-ministerial government department which is answerable to a Board with open meetings where all major decisions are made on the basis of public papers and open discussions.

In several national bodies, the director is appointed by the government (e.g. US FDA, BfR, HPFB), whereas for EU agencies it is usually the Board that appoints the head of the organisation (e.g. EFSA, EMA, ECHA) adding an additional level of independence to all the EU agencies studied albeit on the basis of a list of candidates provided by the Commission. As an additional requirement prior to appointment, nominated European Executive Directors have to appear before the European Parliament where an open exchange on issues raised by the Parliament also opens the appointment process up further.

Many of the organisations have advisory bodies but their roles can be quite different and even at the European level their roles and responsibilities vary. The EFSA Advisory Forum provides the primary link to the Member States' food risk assessment authorities, but notably these national representatives have no voting rights that could be used to influence e.g. a scientific opinion.

[30] Note that one member of EFSA's Management Board represents the European Commission.

ECHA's Member States Committee and the Forum for Exchange of Information and Enforcement also have an advisory function but they provide important links to national implementing bodies; moreover, the national governments are represented on ECHA's Management Board, as they are in EMA. Therefore the EFSA model places the overall power of strategic direction exclusively in the hands of the EFSA Board, not with the Member States or the European institutions.

In some organisations, advisory bodies help to ensure the impartiality of scientific expertise. For example, the Scientific Advisory Committee of ANSES takes part in the application screening for the scientific panels, reviews the disclosure of conflict on interests and gives advice on setting up scientific panels. In EFSA the Advisory Forum is consulted on the draft list of experts for the membership of the Panels and Committee although this is not legally part of the screening process.

Almost all organisations have staff which support the scientific evaluation process and provide the necessary administrative assistance, but their role in the actual development of scientific opinions varies. In some organisations, such as Germany's BfR, US FDA and Canada's HPFB, the staff provide scientific expertise in their own right, including preparing and developing opinions of their scientific advisory committees and publishing opinions also in their own right. This can include provision of comprehensive background information and briefing papers, initial drafts and final opinions.

In those organisations where staff are involved in developing opinions it may be argued that their independence is secured by the *prima facia* fact that they are public employees, employed to act in the public interest and they should have limited possibilities to have conflicts of interest, although these can still exist, e.g. through financial interests, shares, or family associations. EFSA's scientific staff provide support but with certain exceptions (pesticide peer review) do not go as far as developing draft opinions.

In conclusion, EFSA appears to be unique in its clear separation between its Management Board governance structure and the Member States and in particular the EU institutions it serves. It would appear to have the most independent governance structure of the intergovernmental bodies reviewed. For EFSA this degree of functional separation between its governance structure and its main client has enabled it to avoid the potential for direct or indirect influence over its scientific advisory processes and to gain significant credibility for its scientific advisory opinions.

5. Systems for ensuring the independence of scientific advice

As per the previous sections, all of the organisations reviewed utilise to a greater or lesser extent scientific bodies comprised of external experts for assessment of scientific information and for developing scientific opinions to advise regulatory decision-making in the sectors they cover. This section considers the systems, policies and procedures that these organisations have set in place in order to ensure independence of scientific advice.

The effort to ensure that experts serving on scientific advisory bodies are competent, objective and independent begins with the selection process. It also typically considers whether an expert has a financial or other link to a vested interest that could compromise the scientific analysis. The organisations have also developed procedures for handling conflicts of interest if and when they arise.

5.1 Selection of external experts

Procedures

Experts of scientific advisory bodies are appointed through nomination or following a selection procedure. Both ECHA and EMA use a nomination procedure led by the Member States. In the case of ECHA, each Member State is entitled to nominate candidates for the Committee on Risk Assessment and the Committee for Socio-economic Analysis. The list of nominees is then prepared by the Executive Director and published on ECHA's website. The Management Board then appoints committee members from the list, including at least one but not more than two members for each Member State that has nominated candidates. As a general rule, members of EMA's scientific committees are nominated by the Member States, after consultation with the Management Board.[31]

However, more commonly, the organisations studied select the members of their scientific advisory bodies. The selection procedure typically begins with a call for expressions of interest, either through notices in scientific journals, other publications or official journals, or through the internet, *e.g.*, by posting the expert position on the organisation's website. Applications are then reviewed by 'selection panels', usually composed of staff members of the organisation.

EFSA follows a selection procedure, as outlined above, but has introduced additional steps. An EFSA Evaluation Team (EET) is set up chaired by the Director of Risk Assessment and including the Director of Scientific Cooperation and Assistance, the heads of all relevant units in the RA Directorate, the head of the Scientific Committee and Advisory Forum Unit and a Project Coordinator representing the Human Resources Unit. EFSA's HR Unit checks the validity and eligibility of each application and reports the results to the EET, which reviews and confirms the outcome. In order to confirm that the evaluation and scoring of all eligible candidates has been carried out with consistency, three independent external evaluators review the internal evaluation procedure. A short list of the best candidates is then established. At this early stage candidates' applications will have included an initial declaration of interest which will have been considered in the evaluation of the possibility of their membership to a Panel or Committee.

In France, the Scientific Advisory Committee of ANSES is involved in the process of selecting external experts. Two members of the SAC are appointed to take part in the screening of applications by an internal selection committee. A provisional list of experts is then drawn up, taking into account any potential conflicts of interest that have been identified. The SAC then advises on the proposed composition of the panel.

