COUNCIL OF THE EUROPEAN UNION

Brussels, 22 October 2012

15096/1/12 REV 1

FIN 769
GAF 21
AG 4
INST 595

COVER NOTE

from:	Mr Vítor CALDEIRA, President of the European Court of Auditors
date of receipt:	15 October 2012
to:	Mrs Erato KOZAKOU-MARCOULLIS, President of the Council of the European Union
Subject:	Special report No 15/2012: Management of conflict of interest in selected EU Agencies

Sir,

I enclose a copy of special report No 15/2012 entitled "Management of conflict of interest in selected EU Agencies" together with the Commission's and the Agencies' replies.

The special report was adopted by the Court at its meeting on 5 September 2012 and is accompanied by the replies from the Commission and the Agencies, which were notified of the preliminary findings on 7 June 2012.

(Complimentary close).

(s.) Vítor CALDEIRA

Encl.: Special report No 15/2012: Management of conflict of interest in selected EU Agencies[1]

[1] In English only. The other languages of this report are available on the European Court of Auditor's website: http://eca.europa.eu/.

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Special Report No 15/2012

(pursuant to Article 287(4), second subparagraph, TFEU)

Management of conflict of interest in selected EU Agencies

together with the Commission's and the selected Agencies' replies

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GLOSSARY

Accreditation activities (EASA)	Accreditation represents the process through which EASA evaluates the National Aviation Authorities or qualified entities, who applied for allocation of certain certification tasks to be conducted on Agency behalf to authorise this allocation.
Advisory Board (EASA)	The Management Board shall establish an Advisory Board, which it shall consult prior to making decisions in certain specific areas. The Management Board shall not be bound by the opinion of the Advisory Body in its work (see Article 33(4) of EASA Basic Regulation). It comprises organisations representing aviation personnel, manufacturers, commercial and general aviation operators, maintenance industry, training organisations and air sports. In total, the Advisory Board comprises 26 members and an equivalent number of alternate members.
ADoI	Annual Declaration of Interest
Board of Appeal (EASA and ECHA)	The Board of Appeal is responsible for deciding on appeals lodged against decisions of the Agency. The Board of Appeal consists of a Chairman and two members and an equivalent number of alternate members.
Certification activities (EASA)	EASA certification of all aeronautical products, parts and appliances designed, maintained or used by persons under the regulatory oversight of EU Member States.
Conflict of interest (actual)	"*… a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests which could improperly influence the performance of their official duties and responsibilities*"[2].
Conflict of interest (apparent)	"… an *apparent* conflict of interest can be said to exist where it *appears* that a public official's private interests could improperly influence the performance of their duties *but this is not in fact the case*"[3].
Conflict of interest (potential)	"A *potential* conflict arises where a public official has private interests which are such that a conflict of interest would arise if the official were to become involved in relevant (i.e. conflicting) official responsibilities in the future"[4].
DoI	Declaration of interests
EASA	European Aviation Safety Agency
EC	European Commission
ECHA	European Chemicals Agency

[2] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, OECD, Paris, 2003, p. 24.

[3] See footnote 1.

[4] See footnote 1.

EFSA	European Food Safety Agency
EMA (previously EMEA)	European Medicines Agency
NA	National Authority
OECD	Organisation for Economic Co-operation and Development
(Co)rapporteur	Member of the scientific body appointed to (co)lead work and coordination of the specific task (e.g. evaluation of a medicinal product, scientific advice on a specific-product or on general maters, such as: guidelines, data collection, etc).
REACH Regulation	REACH is the European Union Regulation on chemicals and their safe use (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. The aim of REACH is to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the innovation and competitiveness of the EU chemical industry.
Rulemaking activities (EASA)	Rulemaking process refers to the production of EU legislation related to the regulation of the aviation safety and environmental compatibility.
SDoI (EFSA)	The specific declaration of interest is linked to a specific subject matter or set of subject matters (e.g. substances/ product) at a specific meeting or a specific mandate to be covered at one or several meetings.
Stakeholder Consultative Platform (EFSA)	Stakeholder Consultative Platform is composed of EU-wide organisations working in areas related to the food chain and advises EFSA on general matters related to the Agency's work programme, risk assessment methodologies, etc.
Standardisation activities (EASA)	Standardisation activities refer to the inspections carried out by EASA in the national aviation authorities for ensuring that the EU aviation safety legislation is properly, uniformly and consistently applied.

EXECUTIVE SUMMARY

I. This audit aimed at evaluating the policies and procedures for the management of conflict of interest situations for four European Agencies (hereafter "selected Agencies") making vital decisions affecting the safety and health of consumers, namely the European Aviation Safety Agency (EASA), European Chemicals Agency (ECHA), European Food Safety Agency (EFSA) and the European Medicines Agency (EMA). Policies and procedures implemented after the Court completed its audit field work (October 2011) have not been evaluated.

II. There are a number of definitions of conflict of interest situations. For the purpose of the Court's audit, the definition provided in the OECD Guidelines "Managing Conflict of Interest in the Public Service[5] is used *"…there are situations in which the private interests and affiliations of a public official create, or have the potential to create, conflict with the proper performance of his/her official duties"*.

III. Certain conflict of interest risks are embedded in the selected Agencies' structure (e.g. the same organisation is both a management representative and a supplier of services) and in the use of the research performed by the industry. Against this background it is paramount that selected Agencies have robust systems to manage a high inherent risk of conflict of interest.

IV. There is no comprehensive EU regulatory framework dedicated to conflict of interest which would ensure comparable minimum requirements on independence and transparency applicable to all EU Agencies and all key players that influence strategy, operations and decision-making. In the absence of such a regulatory framework, the OECD Guidelines in this respect, which set

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[5] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, OECD, Paris, 2003, p. 28.

an international benchmark for designing a comprehensive conflict of interest policy, have been considered as part of a reference framework for this audit.

V. The Court concluded that none of the selected Agencies adequately managed the conflict of interest situations. The shortcomings identified were, however, of varying degrees.

VI. Out of the selected Agencies, EMA and EFSA have developed the most advanced policies and procedures for declaring, assessing and managing the conflict of interest.

VII. Though ECHA has developed Agency-specific policy and procedures for management of conflict of interest, the policy and procedures for ECHA's staff and Board of Appeal have significant shortcomings.

VIII. The Court found that EASA did not have an Agency-specific conflict of interest policy and procedures. EASA does not obtain or assess the declarations of interest for staff, Management Board, Board of Appeal and experts.

IX. The Court welcomes that all the selected Agencies are continuously developing and enhancing their policies and procedures also in response to different events, outside pressure and the Court's audit.

X. The Court recommends:

(a) for EASA to develop comprehensive Agency-specific policy and procedures for managing conflict of interest;

(b) for ECHA to implement appropriately policy and procedures for staff and Board of Appeal Members;

(c) for the selected Agencies to improve their conflict of interest policies and procedures by:

(i) screening candidates for conflict of interest before their appointment;

(ii) establishing conflict of interest policies and procedures which would ensure that conflict of interest situations are managed to a comparable standard by national authorities performing outsourced tasks (EASA and EMA);

(iii) establishing clear and objective criteria for assessment of declarations of interest and applying them consistently;

(iv) introducing gifts and invitations policies and procedures for the entire Agency (EASA, ECHA and EFSA);

(v) developing clear, transparent and consistent breach of trust policies and procedures for the entire Agency;

(vi) improving the transparency of the declared interests during the meetings and in the context of scientific decision-making processes;

(vii) ensuring comprehensive and compulsory training on conflict of interest;

(viii) the selected Agencies in coordination with all the appointing bodies involved should address the post-employment issues;

(d) for the EU legislator, possibly in consultation with other EU Institutions, to consider further developing the EU regulatory framework dedicated to management of conflict of interest situations, using the OECD Guidelines and existing best practices as a reference;

(e) though this report concludes on four selected Agencies, all EU Institutions and decentralised bodies may wish to examine whether the recommendations of this report are relevant and applicable to them.

INTRODUCTION

Background

1. Conflict of interest situations can occur almost in any workplace at any time. If they are not handled correctly they can negatively affect the decision-making process, give rise to scandals and cause reputational damage. This is most evident when public bodies are concerned since it can lead to a loss of faith in their ability to operate impartially and in the best interests of society. There are a number of definitions of conflict of interest situations. For the purpose of the Court's audit, the definition provided in the OECD Guidelines "Managing Conflict of Interest in the Public Service[6]" (hereafter "OECD Guidelines") is used: *"…there are situations in which the private interests and affiliations of a public official create, or have the potential to create, conflict with the proper performance of his/her official duties".* In this context, the conflict of interest can be: actual, apparent or potential[7].

2. In recent years a number of alleged cases pertaining to conflict of interest involving certain EU Agencies have been reported in the press and have raised concerns within the European Parliament. In 2011 the European Parliament requested the Court to "undertake a comprehensive analysis of the agencies' approach to the management of situations where there are potential conflicts of interest"[8].

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[6] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* OECD, Paris, 2003, p. 28.

[7] *Managing Conflict of interest in the Public Service: OECD Guidelines and country experiences,* p. 24.

[8] Resolution of the European Parliament of 10 May 2011 on the 2009 discharge: performance, financial management and control of EU agencies (OJ L 250, 27.9.2011, p. 269).

3. The European Parliament has postponed its approval of the 2010 accounts of EMA and EFSA partly due to what it considers to be an unsatisfactory management of conflict of interest[9].

4. The Court decided to focus on four agencies (EASA, ECHA, EFSA and EMA hereafter the "selected Agencies") that have the highest exposure to impartiality risk due to their significant decision-making powers in areas of vital importance to the health and safety of consumers. Decisions taken by the selected Agencies personally affect every EU citizen:

(a) EASA has to maintain and develop a high uniform level of civil aviation safety in Europe. In view of achieving these objectives, EASA issues certification specifications for aircraft, takes decisions regarding the airworthiness and environmental certification, conducts standardisation inspections in the Member States and issues opinions and recommendations to the Commission for enhancing civil aviation safety;

(b) ECHA has an important regulatory role in implementing the EU's chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals, performs their labelling and classification and addresses chemicals of high concern;

(c) EFSA has to provide independent information on food and feed safety, thus contributing to a high level of protection of human and animal health. EFSA issues scientific opinions on food ingredients, pesticides, genetically modified organisms, etc. and promotes uniform risk-assessment methodologies for food and feed;

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[9] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0173+0+DOC+XML+V0//EN&language=EN#BKMD-70
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0175+0+DOC+XML+V0//EN&language=EN#BKMD-77

(d) EMA is responsible for the scientific evaluation and supervision of medicines developed by pharmaceutical companies for use in the European Union. In addition, EMA gives scientific advice and assistance to companies for the development of new medicines and publishes guidelines on quality, safety and efficacy requirements. It is considered as the 'hub' of a European medicines network comprising over 40 national competent authorities;

(e) In summary, the selected Agencies determine the licensing of aircraft, chemicals, food ingredients and medicines in the EU. ***Annex I*** provides an overview of each selected Agency's objectives and tasks.

5. Clearly all of the Agencies and EU Institutions and other decentralised bodies (e.g. Joint Undertakings etc.) can be exposed to the risk of conflict of interest and though the conclusions and recommendations of this report relate to the selected Agencies only, other Agencies and EU Institutions may wish to consider if they are relevant for them.

Inherent risks of conflict of interest

6. In view of the importance and the decisions taken by selected Agencies, the risks and consequences of poor management of conflict of interest situations are the greatest for them. Some conflict of interest situations relating to past, current or future interests are inevitable and do not necessarily imply improper conduct or corruption. This is often the case in a highly specialised/unique organisation where expertise is in limited supply and industry "competes" for the same experts.

7. The structure and the operations of the selected Agencies (e.g. governance, interaction with third parties, customers, suppliers, etc.) require close cooperation with national authorities and industry. This however entails inherent conflict of interest risks:

- *Management Board:* In EASA, ECHA and EMA, the Management Board is composed mainly of representatives of the national authorities or Member States. At the same time, EASA and EMA outsource part of their activities to relevant national authorities and take other decisions affecting national authorities (see ***Box 1***). In EFSA, the Members of the Management Board are selected based on their experience and scientific background. However, as foreseen in the founding regulation of EFSA, four out of the 15 EFSA Management Board Members have a background (including current involvement) in organisations representing consumers and other interests in the food industry. Furthermore, the impartiality of EFSA's work and decision-making might be jeopardised since three of these organisations represented on the Management Board are also represented in the Stakeholder Consultative Platform[10];

- *Involvement of external experts (hereafter "experts"):* In carrying out their scientific activities, ECHA, EFSA and EMA work with experts, who have extensive background in the field and may have past or present connections to the industry (such as employment, research funding, etc.). For example, some 3 800 experts are involved in EMA's activities and around 1 200 experts in EFSA's activities. In these three Agencies, the experts are members of the Scientific Committees and Panels directly involved in drafting scientific opinions which underpin vital decisions affecting the health and safety of consumers (e.g. scientific opinions regarding medicines, food, chemicals). In EASA, the experts are mainly involved in rulemaking activities, standardisation inspections in the Member States and to a lesser extent in certification tasks;

- *Partnership with stakeholders:* Given their scientific and supervisory roles, the selected Agencies work closely with industry or consumer

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[10] Stakeholder Consultative Platform is composed of EU-wide organisations working in areas related to the food chain and advises EFSA on general matters related to the Agency's work programme, risk assessment methodologies, etc.

representatives (e.g. manufacturers, operators, distributors, etc.). For example, an important risk factor is that most scientific opinions and decisions prepared by the selected Agencies also use the research carried out or financed by industry.

Box 1 - Examples of conflict of interest risks inherent to the structure of the Agency

In EMA, the Management Board, comprised mainly from representatives of National Authorities (NAs), decides the remuneration for scientific services provided to the Agency by NAs. The Court in a Specific Annual Report[11] has noted the need to introduce a system based on an NA's actual costs. Such a system has not been introduced to date and EMA's Management Board rejected the most recent proposal[12].

A tender procedure to outsource the certification tasks to qualified entities[13] was ongoing in EASA at the time of the audit. Hitherto it delegated certification tasks only to the accredited NAs on the basis of framework contracts concluded without any tendering procedures. The charges paid by EASA in respect of the assigned tasks are stipulated in framework contracts. For the same tasks, the flat rates are different among the NAs and they are not based on actual costs.

According to the legal framework of EASA, the NAs are audited by the Agency in the context of standardisation and accreditation processes, while their interests are represented at the level of the Management Board.

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[11] Paragraph 16 of the Report on the annual accounts of the European Medicines Agency for the financial year 2010, together with the Agency's reply (OJ C 366, 15.12.2011, p. 27).

[12] Reply to paragraph 16 of the Report on the annual accounts of the European Medicines Agency for the financial year 2010, together with the Agency's reply .

[13] A qualified entity is defined as "a body which may be allocated a specific certification task by, and under the control and the responsibility of, the Agency or a national aviation authority". Article 3(f) of Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (EASA's Founding Regulation) (OJ L 79, 19.3.2008, p. 1).

8. Against this background it is paramount that the selected Agencies are able to manage such inherent risks of conflict of interest.

A reference framework

9. For effective management of the conflict of interest situations, the selected Agencies need to have an adequate reference framework.

10. The regulatory framework relevant to EU institutions and decentralised bodies (hereafter "EU regulatory framework") consists of the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities (hereafter "Staff Regulations"), other EC decisions and guidelines for management of conflict of interest. A more detailed list of the reference framework dealing with conflict of interest is presented in ***Annex II.***

11. Staff Regulations contain a number of very general requirements relating to the ethical principles which should be observed by public officials[14]: independence, integrity, objectivity, impartiality and loyalty. The Commission has issued decisions[15] and guidelines for their practical implementation.

12. The Commission's Internal Control Standard No 2 "Ethical and Organisation Values" requires to have in place procedures to ensure that all staff is aware of the relevant ethical and organisational values, in particular ethical conduct, avoidance of conflict of interest, fraud prevention and reporting of irregularities.

13. In addition to the above, three of the four selected Agencies have developed their own Agency-specific conflict of interest policies and procedures (a summary of the Agencies' policies and procedures is presented in ***Annex III***).

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[14] In this context, the term 'official' has a broader meaning, encompassing permanent staff and other categories of EU servants, such as temporary staff, auxiliary staff and contract staff.

14. As far as the public sector at large is concerned there are generally accepted OECD Guidelines. In addition, OECD has also published specific guidelines regarding post-employment issues: "Post Public Employment-Good Practices for Preventing Conflict of Interest"[16].

AUDIT SCOPE AND APPROACH

Audit scope

15. The audit evaluated policies and procedures for the management of conflict of interest situations for four selected Agencies making vital decisions affecting the safety and health of consumers, namely:

- EASA provides safety certificates for civil aviation which require that its staff have a high technical knowledge which is typically gained by working in the industry or for the NA. There is a risk that agency staff with such a background is involved in taking decisions that benefit their former (and/or possibly future) employer;

- ECHA manages the REACH regulation which aims at ensuring a high level of protection of human health and the environment. It provides scientific and technical advice on chemicals which can have a major financial impact on companies operating in the sector;

- EFSA provides information on risks related to food safety. It provides scientific and technical advice on food which can have a major financial impact on companies operating in the sector;

- EMA plays a coordinating role in the authorisation and maintenance of medicinal products in the EU. It has to rely on trials conducted by

[15] For example, Administrative Notice No 85-2004/29.6.2004 Commission Decision C(2004) 1597/10 on outside activities and assignments.

[16] OECD, Paris, 2010.

organisations and companies that have vested interests in the products concerned.

16. The audit focused on key players including organisations working with the selected Agencies who have an important role in the scientific decision-making process and operational activities:

- Members of the Management Boards;
- Members of Scientific advisory Panels, committees, forums and other experts;
- Agencies' staff, in particular Directors and key scientific decision-making personnel;
- Members of Boards of Appeal (EASA, ECHA); and
- Stakeholders' organisations.

17. The audit did not cover conflict of interest situations that could arise in procurement and recruitment procedures. These procedures are subject to the annual audits of the Court.

18. The Court did not assess specific conflict of interest situations as such since this would involve an intensive examination of the circumstances of those situations as well as arbitrary judgements. The Court cannot assess the validity of the methods which selected Agencies use to assess the results of research funded by industry.

19. It should be noted that all of the selected Agencies are continuously developing and enhancing their policies and procedures also in response to different events, outside pressure and the Court's audit. Policies and procedures implemented after the Court completed its audit field work (October 2011) have not been evaluated.

Audit approach

20. The audit aimed to answer the following main audit question:

- Do the selected Agencies adequately manage conflict of interest situations?

and two specific questions:

- Are there adequate policies and procedures in place to manage conflict of interest situations?

- Have selected Agencies adequately implemented their policies and procedures on management of conflict of interest situations?

21. The Agency-specific policies and procedures drafted in the context of the specific legislative requirements applicable to each of them as well as their implementation were assessed using the regulatory framework (see ***Annex II***) relevant to EU institutions and decentralised bodies, the more comprehensive OECD Guidelines and best practices identified in the selected Agencies. In the absence of a comprehensive EU regulatory framework, the OECD Guidelines have been considered as part of a reference framework for this audit since they set an international benchmark for designing a comprehensive conflict of interest policy. OECD Guidelines were used in all cases not (or insufficiently) covered by the EU regulatory framework. The OECD Guidelines are addressed to governments and public institutions at large, aiming to help them to design and implement an efficient conflict of interest policy.

22. The audit work carried out included the following:

- Analysis of the selected Agencies' regulatory framework;

- Meetings with the selected Agencies' management, Agencies' staff and various boards (Management Board, Advisory Board, Board of Appeal);

- Analysis of a questionnaire completed by the selected Agencies;

- Desk review of selected Agencies' policies, procedures, internal guidelines, declarations of interests, minutes of the Scientific Panels/Committees' meetings, staff's personal files, etc.; and

- Examination of how selected Agencies applied their policies and procedures to the specific cases (e.g. staff, experts, Members of the Management Board), including a number of published cases pertaining to conflict of interest (non-governmental organisations, European Ombudsman, media, etc.).

23. The Court presents its observations on a chronological basis i.e. the policies and procedures are analysed for the key players as they apply to the stages of initial appointment (e.g. such as the appointment of experts to the Scientific Committee), while they are at the Agency (including training and the acceptance of gifts etc.) and when they leave (including obligations when taking up new posts that might result in a conflict of interest).

OBSERVATIONS

EU regulatory framework

24. The selected Agencies are bound by the Staff Regulations (see ***Box 2***).

Box 2 - Staff Regulations provisions regarding conflict of interest:

- an official must notify any personal interest that might impair his/her independence[17];
- mitigating measures must be taken[18];
- officials shall seek approval for engaging in outside activities and declare gainful employment of spouses[19]; and

[17] Article 11a of the Staff Regulations.

[18] Article 11a of the Staff Regulations.

[19] Article 12b and Article 13 of the Staff Regulations.

- officials continue to be bound by the duties of integrity and discretion after leaving office as regards the acceptance of certain appointments or benefits and must notify any employment entered into for two years after leaving the service[20].

25. However, the independence requirements set in the Staff Regulations and the Commission guidelines refer only to staff. Other key players involved in decision-making processes such as Members of Management Boards and experts are not covered by them.

26. Provisions on Agencies' independence and transparency requirements can be found in each selected Agency's Founding Regulation, but the extent of requirements varies considerably between the selected Agencies (see ***Annex IV***). These provisions refer to the requirements to fill in and publish annual and specific declarations of interest, to make public the agendas and the minutes of the meetings of the scientific bodies and various boards (e.g. Management Board, Board of Appeal), to publish the results of the scientific studies, etc. As shown in ***Annex IV***, the legal requirements for independence and transparency are stricter for EFSA and EMA, less stringent for ECHA (e.g. no obligation to publish the declarations of interest) and the least prescriptive for EASA (e.g. no obligation to fill in declarations of interests).

27. Hence there is no comprehensive EU regulatory framework dedicated to conflict of interest which would ensure comparable minimum requirements on independence and transparency applicable to all EU Agencies and to all key players that influence strategy, operations and decision-making. ***Annex V*** provides a comparison between the EU regulatory framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures) and the OECD Guidelines.

[20] Article 16 of the Staff Regulations.

Before working with the Agencies

Candidates are not adequately screened

28. In general, the nomination and appointment procedures in EASA, ECHA[21] and EMA do not include adequate screening of the candidates (i.e. experts, Members of the Management Board and of the Board of Appeal) in relation to conflict of interest situations. However, the members of Management Boards and a number of experts (ECHA and EMA) are nominated or appointed by Member States, national bodies or EU Institutions (i.e. Commission, Council, etc.) and the selected Agencies have no or limited influence over their appointment.

29. EFSA's appointment rules for experts foresee the screening of candidates' declarations of interest. However, the screening is not based on clearly specified criteria in cases of conflict of interest situations.

30. In most cases, it is therefore only after the candidates' appointment that a conflict of interest is identified. Furthermore, selected Agencies have no power to replace Members of the Management Board or experts in cases where their interests are assessed as incompatible with their role in the Agency (see ***Box 3***).

Box 3 – Example of a lack of screening of candidates

A member of the Scientific Committee was appointed by the Commission and the declaration of interest was evaluated by EMA only after his[22] appointment. Whilst the

[21] ECHA's policy adopted in September 2011 (MB/45/2011/D) introduced a requirement that candidates nominated to the Risk Assessment Committee (RAC) and the Committee for Socio-Economic analysis (SEAC) have to complete declarations of interests before their appointment by the Management Board.

[22] For the sake of convenience, the masculine form is employed in this report to designate persons of either gender.

evaluation showed conflicting interests which should have precluded his appointment, EMA could not dismiss him.

31. OECD Guidelines recommend screening processes as part of selection procedures to identify and deal with conflict of interest situations at an early stage[23].

Eligibility criteria for stakeholders' organisations in EMA are incomplete

32. The selected Agencies generally have adequate arrangements for engaging with stakeholders' organisations interested in their work. In order to be represented on various of the selected Agencies bodies, these organisations must meet certain eligibility criteria.

33. However, these criteria do not always set clear standards to be met. The transparency criterion in EMA requires that the sources of funding of patient and consumers organisations are disclosed annually. There are, however, no minimum standards for an acceptable financing structure thus potentially allowing patient or consumer organisations fully financed by one pharmaceutical company to participate in EMA's activities.

34. In addition, EMA did not have any eligibility criteria for healthcare professionals' organisations which can be involved in EMA's activities in the same manner as for example patient or consumer organisations.

Outsourced scientific and/or operational activities are not adequately monitored

35. Management of conflict of interest is very important when the activities of the selected Agencies are outsourced, since these activities are not under the

[23] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, p. 34.

selected Agencies' direct control. EASA and EMA outsource significant parts of their scientific and/or operational activities to NAs.

36. EASA uses framework contracts with NAs, which have to ensure that there is no conflict of interest at the level of the outsourced tasks. EASA has, however, no clear criteria and methodology to verify NAs' conflict of interest policies and procedures and their implementation. There is no evidence that EASA carries out such verification.

37. EMA's conflict of interest policies and procedures do not cover national experts working on the tasks outsourced to the NAs. EMA does not perform any verification of the conflict of interest policies and procedures of the NAs.

Working with the Agencies

Agency-specific policies and procedures are developed by EMA, ECHA and EFSA …

38. Of the selected Agencies, EMA and EFSA have developed the most advanced frameworks for declaring, assessing and managing conflict of interest dealing specifically with industry-related risks.

39. A key role in the management of conflict of interest lies with the declaration of interest where individuals disclose their personal circumstances pertinent to conflict of interest as defined by selected Agencies' policies and procedures.

40. Conflict of interest policies and procedures of ECHA, EMA and EFSA require declarations of interests (mostly annually) from staff, Members of the Management Boards, Boards of Appeal, scientific boards, panels and forums.

41. ECHA developed a conflict of interest policy soon after it was set up. A new "Policy for Managing Potential Conflicts of Interests" was adopted by ECHA's Management Board on 30 September 2011. The policy is applicable to the

entire Agency and all of its activities[24]. It introduces a more comprehensive form of the declaration of interest as well as the requirement for staff to complete them annually.

42. EMA has developed a number of clear and realistic descriptions as to what circumstances can lead to a conflict of interest. For the evaluation of experts, EMA and EFSA have defined specific criteria, such as: financial interests, employment, member of a scientific body, consultancy, research funding, intellectual property rights, close family members, gifts and invitations, etc. which could give rise to conflict of interest. Depending on the type of activities and whether they are on-going or performed in the past (last five years), the policies and procedures foresee restrictions for holding certain positions or for participation in different phases of the decision-making process. EMA has developed a clear matrix where the interests declared are linked with a set of prescriptive outcomes (see ***Annex VI***).

43. In addition to EFSA's system of annual declarations of interests, the Agency also introduced an additional layer for the experts, who are required to:

- make specific declarations of interests before each meeting of the Scientific Committee, Panels and Working Groups, and

- declare orally during the meeting any unforeseen interests concerning agenda items.

44. Specialised software for declarations of interest has been used by EFSA since May 2008 in order to ensure the traceability of the assessment process. EMA has also developed certain applications/databases for managing the process of evaluating the declarations of interest. ECHA has no such software to support management and assessment of the declarations of interest.

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[24] ECHA's new policy was not implemented at the time of the audit, and therefore the implementation of previous policy and procedures has been tested by the Court.

… but not by EASA

45. EASA, except for its Approvals and Standardisation Department, does not have an Agency-specific conflict of interest policy and procedures. Declarations of interest are not obtained or assessed by EASA on a regular basis.

Implementation of policies and procedures in ECHA has significant shortcomings

ECHA does not review interests declared before tasks are assigned to staff

46. Under ECHA's previous policy and procedures, staff members were obliged to complete a declaration at the time of their appointment[25]. The initial declarations had to be updated when changes occurred.

47. The declarations of staff members examined by the Court were kept in sealed envelopes in personal files and had not been reviewed and assessed by ECHA for conflict of interest. ECHA fully relied upon the staff's obligation to spontaneously inform superiors if they were aware of any conflict of interest, notwithstanding any previously submitted declaration. An examination of the sealed declarations of interest revealed cases that should have been addressed by management as shown in ***Box 4***.

Box 4 – Examples of sealed declarations of interest not assessed by ECHA

- One senior member of staff declared the rent of an apartment to one of the companies with a large number of applications in ECHA.
- One senior member of staff declared past employment in a large company with many applications dealt with in his unit.

[25] ECHA's new policy was not implemented at the time of the audit, and therefore implementation of previous policy and procedures has been tested by the Court. See also paragraph 41.

- One junior member of staff declared past work in projects funded by one company as well as his spouse's employment in that company with a large number of pending requests in ECHA.

Policies and procedures to assess and manage conflict of interest situations at ECHA's Board of Appeal are not adequate

48. The Board of Appeal deals with appeals from any natural or legal person affected by decisions taken by this Agency. It consists of a Chair and two other permanent members, who are ECHA's staff, as well as additional and alternate members who are not ECHA's staff. It is an independent body within ECHA and has its own code of conduct.

49. Permanent Board of Appeal Members are obliged to complete annual declarations of interest. Alternate and additional Board of Appeal Members are obliged to complete annual declarations of interest and submit specific declarations of interest before being assigned to a case.

50. The responsibility for reviewing the declarations of interest and for handling situations of conflict of interest resides with the Secretariat and the Chair. There is however no formal procedure or documentation of checks carried out at the time when the Board of Appeal starts working on a particular case and there is full reliance on the declarations from permanent Board of Appeal Members.

51. The Court found that the Board of Appeal does not possess sufficient information to make informed decisions as to whether a conflict of interest situation exists. Information is only available in respect of the appellant company, but not on all the companies which have direct interest in the case of an appeal (e.g. (co)registrant company of the chemical substance).

52. The declarations of interest of the Board of Appeal Members do not disclose the details of all substances and cases these members worked with before joining ECHA (see ***Box 5***).

Box 5 – Example of inadequate management of conflict of interest situations in ECHA's Board of Appeal

Two Members of the Board of Appeal declared ownership and/or work in the REACH regulation area[26]. However, policies and procedures do not prevent them from being assigned to cases with past or current connections to them.

Assessment and management of declared interests are not always adequate

53. According to the OECD Guidelines, organisations should provide a clear description of what circumstances and relationships can lead to a conflict of interest situation[27]. The onus for declaring the interest lies with the individual. The organisation's administrative process should simply ensure that the information disclosed is properly assessed and kept up-to-date. Clear resolution measures should be stated in the policies and procedures dealing with conflict of interest situations, for example, liquidation of the interest, restricted access to particular information, transfer of the official to a non-conflicting function, resignation from the conflicting private capacity function, etc.

Inadequate documentation of Management Board Members' conflict of interest assessment

54. In all the selected Agencies, the review of declarations of interests of Management Board Members and the decisions taken in this respect are not adequately documented.

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[26] E.g. help with registration of chemical substances, general consultancy on the REACH Regulation.

[27] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* p. 28 to 30.

Information available is not always used

55. The selected Agencies do not always make use of information provided by the persons concerned and readily available to these Agencies (CVs, previous declarations of interests, information in media, etc.) to check the declarations of interests. The audit revealed a number of cases, where a check of such information would have revealed problems (see ***Box 6***).

Box 6 - Examples of not using the information available for assessment of the declarations of interest

In EMA and EFSA, later declarations of interest of certain experts had clear inconsistencies with their previous declarations of interest. The Agencies did not always seek clarifications from the experts.

In ECHA, one employee did not declare all past employments for the last five years as is required by the policy. A simple check of declaration of interest against the CV of the employee would have revealed this.

A Member of EMA's Scientific Committee was found by EMA to be in conflict of interest situation, due to his private interests. EMA concluded that this expert cannot be a Member of the Scientific Committee. Despite this, the expert continued to participate in the meetings of the Scientific Committee and has been reappointed by the EC for a new term of three years. The updated declaration of interests of this expert no longer mentioned the interests related to the organisation concerned. This was inconsistent with the previous assessment and with the published CV.

Lack of clear assessment criteria and inconsistent application

56. In ECHA, although the policy[28] requires the declarations of all interests potentially causing a conflict, it does not specifically deal with the situations arising from current financial interests, past employment, past consultancy and

[28] Policy for Managing Potential Conflicts of Interests (MB/45/2011/D), adopted by the Management Board on 30 September 2011.

similar activities. Unlike EMA and EFSA, the interests incompatible with the individual's role in ECHA are not defined, nor are the mitigating measures for the most common risks set out. The assessment of the conflict of interest situations therefore depends on the judgement of the responsible individual.

57. Assessment criteria for the evaluation of conflict of interest for EFSA's scientific experts lack clarity which on occasions led to questionable assessments, as demonstrated in ***Box 7***.

Box 7 – Examples of questionable assessment of conflict of interest in EFSA due to lack of clarity

Conflicting roles of the scientific experts: advocates and reviewers of the same concepts

In EFSA, the majority of the members of one scientific body of this Agency have been advocates of a concept (through previous publications, participation in workshops and expert groups, etc.) which has been subject to analysis by the same scientific body.

In another case, two of EFSA experts were simultaneously providing consultancy/advice to a private organisation, while they were reviewing the same concept as members of the EFSA scientific body.

In both cases, EFSA concluded that there was no conflict of interest.

Inconsistent treatment of conflict of interest

In EFSA, the conflict of interest arising from membership of a non-profit, worldwide organisation funded primarily by the agri-alimentary industry and extensively involved in EFSA's activities has been treated differently for the Members of the Management Board and for the experts.

In the case of EFSA's Management Board, two members gave up their positions in that organisation following media criticism of conflict of interest.

There are, however, six experts with links to this organisation (e.g. Members of Board of Trustees, Members of Scientific Committees).

58. In the Court's view, out of the selected Agencies, EMA has the clearest set of assessment criteria for experts. ***Annex VI*** illustrates good practices applied in EMA for the evaluation of the most typical situations for experts and linking them to clear outcomes in terms of restrictions (if any) applied to the expert's activities in EMA. However, the Court found cases in which these criteria were not adequately applied (see ***Box 8***).

Box 8 – Examples of inadequate risk assessment for EMA's Scientific Committee Members

Two experts were wrongly assigned by EMA the lowest risk level although they were employed in the past by pharmaceutical companies whose activities should have led to a higher risk level under EMA's policy on conflict of interest. These interests should have restricted the participation in the committee's activities. The risk levels have been raised by EMA later only when new draft policies were being rolled out.

One expert was a consultant of pharmaceutical companies until August 2007. Under the new conflict of interest policy, his evaluation should have led to restrictions on product or company level in case of specific or cross-product involvement (e.g. quality control of a number of medicinal products). However, EMA did not request further information from the expert and the declaration was wrongly assessed as requiring no restrictions.

59. The OECD Guidelines recommend that any conflict of interest policy takes into account the particular risk attached to certain categories of individuals. They require that organisations identify relevant conflict of interest situations and implement measures to mitigate the related risks[29].

60. However, in some cases, selected Agencies' policies and procedures contain gaps or clear disparities between the level of actual or perceived risk of a conflict of interest and the level of restrictions imposed and measures taken to mitigate the risks (see ***Box 9***).

Box 9 - Examples of inconsistent and incomplete policies

EMA

Staff members are not allowed to have financial interests or patent ownerships but family members may. For one category of staff (e.g. Scientific Secretary to the Scientific Committee), family interests do not lead to any restrictions on the employee's involvement in the product related activities. Direct interests (e.g. current financial interest) of household members are not taken into account in determining the acceptable level of participation in the Agency's activities for the experts even if the spouse of the member of the Scientific Committee has a significant shareholding in a pharmaceutical company.

In the case of past employment in the pharmaceutical companies, the restrictions imposed on experts (e.g. Scientific Committee Members) are less strict than those imposed on staff in the same circumstances, even though the experts play a more vital role in the scientific process of the Agency.

EMA checks conflict of interest before the appointment of a product team leader/member for the initial marketing authorisation for medicines for human use or a project manager for initial marketing authorisation for veterinary medicines. However, there is no equivalent procedure for Members of a Scientific Committee when they are being appointed as (co)rapporteurs.

The restrictions imposed on experts when they or their organisation receive a grant from the pharmaceutical industry are inadequate. For example, a current beneficiary of the grant from a company would not be prevented from being a (co)rapporteur for the medicine from that company.

EFSA

EFSA requires that the interests held by the family members and relatives belonging to the same household or under the care of the members of the household have to be

[29] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* p. 28 to 29.

disclosed in the declarations of interest[30]. Contrary to EMA, its policy does not clarify which interests of the close family members are allowed and the restrictions to be applied.

Policies and procedures on gifts and invitations do not always exist and are incomplete

61. ECHA and EMA have issued guidance on gifts and invitations. For ECHA, the policies and procedures are only applicable to staff, but not to Members of Committees, Forum and Management Board. EFSA has a policy on invitations for staff only, EASA does not have an Agency-specific policy on gifts and invitations, but for its staff it refers to Commission's guidance on gifts and invitations. Under OECD Guidelines, conflict of interest policies should cover those arising from all forms of gifts[31].

Breach of trust policies and procedures do not exist or there is a lack of objective assessment criteria

62. Breach of trust policies and procedures refer to the circumstances when an individual fails, intentionally or through negligence, to fulfil his obligations of declaring in a complete and timely manner the interests which may impair his independence. Policies and procedures should clearly define the consequences of not declaring the interests and the sanctions to be applied.

63. The Staff Regulations stipulate that the institution shall take any appropriate measures if an official failed, in performance of his duties, to deal with a conflict of interest matter. However, they do not set out specific measures and sanctions to be taken or applied to officials in breach of their obligations to declare conflict of interest.

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[30] Implementing Act to the Policy on Declarations of Interest – Guidance document on Declarations of Interest (8 December 2009), in force until 21 February 2012.

[31] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* p. 33.

64. The selected Agencies do not have breach of trust policies and procedures to deal specifically with cases where staff members fail to declare all their relevant interests (e.g. family, financial interests, etc.). In addition, EMA and EASA do not have breach of trust policies and procedures for the Management Board members, experts and Board of Appeal members (applicable to EASA only).

65. ECHA introduced new general breach of trust provisions for staff, experts, members of the Management Board and Board of Appeal in their new "Policy for Managing Potential Conflicts of Interests" adopted on 30 September 2011[32].

66. EFSA has breach of trust provisions for experts of Panels/Scientific Committees in its policy on declarations of interests[33]. The failure to fulfil in a timely and complete manner the obligations of declaring the interests will be considered a "prima facie breach of trust"[34] towards the Agency resulting in appropriate action, even dismissal. The policy does not include equivalent sanctions for the Members of the Management Board, the experts of the working groups and the Agency's own staff.

67. In two cases, EFSA initiated breach of trust procedures which led to the resignation of the respective experts from the Scientific Panels. In these cases, EFSA reviewed the scientific outputs to which experts contributed. This review aimed at assessing the expert's influence and contribution to the final scientific output/decision and to determine any bias due to his conflict of interest. The procedures did not include, however, clear and objective criteria laying down

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[32] Policy for Managing Potential Conflicts of Interests (MB/45/2011/D), adopted by the Management Board on 30 September 2011.

[33] EFSA Implementing Act to the Policy on Declarations of Interest – Guidance Document on Declarations of Interest (8 December 2009), in force until 21 February 2012.

[34] Idem.

which circumstances would lead to sanctions, including the dismissal of a Member of a Panel/Scientific Committee.

68. The OECD Guidelines cite a wide variety of consequences: disciplinary actions and criminal prosecution along with cancellation of tainted decisions and contracts. Non-disclosure of conflict of interest is generally considered a serious breach, which results in a disciplinary actions or even criminal penalties in several countries[35].

Transparency of interests declared and scientific decision-making processes should be improved

69. The requirement for transparency in the decision-making process and the handling of conflict of interest is set out in the selected Agencies' founding regulations as well as in the Agency-specific (except EASA) policies and procedures for managing conflict of interest. Different legal requirements and practices exist among the selected Agencies in respect of transparency which are summarised in ***Annexes IV*** and ***VII.***

70. The OECD Guidelines define transparency as one of the core principles when dealing with conflict of interest situations[36]. It stipulates that declarations of private interests, as well as arrangements for resolving conflicts, should be clearly recorded, to enable the organisation to demonstrate that a specific conflict has been appropriately identified and managed.

Transparency of annual declarations of interests

71. EASA does not obtain any declarations of interests. The other three selected Agencies make public the annual declarations of interests of executive

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[35] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, p. 75 to 76.

[36] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, p. 16, 26 and 31.

staff (Executive Director), scientific experts (Members of the Scientific Committees, Panels, Working Groups) and Management Board Members.

Transparency of specific declarations of interests

72. All selected Agencies publish the minutes of the Management Board meetings on their websites. EFSA even broadcasts the audio recordings of the Management Board meetings. However, the minutes do not contain any information related to the assessment of conflict of interest.

73. EFSA and ECHA also publish the minutes of the meetings of the Scientific Panels and Committees on their website. The SDoIs provided for by EFSA's policy (see paragraph 43) are not made public, but brief conclusions on the assessment of conflict of interest are included in the minutes of the meetings, which are published on EFSA's website. They include the conflict of interest identified and the measures applied (e.g. observer with no voting rights, exclusion from the discussions concerning a specific topic, exclusion from the activities of the panel/working group, etc.). EASA publishes the minutes of the consultative bodies' meetings concerning rulemaking activities. However, minutes of the meetings which would include assessment of conflict of interest of the Agency's staff and experts involved in rulemaking, standardisation and certification activities are not published. EMA does not make public the minutes of the meetings of the scientific bodies which would contain the assessment of conflict of interest.

Transparency in the scientific decision-making process

74. There are different degrees of transparency across the selected Agencies as regards the scientific decision-making process. Some of these differences result from the specific fields of competency of each selected Agency, the level of confidentiality required and the internal rules and regulations.

75. EFSA's founding regulation and the internal rules on the operations of the Scientific Committee, Panels and working groups allow observers to be invited

to the experts' meetings. However, the agendas of the EFSA's working groups are not published in advance. In addition, the working groups' outputs are not published. This lack of publicity impairs the possibility of observers to follow the meetings.

76. Several shortcomings have been identified in the published minutes of the experts' meetings (ECHA, EFSA), which impair the transparency of their activities:

- published minutes do not always contain details on the agenda item or substance affected by the declared interests;

- limited disclosure of the information on the discussions and the conclusions reached in some meetings.

Training on conflict of interest needs to be strengthened

77. ECHA has two types of training that deal with the management of conflict of interest:

- the "Ethics and conduct at work" training covers general information about staff obligations in respect of conflict of interest, integrity, the policy on gifts and other issues related to the code of conduct. This training is voluntary for all staff and its attendance was limited;

- the training on "Staff declarations and guidance" contains more detailed information in respect of declarations of interest, the policy on gifts and other aspects of the conflict of interest policies and procedures. This training is compulsory but the Court was unable to ascertain levels of attendance.

78. EMA and EFSA organise training sessions on conflict of interest for newcomers (staff) and thus there is a dissemination of guidance on interests to be declared and conflict of interest.

79. EASA only provides training on ethics and related provisions of the Staff Regulations to newcomers (staff) but not on conflict of interest per se.

80. The OECD Guidelines make explicit reference to training as a means to be used to provide practical examples and concrete steps to be taken for identifying and resolving conflict of interest situations[37].

Leaving the Agencies – 'revolving doors' and 'insider information'

81. When officials or experts leave public service to work in the private sector, there is a risk that they abuse their position by taking advantage of 'insider information' acquired in the course of their public duties to benefit the private company they join. If not properly managed, these risks undermine public trust in organisations. The movement of key personnel between the public and private sector is known as the 'revolving door' phenomenon.