[31] It is noted that special rules are applied in terms of selection of expert to the following committees: Paediatric Committee (PDCO), Committee for Advanced Therapies (CAT) and Committee for Orphan Medicinal Products (COMP).

After publishing a call for expressions of interest, Germany's BfR pulls together a selection panel comprising members of the BfR's Scientific Research Council, the chair of the Commission on Food Safety and Substances and Resources in Agriculture of the German Research Foundation; and a member of the Governing Board of the Senate of Federal Research Agency. This panel appoints members of the BfR committees on the basis of the applications received.

In some organisations the selection process is opened for scrutiny. For example, EFSA requests the Advisory Forum to comment on the preliminary list of experts before they are further scrutinised by the Board and appointments made. Canada's HPFB may consult with the public as well as with government organisations for suggestions on whom to select; the HPFB may also invite representatives of the public to the HPFB Advisory Board meeting where nominations are discussed, in order to openly share views.

Criteria for selection

Across all the organisations, a key criterion for selection is scientific excellence in the specific field of work. In addition, in order to ensure a plurality of expertise and views, most organisations reviewed have in addition established policies designed to ensure a breadth and depth of expertise across scientific fields, a diversity of professional and scientific backgrounds and geographical, gender and other types of diversity. These additional criteria are seen as valuable in ensuring full discussion and consideration of scientific issues. In particular, ANSES has the issue of breadth of scientific views as a core principle in its selection processes. In terms of independence this issue has some importance as a broader discussion is likely to consider divergent views more readily than one with similar expertise.

In addition, DG SANCO and Germany's BfR take gender parity into account in selecting experts for scientific advisory bodies. The US FDA also considers ethnic origin. Canada's HPFB considers professional standing, affiliation and interests, the skills to exercise independent judgement as well as the demonstrated ability to work in a committee environment and to keep an open mind.

Selection procedures often check not just the scientific expertise and capabilities of the candidates, but also their independence. The declaration of interest document plays a crucial role in the process of nominating experts in almost all of the organisations reviewed at the earliest screening step.

Under EFSA's system, a potential conflict of interest is taken into account in deciding whether an applicant will be further evaluated. In the case of the US NAS, experts are automatically disqualified for selection if they give notice of a conflict. On the other hand, for Canada's HPFB**,** the conflict disclosure will have an impact on the choice of nomination of the expert in a particular panel or working group and on his mission within the committee, but not serve as an automatic disqualification.[32]

5.2 Remuneration of external experts

Concern has been raised as to whether it is possible for external experts to be truly independent. While most of the organisations provide some compensation for an expert's time, in fact the fees are usually modest. This means that the external expert must rely primarily on other resources – whether those of his employer, which could be a research institute or university that receives funding from the regulated industry, or his own independent consulting. This could potentially bring other kinds of conflicts of interest.

[32] More details on this form of declaration of interests can be found under the next session.

The amount remunerated varies depending on the organisation ranging from around €770 for a chair of a meeting or a rapporteur for an opinion for each meeting attended with expenses incurred for EFSA and the Commission, with slightly less for some other organisations.

It is worth noting here that both Germany's BfR and Canada's HPFB have opted to rely primarily on their own expert employees for scientific opinions, with external experts having only limited involvement in the scientific opinion making process. Because the internal experts are on a salaried basis, the risk of a conflict of interest arising could be considered lower and with a possible higher assumption of independence of view.

In these circumstances, however, the organisations need to ensure that their staff are also aware of the need for independence and are acting in the public interest. EFSA's Board and Executive Director have to make declarations of interest and EFSA has chosen to extend this requirement to its professional grade staff. EU organisations are required to have Guides to Good Administrative Practice which emphasises the need to act in the public interest. EFSA has such a guide in place but compared to those of other EU Agencies (e.g. ECHA) this could be developed further.

5.3 Policies aimed at ensuring independence

Most of the institutions that carry out scientific assessments or provide scientific advice have adopted conflict of interest and disclosure policies in order to assure the integrity of, and public confidence in, scientific advice. In addition, to ensure the active involvement of experts, a declaration of commitment is often required.

Declarations of commitment and confidentiality

In order to ensure that scientific committee members act independently of any external influence, some organisations, such as EFSA, ECHA and DG SANCO, require scientific committee members not only to sign declarations of interest but also declarations of commitment stating that they act in the public interest, that they will not delegate their duty, directly or indirectly, to other persons, and will not allow themselves to be influenced in any way in the execution of their duties. For example, EFSA requires the members of its Scientific Committee, Scientific Panels and Working Groups to make declarations of commitment annually in writing. Through signing declarations of confidentiality experts are equally expected to ensure that discussions within scientific committee panels or working groups are not divulged to third parties. Members of DG SANCO's and EFSA's scientific committees also need to make declarations of confidentiality and commitment, including that they undertake to attend meetings regularly.

Declarations of interests

In the organisations studied, declaration of interest requirements are a key tool used to ensure the independence of experts. These declarations can be classified into four main types: (1) initial declarations of interests, (2) annual declarations of interests, (3) specific declarations of interests and (4) spontaneous declarations of interest. Additional forms of declaration of interests were also identified in the organisations reviewed.

An *initial declaration of interests* involves having experts complete a form during the selection process or immediately thereafter. Initial declarations of interest are often used as one of the elements for choosing specialists. For example, at ANSES experts are only appointed once disclosures of interests have been examined. Canada's HPFB and the USA's NAS also have an initial declaration of interest policy for screening purposes and experts can be rejected on the basis of their declarations. Experts selected to serve on a scientific committee are required to disclose spontaneously any change of circumstances that would be regarded as a potential conflict of interest.

In certain organisations, initial declarations of interest are not required for the selection of an expert but after the appointment of the expert. Codex and the FAO/WHO Expert Committees have opted for this practice. Experts are required to disclose any interests once appointed.

Note that initial declarations are not used in all of the organisations. BfR does not require experts to fill in a declaration of interests form during the selection process. However, experts must commit themselves to act independent of political, social and economic interests, if appointed. This practice is fact handled as a special adapted form of declaration of commitment.

Several organisations have also required declarations of interests to be regularly updated as circumstances change, on a voluntary basis or on a regular time basis. A few organisations therefore require *annual declarations of interests*: these include among others EFSA, DG SANCO and ECHA. The annual declaration can be important as the activities of external experts may change rapidly.

Several of the organisations analysed do not, however, require experts to complete an annual declaration of interests. Moreover, some of the officials and experts interviewed for the review considered this annual process to be rather onerous and warned that it could act as a possible deterrent for experts interested in joining a scientific committee.

As found in EFSA a further approach is to require a *specific declaration of interests*, to be made prior to each committee meeting. This procedure requires experts to declare that they have no interests specifically related to the work as per the meeting agenda. In some organisations, this declaration takes the form of a simple signature on the presence sheet (ANSES), in others a verbal statement and in some cases the procedure involves a declaration form. EFSA requires specific declarations of interest to be made prior to a meeting on possible interests which are linked to a specific subject at one meeting or linked to the mandate to be covered at several meetings and is without prejudice to verbal declarations to be made at the beginning of each meeting. Specific declarations of interest are those relevant but not currently covered in the experts Annual Declaration of Interest.

In some organisations, a specific declaration is not required at all meetings: for example, at Canada's HPFB it is up to the chair of the committee to decide whether experts will be required to make a verbal statement related to their affiliation and any potential conflict of interest at the beginning of the meeting.

The next approach, a *spontaneous declaration of interests*, is a requirement that experts declare any potential conflict when it becomes apparent. This practice relies on the relationship of trust between the organisation and the expert. Several organisations studied, including EMA and BfR[33], have included this requirement in their conflict of interest policy. This form of declaration of interests can be seen as a flexibility mechanism, as experts are not limited to declaring only certain interests and are required to declare potential conflicts of interests at any time they occur.

A few organisations have elaborated unique forms of declaration of interests. In the case of Codex, a conflict of interest exists not only when a given interest can prejudice the independence of expert, but also when on the basis of these interests others can question the expert's or the committee's independence. This form of declaration of interest is considered an '*apparent declaration of interests*'.

The US NAS has set up a so-called "alternate conflict of interest" procedure in relation to specific activities, such as review of applications for fellowships or grants. The interests of selection committee members are reviewed in relation to the committee's specific activities. Through this

[33] It is noted that BfR does not use the terminology 'spontaneous' declaration of interests. However, it differentiates between interests that are required to be declared relating to the committee meetings in written form at the start of their term and those which are asked at the beginning of each meeting orally.

procedure NAS ensures that committee members with conflicts are excluded from the deliberation of awards.

Definition of interests

A comprehensive definition of what might constitute a conflict of interest can be an indication of an organisation's determination to prevent situations of compromise. However, it is difficult for a definition to cover all potential conflicts, and therefore some flexibility in the definition can be useful. Requiring the experts to declare any interest which could significantly impair their objectivity is an example of a flexibility mechanism used by some of the organisations reviewed.

Interests to be disclosed by scientific experts can be classified as follow:

- According to type: interests can be financial or non-financial.
- According to its retrospective character: interests can be current or past.
- According to the impact on the individual's behaviours: interests can be direct or indirect.[34]

Experts may also be required to declare the interests of others (e.g. relatives, household members, business partners), in addition to their own.

Nearly all organisations identify *financial interests* as having potential for compromising independence. Among the reviewed organisations, only FDA limits the elements to be disclosed by experts to interests of financial nature. Note that the FDA takes into account only those financial interests exceeding a nominal value of $50,000.

Like EFSA some organisations also consider other types of interests, e.g. intellectual interests as potentially compromising the independence of scientific opinions. For example, the US National Academy of Sciences considers ideological bias and lack of objectivity as potential conflicts of interest. For the NAS, bias relates to 'views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the position or perspectives of a particular group.' Though bias could have a significant impact on an expert's positions, the NAS does not consider bias as sufficient to disqualify scientists during the selection process.

In addition to intellectual interests, the category 'other interests' also covers work or activities carried out in bodies relevant to the operating area of the organisations reviewed as well as employment and consultant work. While interests other than financial may have an important impact on the view presented by the expert, these kinds of interests or bias are more difficult to define and identify.

Most of the organisations have defined *time frames* for the declaration of interests. In certain organisations, the interest to be disclosed by scientific experts is limited to current conflicts, with no reference to the period of time to be considered. An example of this approach is that adopted by the U.S. NAS, where the obligation to declare interests does not apply to past interests that have expired, no longer exist and cannot reasonably affect current behaviour.[35]

[34] Under EMA's policy, interests can be direct or indirect, depending on their potential impact on the individual's behaviour, and may also reach to the expert's household members. Direct interests in the pharmaceutical industry include: (1) employment with the company, (2) consultancy for a company, (3) strategic advisory role for a company, (4) financial interests, (5) ownership of a patent. Indirect interests in the pharmaceutical industry are: (1) principal investigator, (2) investigator, (3) individual's institution receives a grant or other funding. All current and past (back to 5 years) financial, personal and institutional interests must be declared. EMA also has a policy on gifts and invitations.