82. Obligations of the officials and other servants of the EU after leaving the service are laid down in the Staff Regulations. *"Officials intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform their institution thereof"*[38]. In particular circumstances, as foreseen in Article 16 of Staff Regulations, the EU institution or Agency may even forbid that engagement. It is the responsibility of individuals to provide disclosure of post-employment information. According to OECD Guidelines, such a responsibility should be clearly communicated to the individuals and reinforced in the employment arrangements[39].

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[37] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences*, p. 17.

[38] Article 16 of the Staff Regulations of Officials of the European Communities and Articles 11, 54 and 81 of the Conditions of employment of other servants of the European Communities.

[39] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* p. 29 and 30.

83. Furthermore, the OECD published specific guidelines related to post-employment issues, remedies and benchmarks[40]. According to these guidelines, major post-employment conflict of interest arise when the public officials:

- seek future employment outside the public service;
- are involved in lobbying public institutions;
- switch sides in the same process; and
- use 'insider information'.

84. The OECD Guidelines emphasise the fact that negotiations for future employment by a public official prior to leaving the office is widely regarded as a conflict of interest situation[41].

85. The experts, the Members of the Management Board and external Members of the Board of Appeal are not bound by the Staff Regulations, so the post-employment provisions are not applicable to them and there are legal limitations for enforcement of such post-employment obligations upon them. The selected Agencies' policies and procedures for management of conflict of interest do not foresee any obligations and restrictions regarding their post-employment.

86. Provisions on post-employment are included in the implementing rules of Staff Regulations on outside activities, adopted by the selected Agencies and are similar with those of the Commission. In addition, EFSA issued Agency-specific implementing rules regarding post-employment at the end of 2010.

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[40] *Post-Public Employment – Good Practices for preventing Conflict of Interest*.

[41] *Managing Conflict of Interest in the Public Service: OECD Guidelines and country experiences,* p. 24.

87. The selected Agencies require their employees to fill-in an application for authorisation to engage in an occupation after leaving the Agency. However, there are no rules and criteria on how these applications should be assessed and which post-employment activities would be considered incompatible with their previous role in the respective Agency.

88. In general, the selected Agencies failed to perform a thorough assessment of post-employment cases, in order to anticipate and prevent 'revolving doors' type of conflict of interest situations. An example of shortcomings is shown in ***Box 10***.

Box 10 - Example of shortcomings related to assessment of post-employment activities.

In EFSA, a 'revolving doors' case which arose in 2008 was investigated by the European Ombudsman[42], who stated in his draft recommendations that:

(a) EFSA should make clear that negotiations themselves by leaving staff members concerning future jobs of the 'revolving doors' type may amount to a conflict of interest. In this regard, it concluded that such negotiations already may lead to a conflict of interest.

(b) EFSA failed to observe the relevant procedural rules and to carry out a sufficiently thorough assessment of the conflict of interest arising from the move of an employee to a company acting in EFSA's field of competency.

CONCLUSIONS AND RECOMMENDATIONS

89. The Court concluded that none of the selected Agencies adequately managed the conflict of interest situations. A number of shortcomings of

[42] Draft recommendations of the European Ombudsman in his inquiry into complaint 775/2010/ANA against the European Food Safety Agency, as published on the European Ombudsman's website, 7 December 2011.

varying degrees have been identified in Agency-specific policies and procedures as well as their implementation (see the ***Table***).

Table – Overview of selected Agencies' management of conflict of interest situations[1]

	Experts	Staff	Management Board	Board of Appeal
EASA				
ECHA				
EFSA				N/A
EMA				N/A

Key	
Management of conflict of interest situations is not adequate, as the Agency-specific policies and procedures are absent	
Management of conflict of interest situations is not adequate, as the Agency-specific policies and procedures and/or implementation have significant shortcomings	
Management of conflict of interest situations is not adequate, as the Agency-specific policies and procedures and/or implementation have shortcomings	
Management of conflict of interest situations is adequate	
Not applicable, as this Agency does not have a Board of Appeal	N/A

[1] See paragraphs 15 to 23 (Audit Scope and Approach).

90. Out of the selected Agencies, EMA and EFSA developed the most advanced policies and procedures for managing conflict of interest. ECHA's policies and procedures are incomplete and less precise, EASA does not have any.

Recommendation 1

EASA should create comprehensive Agency-specific policies and procedures on the management of conflict of interest. ECHA should improve its policy by introducing clear assessment and evaluation criteria of declared interests. All selected Agencies should (establish or) continue developing conflict of interest policies and procedures that effectively address their specific risks.

91. The selected Agencies lack adequate policies and procedures to identify a conflict of interest before a candidate (i.e. experts, members of the Management Board and of the Board of Appeal) is appointed.

Recommendation 2

Candidates in the selected Agencies should be screened for conflict of interest before their appointment. Mitigating measures should be put in place if a decision is taken to appoint them knowing that there is a conflict of interest situation.

92. Conflict of interest related to tasks outsourced by EASA and EMA is outside of their direct control and not adequately monitored.

Recommendation 3

EASA and EMA should establish policies and procedures which would ensure that conflict of interest situations are managed to a comparable standard by those performing outsourced tasks.

93. The management of conflict of interest whilst working with a selected Agency requires a number of different measures, with the declarations of interest having a key role. There are shortcomings in the assessment of these declarations and management of conflict of interest situations across all of the selected Agencies, notably a lack of clear assessment criteria and/or their inconsistent application. The implementation of ECHA's policies and procedures for staff and the Board of Appeal have significant shortcomings.

Recommendation 4

The selected Agencies should establish clear and objective criteria for the assessment of declarations of interest and apply them consistently using all the information easily available to the selected Agencies. Furthermore, ECHA should significantly improve the implementation of conflict of interest policies and procedures for staff and the Board of Appeal Members.

94. Out of the selected Agencies, only EMA has a policy on gifts and invitations that applies to the entire Agency.

Recommendation 5

EASA, ECHA and EFSA should have gifts and invitations policies and procedures that cover the entire Agency.

95. The selected Agencies do not have adequate breach of trust policies and procedures applicable to the entire Agency.

Recommendation 6

The selected Agencies should develop clear, transparent and consistent breach of trust policies and procedures that cover the entire Agency.

96. The issue of transparency with respect to the publication of annual declarations of interests is properly dealt with by all selected Agencies, except EASA. However, the selected Agencies are less transparent in terms of the publication of interests declared during the meetings of the Management Board and scientific bodies and in the context of the scientific decision-making process.

Recommendation 7

The selected Agencies should fully disclose interests declared during meetings and in the context of scientific decision-making process. EASA should put in

place a system of declarations of interest and ensure transparency by publishing them on its website.

97. Training on conflict of interest is provided by all selected Agencies, but in ECHA and EASA shortcomings of varying importance were found.

Recommendation 8

The selected Agencies should have comprehensive and compulsory training on conflict of interest. In particular, EASA should put in place specialised training on conflict of interest for all parties concerned (e.g. staff, Members of the Management of Board and Members of Board of Appeal).

98. The Court's audit identified a number of significant shortcomings in the selected Agencies' policies and procedures regarding post-employment:

(a) Lack of provisions that address risks associated with post-employment activities of experts and Members of the Management Board and the Board of Appeal;

(b) Absence of objective criteria as to what situations constitute conflict of interest;

(c) Negotiations for future employment are not covered by current policies and procedures of selected Agencies.

Recommendation 9

The selected Agencies in coordination with all the appointing bodies involved should address the post-employment issues.

99. There is no comprehensive EU regulatory framework dedicated to conflict of interest which would ensure comparable minimum requirements on independence and transparency applicable to all EU Agencies and to all key players that influence strategy, operations and decision-making.

Recommendations 10 and 11

The EU legislator, possibly in consultation with other EU Institutions, may wish to consider further developing the EU regulatory framework dedicated to management of conflict of interest situations, using the OECD Guidelines and existing best practices as a reference.

All EU Institutions and decentralised bodies may wish to examine whether the recommendations made to the selected Agencies are relevant and applicable to them.

This Report was adopted by Chamber IV, headed by Mr Louis GALEA, Member of the Court of Auditors, in Luxembourg at its meeting of 5 September 2012.

For the Court of Auditors

Vítor Manuel da SILVA CALDEIRA
President

Annex I

STRUCTURE AND GOVERNANCE OF THE SELECTED AGENCIES

	European Chemicals Agency (Helsinki)	**European Aviation Safety Agency (Cologne)**	**European Medicines Agency (London)**	**European Food Safety Authority (Parma)**
	ECHA	**EASA**	**EMA**	**EFSA**
Legal Base (Founding Regulation)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency	Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency	Regulation (EC) No 726/2004 OF THE European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Objectives	To ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards relating to substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. To ensure that chemicals legislation and the decision making processes and scientific basis underlying it have credibility with all stakeholders and the public. To coordinate communication concerning the REACH Regulation and in its implementation.	To maintain a high uniform level of civil aviation safety in Europe and to ensure the proper functioning and development of civil aviation safety.	To coordinate the scientific resources that the Member States' authorities make available to the Agency for the authorisation and supervision of medicinal products for human and veterinary use. To provide the Member States and the institutions of the European Union with scientific advice on medicinal products for human or veterinary use.	To provide scientific opinions and scientific and technical support for legislation and policies which have a direct or indirect impact on food and food safety. To provide independent information on risks relating to food safety. To contribute to the achievement of a high level of protection of human life and health. To collect and analyse data needed to allow characterisation and monitoring of risks.
Tasks	- To manage and carry out the technical, scientific and administrative aspects of the REACH Regulation. - To ensure consistency at Union level in relation to these aspects. - To provide the Member States and the institutions of the Union with the best possible scientific and technical advice and scientific guidance. - To perform classification and labelling of chemical substances deriving from the CLP Regulation (EC) No 1272/2008.	- To issue opinions and recommendations to the Commission. - To issue certification specifications, including airworthiness codes and acceptable means of compliance, and any guidance material for the application of the Basic Regulation and its implementing rules. - To take decisions regarding airworthiness and environmental certification, pilot certification, air operation certification, third country operators, inspections of Member States and investigation of undertakings. - To conduct standardisation inspections of the competent authorities in the Member States.	- To coordinate the scientific evaluation of medicinal products which are subject to Union marketing authorisation procedures. - To coordinate the supervision of medicinal products which have been authorised within the Union (pharmaco-vigilance). - To advise on the maximum limits for residues of veterinary medicinal products which may be accepted in foodstuffs of animal origin. - To coordinate verification of compliance with the principles of good manufacturing practice, good laboratory practice and	- To issue scientific opinions and studies. - To promote uniform risk-assessment methodologies. - To assist the Commission. - To search analyse and summarise the requisite scientific and technical data. - To identify and characterise emerging risks. - To establish a network of organisations operating in similar fields. - To provide scientific and technical assistance in crisis management. - To improve international cooperation. - To provide the public and interested

	European Chemicals Agency (Helsinki)	European Aviation Safety Agency (Cologne)	European Medicines Agency (London)	European Food Safety Authority (Parma)
	ECHA	**EASA**	**EMA**	**EFSA**
			good clinical practice. - To record the status of marketing authorisations granted for medicinal products.	parties with reliable, objective and easily comprehensible information. - To take part in the Commission's rapid alert system.
Management Board	- 27 Members from the EU Member States, - 6 representatives of the Commission, including 3 members without voting rights appointed to represent interested parties, - 2 representatives of the European Parliament.	- 27 members from the EU Member States, - 1 representative of the Commission.	- 27 members from the EU Member States, - 2 representatives of the European Commission, - 2 representatives of the European Parliament, - 2 representatives of patients' organisations, - 1 representative of doctors' organisations, - 1 representative of veterinarians' organisations.	- 14 members appointed by the Council in consultation with the European Parliament (from a shortlist of candidates drawn up by the European Commission). Four of these members have a background in organisations representing consumers and interests in the food chain. - 1 representative of the Commission.
Board of Appeal	The Board of Appeal guarantees the processing of appeals of any party affected by the ECHA's decisions and concludes on these appeals. The Board of Appeal consists of a Chairman and two members who are employees of ECHA. In addition, the Management Board has appointed alternate and additional Members of the Board of Appeal who are not employees of ECHA.	The Board of Appeal is responsible for deciding on appeals lodged against decisions of the Agency. The Board of Appeal consists of a Chairman and two Members and an equivalent number of alternates, who are appointed by the Management Board from a list of qualified candidates adopted by the European Commission. There are two technically qualified members and one legally qualified member, who is the Chairperson of the Board. They are not members of EASA's staff.	Not applicable	Not applicable

	European Chemicals Agency (Helsinki)	European Aviation Safety Agency (Cologne)	European Medicines Agency (London)	European Food Safety Authority (Parma)
	ECHA	**EASA**	**EMA**	**EFSA**
Committees /Panels; Advisory Boards/Forums	- Committee for Risk Assessment - Member States Committee - Committee for Socio-Economic Analysis - Forum for Exchange of Information on Enforcement which coordinates a network of Member States authorities responsible for enforcement of REACH Regulation.	Advisory Board: it assists the Management Board in its work and comprises organisations representing aviation personnel (5), manufacturers (5), commercial and general aviation operators (9), maintenance industry (1), training organisations (1), air sports (1), airports (1), Air Traffic Control (1), IFATCA (1) and an Executive Secretary. In total, the Advisory Board comprises 26 members and an equivalent number of alternates. The Advisory Group of National Authorities (AGNA) is composed of one person per Member State and provides a mechanism for the involvement of the national authorities in the rulemaking process. The Safety Standards Consultative Committee (SSCC) provides the EASA with advice on the content, priorities and execution of the Agency's Rulemaking Programme. It is composed of representatives from organisations and trade associations representing the industries, professions and end user groups concerned.	- Committee for medicinal products for human Use - Committee for medicinal products for Veterinary Use - Committee for Orphan medicinal products - Committee on Herbal medicinal products - Paediatric Committee - Committee for Advanced Therapy - Working parties and other groups	(a) Scientific Committee and 10 Scientific Panels: •Additives and products or substances used in animal feed (FEEDAP) •Animal health and welfare (AHAW) •Biological hazards (BIOHAZ), including BSE-TSE-related risks •Contaminants in the food chain (CONTAM) •Dietetic products, nutrition and allergies (NDA) •Food additives and nutrient sources added to food (ANS) •Food contact materials, enzymes, flavourings and processing aids (CEF) •Genetically modified organisms (GMO) •Plant health (PLH) •Plant protection products and their residues (PPR) EFSA's Scientific Panels are responsible for EFSA's risk assessment work including delivering scientific opinions. (b) Advisory Forum: it connects EFSA with the national food safety authorities and advises EFSA on scientific matters, its work programme and priorities. (c) Stakeholder Consultative Platform: it is composed of EU-wide organisations working in areas related to the food chain and advises EFSA on general matters related to the Agency's work programme, risk assessment methodologies, etc.

Annex II

REFERENCE FRAMEWORK ON ETHICS AND CONFLICT OF INTEREST

EU Regulations and Guidelines

- Staff Regulations of Officials and Conditions of Employment of Other Servants of the European Community - Regulation No 31 (EEC) with subsequent amendments laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community (CEOS)[1].
  The relevant articles for independence/prevention of conflicts of interests: Articles 11, 11a, 12b, 13, 15, 16, 17 of the Staff Regulations Articles 11, 54, 81 and 124 of the CEOS;

- EC Code of Good Administrative Behaviour - Commission Decision 2000/633/EC,ECSC,Euratom of 17 October 2000 amending its Rules of Procedure[2];

- EC Guidelines on Ethics and Conflict of Interests, covering the following topics: gifts, decorations and honours, activities of spouse or partner, external activities;

- Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the budget of the European Communities (Article 52)[3];

- Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial

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[1] OJ P 45, 14.6.1962, p. 1385.

[2] OJ L 267, 20.10.2000, p. 63.

[3] OJ L 248, 16.9.2002, p. 1.

Regulation applicable to the general budget of the European Communities (Article 32)[4].

The selected Agencies' Regulations

- Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency;

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (in particular articles 88(2), 88(3) and 90(5), 90(6));

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (in particular articles 25(1), 28(3), 28(4), 32(1), 37, 38, 42, 48);

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Article 63(2)).

The selected Agencies' main policies and procedures dealing with Ethics, Code of Conduct and Conflict of Interest

European Aviation Safety Agency (EASA)

- EASA Code of Administrative Practice for the staff in their relation with the public (ED Decision 2009/078);

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[4] OJ L 357, 31.12.2002, p. 1.

- Standardisation Inspectors' Code of Conduct (WI.STDI.00015-001/ 29/07/2010);

- EASA Management Board Decision 06-2011 adopting the Rules of Procedure of the Management Board;

- EASA Management Board Decision 01-2011 adopting the guidelines for the allocation of certification tasks to National Aviation Authorities and qualified entities;

- Decision 2007/006/A of the Executive Director on outside activities and assignments (2 February 2007);

- Decision 2009/169/E of the Executive Director of laying down rules on the secondment to the European Aviation Safety Agency of national experts (11 December 2009).

European Chemicals Agency (ECHA)

- Policy for Managing Potential Conflicts of Interests (MB/45/2011/D, adopted by the Management Board on 30 September 2011)[5];

- Guidance on conflicts of interest and invitations and gifts as well as declarations of commitment, confidentiality and interests (ED/01/2007, Decision of the Executive Director of 31 October 2007);

- ECHA guidance on conflicts of interest for ECHA Committees and Forum Members, their advisers and invited experts;

- Code of good administrative behaviour for the staff of the European Chemicals Agency in relation with the public (adopted by the Management Board on 13/14 February 2008, MB/11/2008);

- Code of conduct of the (regular/alternate/additional) Members of the Board of Appeal (BoA/02/2010, adopted by the Board of Appeal on 22 June 2010)[6];

- Management Board Rules of procedure (MB/02/2007, adopted by the Management Board on 30 September 2009)[7];

- Rules of procedure for the Member State Committee (MB/50/2010, adopted by the Management Board on 30 September 2010)[8];

- Rules of procedure for the Committee for Risk Assessment (MB/05/2010, adopted by the Management Board on 4 March 2010)[9];

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[5] http://echa.europa.eu/documents/10162/17208/mb_45_2011_d_policy_conflict_interest_en.pdf

[6] **http://echa.europa.eu/documents/10162/13573/code_of_conduct_en.pdf**

[7] http://echa.europa.eu/documents/10162/17208/mb_02_2007_final_rules_of_procedure_en.pdf

[8] **http://echa.europa.eu/documents/10162/13578/mb_50_2010_rop_msc_en.pdf**

- Rules of procedure for the Committee for Socio-Economic Analysis (MB/06/2010, adopted by the Management Board on 4 March 2010)[10];

- Rules of procedure for the Forum for Exchange of Information on Enforcement (MB/35/2011, adopted by the Management Board on 21 June 2011)[11];

- Commission decision on outside activities and assignments of 28 April 2004 adopted by ECHA per analogy in 2008 (Commission decision C(2008)3471);

- Rules applicable to seconded national experts of ECHA of 28 June 2007 (MB/08/2007);

- Management Board decision of 23 April 2009 on internal investigations in relation to the prevention of fraud and corruption (MB/30/2009).

European Food Safety Authority (EFSA)

- EFSA Code of Good Administrative Behaviour (adopted by Management Board on 16 September 2003);

- EFSA Practical Guide to Staff Ethics and Conduct (2010);

- Code of conduct of the Management Board of EFSA (adopted by Management Board on 16 June 2011);

- Rules of Procedure of the Management Board of EFSA (adopted by Management Board on 31.3.2009 and updated on 20 October 2011);

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9 **http://echa.europa.eu/documents/10162/13608/mb_04_06_2010_revison_rop_committees_en.pdf (pages 16-30)**

10 **http://echa.europa.eu/documents/10162/13608/mb_04_06_2010_revison_rop_committees_en.pdf (pages 31-45)**

11 **http://echa.europa.eu/documents/10162/13577/mb_35_2011_revised_rop_of_the_forum_en.pdf**

- EFSA Policy on Declarations of Interest (adopted by Management Board on 11 September 2007)[12];

- Implementing Act to the Policy on Declarations of Interest. Guidance Document on Declarations of Interest (adopted by Executive Director on 8 September 2009);

- Implementing Act to the Policy on Declarations of Interests. Procedure for identifying and handling potential conflicts of interest (adopted by Executive Director on 8 September 2009);

- Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their working groups (adopted by Management Board on 17 December 2009);

- Decision of the Executive Director concerning the selection of Members of the Scientific Committee, Scientific Panels and experts to assist EFSA with its scientific work (adopted by Executive Director on 14 March 2011);

- EFSA Stakeholder Consultative Platform: Terms of Reference (adopted by Management Board on 17 June 2010);

- Post sensitivity assessment and management in EFSA (adopted by Executive Director on 27 January 2009 and updated on 26 October 2011);

- Decision implementing articles 16, 17(2) and 19 of the Staff Regulations and articles 11 and 91 of the Conditions of Employment of Other Servants (adopted by Executive Director on 7 December 2010);

- Decision of the Executive Director on declaration of interests in the context of EFSA procurement contracts and grants (adopted by Executive Director on 5 April 2011).

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[12] http://www.efsa.europa.eu/en/topics/topic/independence.htm

European Medicines Agency (EMA)

- The EMEA Code of Conduct (EMEA/6470/03/2368, 18 August 2006)[13];
- European Medicines Agency policy on the handling of conflicts of interests of Scientific Committee Members and experts (EMA/513078/2010, 13 October 2010)[14];
- Overview of the Allowable Interests for the EMA Scientific Activities (EMA/358101/2010, 13 October 2010)[15];
- Decision of the Management Board on the adoption of implementing rules for external activities (EMEA/MB/143750/2007);
- Implementing rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency (EMA/565945/2009, 9 June 2011);
- Communication on professional integrity at the EMA – conflicts of interest arising from personal relationships (EMA/511563/2010, 7 September 2010);
- Executive Director Decision laying down rules on the secondment of national experts to the Agency (EMA/545578/2011, 1 August 2011)[16]
  Revised criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency (EMA) activities (EMA/MB/24913/2005 rev.1 adopted 13 September 2011).