[35] Resource used: www.nationalacademies.org/coi/bi-coi_form-2.doc.

Requirements to declare past interests recognise the possibility that conflicts may continue to be present even when the underlying financial or other link has been extinguished. Timeframes for declaring past interests vary depending on the organisation. European agencies in general require the experts to declare certain interests back to 5 years, although EMA indicates that experts also may declare interests they had over five years ago. National organisations often operate with shorter retrospective disclosure periods.

In some organisations, whether a risk is current or past has a practical implication. At EMA, if a declared interest is current, it is considered to pose a higher risk. If an interest is from five years in the past, it is not used during the evaluation of declared interests, but is considered as useful in the context of increased transparency regarding previous interests.[36]

A further element is whether the interests concerned relate specifically to the expert or also to persons close to them. Most of the organisations studied require experts also to disclose the interests that members of their close family, their business partners or their employers might have.

As an example, ANSES requires experts to declare in addition to their personal professional activities, certain activities of their close relatives. Some organisations, such as FDA or NAS, require experts also to declare other imputed interests (e.g. interests of business partners).

Two European agencies, ECHA and EMA, require the experts to declare as 'any other interests' matters relating to their household members.[37] The term 'household member' appears to be a wider category than the one in place within EFSA ("close family members").

Under WHO rules, experts in the joint FAO/WHO expert committees advising Codex are required to declare all interests of any nature, including *apparent conflicts of interest*s. This is defined as an interest that would not necessarily influence a particular expert but could result in others' questioning the expert's and the committee's objectivity or independence. This is an example of a flexibility approach to defining a conflict of interest.

Gifts, invitations and hospitality

Gifts, invitations and hospitality are a specific element of the conflict of interest policies in some organisations, as acceptance of these may give an appearance of impropriety on the part of experts (and could indeed give rise to conflicts of interest).

Such specific policies are found at the EMA and the UK FSA. At the UK FSA, Management Board members must refuse gifts and hospitality. Gifts of trivial nature over a nominal value of £10 must be registered with the Personnel and Establishments Division. At the EMA, committee members are required to seek permission from the chair or another executive before accepting gifts of a non-personal nature.

Other policies

Some organisations reviewed safeguard the independence of the scientific advisory processes through additional mechanisms. For example, the UK FSA involves lay members in the work of scientific advisory committees. The role of lay members is to ensure that decisions are evidence-based and that explanations are clear and understandable. Moreover, the UK FSA requires the members of advisory committees to respect the so-called "Nolan principles" -- that people who hold public positions should respect among others, the principles of selflessness, objectivity and honesty.

[36] http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500005211.pdf.
[37] According to the definition used by EMA, household members are the spouse, partner or child living at the same address as the individual.

Among the European agencies, ECHA, EMA and DG SANCO have established additional measures to ensure the independence and objectivity of scientific advisory processes. ECHA requires committee and working group members and other experts to refrain from accepting instructions from Member States. EMA requires scientific committee members to consider all relevant factors during the scientific advisory processes. Finally, DG SANCO scientific committee members, experts and advisors are to inform the secretariat in case of receiving information from third parties or being contacted by third parties.

5.4 Procedures for addressing conflict of interests when they arise

Management of declared conflict of interests

When conflicts of interest arise, they need to be managed in a balanced way. Overall, the organisations examined have put in place considerable systems for identifying possible conflicts of interest on the basis of a declaration of interests which is in fact a declaration of honour signed by the individual. All organisations face the difficulty of maintaining access to the top experts. If the best experts are excluded from discussions or there are only a limited number of experts, e.g. in a new/emerging field, a balance has to be found to ensure that the best experts can contribute while their influence in the final outcomes is restricted.

In terms of processes, as a general rule, declared interests are assessed by the chairpersons of the committee or by the secretariat in consultation with the chair. This practice is used by ECHA as well as by the DG SANCO scientific committees.

Both ANSES and EMA have established specialist bodies which are involved in addressing conflict of interest situations. At ANSES, the Scientific Advisory Committee is responsible for reviewing the disclosures of conflicts of interests by scientists at the nomination phase, while the Committee for Ethical Standards and Prevention of Conflicts of Interest assists ANSES to adhere to stringent ethical rules and can advise on the general rules and principles to avoid conflicts of interest. The Committee can intervene in all circumstances and all stages of collective expert assessment, from a formal request to the issuance of an ANSES opinion. Once it has finalised its investigation, the Committee sends its opinion, together with its recommendations to the petitioning body, to the Agency's Board of Directors, the Director General and to the supervising ministries.

At EMA, declared interests are first assessed by Agency staff in terms of level of risk of conflict.[38] When the outcome of the assessment is that the declared interests fall under a higher risk category (risk level II or III), all documents are sent for evaluation to a separate Declaration of Interest Assessment Group (DIAG). On the basis of the documents received and its assessment of the risk level, DIAG decides on the extent of the involvement of the person in the Agency's activities.

The measures applied by organisations, such as EMA, EFSA or DG SANCO, in case of conflict of interests depend on a variety of factors. In general, measures differ according to the nature and importance of the conflict of interests, the nature of the input required from the person, the role of the individual in the given phase and the type of the matter addressed. Usually, more stringent rules are applied to chairs and rapporteurs of the committee: in EMA and EFSA Chairs and Vice Chairs have to comply with an evaluation which puts them in the lowest risk category..

[38] According to EMA rules, a declared interest can fall into one of three risk levels: risk level III refers to having direct interests with the pharmaceutical industry, and leads to a restriction of the involvement of the expert in the Agency's activities. Risk level II refers to having indirect interests in the pharmaceutical industry; in such cases the Agency seeds to find a balance between the limited involvement of the expert and the need to work with the best scientists. Risk level I is no risk.

Typical measures applied by the organisations reviewed include the following:

- Asking the person to withdraw from the meeting,
- Asking the person to withdraw from the discussion of the point concerned,
- Limiting the person's participation (e.g., observer status only)

For example, under a recently adopted BfR policy (October 2010), the chair asks the experts on the committee if they have any potential conflicts of interest with any topics on the agenda. If a person has a conflict of interest, that person is asked to leave the room and the other committee members present decide by simple majority whether the person may participate during the discussion of the given agenda item.

Certain organisations, such as ECHA and HPFB, may terminate the contract of the person concerned. ANSES has the most stringent approach for addressing conflicts of interest in that it foresees the possibility of bringing a legal action against those experts who do not declare conflicts of interests or commit major faults related to his or her ethical obligations. The legal action could result in the imposition of a fine. Moreover, certain kinds of unethical behaviours, such as accepting advantages from a company, could even constitute criminal offences and lead to criminal sanctions, including fines or imprisonment.

Waivers

In some highly specialized fields, the pool of suitably qualified experts can be very limited. In these areas, it is often the case that experts have conflicts of interest, since they tend to act for a number of different actors at different times. In order to benefit from the expertise of these individuals, certain organisations such as EFSA, ANSES, US NAS and US FDA have included the possibility of waivers in their conflict of interest policies. At ANSES and US FDA, experts with a conflict of interest may request a waiver but will not be able to take part in the vote on the subject. Under the NAS approach, the expert concerned may still participate if a conflict of interest is recognized as "unavoidable".

A waiver policy can help to ensure that an organisation's conflict of interest rules are not overly prescriptive and rigid, which could deprive the organisation of important expertise. It is equally important, however, for the policy to avoid being overly loose, which could open the organisation to criticism.

For example, before the adoption of the current US FDA waiver policy, concerns had been expressed over an extensive use of waivers by external experts serving on scientific bodies. US FDA has now introduced a maximum number of waivers that can be granted per year.[39]

Consequences of undisclosed conflict of interests

An undisclosed conflict of interest that comes to light later on could have a significant negative impact on the credibility of an entire organisation. This is particularly true if the conflict is unearthed after a decision or recommendation has been made based at least in part on information or analysis provided by the expert in the situation of conflict of interest.

In some organisations, a decision or recommendation based on information from an expert found to have an undisclosed conflict of interest can be reviewed. EFSA and ANSES appear to have the most detailed procedures for handling cases of breach of trust by experts. Under EFSA's procedures, an investigation can be conducted and not only could the expert face dismissal from further involvement in EFSA's activities, but following the a final decision taken by the Management Board the scientific

[39] As of 2012, the Agency may issue a maximum of 75% of the waivers issued in 2007.

outputs in which that expert was involved can be reviewed by the EFSA internal auditor to find out the extent of the expert's influence on those outputs. The auditor's report is submitted to the Executive Director and the Audit Committee of EFSA.

As mentioned above, ANSES has formed a specific committee as well as specific procedures to handle conflicts of interest and the consequences could extend to dismissal of experts. Ultimately, a decision found to have been unduly influenced by the expert with a conflict could be withdrawn.[40]

Other interesting measures

In order to facilitate the understanding of rules applied to experts, the US FDA established a programme which provides employees with advice and assistance on ethic related laws and regulation. The US FDA Ethics Programme also aims to ensure that the decisions taken by employees are not prejudiced by conflict of interests or by an appearance of conflict of interests. In the European context, the use of Guides to Good Administrative Practice and the specific requirements to act in the public interest and to follow ethical practices also provides a tool for focusing staff on these matters.

[40] Article 13 of the "*Décret n°2006-672 du 8 juin 2006 relatif à la création, à la composition et au fonctionnement de commissions administratives à caractère consultatif*".

6. Transparency of scientific advisory processes

Many of the organisations studied consider the transparency of the process for selection of experts and chairs of committees as an important element to support the independence of scientific decision-making. All organisations have policies for public access to information; some also have specific measures to support public participation. Independence -- although not specifically guaranteed by openness and transparency -- can be enhanced by the ability of observers to assess the independence measures, working methods and processes of an organisation.

6.1 Participation of public and stakeholders in discussions

A significant number of organisations have provided ways to permit stakeholders, members of the public or advocacy organisation, international organisations and other interested bodies to participate in specific meetings of the organisation. In a minority of the organisations studied –including EMA, US FDA and HPFB – stakeholders can be full members of the management board and/or scientific committees and as such fully involved in the decision-making process.

Although the members of EFSA's Board do not *per se* represent any sector, at least four have their background in organisations representing consumer organisations and other interests in the food chain but all the same are appointed in their personal capacity.

Stakeholder involvement in the scientific processes varies and may be tailored by the organisation to bring clarity to discussions, to make discussions more open to the public or be aimed at opening up the process to build trust or understanding. These aspects are in some cases built into the founding regulation of the agency or have been developed as a matter of policy. All national agencies studied have developed policies to meet with and discuss their work with stakeholders, and the EU agencies have similar activities. The legal frameworks of national and European agencies also promote such engagement. For example, ECHA may invite stakeholders, or representatives of third countries and international organisations, to participate as observers in ECHA's work. .