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[13] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf

[14] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

[15] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097906.pdf

[16] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500038456.pdf

OECD Guidelines

- Managing Conflict of Interest in the Public Service: OECD Guidelines and Country Experiences, OECD, Paris, 2003;

- Post-Public Employment: Good Practices for Preventing Conflict of Interest, OECD, Paris, 2010.

Annex III

OVERVIEW OF THE AGENCY-SPECIFIC POLICIES AND PROCEDURES APPLICABLE TO STAFF, EXPERTS, MANAGEMENT BOARD AND BOARD OF APPEAL

	EASA				ECHA				EFSA				EMA		
	Experts	*Employees*	*Management Board*	*Board of Appeal*	*Scientific Committees' Members and other experts*	*Employees*	*Management Board*	*Board of Appeal*	*Scientific Committee and Panels' Members and other experts*	*Employees*	*Management Board*	*Advisory Forum and other consultative bodies*	*Scientific Committees' Members and other experts*	*Employees*	*Management Board*
Conflict of interest policies and procedures	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Declarations of interests and related policies	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Policies for screening the candidates (experts, Management Board, Board of Appeal)	No	N/A	No	No	Yes[1, 2]	N/A	No	No	Yes	N/A	No	No	No	N/A	No
Conflict of interest policies for the outsourcing of scientific activities	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No	N/A	N/A
Policy on gifts and invitations	No	No	No	No	No	Yes	No	Yes	No	Yes[3]	No	No	Yes	Yes	Yes
Breach of trust procedures	No	No	No	No	Yes[2]	Yes[2]	Yes[2]	Yes[2]	Yes	No	No	No	No	No	No
Post-employment policies ('revolving door' policies)	No	Yes	No	No	No	Yes	No	No	No	Yes	No	No	No	Yes	No

[1] Only for Risk Assessment Committee and the Committee for Socio-Economic Analysis.
[2] Policy for managing Potential Conflicts of Interests (MB/45/2011/D), adopted by the Management Board on 30 September 2011. The implementation of this policy has not been tested.
[3] EFSA has a policy on invitations only.

Annex IV

INDEPENDENCE AND TRANSPARENCY REQUIREMENTS STATED IN THE SELECTED AGENCIES' FOUNDING REGULATIONS

	EASA				ECHA				EFSA				EMA		
	Experts	***Staff (including the Executive Director)***	***Management Board***	***Board of Appeal***	***Scientific Committees' Members and other experts***	***Staff (including the Executive Director)***	***Management Board***	***Board of Appeal***	***Scientific Committee and Panels' Members and other experts***	***Staff (including the Executive Director)***	***Management Board***	***Advisory Forum and other consultative bodies***	***Scientific Committees' Members and other experts***	***Staff (including the Executive Director)***	***Management Board***
General independence requirements	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
General transparency requirements	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Annual Declarations of interests (ADoIs)	No	No	No	No	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	No	Yes
Specific Declarations of interest (SDoIs)	No	No	No	Yes	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	No	Yes
Requirement to publish the ADoI	No	No	No	No	NO, but the ADoIs should be accessible to the public on request	Executive Director - No, but the ADoIs should be accessible to the public on request	No, but the ADoIs should be accessible to the public on request	No	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	No	Yes
Requirement to publish the SDoI/oral declaration of interest during the meetings	No	No	No	No	No	No	No	No	Yes	Legal requirement for the Executive Director only	Yes	Yes	Yes	No	Yes
Requirement for policy and implementing rules on acceptance of gifts	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes

Requirement to make public the agendas and the minutes of the meetings	No	No	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No	No	Yes
Requirement to publish the results of the scientific studies and opinions	Yes	Yes	N/A	N/A	Yes	Yes	N/A	N/A	Yes	Yes	N/A	N/A	Yes	Yes	N/A

Annex V

MANAGEMENT OF CONFLICT OF INTEREST - COMPARISON BETWEEN THE OECD GUIDELINES AND THE EU REGULATORY FRAMEWORK

Areas	OECD Guidelines	EU Regulatory Framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures)
Scope and objectives	The OECD Guidelines set the first international benchmark for designing and implementing a comprehensive conflict of interest policy. The Guidelines are addressed to governments and public institutions, aiming to help them to design and implement an efficient conflict of interest policy. The Guidelines also provides a comparative overview of policies implemented in 30 OECD member countries to identify and resolve conflict of interest situations, showing overall trends, good practices and emerging areas where improvements could be made.	General obligations for identification and management of conflict of interest are laid down in the Staff Regulations, which are applicable to all EU officials. *NB:* Practical guidelines issued at the level of each DG were not analysed in the scope of the audit. More detailed decisions and guidelines on conflict of interest were issued by the European Commission (EC), which are applicable to its staff.
Categories of individuals	The OECD Guidelines refer to public officials in general, with a particular attention to: - Policy-makers and public office holders in the most senior positions (e.g. ministers); - Public officials working in key functions of the state, such as law enforcement (e.g. judges, prosecutors, tax officials); - Decision-makers in sensitive areas at the interface between the public and private sector (e.g. contract managers, auditors, etc).	The Staff Regulations refer only to staff (officials, temporary agents, contract and auxiliary agents). Other individuals with a significant role in the decision-making process, such as: Members of the Management Board, experts, Members of Board of Appeal, etc., are not bound by the Staff Regulations. The selected Agencies (EFSA, EMA and ECHA) adopted policies and procedures for staff and other categories of individuals with decision-making power (e.g. experts, Members of the Management Board, Members of the Board of Appeal)
Core values and principles (objectivity, impartiality,	Public officials and public organisations should not only act within the letter of the law, but also respect broader public	Public officials should carryout their duties with objectivity, impartiality and loyalty to the EU (Staff Regulations,

Areas	OECD Guidelines	EU Regulatory Framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures)
integrity)	service values such as disinterestedness, impartiality and integrity.	Article 11). These values are reinforced in the Rules of Procedures of the European Commission (Decision 2000/633/EC, ECSC, Euratom).
Definition of conflict of interest	The OECD Guidelines define the conflict of interest as *"a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests which could improperly influence the performance of their official duties and responsibilities"*. In this context, the conflict of interest can be: actual, apparent or potential.	The Staff Regulations stipulate that the official shall not, in performance of his duties, deal with a matter such as to impair his independence, in particular, family and financial interests (Article 11a). However, the conflict of interest is not defined in the Staff Regulations.
Conflict of interest policy - general requirements	According to the OECD Guidelines, a modern approach to a conflict of interest should: ● Identify risks to the integrity of public organisations and public officials. ● Prohibit specific unacceptable forms of private interest. ● Make public organisations and individual officials aware of the circumstances in which conflicts can arise. ● Ensure that effective procedures are deployed for the identification, disclosure, management, and promotion of the appropriate resolution of conflict of interest situations.	The Staff Regulations identify certain risk areas for conflict of interest, such as: outside activities, family relationship, gifts and other benefits, inside information and post-employment. However, the Staff Regulations do not identify specific circumstances in which conflicts can arise nor indicate unacceptable forms of private interests.
Declaration/disclosure of interests	According to the OECD Guidelines, one of the core principle for managing conflict of interest is the transparency and scrutiny. Initial disclosure on appointment - Public officials' private interests should be disclosed appropriately, to enable adequate control and management of a resolution. The public officials should disclose their relevant interests on appointment and thereafter at regular intervals. Such disclosure is usually formal, is required to be presented periodically (usually annually) and in writing. In-service disclosure in office - Public officials should promptly	According to the Staff Regulations, the officials have the obligation to notify the Appointing Authority of any personal interest that may impair his/her independence (Article 11a). Thus, the officials should spontaneously inform the hierarchical superiors about any interests, which in their view can create a conflict of interest situation. However, there is no obligation for the EU officials to fill in a declaration of interests on appointment and periodically thereafter (e.g. annually).

Areas	OECD Guidelines	EU Regulatory Framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures)
	disclose all relevant information about a conflict of interest when circumstances change after the initial disclosure has been made or when new situations arise.	
Assessment of the interests disclosed	The organisations should assess the completeness of disclosure, by ensuring that the disclosure of interests contains sufficient details on the conflicting interests to enable an informed decision to be made about the appropriate resolution. The organisations should assist full disclosure of interests and ensure that the interests disclosed are properly assessed and maintained in up-to-date form.	The Staff Regulations state that in case of conflicting interests *"the Appointing Authority shall take any appropriate measure, and may in particular relieve the official from responsibility in this matter"* (Article 11a.2). The Staff Regulations do not provide details regarding the assessment of the interests disclosed (e.g., completeness, update information, etc).
Screening process	The OECD Guidelines recommend the use of preventive measures that deal with conflict of interest situations. One of these measures is the screening of candidates/ organisations during the selection process. This requires the identification in advance of any relevant interests and discussion of possible strategies or resolution of identified conflicts.	There are no provisions in the Staff Regulations which would require the screening of candidates for possible conflict of interest during the selection process.
Sensitive areas and policy requirements for various categories of individuals	The OECD Guidelines recommend that, in addition to the general policy for all public officials, particular attention should be paid to senior positions and sensitive areas:- Policy-makers and public office holders in the most senior positions;- Public officials working in key functions of the state, such as law enforcement;- Decision-makers in sensitive areas at the interface between the public and private sector. Measures used for these groups should take into consideration the categories of public officials. In general, as higher the position, the stricter the policy and the more transparency is requested.	There are no similar requirements in the Staff Regulations.The Agencies' Founding Regulations foresee different obligations for various categories of individuals (e.g. executive staff, Members of the Management Board, experts, Board of Appeal, etc).
"At risk" areas for conflict of interest situations	Organisations need to consider reviewing existing management arrangements on a regular basis to assess whether they remain adequate in recognising potential risk areas. The Guidelines mention the following "at risk" areas: additional	The Staff Regulations include provisions for the following risk areas for conflict of interest: gifts and other benefits, outside activities, family relationship (spouse of the official in gainful employment), inside information and obligations after leaving the office (Articles 11, 12b, 13, 16 and 17).

Areas	OECD Guidelines	EU Regulatory Framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures)
	employment, inside information, contracts, gifts and other forms of benefits, family and community expectations, outside appointments and activity after leaving public office.	The EC has issued internal guidelines for dealing with these risk areas.
Outside activity/Additional employment	The OECD Guidelines recommend clear definition of circumstances of outside activities (employment or appointment), authorisation process and resolution measures. Additional employment - Define circumstances, including the required authorisation procedure, under which public officials may engage in outside employment, while retaining their official position. Outside appointments - Define circumstances, including the required authorisation procedure, under which a public official may undertake an appointment on the board or controlling body of a NGO, professional or commercial organisation, etc, which is involved in a contractual, regulatory or sponsorship arrangement with the employing organisation.	The Staff Regulations stipulate that the official should seek permission before engaging in an outside activity or assignment: *"An official wishing to engage in an outside activity, whether paid or unpaid or to carry out an assignment outside the Communities, shall first obtain permission of the Appointing Authority. Permission shall be refused only if the activity interferes with the official's duties or it is incompatible with the interests of the institution."* (Article 12b) The EC Decision 85-2004/28.4.2004 on outside activities and assignments provides further details, such as: prohibited activities (professional and commercial activities), maximum net remuneration (4,500 euro/p.a.), special provisions for officials on leave on personal grounds, authorisation procedure, post-employment obligations, etc. This decision applies only to the EC staff (i.e. officials, temporary, auxiliary and contract staff).
Personal and family relationship	The OECD Guidelines recommend that the organisation's policy is adequate in recognising conflict of interest arising from expectations placed on public officials by their family and community.	The Staff Regulations require that officials disclose the gainful employment of the spouse. If the nature of the spouse's employment is incompatible with the duties of the official, the Appointing Authority will decide whether the official shall continue his post or be transfer to another post. (Article 13)
Gifts and other benefits	The OECD Guidelines recommend that the organisation's policy is adequate in recognising conflict of interest arising from gifts and other benefits.	The Staff Regulation stipulate that an official shall not, without the permission of the Appointing Authority, accept any honour, decoration , favour, gift or payment of any kind. (Article 11).The EC issued internal guidelines on gifts and hospitality, which were updated on 7 March 2012. Gifts and hospitality should only be accepted if in line with or if

Areas	OECD Guidelines	EU Regulatory Framework (except for Agencies' Founding Regulations and Agency-specific policies and procedures)
		required by social convention, courtesy or diplomatic usage. Explicit prior permission by the Appointing Authority is required for a gift worth between 50 euro and 150 euro. Authorisation for gifts of a higher value than 150 euro will be refused by the Appointing Authority.
Inside information	The organisations should ensure that any information which is not made public and/ or is confidential, it is understood to be privileged and is effectively protected for improper use or disclosure.	Confidentiality obligations for officials are foreseen at Article 17 of the Staff Regulation: *"1. An official shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public.* *2. An official shall continue to be bound by this obligation after leaving the service."*

Annex VI

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SCIENCE MEDICINES HEALTH
An agency of the European Union

1 July 2011
EMA/XXXXXX/2011
Unit/sector name

Evaluation of Conflicts of Interests Form

(in relation to specific EMA activity)

Please note that once the evaluation is completed, this form should be filed, together with all relevant supporting documentation (emails, copy of Public Declaration of Interests and Confidentiality Undertaking form, etc.) in the product or meeting folder, as appropriate.

Name of Expert:

Date of Declaration of Interest under evaluation:

EMA Activity (subject of this evaluation)

	Name of meeting	**Role** Chair / Member / Alternate Observer / Core member	**Topic** of meeting	**Date** of meeting
Committee				
Working Party				
SAG				
Other meeting				

	Scope of Inspection	**Product**
Inspection		

Other activity (please provide details):

Evaluation:

Evaluate the interests declared against the activity for which the involvement of the Expert is required. Please fill-in the background of the appropriate cell in white and record the outcome in the Table 3.

		Committee Chair	Working Party Chair	Committee / WP member / Expert	Inspection	Guideline Dev.	SAG Chair / member	EW*
Employee	Current	1	1	1	1	1	1	1
	0 to 2	1	2	3	5	[3]	4	EW
	>2 to 5	1	2	4	5	7	7	EW
Consultant/ Strategic Advisory Role	Current	1	1	1	1	1	3	EW
	0 to 2	1	2	3	5	[3]	4	EW
	>2 to 5	1	2	4	5	7	7	EW
Financial Interest	Current	1	1	1	1	1	1	EW
Patent	Current	1	1	1	1	1	1	EW
Principal Investigator	Current	1	2	3	5	[3]	4	EW
	0 to 2	1	2	3	5	7	7	EW
	>2 to 5	1	2	4	5	7	7	EW
Investigator	Current	1	2	4	5	7	7	EW
	0 to 2	1	2	4	5	7	7	EW
	>2 to 5	1	7	7	7	7	7	7
Grant	Current	6	7	7	7	7	7	7

*EW = Expert Witness

Outcome of Evaluation

Please fill-in the background of the appropriate cell in white following the legend to record the outcome :
e.g. 1 – No involvement, 3 – No involvement in discussions, deliberations, voting for…

Where outcome is 1, 7 or where the expert is to be used as Expert Witness, no further details need to be given.
Where outcome is 2, 3 or 4: list products and indications concerned under relevant columns.
Where outcome is 5 or 6: list Company concerned.

Legend

Outcome	Impact		
1	**No involvement in activity**		
2	**To be replaced for the discussions, final deliberations and voting** as appropriate in relation to the relevant product or a competitor product.	Product:	Indication:
3	**Where Individual product involvement is declared:** - **No involvement** with respect to procedures involving the relevant product or a competitor product in the relevant indication i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products. - **Cannot act as Rapporteur** for these products. - **[Cannot act as Rapporteur** for development of guidelines in concerned therapeutic area]. **Where cross product / general involvement is declared:** - **No involvement** (as outlined above) with respect to products from the specified company. - **Cannot act as Rapporteur** for products from the relevant company(ies).	Product:	Indication:
4	**Where Individual product involvement is declared:** - **Involvement in discussions only** with respect to procedures involving the relevant product or a competitor product i.e. no part in final deliberations and voting as appropriate as regards these medicinal products. - **Cannot act as Rapporteur** for these products. **Where cross product / general involvement is declared:** - **Involvement in discussions only** with respect to products from the specified company. - **Cannot act as Rapporteur** on products from the relevant company(ies).	Product:	Indication:
5	**Cannot participate in Inspections** relating to the relevant company (all products) nor in (product specific) inspections relating to competitors to the named product(s).	Company:	

6	**To be replaced for the discussions, final deliberations and voting** as appropriate in relation to any medicinal product from the relevant company giving a grant or other funding to the institution.	Company:
7	**Full involvement** – No restriction	
Expert Witness	Where declared interested are such that involvement in the relevant activity is not possible, consideration may be given to involvement as Expert Witness. EW may testify and give specialist advice on a specific issue by providing information and replying to any questions.	

Date:

Signature

Annex VII

TRANSPARENCY OF DECLARATIONS OF INTERESTS AND DECISION-MAKING PROCESS

Area	Type of document published on Agency's website	EASA	EMA	EFSA	ECHA
Management	Declaration of interest of Executive Director	No	Yes	Yes	Yes
	Curriculum vitae of Executive director	Yes	Yes	Yes	Yes
	Declarations of interest of Agency's management (e.g., Directors, Head of Units)	No	No	Yes	No
	Declaration of interest of Management Board Members	No	Yes	Yes	Yes
	Curriculum vitae of Management Board Members	No	Yes (not for all)	Yes	Yes
	Declarations of interest of Board of Appeal	No	N/A	N/A	No
	Minutes of the meetings of the Management Board	Yes	Yes	Yes[3]	Yes
Experts	List of Experts or Members of committees	No	Yes	Yes	Yes
	Declaration of interest of Experts	No	Yes	Yes	Yes
	Curriculum vitae of Experts	No	Yes[2]	Yes	Yes
	Minutes of the meetings of the Scientific Committees and bodies and experts	Yes (not for all)[1]	Yes (not for all)	Yes	Yes
	Results of the scientific studies	Yes	Yes	Yes	Yes
Other	Public consultations on independence policy	No	No	Yes	No
	Involvement of external evaluators in the recruitment of the scientific bodies' experts	No	No	Yes	No
	Possibility of external observers to participate in the scientific bodies' or Management Board' meetings	Yes	Yes	Yes	Yes

[1] EASA publishes the minutes of the consultative bodies' meetings concerning rulemaking activities. However, minutes of the meetings which would include

assessment of conflict of interest are not published.

[2] For Members of the Committees.

[3] EFSA audiocasts live on its website the meetings of the Management Board.

REPLIES OF THE COMMISSION TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS

"MANAGEMENT OF CONFLICT OF INTEREST IN SELECTED EU AGENCIES"

EXECUTIVE SUMMARY

I. The Commission welcomes this report and supports the improvement of the management of conflicts of interest in EU decentralised agencies.

The Inter-Institutional Working Group on EU decentralised agencies, steered by the Commission, is about to formally agree on a Common Approach where the issue of conflicts of interests is addressed in the following way:

- paragraph 11: "A coherent policy on preventing and managing conflict of interests concerning members of the Management Board, whether or not they sit in personal capacity, should be developed and applied in all agencies."

- paragraph 18: "A coherent policy on preventing and managing conflict of interests concerning the Director should be developed and applied in all agencies. The Commission should examine, together with the agencies, whether there is scope for a harmonised approach."

Furthermore, the need to ensure the independence of members of scientific committees and boards of appeal is also mentioned.

The Commission will present a roadmap on the implementation of the Common Approach by the end of 2012, where it will, amongst other things, indicate how it intends to work with agencies to follow-up on these provisions. In this context, the potential need to develop an EU regulatory framework will be duly considered.

Finally, there are other instruments are in place to avoid conflict of interest. In particular: collegiality of the Scientific Committee/Panels (about 20 members of the Committee/Panels peer reviewing Working Groups drafts) to avoid an individually-led process; inter-disciplinarity and multi-disciplinarity (composition ensuring all scientific aspects); absence of hierarchical links among and between experts; decisions adopted by majority and minority opinions recorded.

IV. Although there is no detailed regulatory framework, as far as the staff of the agencies covered by the Staff regulations is concerned, the legislator, while setting the general principles, left the margin of discretion to the Appointing Authority of each institution/agency to adjust the rules to their specificities and adopt detailed/tailor-made implementing rules.

X. (c) (vii) In view of raising awareness of the importance of good management of issues such as conflict of interest, the Commission offers training in the area of ethics. The agencies may benefit from this offer by signing service level agreements with the Commission.

The training on ethics and integrity is a one-day comprehensive training that presents the principle of professional ethics. Its main objective is to raise staff awareness on the main obligations as provided for in the Staff Regulations. The crux of the training is to give clear and basic guidelines to a staff member so that he/she acts in an objective, impartial and loyal way. The understanding of the main principles is vital in order to

achieve that staff covered by the Staff Regulations respect the interests of the European Union. It is more effective to present clearly the goal (the principles of professional ethics) than the specific ways to reach the goal.

X. (c) (viii) The Commission has given effect to the provisions of the Staff Regulations governing post-employment issues by Decision 85-2004 of 29 June 2004 on outside activities. The Commission considers that it should apply by analogy to the staff of the agencies.

Within the confines of the procedure under Article 110 of the Staff Regulations, all agencies in question (for their staff covered by the Staff Regulations) have submitted to the Commission for agreement the draft implementing rules on outside activities. The Commission gave its agreement to:

EASA by decision C(2006) 7264

EMA by decision C(2006) 7264

EFSA by decision C(2009)5682

ECHA by decision C(2008) 3471.

X. (e) The Commission supports and encourages the improvement in terms of management of conflict of interests which has been emphasized during the discussions within the Inter-institutional working group on decentralized agencies.

According to the Staff Regulations, the agencies have an independent status and the Appointing Authority powers are exercised by them. This includes the application/implementation of the rules in question.

In accordance with Article 110 of the Staff Regulations, agencies adopt implementing rules giving effect to the SR or CEOS measures in agreement with the Commission. This implies that each agency is bound to submit to the Commission any draft rule giving effect to the SR before its adoption.

The Commission proposed, in the context of the revised procedure of Article 110 of the Staff Regulations, a by default application of the Commission rules to statutory staff of the agencies.

See also reply to paragraph I.

INTRODUCTION

1. See reply to paragraph 21.

10. These rules only apply to staff employed and paid by agencies. It is not possible to apply them to persons designated "*ad personam*" (not employed by the agencies) such as members of Management Boards and scientific experts in general or to persons representing MS (members of agencies' Boards representing MS and institutions).

AUDIT SCOPE AND APPROACH

21. The OECD guidelines (like the EU staff regulations) only focus on public officials employed by public authorities (and not on those who are not staff). OECD guidelines may be applied to other categories of

professionals by analogy. However, the principles of these guidelines need to be followed taking into account the specific situation in which they are intended to be applied.

80. In view of raising awareness of the importance of good management of issues such as conflict of interest, the Commission offers training in the area of ethics. The agencies may benefit from this offer by signing service level agreements with the Commission.

The training on ethics and integrity is a one-day comprehensive training that presents the principle of professional ethics. Its main objective is to raise staff awareness on the main obligations as provided for in the Staff Regulations. The crux of the training is to give clear and basic guidelines to a staff member so that he/she acts in an objective, impartial and loyal way. The understanding of the main principles is vital in order to achieve that staff covered by the Staff Regulations respect the interests of the European Union. It is more effective to present clearly the goal (the principles of professional ethics) than the specific ways to reach the goal.

82. The obligations under Article 16 of the staff regulations are regularly drawn to the attention of the staff. This is particularly so in pre-retirement courses where a specific module is offered on the continuing ethical responsibilities after leaving the service with a particular focus on Article 16. The ethics pages of the Commission intranet feature a section on Article 16. Pending adoption of the new staff regulations, a major awareness raising campaign will run to accompany proposed new guidelines on outside activities, including those carried out after leaving the service. As all officials are bound by the staff regulations, the employment arrangements already contain appropriate messages.

CONCLUSIONS AND RECOMMENDATIONS

Recommendation 8

In view of raising awareness of the importance of good management of issues such as conflict of interest, the Commission offers training in the area of ethics. The agencies may benefit from this offer by signing service level agreements with the Commission.

The training on ethics and integrity is a one-day comprehensive training that presents the principle of professional ethics. Its main objective is to raise staff awareness on the main obligations as provided for in the Staff Regulations. The crux of the training is to give clear and basic guidelines to a staff member so that he/she acts in an objective, impartial and loyal way. The understanding of the main principles is vital in order to achieve that staff covered by the Staff Regulations respect the interests of the European Union. It is more effective to present clearly the goal (the principles of professional ethics) than the specific ways to reach the goal.

98. First bullet The Commission has given effect to the provisions of the Staff Regulations governing post-employment issues by Decision 85-2004 of 29 June 2004 on outside activities. The Commission considers that it should apply by analogy to the staff of the agencies.

Within the confines of the procedure under Article 110 of the Staff Regulations, all agencies in question (for their staff covered by the Staff Regulations) have submitted to the Commission for agreement the draft implementing rules on outside activities. The Commission gave its agreement to:

EASA by decision C(2006) 7264

EMA by decision C(2006) 7264

EFSA by decision C(2009)5682

ECHA by decision C(2008) 3471.

99. Although there is no detailed regulatory framework, as far as the staff of the agencies covered by the Staff regulations is concerned, the legislator, while setting the general principles, left the margin of discretion to the Appointing Authority of each institution/agency to adjust the rules to their specificities and adopt detailed/tailor-made implementing rules.

The Inter-Institutional Working Group on EU decentralised agencies, steered by the Commission, is about to formally agree on a Common Approach where the issue of conflicts of interests is addressed in the following way:

- paragraph 11: "A coherent policy on preventing and managing conflict of interests concerning members of the Management Board, whether or not they sit in personal capacity, should be developed and applied in all agencies."

- paragraph 18: "A coherent policy on preventing and managing conflict of interests concerning the Director should be developed and applied in all agencies. The Commission should examine, together with the agencies, whether there is scope for a harmonised approach."

Furthermore, the need to ensure the independence of members of scientific committees and boards of appeal is also mentioned.

The Commission will present a roadmap on the implementation of the Common Approach by the end of 2012, where it will, amongst other things, indicate how it intends to work with agencies to follow-up on these provisions. In this context, the potential need to develop an EU regulatory framework will be duly considered.

Recommendations 10 and 11

The Commission supports and encourages the improvement in terms of management of conflict of interests which has been emphasized during the discussions within the Inter-institutional working group on decentralized agencies.

According to the Staff Regulations, the agencies have an independent status and the Appointing Authority powers are exercised by them. This includes the application/implementation of the rules in question.

In accordance with Article 110 of the Staff Regulations, agencies adopt implementing rules giving effect to the SR or CEOS measures in agreement with the Commission. This implies that each agency is bound to submit to the Commission any draft rule giving effect to the SR before its adoption.

The Commission proposed, in the context of the revised procedure of Article 110 of the Staff Regulations, a by default application of the Commission rules to statutory staff of the agencies.

(See also reply to paragraph 99).

THE AGENCY'S REPLY TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS "MANAGEMENT OF CONFLICT OF INTEREST IN SELECTED EU AGENCIES"

EXECUTIVE SUMMARY

I.

The selected Agencies acknowledge the report and recommendations. The report could serve as a basis for a shared work to be undertaken with the European Commission and the other EU institutions to develop a common Union framework and/or minimum standards, as it was concluded by the EU legislator in the context of the Inter-Institutional Working Group on regulatory agencies.

IV.

There are specific legislative requirements applicable to the individual Agencies. In this context, the selected Agencies developed policies and procedures; and are continuously enhancing these, mainly on the basis of Agency-specific regulatory requirements. In the absence of a comprehensive EU framework, some Agencies indeed referred to the OECD Guidelines.

However, the OECD guidelines (like the European Staff Regulations) only focus on public officials employed by public authorities (and not on those who are not officials like members of Management Board and Board of Appeal, external experts). OECD guidelines may be applied to other categories of professionals by analogy. However, when applied, the principles of these guidelines need to be followed taking into account the specific situation in which they are intended to be applied. In the light thereof, EASA will primarily follow the European Commission guidelines in the area of Code of Conduct/Ethics; but also takes into account the OECD guidelines where needed and consider the specific situations in which they are intended to be applied.

V.

EASA acknowledges that at the time of the audit, shortcomings were identified when benchmarking the Agency's policies and procedures against OECD guidelines. It is, however, important to recall in this context that policies and procedures adopted and/or implemented after the Court completed its fieldwork (October 2011) have not been evaluated. A significant number of recommendations have thus been addressed by the time of publication of this report. With regard to the finding that "none of the selected Agencies adequately manages conflict of

interests situations", it deserves clarification that EASA fully comply with its founding regulations and other laws that apply to the Agency, such as the EU Financial Regulation and the EU Staff Regulations. In addition, EASA in the current aforementioned context adopted its own regulations/policies and procedures - taking into account its particular governance and legal requirements from its founding legal acts. EASA wishes to highlight the specific governance structure of EASA and its lack of direct influence on its Management Board, Board of Appeal and external experts/organisations. In particular, EASA makes a clear differentiation between EASA itself (Agency staff) and its Management Board (MB)/Board of Appeal, when analysing the issue of potential conflict of interests. EASA and its Management Board have different functions and competences as well as different procedures to adopt decisions.

VIII.

EASA currently follows the European Commission guidelines on conflict of interest which EASA think are in line with the OECD guidelines. In order to handle a risk, there are several mitigating controls that can be applied. Regarding the risk on potential conflict of interest when taking technical decisions, the Agency applies the "no single point of decision" approach as the most appropriate mitigating control for prevention of conflict of interest scenarios within EASA context. Impartiality of the decision making in the EASA operational processes is guaranteed through the collegiality of the technical assessment and the decision-making process.

The aforementioned has been recently recognised by the European Parliament in a Resolution from 10 May 2012 (European Parliament resolution of 10 May 2012 with observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Aviation Safety Agency for the financial year 2010 (C7-0285/2011 – 2011/2224(DEC); see in particular Point 16)

To further improve the already existing measures: Code of Good Administrative Practices (in particular Articles 7 and 8), EU Commission guidelines on gifts , specific policy on conflict of interest for standardisation activities, principle of collegiality in decision-making, provisions regarding conflict of interest within outsourcing contracts, the Agency is currently setting- up a specific Agency wide policy relating to conflict of interest (i.e. identification, prevention, monitoring and dealing with the consequences of conflict of interest cases). This was also noted by the European Parliament in the abovementioned Resolution.

X. (a)

In line with the reply to section VIII, and taking into account that EASA has no direct influence on external experts, Management Board and Board of Appeal as per the governance structure established by the Founding Regulation, EASA is currently setting up a specific Agency-wide policy on conflict of interest management by extending its existing Agency policy on Code of Conduct (i.e. Code of Good Administrative Practices); and will propose a dedicated policy on conflict of interest for Management Board and Board of Appeal to be adopted by them with the support from an external consultant using the existing framework contract (Framework Contract No -30-CE-0390041) from the European Commission DG Budget related to Internal Control Standards (ICS).

X. (c) (i)

Taking into account that Agencies have no direct influence on certain appointments (e.g. Management Board, Board of Appeal, Committee members directly appointed by Member States) they can only perform the screening of candidates to be appointed by the Agency. Therefore, EASA will define criteria and methodology for the screening of candidates to be employed by the Agency under European Staff Regulations and Conditions of Employment of Other Servants of the European Community in line with the specific Agency-wide policy on conflict of interest under evaluation, here above mentioned. For other members, the Agency could foresee to propose to the related appointing bodies (i.e: Member States, EU Commission, industry, etc) to establish screening procedures before appointment of the concerned member(s).

X. (c)(ii)

EASA outsources a non-significant part of its certification tasks to NAAs and Qualified Entities (20% in average and being minor projects in its scope). A dedicated standardised Framework Contract template is systematically used and contains a clause on conflict of interest management measures to be put in place in these organisations and a clause on the right for EASA to verify these measures. In line with the explanation given by the Court in paragraph 36, EASA will develop criteria and methodology (based on EASA specific policy on conflict of interest management) required to fulfil this clause during accreditation activities when deemed necessary. EASA may only require NAAs and Qualified Entities to put in place additional measures but has clearly no direct influence on these organisations to ensure that conflict of interest is managed to a comparable standard.

X. (c) (iii)

Taking into account that EASA has no direct influence on the Management Board and Board of Appeal, EASA will establish criteria for assessment of declarations of interest to be applied consistently for the Agency staff members; and foresees to propose specific criteria for assessment of declarations of interests to be adopted by the Management Board and the Board of Appeal for their respective members.

X. (c) (iv)

EASA already refers to and follows the EU Commission guidance on gifts and invitations for the Agency staff members. EASA introduced a chapter on gifts and invitations in its conflict of interest policy, here above mentioned. For the Management Board and Board of Appeal, EASA foresees to propose a chapter on gifts and invitations in the dedicated conflict of interest management policy, to be adopted by the Management Board and the Board of Appeal for their respective members. These policies will be based on the existing EU Commission guidance.

X. (c) (v)

EASA is bound to follow EU staff regulations. In case of breach of any Agency policy or procedure by a staff member, EASA will follow the existing disciplinary procedure in the EU Staff Regulations to handle such case. Taking into account that EASA has no direct influence on the Management Board and Board of Appeal, the Agency introduced breach of trust policies and procedures related to conflict of interest with respect to existing disciplinary

procedure in the specific conflict of interest policy, here above mentioned. EASA foresees to propose the introduction of a specific breach of trust policies and procedures chapter in the conflict of interest management policy to be adopted by the Management Board and the Board of Appeal for their respective members.

X. (c) (vi)

EASA, since its creation, ensures transparency in its technical decision-making proceses as requested in the respective technical and operational Agency procedures. In addition, the Agency has set-up its Integrated Management System (IMS) being ISO9001 certified since 2010. The EASA IMS strongly supports the implementation of transparency requirements, among others, in all Agency procedures.

EASA has no scientific committee or panel. During its Management Board in June 2012, EASA asked the Management Board members to complete a declaration of interests before the next Management Board in September 2012 and subsequently to be published on the EASA web-site. In addition, the EASA website, since June 2012, states that all members of the Executive Committee completed a declaration of interests and those from the five Directors of the Agency are published on the EASA web-site.

EASA will extend the declaration of interests for its Agency staff playing an important role in the technical decision-making processes of the Agency.

X. (c) (vii)

EASA provides already a dedicated compulsory training to newcomers (Agency staff) on its Code of Conduct (i.e Code of Good Administrative Practices) including the provisions related to conflict of interest contain therein. As part of the on-going consultancy framework contract (Framework Contract No -30-CE-0390041) from the European Commission DG Budget related to Internal Control Standards (ICS), EASA will improve its existing compulsory training for newcomers to further detail the conflict of interest area and foresees to propose a dedicated training on the specific conflict of interest policy to the members of the Management Board and Board of Appeal.

X. (c) (viii)

The Commission has given effect to the provisions of the Staff Regulations governing post-employment issues by Decision 85-2004 of 29 June 2004 on outside activities. The Commission considers that it should apply by analogy to the staff of the agencies. Within the confines of the procedure under Article 110 of the Staff Regulations, all agencies in question (for their staff covered by the Staff Regulations) have submitted to the Commission for agreement the draft implementing rules on outside activities. The Commission gave its agreement to EASA (ED Decision 2007/006/A) by decision C(2006) 7264. (ED Decision listed in Annex II by the Court).

With experts and members of the Management Board and Board of Appeal, who are not staff, the Agency has no legal power to impose conditions on their freedom of employment after the end of their mandate. Therefore EASA could endeavour to address post-employment issues for these members or any other external experts involved in EASA activities. Moreover, EASA wishes to highlight that, with regards to staff members there are certain limitations, resulting from the temporary nature of contracts that can be offered by Agencies and fundamental rights of the individuals working with them.

X. (d)

It is crucial for EASA that the EU legislator develops further the EU regulatory framework in the area of conflict of interest management in order to have a compliant and consistent approach on conflict of interest management not only within the selected Agencies but within all EU Institutions and decentralised bodies.

INTRODUCTION

7. Second indent

EASA has no scientific committee or panel. EASA wishes to clarify that the only external experts to be considered are Seconded National Experts (SNEs), NAAs involved in drafting Rulemaking Groups, NAAs involved in standardisation activities and NAAs/Qualified Entities involved in outsourcing.

7. Third indent

ECA refers, as example, of risk for decision based on research carried out or financed by industry. EASA uses research activities to gather information and not as exclusive source for technical decision-making.

Box 1

The tendering process which was completed by end of May 2012 is now compliant with EU and EASA financial rules. EASA is also bound by the system laid down within its Founding Regulation (Regulation (EC) No 216/2008 of the European Parliament and of the Council.)

8. In order to handle a risk, there are several mitigating controls which might be applied. Regarding the risk on potential conflict of interest when taking technical decisions, the Agency applies the "no single point of decision" approach as the most appropriate mitigating control for prevention of conflict of interest scenarios within EASA context. This principle is formally taken into account in each operational procedure and applied accordingly. This principle was recognised by the EU Parliament in its Resolution from 10 May 2012.

10. These rules only apply to staff employed by agencies. It is not possible to apply them to persons designated "*ad personam*" (not employed by the agencies) such as members of Management Boards and scientific experts in general or to persons representing MS (members of agencies' Boards representing MS and institutions).

13. EASA currently follows the European Commission guidelines on conflict of interest which EASA think they are in line with the OECD guidelines. In order to handle a risk, there are several mitigating controls which might be applied. Regarding the risk on potential conflict of interest when taking technical decisions, the Agency applies the "no single point of decision" approach as the most appropriate mitigating control for prevention of conflict of interest scenarios within EASA context. Impartiality of the decision making in the EASA operational processes is guaranteed through the collegiality of the technical assessment and the decision-making process. Each operational process has been described in the corresponding applicable procedure.
The aforementioned has been recently recognised by the European Parliament in a Resolution from 10 May 2012 (European Parliament resolution of 10 May 2012 with

observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Aviation Safety Agency for the financial year 2010 (C7-0285/2011 – 2011/2224(DEC); see in particular Point 16).

AUDIT SCOPE AND APPROACH

15. First indent

The European Parliament in its resolution from 10 May 2012 has recognised the following mitigation measures in this regard:

"Notes that the Agency's technical staff members need to be commonly recruited from national aviation authorities and the aviation industry; understands that the staff members must have sufficient and up-to-date technical experience of working in the field of aviation to perform a technical check of documents demonstrating compliance for the purposes of ensuring an adequate level of aviation safety as requested by the applicable Union legislation; is concerned however that this situation could cause conflicts of interest if a staff member recruited from an aircraft manufacturer works and takes decisions at the Agency on the certification of the aircraft he/she used to work on while employed by the manufacturer and, if not detected and adequately managed, could result in a conflict of interest situation; recognises however that the Agency has put in place a certification procedure where impartiality of the decision-making process is guaranteed through the collegiality of the technical assessments and the decision-making process itself".

21. The OECD guidelines (like the EU staff regulations) only focus on public officials employed by public authorities (and not on those who are not officials like members of Management Board and Board of Appeal, external experts). OECD guidelines may be applied to other categories of professionals by analogy. However, when applied, the principles of these guidelines need to be followed taking into account the specific situation in which they are intended to be applied. Therefore EASA will primarily follow the EU Commission guidelines in the area of Code of Conduct/Ethics; but also takes into account the OECD guidelines where needed and considers the specific situations in which they are intended to be applied.

OBSERVATIONS

26. EASA has no direct influence on the Management Board and Board of Appeal members as per the governance structure established by the Founding Regulation. This implies that EASA can only propose to the Management Board members to complete and publish a Declaration of Interests as done during the Management Board in June 2012.

28. In cases where the Agencies are not the appointing authority, it should be the duty of the respective appointing authority to screen the candidates before appointment.

35. EASA outsources a non-significant part of its certification tasks to NAAs and Qualified Entities (20% in average and being minor projects in its scope).

36. A dedicated standardised Framework Contract template is systematically used and contains a clause on conflict of interest management measures to be put in place by the

NAAs and Qualified Entities; and a clause on the right for EASA to verify these measures. EASA will develop criteria and methodology (based on the EASA specific policy on conflict of interest management) required to fulfil its clause during accreditation activities when deemed necessary. EASA may only require NAAs and Qualified Entities to put in place additional measures but has clearly no direct influence on these organisations to ensure that conflict of interest is managed to a comparable standard

45. The ECA report lists in its Annex II the existence of the Code of good Administrative Practice, which contains a clause on "impartiality and independence" at the Agency level, and the specific procedure for standardisation activities. In addition, EASA use the principle of collegiality of technical assessments and decision-making to guarantee the impartiality of its operational activities (i.e: certification, rulemaking, standardisation, etc). This principle is formally taken into account in each operational procedure and applied accordingly. It is also recognised by the EU Parliament in its Resolution from 10 May 2012. Therefore, EASA, in the current aforementioned context, adopted its own regulations/policies and procedures to deal with conflict of interest management - taking into account its particular governance and legal requirements from its founding legal acts.
During its Management Board in June 2012, EASA asked the Management Board members to complete a declaration of interests before the next Management Board in September 2012 and subsequent publication on the EASA web-site. In addition, the EASA website, since June 2012, mentions that the Executive Committee performs a declaration of interests and those from the five Directors of the Agency are now published on EASA web-site.

61. EASA provides a reference to the EU Commission guidance on its intranet page and mentioned it when dealing with individual cases.

64. EASA is bound to follow EU staff regulations. In case of breach of any Agency policy or procedure by a staff member, EASA will follow the existing disciplinary procedure in the EU Staff Regulations to handle such case.

69. EASA, since its creation, ensures transparency in its technical decision-making processes as requested in the respective technical and operational Agency procedures. In addition, the Agency has set-up its Integrated Management System (IMS) being ISO9001 certified since 2010. The EASA IMS strongly supports the implementation of transparency requirements, among others, in all Agency policies and procedures which cover decision-making situations and the gifts (Code of Good Administrative Practices (in particular Articles 7 and 8), EU Commission guidelines on gifts, specific policy on conflict of interest for standardisation activities, principle of collegiality in decision-making, provisions regarding conflict of interest within outsourcing contracts) as put in place by the Agency to deal with conflict of interest area.

71. During its Management Board in June 2012, EASA asked the Management Board members to complete a declaration of interests before the next Management Board in September 2012 and subsequent publication on the EASA web-site. In addition, the EASA website, since June 2012, mentions that the Executive Committee performs a declaration of interests and those from the five Directors of the Agency are now published on the EASA web-site.

73. EASA has no scientific committee or panel. The minutes of meetings with external experts involved in rulemaking, standardisation and certification activities are not published on the EASA web-site. However, the outputs of those meetings are made available in

different ways when necessary. For example, draft rules are published for public consultation including explanatory memoranda providing the background, reasons and justifications for the approach followed by the Agency on the issue at hand.