EFSA since its inception has developed different activities to engage with stakeholders and the public through active communication as well as specific initiatives: stakeholder technical consultations on scientific matters of interest, public consultation on certain opinions, stakeholder conferences and a specific stakeholder platform. In addition, its Management Board meetings are open to the public and have been web-streamed. EFSA has also put in place activities to open its books to scrutiny.

Other organisations have also put such initiatives in place. The UK FSA Management Board and advisory committee meetings are open to the public. The FSA publishes meeting agendas in advance. Reports and papers are published as a matter of course in draft form, before issuing the final version. This transparent practice enables stakeholders and the public to transmit their comments, and gives a greater possibility that alternative viewpoints will be taken into account.

Similar to EFSA's stakeholder platform, other agencies have developed formal meeting possibilities for participation and engagement: e.g., at EMA as well as the FSA in the UK.

6.2 Publication of committee members' names & declaration of interests

The publication of data related to committee members varies by institution. Some organisations publish full information related to the composition of committees and their members, minutes of advisory body meetings, records of proceedings and final reports, while others carry out minimal disclosure of data.

Regarding committee members, the most common approach consists of publishing their names together with a summary of their affiliations on the organisation website.

ECHA, FSA and DG SANCO are among those organisations which publish the annual declaration of interests of experts on their websites. EFSA posts the annual declaration of interests on the web. The minutes of its meetings will outline any conflicts of interests and the actions taken as a result of the conflicts identified in the annual declarations of interest or specific declarations of interest. EMA until recently has not published these but with the revision of its "*Policy on the handling of conflicts of interests of Scientific Committee members and experts* "this has been changed to allow for greater scrutiny.[41]

Some organisations take an opposite approach: for the NAS, all information related to conflicts is treated confidentially and declarations of interest are not published.

More limited approaches to publication are also in existence at the HPFB and the WHO. HPFB only publishes information contained in the declaration of interest form if the committee member gives his or her permission. In the case of the WHO, declarations of interests will only be made public if the expert's or the committee's objectivity is questioned.

As discussed above, the US FDA's extensive use of waivers for experts has been widely criticized. To ensure an improved practice in respect of waivers and transparency of expert selection, the US Congress has imposed on the FDA an obligation to publish all waivers delivered to experts in situations of conflict of interests[42] on the organisation's website during a period of at least 15 days before the meeting date.

Related to transparency is the practice of the UK FSA of organising a listing of committee members' outside interests into a publicly available register. Not only does this provide a way to track the interests of committee members, but it also enables the public to easily look up the declared interests of all committee members.

6.3 Publication of committee reports and minority opinions

To ensure a greater transparency of the discussions among experts on scientific committees, it is important to note where contradictory opinions have been aired, debated and dealt with. In the course of the adoption of scientific advisory opinions, whether taken by consensus or by formal vote, some experts may take minority positions.

In several organisations, including Codex expert Committees, HPFB and EMA, scientific opinions should be adopted by consensus. If such consensus cannot be attained, the opinion consists of the position of the majority, with divergent positions noted, along with an explanation of the grounds on which they are based. In these cases, minority opinions have to be recorded along with the explanations of these opinions in the final report.

Organisations also vary in terms of recording and highlighting dissenting opinions. ECHA and DG SANCO publish all regulatory, scientific and technical information, including majority and minority opinions, draft agendas and minutes of meetings. ANSES, EFSA and HPFB publish or record minority opinions.

In some organisations, minority opinions are recorded in the meeting minutes. As an example, at US FDA scientific opinions are often adopted by voting. Following the voting, the chair can provide the members with the opportunity to explain the reasons for their vote. These opinions are included in the meeting minutes. At WHO, minority opinions are recorded and included in the report. However, the reports and

[41] Policy 00/44 (14.10.2010)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

[42] The US Congress in October 2005 has passed an amendment to the FDA Appropriation bill. In *Ensuring Independence and Objectivity at the National Academies*, Center for Science in the Public Interest, 2006.

preparatory documents will be made available to public consultation only if the Director General has decided to make them available to the public.

7. Conclusions

This review of ten peer organizations compares their governance structures and policies on independence scientific advice and transparency to those of EFSA. These organisations, like EFSA, face the challenge of achieving high standards of scientific expertise while at the same time ensuring the independence of experts engaged in scientific decision-making. They have also put in place mechanisms to provide transparency in decision-making.

The most commonly used technique is to require experts to complete declarations of interest before or after being appointed to a scientific committee. This approach requires experts to consider the various aspects of their lives that could interfere with scientific objectivity. The process relies on trust. While nothing excludes the possibility of a false declaration, this concern is mitigated to some extent by the impact a fraudulent declaration would have on an expert's reputation and ability to exercise his or her profession on an ongoing basis.

The organizations studied vary significantly in terms of how they define and handle conflicts of interest when they arise. In some organisations, disclosure of potential conflict of interest is part of the process of selecting experts to serve on scientific committees, while in other organisations experts are not asked to fill out disclosure forms until they have been appointed.