79. EASA provides already a dedicated compulsory training to newcomers (Agency staff) on its Code of Conduct (i.e Code of Good Administrative Practices) including the provisions related to conflict of interest contain therein. As part of the on-going consultancy framework contract (Framework Contract No -30-CE-0390041) from the European Commission DG Budget related to Internal Control Standards (ICS), EASAwill improve its existing compulsory training for newcomers to further detail the conflict of interest area. and foresees to propose a dedicated training on the specific conflict of interest policy to the members of the Management Board and Board of Appeal.

81. Agencies that provide scientific and technical advice or decisions as part of regulatory processes will always need staff and experts with experience from companies and associations operating in these markets. The policies and procedures on conflict of interest should not prevent the Agencies from having access to such expertise. Otherwise the problem may shift towards an inferior (scientific/technical) assessment with negative consequences for the life of citizens and consequent loss of trust by the general public in the regulators' work.

It should also be noted that Agencies, unlike EU institutions, can mainly offer only temporary positions to staff and that the current EU Staff Regulation does not provide the Agencies with provisions adequately basis adapted to this situation. The individuals must have the opportunity to take on jobs in industry, for example, after having worked with an Agency.

86. With experts and members of the Management Board and Board of Appeal, who are not staff members, EASA has no legal power to impose conditions on their freedom of employment after the end of their mandate. Also with regards to staff members there are certain limitations, resulting from the temporary nature of contracts that can be offered by Agencies and fundamental rights of the individuals working with them.

In addition, EASA aligned its existing template on post-employment with the one from the European Commission. Post-employment will be further improved within the on-going consultancy here-above mentioned for the Agency staff members where needed. As EASA has no direct influence on the members of the Management Board and Board of Appeal members, EASA cannot address post-employment issues for these members or any other external experts involved in EASA activities.

87. It should be noted that Agencies can not impose an absolute prohibition to take certain posts after working with them. This would conflict with the current interpretation of the staff regulations (constitutional right to work, no absolute prohibition).

CONCLUSIONS AND RECOMMENDATIONS

89. EASA acknowledges that at the time of the audit, shortcomings were identified when benchmarking the Agency's policies and procedures against OECD guidelines. It is, however, important to recall in this context that policies and procedures adopted and/or implemented after the Court completed its fieldwork (October 2011) have not been evaluated. A significant number of recommendations have thus been addressed by the time of publication of this report. With regard to the finding that "none of the selected Agencies adequately manages conflict of interests situations", it deserves clarification that EASA fully comply with its founding regulations and other laws that apply to the Agency, such as the EU Financial Regulation and the EU Staff Regulations. In addition, EASA in the current aforementioned context adopted its own regulations/policies and procedures - taking into account its particular governance and legal requirements from its founding legal acts. EASA has not identified an instance where a regulatory decision or technical opinion would have been compromised by an undue interest.

Recommendation 1

In addition to its existing measures, EASA is currently setting-up a specific Agency-wide policy on conflict of interest by extending the existing policy on Code of Conduct for Agency staff and will propose a dedicated policy on conflict of interest for Management Board and Board of Appeal to be adopted by them.

91. It needs to be taken into account that Agencies have no direct influence on certain appointments (e.g. Management Board, Board of Appeal, Committee members directly appointed by Member States) they can only perform the screening of candidates to be appointed by the Agency. Nevertheless, EASA could foresee to propose to the related appointing to establish screening procedures before appointment of the concerned member(s).

Recommendation 2

EASA introduced a chapter in its Agency-wide policy on conflict of interest for staff on screening before appointment. Regarding the Management Board and Board of appeal, the Agency foresees to propose a screening before appointment for conflict of interest in the dedicated policy to be adopted by the Management Board and the Board of Appeal for their respective members.

Recommendation 3

EASA will develop criteria and methodology (based on EASA specific policy on conflict of interest management) to perform verification on management of conflict of interest put in place in NAAs and Qualified Entities during their accreditation when deemed necessary. EASA may require NAAs and Qualified Entities to put in place additional measures but has clearly no direct influence on these organisations to ensure that conflict of interest is managed to a comparable standard.

Recommendation 4

EASA will establish clear and objective criteria for assessment of declarations of interest and apply them consistently for the Agency staff members. EASA foresees to propose specific clear and objective criteria for assessment of declarations of interests to be adopted by the Management Board and the Board of Appeal for their respective members.

94. EASA refers to and follows the EU Commission guidance on gifts and hospitality.

Recommendation 5

EASA defined its implementing rules on gifts and invitation for the Agency staff members within the Agency-wide policy under evaluation; and foresees to propose gifts and invitation chapter within the dedicated policy on conflict of interest to be adopted by the Management Board and the Board of Appeal for their respective members.

95. In case of breach of trust policies and procedures EASA apply the existing disciplinary procedures in EU Staff Regulations.

Recommendation 6

EASA introduced a chapter in its Agency-wide policy under evaluation related to breach of trust policies and procedures for the Agency staff members taking into account existing disciplinary procedures in EU Staff Regulations. EASA foresees to propose a chapter for breach of trust policies and procedures within the dedicated policy for conflict of interest to be adopted by the Management Board and the Board of Appeal for their respective members.

96. EASA has no scientific committee or panel. EASA publishes the Declaration of Interests of its five Directors and asked the Management Board to fill a declaration of interest to be published on EASA web-site.

Recommendation 7

EASA, since its creation, ensures transparency in its technical decision-making processes as requested in the respective technical and operational Agency procedures. In addition, the Agency has set-up its Integrated Management System (IMS) being ISO9001 certified since 2010. The EASA IMS strongly supports the implementation of transparency requirements, among others, in all Agency procedures.

EASA has no scientific committee or panel. During its Management Board in June 2012, EASA asked the Management Board members to complete a declaration of interests before the next Management Board in September 2012 and subsequently to be published on the EASA web-site. In addition, the EASA website, since June 2012, states that all members of the Executive Committee filled a declaration of interests and those from the five Directors of the Agency are published on EASA web-site.

EASA will extend the declaration of interests for its Agency staff playing an important role in the technical decision-making processes of the Agency.

97. EASA provides a mandatory training on its Code of Conduct to all newcomers (Agency staff).

Recommendation 8

EASA will improve its existing mandatory training for newcomers (Agency staff) to further detail the conflict of interest area. EASA foresees to propose a chapter on mandatory training as part of the dedicated policy to be adopted by the Management Board. and the Board of Appeal for their respective members.

98. EASA adopted its implementing rules on outside activities, which covers the post-employment area. EASA aligned its existing template on post-employment with the one from the European Commission. Post-employment will be further improved within the Agency-wide policy under evaluation for the Agency staff members where needed. As EASA has no direct influence

on the members of the Management Board and Board of Appeal members, EASA cannot address post-employment issues for these members or any other external experts involved in EASA activities.

With experts and members of the Management Board and Board of Appeal, who are not staff members, the Agency has no legal power to impose conditions on their freedom of employment after the end of their mandate. Also with regards to staff members there are certain limitations, resulting from the temporary nature of contracts that can be offered by Agencies and fundamental rights of the individuals working with them.

Recommendation 9

EASA will further improve the post-employment issues for its Agency staff members where needed. EASA could foresee to raise the post-employment issues for members of the Management Board and Board of Appeal. However, for Management Board members, Board of Appeal members and external experts, the Agency has no legal power to impose conditions on their freedom of employment after the end of their mandate.

Recommendation 10 and 11

It is crucial for EASA that the EU legislator develops further the EU regulatory framework in the area of conflict of interest management in order to have a compliant and consistent approach on conflict of interest management.

25 July 2012

REPLIES OF THE EUROPEAN CHEMICALS AGENCY TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS

"MANAGEMENT OF CONFLICT OF INTEREST IN SELECTED EU AGENCIES"

EXECUTIVE SUMMARY

I. ECHA acknowledges the Court of Auditors' special report and its recommendations. The report could serve as a basis for shared work to be undertaken with the European Commission and the other EU institutions to develop a common Union framework and/or minimum standards, as was concluded by the EU legislator in the context of the Inter-Institutional Working Group on regulatory agencies.

III. When evaluating the systems for safeguarding independence in ECHA, one has to consider all instruments in place. This includes the collegial opinion / decision-making of the Committees to avoid an individually-led process; the inter-disciplinary and multi-disciplinary composition of these bodies; the absence of hierarchical links among and between experts; and the fact that minority positions are recorded in case of majority opinions or decisions. Decisions by the Member State Committee even require unanimity. Moreover, observers from accredited stakeholder organisations are present in Committee meetings.

The regulatory processes managed by ECHA require that research performed by industry is used as the starting point. However, the scientific and technical assessment equally uses all other scientific data, be it from independent research, scientific literature and knowledge of experts, respecting the characteristic of quality science. Public consultations are organised to collect all relevant scientific information for specific opinions or decisions.

IV. Even if a comprehensive EU framework for managing conflicts of interest situations is lacking, there are specific legislative requirements concerning independence that are applicable to ECHA. In this context, ECHA developed policies and procedures, and is continuously enhancing these, mainly on the basis of Agency-specific regulatory requirements. In the absence of a comprehensive EU framework, some Agencies referred to the OECD Guidelines. However these are designed for public officials, which leaves uncovered the Management Board and Committee members.

V. ECHA acknowledges that at the time of the audit, shortcomings were identified when benchmarking the Agency's policies and procedures against OECD guidelines. It is, however, important to recall in this context that policies and procedures adopted and/or implemented after the Court completed its fieldwork (October 2011) have not been evaluated. A significant number of recommendations have thus been addressed by the time of publication of this report.

With regard to the finding that "none of the selected Agencies adequately manages conflict of interests situations", it deserves clarification that ECHA complies with its founding regulation and other laws that apply to the Agency, such as the EU Financial Regulation and the EU Staff Regulations. In addition, ECHA adopted its own procedures and policies, including a code of conduct - taking into account the particular governance and legal requirements from its founding legal act. ECHA has not identified an instance where a regulatory decision or scientific/technical opinion would have been compromised by an undue interest.

VII. ECHA acknowledges that its previous practices had shortcomings. The Agency notes, however, that the implementation of the new policy, initiated in February 2011 and adopted in September 2011, was not subject to

the audit scope of the Court. Details on the developments which address the recommendations are provided in the replies to the relevant observations and recommendations in this report.

X. (b) ECHA acknowledges that its previous practices had shortcomings. The Agency notes, however, that the implementation of the new policy, adopted in September 2011, was not subject to the audit scope of the Court. Details on the developments which address the recommendations are provided in the replies to the relevant observations and recommendations in this report.

X. (c) (i) ECHA acknowledges this recommendation. Taking into account that the Agency as such, or the Secretariat, have no direct influence on certain appointments (e.g. Management Board, Board of Appeal, Committee members directly appointed by Member States) the Agency can only and will perform the screening of candidates to be appointed by it. Nevertheless, the Agency could propose to the respective appointing authority to establish screening procedures before appointment of the concerned member(s).

As regards Committee members appointed by the Management Board, ECHA has had guidelines for these appointments in place since 2008, and which were turned into eligibility criteria in 2012. The Agency is in the process of further developing these criteria for all ECHA bodies.

X. (c) (iv) The first formal internal decision issued by the (Interim) Executive Director of ECHA after the establishment of the Agency concerned "Guidance for staff on conflicts of interest and invitations and gifts as well as declarations of commitment, confidentiality and interests" (Decision ED/01/2007 of 31 October 2007).

The ECHA Management Board adopted on 22 March 2012 its own Code of Conduct which has been published and which covers, *inter alia,* aspects such as gifts and invitations. The Management Board invited the ECHA Committees and other bodies to agree upon similar Codes of Conduct and work in this respect is ongoing.

X. (c) (v) ECHA acknowledges that it had no specific breach of trust procedures in place at the time of the audit. However, general breach of trust procedures were in place, with regard to staff, in the form of disciplinary proceedings and other possible procedures under the EU Staff Regulations. These general procedures are also applied by the European Commission, e.g. for cases where a staff member fails to declare an interest to the appointing authority. Furthermore, the rules of procedure of the ECHA Committees and other bodies, in place at the time of the audit, are a general instrument which are suitable to deal with a breach of the obligations incumbent on the experts.

Based on its new policy, ECHA will develop detailed and specific breach of trust provisions for situations related to potential conflicts of interests.

X. (c) (vii) ECHA is continuously improving its training provided to staff on conflict of interests. The Agency notes that part of its obligatory newcomer training, since the early phase of the set-up of the Agency, is a dedicated session on declarations of conflict of interests and confidentiality as well as post-employment duties. The induction training courses provided by ECHA since 2008 also include training on Conduct and Ethics at work.

X. (c) (viii) ECHA has adopted in 2008 by analogy the Commission decision on outside activities and assignments of 28 April 2004. This decision, implementing Article 16 of the EU Staff Regulations, is part of the Agency's internal rules and requires employees to inform ECHA if they intend to engage in an occupational activity within two years after leaving the Agency. The rules foresee that the engagement can be forbidden or conditions imposed.

It is noted, however, that there are certain limitations, resulting from the temporary nature of the contracts that can be offered by ECHA and the fundamental rights of the individuals working with the Agency. Furthermore, as regards experts and members of the Management Board, the Forum and the Committees who are not staff members, the Agency has no legal power to impose conditions on their freedom of employment after the end of their mandate.

X. (d) This report could serve as a basis for a shared work to be undertaken with the European Commission and the other EU institutions to develop a common Union framework and/or minimum standards, as it was concluded by the EU legislator in the context of the Inter-Institutional Working Group on regulatory agencies.

INTRODUCTION

8. When evaluating the systems for safeguarding independence in ECHA, one has to consider all the instruments in place. This includes the collegial opinion/ decision-making of the Committees to avoid an individually-led process; the inter-disciplinarily and multi-disciplinarily composition of these bodies; the absence of hierarchical links among and between experts, and the fact that minority positions are recorded in case of majority opinions or decisions. Decisions by the Member State Committee even require unanimity. Moreover, observers from accredited stakeholder organisations are present in Committee meetings.

10. These rules only apply to staff employed by Agencies. It is not possible to apply them to persons designated "*ad personam*" (not employed by the Agencies) such as members of Management Boards and scientific experts in general or to persons representing MS (members of Agencies' Boards representing MS and institutions).

AUDIT SCOPE AND APPROACH

21. The OECD guidelines (like the EU staff regulations) only focus on public officials employed by public authorities. OECD guidelines may be applied to other categories of professionals by analogy. However, the principles of these guidelines need to be followed taking into account the specific situation in which they are intended to be applied.

OBSERVATIONS

28. In cases where the Agency is not the appointing authority, it should be the duty of the respective appointing institution to screen the selected persons before they are appointed.

32. In 2008, the ECHA Management Board adopted a procedure and eligibility criteria to select and invite stakeholder organisations to participate as observers in Forum and Committees meetings. These criteria were revised in 2011. The Commission gave its agreement by the Decision of 23 March 2011 (C(2011) 1823 final.

47. ECHA acknowledges that its previous practices had shortcomings. With the implementation of the new policy, initiated in February and adopted in September 2011, a new template for staff declarations was taken into use in November 2011 and managers have access to the declarations of their staff since 2012.

As regards the practice at the time of the audit, it should be noted that the fact that the interests declared in the initial declaration had not been assessed at that point in time did not mean that these issues had not been highlighted in spontaneous declarations whenever tasks were assigned. In fact, as is their duty, the staff members concerned have consistently highlighted a conflict of interest regarding files involving the companies mentioned in their declarations and no such tasks have ever been assigned to them. As such, no actual conflict of interest has ever occurred at ECHA.

Box 4

The examples represent cases that were not assessed at the time of recruitment, while they were subsequently addressed during the course of work at the Agency. The Agency has duly assessed the issues identified by the Court and established that no conflict of interest situation occurred. The issue as such as been addressed with the implementation of the new policy on the management of potential conflicts of interests.

49. Specific declarations of interests submitted in a written form (before, this was done verbally) are now also compulsory for permanent members, before being assigned to a case.

50. The Board of Appeal has in the meantime put in place a verification system, and since March 2012, the Chair has a confidential list of the TQM's previous clients to refer to when undertaking the verification.

51. The Agency's procedures foresee that only the appellant's identity is known to the Board of Appeal. Since there are possibly hundreds of co-registrants affected by a single appeal case, the possibilities to verify any conflicts of interest, and document conflict of interests situations, would otherwise be limited. See also reply to Box 5.

52. Since the audit, the Chair consults a list of companies that the member has worked with on REACH issues; this list has been provided under condition of confidentiality. It is checked before the assignment of each case. It should be noted however that this list cannot be complete due to the deontological rules of certain professional associations (e.g. attorneys) which means that members cannot reveal their clients' identity[1]

Box 5

The legislative authority of the European Union determined in ECHA's founding regulation a number of specific independence safeguarding measures for the members of the Board of Appeal, including an obligation to provide information on cases in which a member has a personal interest and may, thus, not take part in the proceedings. See Article 90(5) and (6) of Regulation (EC) No 1907/2006. These provisions are duly followed by the Board of Appeal. Additional measures, such as a code of conduct and the obligation to produce annual declarations of interest, have been put in place. The permanent members are also subject to the Staff Regulations which contain provisions on independence. Furthermore, the Chair now has the list of previous work activities to refer to (see above).

54. The minutes of the ECHA Management Board record, for each meeting, the Chair's request for specific declarations of interest. Should such a declaration be made, the minutes duly reflect it. The minutes will in future also clarify the action taken in the rare cases when this becomes relevant. The annual declarations of interest by Management Board members are published on the internet and reviewed by the Chair (Deputy Chair for the Chair's declaration). Based on the remark of the Court, this review has, since the end of 2011, been formally documented.

Box 6

ECHA acknowledges that its previous practices had shortcomings and these have been addressed since the time of the audit.

56. ECHA acknowledges that it has not predefined in detail what the consequences are of having a certain private interest. ECHA has relied in the past on a specific case-by-case analysis of each case of potential conflicting interests. ECHA's new policy on conflicts of interest, of September 2011, includes financial interests,

[1] Circumstance confirmed by the Finnish Bar Association after ad hoc request on this matter.

past employment and past consultancy work. The implementation of the new policy addresses the Court's finding.

61. The first formal internal decision issued by the (Interim) Executive Director of ECHA after the establishment of the Agency concerned "Guidance for staff on conflicts of interest and invitations and gifts as well as declarations of commitment, confidentiality and interests" (Decision ED/01/2007 of 31 October 2007). The ECHA Management Board adopted on 22 March 2012 its own Code of Conduct, and which has been published. This covers aspects such as, *inter alia,* gifts and invitations. The Management Board invited the ECHA Committees and other bodies to agree upon similar Codes of Conduct and work in this respect is ongoing.

64. ECHA acknowledges that it had no specific breach of trust procedures in place at the time of the audit. However, general breach of trust procedures, with regard to staff, were in place in the form of disciplinary proceedings and other possible procedures under the EU Staff Regulations. These general procedures are also applied by the European Commission, e.g. in cases where a staff member fails to declare an interest to the appointing authority.

65. Based on its new policy, ECHA will develop detailed and specific breach of trust provisions (see reply to point 64).

72. See reply to point 54.

76. - First indent

At the time of the audit, the public minutes of the ECHA bodies did already record for each meeting the Chair's request for specific declarations of interest, as well as any interest declared. Based on the Court's remark, the minutes will in future also clarify the action taken in the cases where this becomes relevant.

77. – Second indent

Training on staff declarations and post-employment duties is organised for all ECHA newcomers on an obligatory basis. Attendance for individual sessions is duly limited to newcomers.

81. ECHA acknowledges this observation. However, it should also be noted that ECHA, unlike EU institutions, can only offer temporary positions to staff. The individuals must have the opportunity to take on jobs in industry, for example, after having worked with an Agency.

As regards the issue of movement of personnel between the public and private sector, it is noted that Agencies that provide scientific and technical advice or decisions as part of regulatory processes will always need staff and experts with experience from companies and associations operating in these markets. The policies and procedures on conflict of interest should not prevent the Agencies from having access to such expertise. Otherwise, the problem may shift towards an inferior (scientific/technical) assessment with negative consequences for the life of citizens and a consequent loss of trust by the general public in the regulators' work.

See also the reply to point 98 / recommendation 9.

82. In line with the Commission decision on outside activities and assignments of 28 April 2004, which ECHA adopted by analogy in 2008, staff members are asked to sign a declaration, acknowledging their duties under Article 16 of the Staff Regulations, when they leave the service of the Agency. The form has been improved since the audit visit in October 2011 (new form taken in use in May 2012).

85. With regard to the "post-employment" of experts and members of the Management Board, who are not staff members and hence not employed by the Agency, ECHA has no legal power to impose conditions on their freedom of employment after the end of their mandate. Agency policies or procedures in this respect would thus have no valid legal basis, nor would they have any impact, as the Agency could not enforce them.

86. Agencies cannot impose on an individual an absolute prohibition to take certain posts after having worked at the said Agency. This would conflict with the current interpretation of the staff regulations (constitutional right to work, no absolute prohibition).

88. ECHA acknowledges this observation. The Agency addresses post-employment aspects more systematically than it used to, within its new policy on the management of (potential) conflicts of interests. Moreover, since May 2012, an improved form for declaring post-employment circumstances has been taken into use.

CONCLUSIONS AND RECOMMENDATIONS

89. ECHA acknowledges that at the time of the audit, shortcomings were identified when benchmarking the Agency's policies and procedures against OECD guidelines. It is, however, important to recall that policies and procedures adopted and/or implemented after the Court completed its fieldwork (October 2011) have not been evaluated. A significant number of recommendations have thus been addressed by the time of publication of this report.

With regard to the finding that "none of the selected Agencies adequately manages conflict of interests situations", it deserves clarification that ECHA complies with its founding regulation and other laws that apply to the Agency, such as the EU Financial Regulation and the EU Staff Regulations. In addition, ECHA adopted its own procedures and policies - taking into account its particular governance and legal requirements from its founding legal act. ECHA has not identified an instance where a regulatory decision or scientific/technical opinion would have been compromised by an undue interest.