Because of their varied and multifaceted nature, conflicting interests and their link to an organization are often quite difficult to detect. Direct financial interests are generally accepted as important for experts and other members of the studied institutions to disclose. But difficulties arise where the definition of interest is limited to financial matters, given that many different kinds of relationships may cause an individual to be non-partial, or at least appear to be non-partial. The definition of conflicts of interest needs to be as precise as possible but also broad enough to include ideological or intellectual and political interests, in addition to financial interests.[43]

Some academics have argued that completely eliminating conflicts of interests may be impossible.[44] While their debate may be theoretical, organisations seeking scientific advice face a challenge when only a few highly specialized scientists have the necessary expertise on a given topic: in such a case, the probability is greater that they may have links to industrial groups or other stakeholders that could be affected by the decision. In this case, a strict policy on conflict of interest could significantly limit the number of experts who could be nominated and the expertise available to the scientific committee.

EFSA has a well-established and well-documented policy on conflict of interest and disclosure. It has put into place a robust system for the declaration of interests including initial declarations of interest during the selection procedure, annual declarations of interests after experts are appointed, and specific declaration of conflict of interest forms before each committee meeting. EFSA has also aimed to build a balanced committee of experts who demonstrate scientific excellence but also by selecting a experts with complementary experiences and perspectives, and representing a broad geographical base. It publishes the lists of experts selected, along with their curricula vitae and their declarations of interest. In addition, EFSA has established policies aimed at providing some teeth to instances where non-declared conflicts of interest emerge at a later date including the possible dismissal of the expert from further involvement in EFSA's

[43] Didier Tabuteau, *L'expert et les politiques de santé publique*. Available at http://www.has-sante.fr/portail/upload/docs/application/pdf/2009-12/p1_article_dtabuteau_sept09.pdf .

[44] According to Catherine de Angelis, "A complete independence does not exist, we all have conflicts of interests whether moral, financial, intellectual or political." *Rencontres HAS 2009, "Indépendance de l'expertise : vers une approche internationale?*" Available at http://www.has-sante.fr/portail/jcms/c_867971/rencontres-has-2009-independance-de-lexpertise-vers-une-approche-internationale.

work and a review and report to the audit committee and Executive Director by the internal auditor of the extent to which that expert influenced the scientific outputs with which he or she was involved.

In sum, EFSA, with its wide definition of conflict of interests, a good system of management of conflicts, sound procedures for the declaration of interests, a transparent system and the involvement of stakeholders and other affected organisation, seems to have one of the most advanced and robust systems in place towards ensuring independence of scientific expertise.

Nonetheless, among the other organisations reviewed, a few best practices have been identified that EFSA might consider in its efforts towards continuous improvement of its system to ensure the independence of its scientific advice. These practices have provided the institutions using them with a certain flexibility and visibility, e.g., with stakeholders, and are discussed below:

More comprehensive definition of conflict of interest. EFSA has a solid definition of conflict of interest that goes beyond strictly financial interests and includes intellectual and other interests. It could consider however adding to this the definition used by WHO which includes anything that could call into question the expert's or committee's independence.

Positive obligation to inform of any matter that could undermine independence. Experts serving on one of DG SANCO's scientific committees are under a positive obligation to inform the chair of any matter that could undermine the independence of the committee's work. This is a very broad-ranging obligation to volunteer any information which should be considered to give rise to a potential conflict of interest.

Differentiated categories of acceptable risk of conflict of interest. The EMA has an established system of differentiated conflict of interest disclosure rules according to an expert's level of responsibility within the committee or organisation. EFSA has a similar system but may wish to consider if there are further lessons to be learned from EMA's experience in this regard.

Special dedicated committees to advise on issues related to conflicts of interest. Both EMA and ANSES have established groups (internal in EMA, the so-called DIAG) or bodies *(Comitè de Deontologie et de prévention des conflits d'intérêt* [45]) to provide support when confronted with ethical issues or conflicts of interest. For example, the group established by EMA assesses whether the involvement of experts found to have conflicts of interest has a significant enough extent to warrant action. ANSES has set up a body that advises the organisation on ethical questions such as conflicts of interests. The French committee (which was being constituted at the time the report was written) is expected to group high-level personalities well recognized nationally in their area of expertise and independent from the Agency who should investigate the nature and extent of the conflict of interest of experts.

This kind of support structure is potentially useful for the organizations in providing specialist analysis of highly technical ethical questions, to assist in assessments of declarations of interest especially in case sensitive subjects and to advise on the management of all conflict of interest related matters. EFSA may wish to formalize an internal group composed both by legal and senior scientific staff tasked to evaluate the potential and real interests of experts. Moreover, based on the French experience, this internal committee could report to an ad-hoc group of external "wise men" who have experience in assessing the borderline of conflicts of interest. Hence, EFSA may wish to consider combining the two functions of these internal and external committees and therefore rely also on this latter authoritative committee for the management of critical conflicts of interest.

Focus on scientific work carried out by own staff members. Germany's BfR and Canada's HPFB have both opted to rely primarily on their own expert employees for scientific opinions, with external experts having only limited involvement in the development and adoption process. Because the internal experts are on a salaried basis, there is a lower risk of a conflict of interest arising and a higher assumption of independence.

[45] http://www.anses.fr/index.htm.

This mixture of employee experts and more limited use of external experts can help to balance the risk of conflicts of interests on the part of external experts and reinforce scientific credibility. Where EFSA staff are involved in matters which may affect the consideration of a scientific issue, EFSA may wish to consider expanding the existing requirements for staff Annual Declarations of Interest, and re-examining the comprehensiveness of the existing code of administrative practice for EFSA staff including whether these are sufficient in relation to ethical issues.[46]

More input from the public on potential conflicts of interest. The UK FSA has organised a listing of committee members' outside interests into a publicly available register. Not only does this provide a way to track the interests of committee members, but it also enables the public to easily look up the declared interests of all committee members. Another related best practice is that used by the USA's NAS of posting the members of a committee on-line and inviting the public to comment before the first meeting takes place.