Recommendation 1

ECHA acknowledges that at the time of the audit shortcomings were identified when benchmarking its policies and procedures against OECD guidelines. It is, however, important to recall that policies and procedures adopted and/or implemented after the Court completed its fieldwork (October 2011) have not been evaluated. A number of recommendations have been addressed by the time of publication of this report. Reference is made to the more specific replies to the relevant parts of the report.

The following measures which were not mentioned in other replies have been taken since the audit in October 2011:

- Implementing rules (work instruction) on prevention of conflicts of interest adopted in June 2012;
- New guidance for filling in declarations of interests adopted in November 2011;
- New template for annual declarations taken into use in November 2011, while giving managers access to the declarations of their staff;
- Publication of declarations of interest of the ECHA managers on the website, since 2012;
- An advisory Committee for conflict of interest situations with a Management Board appointee and a external expert was established in June 2012.

Recommendation 2

This is correct and, to a large extent, already presently undertaken by ECHA. However, it should be taken into account that Agencies have no direct influence on certain appointments (e.g. Management Board, Board of Appeal, Committee members directly appointed by Member States): they can only perform the screening of candidates to be appointed by the Agency. Nevertheless, the Agency could propose to the respective appointing authority to establish screening procedures before appointment of the concerned member(s).

As regards Committee members who are appointed by the Management Board, ECHA has had guidelines in place since 2008 which were turned into eligibility criteria in 2012. The Agency is in the process of further developing these criteria. Furthermore, the ECHA Secretariat has proposed to the Management Board to establish eligibility guidelines for members of the Management Board, the Member State Committee and the Forum, which are appointed directly by the Members States or the EU institutions.

Recommendation 4

ECHA acknowledges that its previous practices had shortcomings. The Agency notes, however, that the implementation of the new policy adopted in September 2011 was not subject to the audit scope of the Court. Reference is made to the actions taken since the audit and the planned activities as indicated in the replies to the Court's report.

In addition to that, ECHA will take the following specific actions

- implementation of a specific conflict of interest breach of trust procedure
- Sample checks of the declarations of interests received against the information available in ECHA's own files (e.g. CVs provided by the Management Board, Committee and Forum members and by the ECHA staff)

Recommendation 5

The first formal internal decision issued by the (Interim) Executive Director of ECHA after the establishment of the Agency concerned "Guidance for staff on conflicts of interest and invitations and gifts as well as declarations of commitment, confidentiality and interests" (Decision ED/01/2007 of 31 October 2007).

The ECHA Management Board adopted on 22 March 2012 its own Code of Conduct, and which has been published. This covers aspects such as, inter alia, gifts and invitations. The Management Board invited the ECHA Committees and other bodies to agree upon similar Codes of Conduct and work in this respect is ongoing. See reply to point 61.

Recommendation 6

At the time of the audit, ECHA had breach of trust procedures in place with regard to its staff, while the rules of procedure of the scientific committees also included instruments to deal with a breach of the obligations incumbent on the experts. Based on its new policy, ECHA will develop specific breach of trust provisions. See also reply to points 64-65.
The following measures have been taken since the audit in October 2011:

- New Policy of September 2011 includes general provisions with regard to breach of trust procedures for the Management Board, Committees and Forum, but also for the BoA and ECHA staff;
- New implementing rules to the Staff Regulations regarding administrative inquiries and disciplinary proceedings were adopted by the Management Board on 23 March 2012.

Recommendation 7

The minutes for each meeting of the ECHA bodies did already record, at the time of the audit, the Chair's request for specific declarations of interest as well as any interest declared. Based on the Court's remark, the minutes will in future also clarify the action taken in cases when this becomes relevant. See also replies to points 54 and 76.

Recommendation 8

ECHA is continuously improving its training provided to staff on conflict of interests. The Agency notes that part of its obligatory newcomer training, since the early phase of the set-up of the Agency, is a dedicated session on declarations of conflict of interests and confidentiality as well as post-employment duties. The induction training courses provided by ECHA since 2008 also include training on Conduct and Ethics at work. See also reply to point 77.

Recommendation 9

ECHA has adopted in 2008 by analogy the European Commission decision on outside activities and assignments of 28 April 2004. This decision, implementing Article 16 of the EU Staff Regulations, is part of the Agency's internal rules and requires employees to inform the Agency if they intend to engage in an occupational activity within two years after leaving the service. The rules foresee that the engagement can be forbidden or conditions imposed.

It has to be noted in this context that a fundamental flaw undermines the post-employment duties as described in Article 16 of the EU Staff Regulations. This provision was drafted decades ago to address the issue of officials who, after a life long employment took up a form of side-employment upon retirement. The institutions would then have the possibility to cut the pension payments in cases of a breach. This provision was later made applicable to the staff categories usually employed in the Agencies. There is, however, one important aspect that was not addressed: Agency staff have short-term contracts (as opposed to officials). This implies that these temporary staff will need to seek other employment after the end of their contract. This is guaranteed by the fundamental right to employment. A certain level of "revolving doors", with staff moving on to be employed by industry or NGOs is therefore normal, given that ECHA employs experts in highly specialised areas, and subsequent employment will naturally be found in the corresponding sector.

With regard to members of the Management Board or the Committees, see reply to point 85.

Recommendations 10 and 11

It is considered crucial that the EU legislator develops further the EU regulatory framework in the area of conflict of interest management in order to have a compliant and consistent approach on conflict of interest management. The report could serve as a basis for shared work to be undertaken with the Commission and the other institutions to develop a common Union framework and/or minimum standards, as was concluded by the EU legislator in the context of the Inter-Institutional Working Group on regulatory Agencies.

REPLIES OF THE EFSA TO THE SPECIAL REPORT OF THE COURT OF AUDITORS "MANAGEMENT OF CONFLICT OF INTEREST IN SELECTED EU AGENCIES"

EXECUTIVE SUMMARY

I. EFSA welcomes the review carried out by the ECA and the recommendations put forward to strengthen the procedures in place to manage any potential conflicts of interest in the EU agencies.

EFSA has required the submission of declarations of interest by its scientific experts from the establishment of its first scientific panels in 2003 and laid down a policy on Declarations of Interest in 2007, which was strengthened in 2011 in the comprehensive Policy on Independence and Scientific Decision Making Processes.

In the absence of a comprehensive EU regulatory framework, EFSA, working within the legal instruments available, has focused its time and resources on the category considered of highest risk – the experts involved in the development and delivery of scientific advice informing policy makers, and EFSA's staff who support them in this task.

EFSA's Policy on Independence and Scientific Decision-Making Processes published in 2011 integrates all the steps EFSA has taken to ensure the implementation of its core values – scientific excellence, openness, transparency and independence – in its scientific outputs and decision-making processes. These rules and procedures put in place over time cover: organisational governance; scientific decision-making processes, such as the processing of requests and mandates; EFSA's Scientific Committee and Panels, including the selection of experts; and other elements, for example transparency in the decision-making process.

II. The OECD definition of conflicts of interest was designed specifically to cover the interests of public officials. However, around 3/4 of those who work with EFSA and who are subject to the procedures under review for this report, namely scientific experts and Management Board members, do not work for EFSA in the capacity of public officials responding to the obligations of an employment contractual relationship.

EFSA is enforcing very strict standards when it comes to handling potential conflicts of interests as part of comprehensive policies covering all key dimensions critical to the delivery of independence and excellence in addition to its declarations of interest policy.

As part of the regular review of these policies, the procedures and rules used to implement its 2011 Policy on Independence and Scientific Decision-Making Processes provide a clear definition of conflicts of interests for staff, experts and Management Board members, which are compatible with OECD guidelines.

III. Every system presents risk and EFSA has in place control assurance measures deployed to identify and mitigate the risks in proportion to the sensitivity of the tasks carried out. For example, it has focused its efforts on the category considered of highest risk – the scientific experts involved – in the development and delivery of scientific advice informing policy makers, and EFSA's staff who support them in this task.

Besides the policies and procedures in place concerning Declarations of Interest, it is important to note that there are other mechanisms which ensure EFSA's work is impartial and free from undue influence.

In particular:

- ✓ opinions are the outcome of collective decision-making of the Scientific Committee/Panels, no one expert can unduly influence the decisions of the Panel;
- ✓ minority opinions are recorded;
- ✓ the inter-disciplinarity and multi-disciplinarity of Scientific Committee/Panels membership;

- ✓ absence of hierarchical links among and between experts;
- ✓ the guidance published by the Scientific Committee on the relevant information to be included in EFSA opinions to ensure the transparency of risk assessments.

Additionally, there exist procedures governing the processing of mandates and requests, information gathering, selection of experts as well as public consultations and a comprehensive quality review programme. EFSA is also offering stakeholders the possibility of attending some plenaries of its Scientific Committee and Panels as observers and is in the process of developing this further.

EFSA also has a risk communication mandate which contributes and helps ensure the transparency and independence of its work.

As for the Management Board, members are required to sign a declaration of commitment, including a commitment to act independently, and to provide an annual Declaration of Interests. Members are also required to sign a Code of Conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest and provides guidance on standards expected by EU institutions and the general public.

IV. EFSA would welcome a comprehensive EU regulatory framework that would officially regulate the structure of the evaluation and handling of conflicts of interest and support the assessment of compliance by any controlling authority.

In the absence of such a comprehensive EU regulatory framework, EFSA has introduced and regularly updates its policies and procedures aimed at mitigating risks associated with individuals' interests most relevant to its independence.

EFSA has required the submission of declarations of interests by its scientific experts since the establishment of its first scientific panels in 2003 and published a policy on Declarations of Interest in 2007, which was strengthened in 2011 in the integrated Policy on Independence and Scientific Decision-Making Processes.

Rules used to implement the 2011 Policy provide a clear definition of conflicts of interests for staff, experts and Management Board members, which are compatible with OECD guidelines.

V. EFSA since 2007 introduced and regularly updated, and strengthened in 2011, a comprehensive framework for avoiding potential conflicts of interests, in particular through its robust Declarations of Interests (DoI) Policy. EFSA has already planned its review for 2013.

In the absence of a comprehensive EU regulatory framework, EFSA has focused its time and resources on the category considered of highest risk – the experts involved in the development and delivery of scientific advice informing policy makers, and EFSA's staff who support them in this task.

EFSA has required the submission of declarations of interest by its scientific experts already since 2003 and laid down a policy on Declarations of Interest in 2007, which was strengthened in 2011.

As an example of the breadth of its DoI policy, EFSA, in 2011, screened more than 8 000 annual and specific Declarations of Interests and scrutinised almost 40 000 agenda items. On 356 occasions experts have been excluded totally or partially from EFSA activities.

VI. EFSA welcomes the acknowledgement of the Court.

X. (c) (i) For EFSA Staff, annual declarations of interest are required since 2007 and since 2011 additional steps have been introduced to assess candidates prior to appointment.

For experts, screening was implemented before appointment from 2007 in EFSA and improved in 2011 with the new Policy on Independence and the related implementing acts.

For Management Board members, screening is performed by EFSA after their appointment by the Council.

For Advisory Forum members, screening is performed by EFSA after their appointment by Member States.

In particular, the EFSA's expert Candidates (higher category of risk) are screened twice before appointment, during the selection process (1) and if selected before the appointment process (2). This has been the case and is documented since 2007. The screening is based on clearly specified criteria and these were strengthened by the independence policy adopted in December 2011.

X. (c) (iii) Criteria implemented since 2007, and further improved in 2011 (with the Policy on Independence and Scientific Decision Making Processes and related implementing acts) by introducing in two self-explanatory synoptic tables the description of compatible and incompatible interests.

X. (c) (iv) Invitation policy implemented since 2009 in EFSA.

In relation to gifts, EFSA has since many years applied the framework provided by the European Commission on ethics and integrity, and has adopted a specific policy on July 2012.

X. (c) (v) Breach of trust procedures have been defined and implemented for the following categories of population:

- for all experts (Scientific Committee, Scientific Panels and Working Groups) ("Implementing act to the Policy on Declaration of Interests – Guidance document on Declarations of Interest, page 7; signed 8 September 2009").

- for staff members: Art. 16, 17, 19 of Staff Regulation (disciplinary procedure)

- for Management Board members (Article 15 of the Rules of Procedures of the Management Board of EFSA, 31 March 2009)

It is important to highlight that in case of breach of trust of a Management Board member, EFSA has to refer to the appointing Authority (Council) since the Executive Director cannot dismiss a member of the Management Board.

X. (c) (vi) Declarations of Interest of scientific experts, members of the Management Board and Management Team are all published on EFSA's website. Transparency in the scientific decision-making process is ensured through the publication on EFSA's website of minutes of meetings of the Scientific Committee, the scientific Panels and Working Groups, where all decisions in the risk assessment process are recorded as well as the publication of final scientific outputs.

EFSA is offering to stakeholders the possibility of attending plenaries of some of its Scientific Committee and Panels meetings as observers and is in the process of developing this further.

X. (c) (vii) Training on conflict of interest is compulsory for every member of EFSA staff since 2010 (2007 for experts) supported by a dedicated manual and training material on the issue.

EFSA Management Board Members will receive dedicated training on Ethics and Integrity as of 2012.

X. (c) (viii) Since 2010 EFSA has actively sought information on post employment status from departing and former staff and has designed a specific process for assessing and if necessary imposing restrictions. EFSA is fully in line with the provision of article 16 of the Staff Regulations.

X. (d) EFSA would welcome such a comprehensive EU framework.

INTRODUCTION

1. This OECD definition covers only some of the actors EFSA is working with, as defined by the legislator, namely the officials and by extension the public agents under time limited contractual relationships.

7. EFSA wants to stress that:

- The mandate of EFSA's Management Board is administrative and strategic supervision and it is never involved in the development of scientific risk assessment outputs.

- EFSA Management Board Members are nominated for their competences by the Council out of a competitive process managed by the European Commission and participate in EFSA Management Board 'ad personam' and not as representatives of the organisations they collaborate with.

- The Stakeholder Consultative Platform is solely a consultative body used by EFSA to keep abreast of the general expectations and concerns of societal and productive sectors concerned by its remit. It does not play any role in the scientific decision- making processes of EFSA.

8. EFSA agrees with the Court statement and has developed since 2007 a comprehensive framework to mitigate the risk and perception of it.

9. EFSA welcomes the call for an adequate framework which does not currently exist.

AUDIT SCOPE AND APPROACH

21. The OECD guidelines (like the EU staff regulations) focus on public officials employed by public authorities (and not on those who are not staff). OECD guidelines may be extrapolated only to some extent to other populations.

In the actual legal provision EFSA holds an employment relationship only with its staff representing around 1/4 of the population under review.

OBSERVATIONS

29. For experts, screening was implemented before appointment from 2007 in EFSA and improved in 2011 with the new Policy on Independence and Scientific Decision-Making Processes and the related implementing acts.

In particular, EFSA's expert Candidates (higher category of risk) are screened twice before appointment, during the selection process (1) and if selected before the appointment process (2). This has been the case and is documented since 2007. The screening is based on clearly specified criteria and these were strengthened by the independence policy adopted in December 2011.

38. EFSA welcomes the acknowledgement of the Court.

55. and Box 6: EFSA is committed to high quality and consistent assessment of declarations of interest since 2007.

It has gradually improved its policy and instruments and in 2011 (with the new Policy on Independence and Scientific Decision-Making Processes and the related implementing acts) introduced in particular two self-explanatory synoptic tables that describe compatible and incompatible interests with the objective of supporting the consistency of assessments.

Any breach is considered and conclusions are drawn.

57. and Box 7 The experts working with EFSA are not the originators of the risk assessment 'concepts'. These 'concepts' are usually contained in international standards (in use by WHO, OECD, FDA, etc.) which have been in use well before EFSA's creation.

Experts, by the very nature of scientific expertise itself, have to have a deep involvement and knowledge on the subjects they are to contribute to (interest). They elaborate the collective and multidisciplinary expertise through collegial working methods confronting different schools of thoughts and disciplines

Collegiality in itself (among the 21 members of each panel) is a very significant, but not exclusive, mitigation to any potential disproportional influence from a single expert.

The role of EFSA panels (21 experts) is to peer review the outputs prepared by the working groups (referred to by the Court as 'Scientific Body') following international peer review standards.

There is no involvement of ILSI as such in any EFSA scientific activities.

60. and Box 9 EFSA will consider this point as part of the planned review of its Policy on Independence and Scientific Decision-Making Processes by the end of 2013.

61. In relation to gifts, EFSA has for many years applied the framework provided by the European Commission on ethics and integrity, and has adopted a specific policy in July 2012.

66. Breach of trust procedures have been defined and implemented for the following categories of population:

- for all experts (Scientific Committee, Scientific Panels and Working Groups) ("Implementing act to the Policy on Declaration of Interests – Guidance document on Declarations of Interest, page 7; signed 8 September 2009").

- for staff members: Art. 16, 17, 19 of Staff Regulation (disciplinary procedure)

- for Management Board members (Article 15 of the Rules of Procedures of the Management Board of EFSA, 31 March 2009)

It is important to highlight that in the case a breach of trust of a Management Board member, EFSA has to refer to the appointing Authority (Council) since the Executive Director cannot dismiss a member of the Management Board.

72. In line with its 2007 policy and rules of operation of Scientific Committee/Scientific Panels all Declarations of Interest (DoI) and minutes of the meetings, including assessment of DoI, are published on EFSA's website.

88. and Box 10 The review by the Ombudsman of the allegation of revolving doors is ongoing.

It must be noted that since 2004, 160 staff members have left EFSA and only 2 have moved to industry in areas covered by EFSA's remit (one has been imposed restriction).

Since 2010 EFSA has been actively seeking information on post- employment status from departing staff and has designed a specific process for assessing and if necessary imposing restrictions.

EFSA is fully in line with the provisions of article 16 of the Staff Regulations.

CONCLUSIONS AND RECOMMENDATIONS

89. EFSA since 2007 introduced, regularly updated and strengthened in 2011, a comprehensive framework for avoiding potential conflicts of interests, in particular through its robust Declarations of Interests (DoI) Policy. EFSA has already planned its regular review for 2013.

In the absence of a comprehensive EU regulatory framework, EFSA has focused its time and resources on the category considered of highest risk – the experts involved in the development and delivery of scientific advice informing policymakers, and EFSA's staff who support them in this task.

EFSA has required the submission of declarations of interest by its scientific experts already in 2003 and laid down a policy on Declarations of Interest in 2007, which was strengthened in 2011.

As an example of the breath of its DoI control policy, EFSA, in 2011, screened more than 8,000 annual and specific Declarations of Interests and scrutinised more than 40,000 agenda items. On 356 occasions experts have been excluded totally or partially of EFSA activities.

91. For EFSA Staff, annual declarations of interest are required since 2007 and since 2011 additional steps have been introduced to assess candidates prior to appointment.

For experts, screening was implemented before appointment from 2007 in EFSA and improved in 2011 with the new Policy on Independence and Scientific Decision-Making Processes and the related implementing acts.

For Management Board members, screening is performed by EFSA after their appointment by the Council.

For Advisory Forum members, screening is performed by EFSA after their appointment by Member States.

In particular, EFSA's expert Candidates (higher category of risk) are screened twice before appointment, during the selection process (1) and if selected before the appointment process (2). This has been the case and is documented since 2007. The screening is based on clearly specified criteria and these were strengthened by the independence policy adopted in December 2011.

Recommendation 2

See point 91 above.

94. Invitation policy implemented since 2009 in EFSA.

In relation to gifts, EFSA has for many years applied the framework provided by the European Commission on ethic and integrity, and has adopted a specific policy in July 2012.

Recommendation 6

Breach of trust procedures have been defined and implemented for the following categories of population:

- for all experts (Scientific Committee, Scientific Panels and Working Groups) ("Implementing act to the Policy on Declaration of Interests – Guidance document on Declarations of Interest, page 7; signed 8 September 2009").

- for staff members: Art. 16, 17, 19 of Staff Regulation (disciplinary procedure)

- for Management Board members (Article 15 of the Rules of Procedures of the Management Board of EFSA, 31 March 2009)

It is important to highlight that, in the case of a breach of trust of a Management Board member, EFSA has to refer to the appointing Authority (Council) since the Executive Director cannot dismiss a member of the Management Board.

Recommendation 7

In accordance with Article 37 of EFSA's Founding Regulation, experts shall declare interests. In 2007, EFSA has adopted a policy, and Guidance and Procedures in order to implement this provision. In particular, experts shall declare annually (annual DoI) and before the meeting in relation with the agenda (specific DoI) and these interests are screened and assessed. The outcome of this assessment is made available in the minutes of Working Groups and Panels/Scientific Committee which are available on EFSA's website.

Recommendation 8

Training on conflict of interest is compulsory for every EFSA staff member since 2010 (2007 for experts) supported by a dedicated manual and training material on the issue.

EFSA Management Board Members will receive a dedicated training on Ethics and Integrity in October 2012.

98. Since 2004, 160 staff members have left EFSA and only 2 have moved to industry in areas covered by EFSA's remit (restrictions have been imposed in one case).

98. (b) Criteria implemented since 2007 and further improved in 2011(with the new Policy on Independence and Scientific Decision-Making Processes and the related implementing acts) by introducing two self-explanatory synoptic tables that describe compatible and incompatible interests.

98. (c) Implemented since 2012 according to the new Policy on Independence and Scientific-decision Making Processes issued in 2011 for EFSA staff.

99. EFSA would welcome such a comprehensive EU framework.

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THE AGENCY'S REPLIES/ REPONSES DE L'AGENCE

Executive Summary

I. EMA takes note of the Court's Report and emphasises that the Agency is committed to further improve its handling of conflicts of interests as the Agency has done over the past 8 years, hereby complying with the legal provisions on the handling of conflicts of interests applicable to EMA as laid down in its Founding Regulation, the EMA Code of good administrative behaviour and the Staff Regulations. Since the Court's audit field work in October 2011 various initiatives have been taken by EMA (as further elaborated upon in various sections of this Report) to further increase the robustness of its procedures and to improve transparency in this field. As a consequence, EMA has already addressed most recommendations made by the Court.