Consequences if a conflict of interest is found. As noted above, EFSA is one of the few organisations with a policy laying out the potential consequences if a conflict of interest comes to light. As in the UK FSA, EFSA retains the ability to allow for experts in such cases where they clearly have a conflict of interest to present their knowledge in a hearing, in order for the committee to benefit from his or her expertise without having the same rights on the issue as a member. EFSA also has a waiver policy for utilising experts who have such specific expertise, including the use of the so called 'hearing experts' to bring important information to a discussion. However, EFSA could be clearer about the role of such experts and the limits of their involvement.

In addition to these best practices, two other elements – shortening of the retrospective period and more opportunities for stakeholder participation – were considered useful to bring to EFSA's attention.

Shortening of the retrospective period. One issue which came up during the interviews was whether EFSA's system of declaration of interests may be too demanding. One aspect mentioned in particular was the fact that EFSA requires a 5-year period retrospectively for declaring an expert's interests. It was noted that this 5 year retrospective period could be overly limiting in terms of reducing the pool of experts and not necessary as a practical matter to capture those relationships which could truly create conflicts, and that a 3 year period might be more appropriate. It should be noted that EMA places less weight on interests which occurred in the distant past compared to those which are more up to date.

Increased opportunities for stakeholder involvement. Several of the organisations studied, including UK-FSA, EMA and the Codex Alimentarius, have provided for increased involvement of stakeholders and other interested parties, such as advocate organizations, in certain processes such as the possibility to participate in meetings as observers or to provide comments to draft reports. This has been criticised by some as having the unwanted effect of making it difficult for members of scientific committees to air any differences of opinion openly and therefore serve to limit scientific debate. However, it also increases the transparency of reasoning behind the conclusions reached and can lead to greater visibility with stakeholders.

[46] EMA guidance on Confidentiality and Discretion (2005) – Annex 2 of the in EMA Code of Conduct available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf.
ECHA Code of good administrative behaviour for the staff of the European Chemicals Agency in their relation with the public. http://echa.europa.eu/doc/ECHADocuments/Code_of_Good_Administrative_Behaviour.pdf

References

Bekelman JE (2003) *Scope and impact of financial conflicts of interest in biomedical research*. JAMA 2003 ; 289 : 454-65.

Borras Susana, Koutalakis, Charalampkos and Wendler, Frnak (2007) *European Agencies and input legitimacy EFSA, EMA and EPO in the post-delegation phase* Journal of European Integration, volume 29, nr.5. www.cbs.dk/.../European%20agencies%20and%20input%20legitimacy.pdf

Carré. P., (2004) *Les conflits d'intérêt, ce qui qui compte, c'est la transparence*. 2004 http://www.splf.org/rmr/accesLibre/RMR2004_21_1073carre.pdf

Centre for analysis of risk and regulation: *Institutional Polymorphisms: The Designing of the European Food Safety Authority with regard to the European Medicines Agency* http://www.lse.ac.uk/collections/CARR/pdf/DPs/Disspaper50.pdf

Center for Science in the Public Interest (2006) *In Ensuring Independence and Objectivity at the National Academies.*

Charles W. Schmidt, *Research issue: A question of balance*. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1665430/

Fischer Robert (2008) *European Governance still technocratic? New modes of Governance for Food Safety regulation in the European Union European Integration.* Online Papers (EIoP) Vol.12 (2008) http://eiop.or.at/eiop/index.php/eiop/article/view/2008_006a/85

Gilardi Fabrizio and Maggetti Martino, *The independence of regulatory authorities* http://www.fabriziogilardi.org/wip_files/gilardi_maggetti_handbook.pdf

Goozner Merrill (2004) *Unrevealed: non-disclosure of conflict of interest in four leading medical and scientific journals*, http://www.cspinet.org/new/pdf/unrevealed_final.pdf

Inventing a better future: Science, technology, and society http://www.interacademycouncil.net/Object.File/Master/6/736/Chapter%202.pdf

Krapohl Sebastien, *Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstaff* http://www.essex.ac.uk/ecpr/events/jointsessions/paperarchive/edinburgh/ws15/Krapohl.pdf

OECD, *Recommendation of the Council on guidelines for managing conflict of Interest in the public service* http://www.oecd.org/dataoecd/13/22/2957360.pdf

Rencontres HAS (2009), *"Indépendance de l'expertise : vers une approche internationale?"* http://www.has-sante.fr/portail/jcms/c_867971/rencontres-has-2009-independance-de-lexpertise-vers-une-approche-internationale

Scientific Advice to Public Policy-Making http://www.feem.it/Feem/Pub/Publications/WPapers/default.htm; also at http://ssrn.com/abstract=593662

Union of Concerned Scientists: *Ensuring the independence of Scientific Advisory Committees* http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/scientific-advisory-committees.html

Tabuteau Didier (2009) *L'expert et les politiques de santé publique*. http://www.has-sante.fr/portail/upload/docs/application/pdf/2009-12/p1_article_dtabuteau_sept09.pdf

White Paper on Governance: Report of the Working Group *'Democratizing expertise and establishing scientific reference systems',* http://ec.europa.eu/governance/areas/group2/report_en.pdf