II. The OECD Guidelines are not legally binding on EMA Staff, Management Board members, or Scientific Committees' members and experts.

EMA has put in place for its handling of conflicts of interests policies and procedures, which comply with legislation applicable to the Agency in this field, and in developing such policies and procedures has applied a set of robust principles, compatible with the OECD Guidelines.

III. Although research is carried out/ data are provided by pharmaceutical industry, EMA takes into account all available information, including any other data brought to the attention of the Agency. All such data are subsequently assessed through a robust scientific review process, which includes evaluation by both a Rapporteur and a Co-Rapporteur and a peer review of the Rapporteur/ Co-Rapporteur assessment at the level of the Scientific Committee, resulting in collegial opinion-making. Therefore, the EMA opinions are based on peer-reviewed science-based assessments, on the basis

of all available information (data provided by industry, supplemented by any other data provided to EMA).

IV. In the absence of an EU regulatory framework laying down common minimum requirements on the handling of conflicts of interests, EMA has complied with the legal provisions applicable to the Agency in this field, as laid down in EMA's Founding Regulation, the EMA Code of good administrative behaviour and the Staff Regulations. As regards the use of OECD Guidelines it should be noted that these are not legally binding on EMA Staff, Management Board members, or Scientific Committees' members and experts, but EMA in developing its policies and procedures in the field of the handling of conflicts of interests has applied a set of robust principles, compatible with the OECD Guidelines.

V. EMA is of the view that it adequately manages conflicts of interests, although it acknowledges that there was further room for improvement at the time of the Court's audit field work (October 2011). EMA in particular emphasises the following aspects:

- Notwithstanding the absence of an EU regulatory framework on the handling of conflicts of interests EMA has since its creation implemented the specific legal provisions applicable to the Agency in this field, and, as a result, has complied with the legal requirements. Furthermore, EMA has over the past 8 years continuously monitored its handling of conflicts of interests, has analysed experience obtained, has looked into lessons learned and taken remedial action whenever necessary. As a consequence, EMA has strengthened the robustness of its handling of conflicts of interests over the past 8 years and has increased transparency in this field (several policies and procedures have been developed and revised over the past 8 years, see below for further information).
- As stated in its policy on the handling of conflicts of interests of Scientific Committees' members and experts, when dealing with conflicts of interests there is a need to find the best balance between ensuring that Scientific Committees' members and experts participating in EMA activities

have no interests in the pharmaceutical industry which could affect their impartiality vis-à-vis securing the best possible scientific expertise. Otherwise the problem may shift towards an inferior scientific assessment with negative consequences for the protection of public health and subsequent loss of trust by the general public in EMA's work.

- The Court's audit field work took place in October 2011 and the Court's observations, conclusions and recommendations have been drafted in accordance with the outcome of the audit performed at that time.

Since the Court's audit field work in October 2011 EMA has taken various **NEW** initiatives, addressing already most recommendations made in the Court's Report. EMA thus demonstrates that it takes the issue of management of conflicts of interests very seriously, reviews its policies and the implementation on a continuous basis and takes remedial action whenever necessary. These **NEW** developments relate to:

- A revised EMA policy on the handling of conflicts of interests of Scientific Committees' members and experts which came into effect on 29 September 2011 and was rolled-out during the Court's audit field work in October 2011. The main characteristics of the revised policy are a more robust and transparent system, with stricter requirements in case of direct interests in pharmaceutical industry, stricter requirements for members of decision-making bodies compared to advisory bodies, and stricter requirements for Chairpersons/ Rapporteurs/ other persons in a lead role compared to other members of the scientific fora. Such EMA policy was further revised in 2012 (to give clearer guidance on experts' involvement in academic trials and publicly funded research, to align restrictions for the different roles in the scientific review process and to tighten the rules on grants from pharmaceutical industry) and became effective on 3 April 2012 (EMA/531078/2010).
- A revised EMA policy on the handling of conflicts of interests of the Management Board came into effect on 3 April 2012 (EMA/MB/64234/2012) in line with the revised policy for Scientific Committees' members and experts.
- Breach of Trust procedures were developed for both Scientific Committees' members/ experts (EMA/154320/2012) (which came into effect on 3 April 2012) and Management Board members (EMA/MB/309079/2012) (which came into effect on 7 June 2012).

- Transparency on conflicts of interests was further increased through the publication online of the declarations of interests of all experts (on 30 September 2011) and their assigned risk level (on 29 February 2012), and through the publication of the declarations of interests of all EMA management (on 29 February 2012).
- On 9 June 2011 EMA adopted rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of EMA employees (EMA/500408/2011) which officially entered into force, following the agreement of the European Commission, on 1 February 2012. These rules were subsequently extended by decision of the Executive Director of 1 February 2012 to trainees, national experts on secondment, interims and visiting experts (EMA/78396/2012).

X. (c) (i) EMA notes the Court's recommendation but would like to emphasise that, in line with EMA's Founding Regulation, Scientific Committees' members and experts first need to be nominated after which they need to be included in the European expert list (inclusion is only possible once the nomination form, the declaration of interests and confidentiality undertaking form and the curriculum vitae have been submitted). Only when this has been completed they may be appointed for involvement in EMA activities, but prior to such appointment an evaluation by EMA of the individual's declared conflicts of interests takes place, resulting, where applicable, in restricted or refused involvement, depending on the nature of the declared interest, the timeframe during which such interest occurred and the type of EMA activity. This shows EMA had already acted upon this recommendation prior to the Court's audit field work in October 2011.

In addition, since 29 September 2011 EMA has introduced a compulsory screening of the declared conflicts of interests of Scientific Committees' members prior to any formal nomination by the Competent Authority, in order to inform the Nominating Authority in advance in case of incompatibility of the declared conflicts of interests with the Scientific Committee membership, or of the extent of the imposed restrictions. In addition, EMA offers to any Nominating Authority the possibility of pre-screening by EMA of any expert prior to the formal EMA evaluation for involvement in an EMA activity.

However, EMA is of the view that further broadening this concept of screening as recommended by the Court is not feasible taking into account the nomination process laid down in EMA's Founding Regulation. Rather EMA considers that full transparency in the field of the handling of conflicts of

interests, combined with a robust ex-post control check and a Breach of Trust procedure add more value to a strengthening of the handling of conflicts of interests. EMA has already taken several initiatives along these lines since the Court's audit field work in October 2011, as elaborated upon in various sections of this Report.

X. (c) (ii) EMA notes the Court's recommendation and emphasises (as recognised by the Court in observation number 92) that this is outside EMA's direct control. EMA has undertaken everything it can do as per its legal mandate.

The initiatives taken by EMA, and already in place at the moment of the Court's audit field work in October 2011, are:

(1) a Memorandum of Understanding (MoU) (EMA/150487/2012) signed between each National Competent Authority and EMA putting explicit responsibilities on the National Competent Authorities on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to EMA. All MoUs were signed by 14 September 2011. In the MoU it is explicitly stated that the National Competent Authorities are responsible for putting in place and maintaining a documented system ensuring that their experts and staff participating at national level in work for services provided to EMA have no financial interests or other interests in pharmaceutical industry which could affect their impartiality. They also have to ensure that any request by the Court of Auditors and/ or the European Anti-Fraud Office to access/ inspect/ audit records on the handling of conflicts of interests can be accommodated within a reasonable timeframe.

(2) at the request of EMA, the agreement reached by Heads of Agencies of the National Competent Authorities at their meeting in July 2011 "that EMA standards will constitute the minimum standards of the conflict of interest with any national variations whenever necessary".

X. (c) (iii) EMA notes the Court's recommendation and emphasises that clear and objective criteria have already been put in place by EMA prior to the Court's audit field work in October 2011 and have been strengthened over the past 8 years, most recently in 2012, and are applied consistently through risk mitigation measures (restricted or refused involvement) following evaluation of the declared

interests. Reference is made to the Court's observation number 58 whereby the Court recognises that EMA has the clearest set of assessment criteria and that good practices are applied in EMA for the evaluation of declared conflicts of interests and resulting restrictions, as summarised in Annex VI to this Report.

X. (c) (v) EMA notes the Court's recommendation and would like to emphasise that the following **NEW** initiatives have been taken since the Court's audit field work in October 2011:

- A Breach of Trust procedure for Scientific Committees' members/ experts has been developed and came into effect on 3 April 2012.
- A Breach of Trust procedure for Management Board members has been developed and came into effect on 7 June 2012.
- The Staff Regulation applies to EMA Staff. Article 13 provides for transfer of Staff where spouse employment creates a conflict of interest. At EMA the supplementary SOP/EMA/0101 sets out the procedure to follow to assess and to mitigate conflict through restricting the work of the conflicted Staff member. Article 9, Annex IX lists the sanctions that may be applied. Article 23, Annex IX provides for suspension of a Staff member. Implementing rules on administrative enquires and disciplinary procedures (EMA 7/20.8, 8 June 2012) govern an administrative enquiry. EMA also has a policy on reporting improprieties (EMA/11591/2006, 4 January 2006). Any additional rules on breach of trust for Staff would need careful construction not to undermine any of the existing provisions.

X. (c) (vi) EMA notes the Court's recommendation but would like to emphasise that at the outset of each meeting Management Board and Scientific Committees' members and experts participating at the meeting are requested to declare any conflict of interest in respect of the agenda points, in addition to the evaluation of the declared interests already done by EMA prior to the start of the meeting. Such declarations of interests are subsequently minuted. As regards the publication of the

minutes, Management Board minutes (including a section on declared conflicts of interests) have already been published for several years.

As a **NEW** development, the recording of the declared interests has been further fine-tuned since the Court's audit field work in October 2011 in so far as all restricted involvements put in place vis-à-vis the agenda points of the meeting are now recorded. In addition, on 18 July 2012 EMA has started to make public Scientific Committee meeting minutes (including information on declared conflicts of interests and resulting restricted involvement) in a stepwise approach for all its Scientific Committees. On 18 July 2012 the first PDCO minutes were published, to be followed with the PRAC and COMP minutes in 3Q2012, and all other Scientific Committees' minutes before the end of 2013.

X. (c) (vii) EMA has provided extensive training to all Staff on its new policies on handling conflicts of interests and training is also provided to all new Staff on this matter. Such training is compulsory. In addition, EMA at regular intervals informs the Scientific Committees and other scientific fora on the Agency's handling of conflicts of interests.

X. (c) (viii) EMA follows Art 16 of the Staff Regulations in respect of post-employment of its Staff. For Management Board and Scientific Committees' members as well as experts EMA does not have a legal basis on which to act on their post-employment activities.

Introduction

1. The OECD Guidelines are not legally binding on EMA Staff, Management Board members, or Scientific Committees' members and experts. EMA has put in place for its handling of conflicts of interests policies and procedures, which comply with legislation applicable to the Agency in this field, and in developing such policies and procedures has applied a set of robust principles, compatible with the OECD Guidelines.

7. Involvement of external experts: EMA notes the Court's statement but would like to emphasise that although the members of the Scientific Committees are involved in the drafting of scientific opinions, such scientific opinions go through a peer review process and subsequent collegial opinion-making within the Scientific Committees.

Partnership with stakeholders: EMA notes the Court's statement but would like to emphasise that in addition to research carried out/ data provided by pharmaceutical industry, EMA takes into account all available information, including any other data brought to the attention of the Agency. All such data are subsequently assessed through a robust scientific review process, which includes evaluation by both a Rapporteur and a Co-Rapporteur, and a peer review of the Rapporteur/ Co-Rapporteur assessment at the level of the Scientific Committee, resulting in collegial opinion-making. The opinions of EMA are thus based on peer-reviewed science-based assessments, on the basis of all available information (data provided by industry, supplemented by any other data brought to the attention of EMA).

Box 1 - Examples of conflict of interest risks inherent to the structure of the Agency

EMA notes the Court's statement but would like to emphasise that as regards the remuneration system for scientific services provided by the National Competent Authorities to EMA, EMA (at any level) has made repeated attempts to create a mechanism of actual cost payments which has not been accepted so far by its Management Board. Discussions on an alternative payment system will continue in 2012.

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10. EMA notes the Court's statement but would like to emphasise that these rules only apply to Staff employed and paid by EMA. It is not possible to apply them to persons designated "*ad personam*" (not employed by EMA) such as Management Board/ Scientific Committees' members, as well as experts.

14. EMA notes the Court's statement but refers to EMA replies under points 1 and 10.

15. EMA notes the Court's statement but refers to EMA reply under point 7, 3rd indent. (Partnership with stakeholders).

21. EMA notes the Court's statement but would like to emphasise that the OECD guidelines are not legally binding on EMA Staff, Management Board members, or Scientific Committees' members and experts. In the absence of an EU regulatory framework laying down common minimum requirements on the handling of conflicts of interests, EMA has complied with the legal provisons applicable to EMA in this field as laid down in EMA's Founding Regulation, the EMA Code of good administrative behaviour and the Staff Regulations. EMA has, when developing its policies and procedures on the handling of conflicts of interests, applied a set of robust principles, compatible with the OECD Guidelines.

28. EMA notes the Court's observation but would like to emphasise that EMA had already acted upon this observation prior to the Court's audit field work in October 2011. Declarations of interest of EMA Scientific Committees' members and experts as well as Management Board members are already evaluated in advance of appointment for involvement in an EMA activity. In case of declared interests, restrictions are put in place with respect to involvement in procedures for which a potential conflict has been identified. In case of interests incompatible with involvement in an EMA activity, the Nominating Authority is informed of such incompatibility. As regards the Management Board there

has been to date one instance of incompatibility which was resolved prior to formal nomination (December 2011).
Furthermore, there is a **NEW** development, which was rolled-out during the Court's audit field work in October 2011: since 29 September 2011 a compulsory screening by EMA has been introduced of the declared conflicts of interests of Scientific Committees' members prior to any formal nomination by the Competent Authority, in order to inform the Nominating Authority in advance in case of incompatibility of the declared conflicts of interests with the Scientific Committee membership, or of the extent of the imposed restrictions. In addition, the possibility of pre-screening by EMA of any expert prior to the formal EMA evaluation for involvement in an EMA activity is offered to the Nominating Authority.

30. EMA notes the Court's observation but would like to point out that in the cases where interests are incompatible with existing policies, Nominating Authorities are informed of such cases and, in the past steps have been taken by a candidate to divest interests before becoming Management Board member (December 2011).

Box 3 – Example of a lack of screening of candidates
EMA would like to point out that the examples in Boxes 3 and 6 refer to the same expert.
As highlighted in the EMA reply to point 28 the situation has changed: in the appointment procedure whereby calls for expression of interest were launched in September 2011 for the appointment notably of civil society representatives in 3 Scientific Committees and the Management Board, the declarations of interest have been submitted and evaluated prior to appointment. Similarly, where there was a situation where the appointment by a Member State was incompatible with Management Board membership, the Nominating Authority was informed and the person concerned divested the interests before becoming a Management Board member (December 2011).

33. EMA notes the Court's observation but would like to emphasise the following **NEW** development since the Court's audit field work in October 2011: the procedure for evaluation of eligibility criteria for patients' and consumers' organisations is being revised to include guidance/ criteria with respect to the funding of such organisations.

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34. EMA notes the Court's observation but would like to emphasise the following **NEW** development since the Court's audit field work in October 2011: eligibility criteria for healthcare professionals' organisations have been adopted by EMA Management Board on 15 December 2011 and have been published.

37. EMA notes the Court's observation but wants to emphasise (as recognised by the Court in observation number 92) that this is outside EMA's direct control. EMA has undertaken everything it can do as per its legal mandate, hereby respecting the specificities of the operation and organisation of the EU Regulatory Network in the field of medicines regulation. Since EMA cannot intervene in the handling by the Member States of the conflicts of interests at national level, two initiatives have been taken by EMA, already in place at the moment of the Court's audit field work in October 2011:

- Staff and experts at the level of the National Competent Authorities participating in the (evaluation) work (with respect to the authorisation and surveillance of medicinal products) at national level for services provided to the Agency are covered by a Memorandum of Understanding (MoU) concluded between EMA and each National Competent Authority. All MoUs were signed by 14 September 2011.
- Heads of Agencies of the National Competent Authorities agreed at their meeting in July 2011, at the request of EMA, "that EMA standards will constitute the minimum standards of the conflict of interest with any national variations whenever necessary".

54. EMA notes the Court's observation but wants to highlight that the conflicts of interests assessment forms for Management Board members have been in use since the past eight years, and declared interests were discussed with the Management Board Chairman. Since October 2011, the procedures have been further strengthened and the discussions and decisions made on the handling of conflicts of interests are now being recorded by way of minutes.

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55. EMA notes the Court's observation but would like to emphasise that a greater confidence in the handling of conflicts of interests can be achieved through full transparency in the field, combined with a robust ex-post control system and a Breach of Trust procedure, rather than any prior checking of the correctness of the information declared. EMA agrees that information provided by the concerned persons (CVs, previous declarations of interests) could be used in the context of such ex-post control system but is not in favour of screening sources of information such as information in media, websites, etc. since this is not considered to be the most cost-effective approach. However, any information brought to the attention of EMA at any point in time will be used to check the correctness of the declared interests and, where needed, the appropriate measures will be taken in line with the Agency's policies and procedures, including the Breach of Trust procedures.

Box 6 - Examples of not using the information available for assessment of the declarations of interest

EMA would like to point out that the examples in Boxes 3 and 6 refer to the same expert.

Box 8 – Examples of inadequate risk assessment for EMA's Scientific Committee Members

EMA notes the Court's observation but would like to highlight regarding the second example given in Box 8 that the evaluation of the declaration of interest was a preliminary evaluation carried out in advance of formal implementation of the new EMA policy on the handling of conflicts of interests and subject to confirmatory checks by the Agency's internal Declaration of Interests Advisory Group (DIAG). Information provided in the initial Declaration of Interest form was insufficient to allow imposition of any restrictions. Further to advice from DIAG and additional information from the expert, an evaluation was carried out on the updated declared interests and appropriate restrictions were imposed.

Box 9 - Examples of inconsistent and incomplete policies

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EMA notes the Court's observation but would like to point out that a **NEW** development has taken place since the Court's audit field work in October 2011: the revised EMA policy on the handling of conflicts of interests of Scientific Committees' members and experts (which became effective on 3 April 2012) now clearly states that current direct interests of household members (including financial interests) are taken into account and will lead to restrictions as regards the expert's involvement in EMA activities, depending on the type of activity and the role of the individual in such activity. Likewise, the revised policy also introduces restrictions in the case of grants or other funding to the expert's institution/ organisation. Restrictions in the case of past employment in pharmaceutical industry also have been revised. A procedure for documenting checks on declared interests at the time of appointment of the Rapporteurs has been implemented. In conclusion, EMA considers that it has taken the necessary steps addressing the Court's observations.

63. EMA notes that for its Staff, Annex IX of the Staff Regulations sets out the basis for administrative enquiries and disciplinary measures including for Art 11. EMA has also adopted implementing rules in line with Art 110 on administrative enquiries and disciplinary measures. Annex IX also sets out the sanctions applicable to Staff. It is not clear that EMA alone could adopt sanctions outside the Staff Regulations about conflict of interest.

64. EMA notes the Court's observation and would like to inform the Court of the following **NEW** developments following the Court's audit field work in October 2011:

- A Breach of Trust procedure on conflicts of interests for Scientific Committees' members and experts has been developed and became effective on 3 April 2012.
- A Breach of Trust procedure on conflicts of interests for Management Board members has been developed and became effective on 7 June 2012.

71. EMA would like to inform the Court of the following **NEW** developments: in addition to the publication on its website of the declarations of interests of all experts as of 30 September 2011, also the risk level for each expert (assigned on the basis of the information contained in the declaration of interests) is published since 29 February 2012. In addition, declarations of interests of all EMA management have been published on the Agency's website since 29 February 2012.

72. EMA would, however, like to emphasise that Management Board minutes contain a section about declarations of interests made at the meeting. This has been in place for several years.
With the entry into force of the revised procedure for managing conflicts of interests of Management Board members, restrictions that will apply to individual members are now also being reflected in the published meeting minutes.

73. EMA notes the Court's observation but would like to emphasise the following **NEW** development: on 18 July 2012 EMA has started to make public minutes of the Scientific Committees (including information on declared conflicts of interests and resulting restricted involvement) in a stepwise approach for all its Scientific Committees. On 18 July 2012 the first PDCO minutes were published, to be followed with the PRAC and COMP minutes in 3Q2012, and the minutes of all other Scientific Committees before the end of 2013.

82. Art 16 of the Staff Regulations applies to EMA whereby all departing or former Staff are required to inform the Agency for two years of their post-employment activities whether paid or not. EMA reviews each case and it has imposed restrictions on several Staff in respect of their post-employment activities to prevent conflicts of interest arising. A **NEW** development since the Court's audit field work in October 2011 is that EMA has extended the application of Art 16 of the Staff Regulations also to trainees, national experts and interims. (1 February 2012; EMA/78396/2012). All departing Staff are reminded in writing of their obligations of confidentiality and the need to apply to EMA regarding any post-employment activities whether paid or not for the two year period.

85. EMA notes the Court's observation but would like to emphasise the following **NEW** development since the Court's audit field work in October 2011: in its revised policy on the handling of conflicts of interests of Scientific Committees' members and experts (which became effective on 3 April 2012) it is stated that when a member of an EMA scientific forum intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate, the member shall immediately inform EMA and refrain from any activities which may have an impact on the pharmaceutical company concerned. In addition, the member shall comply

with any additional conditions or limitations EMA may impose. The same provision is provided in the revised policy for Management Board members (which became effective on 3 April 2012).

86. Art 16 of the Staff Regulations applies at EMA whereby all departing or former Staff are required to inform the Agency for a two year period of their post-employment activities. EMA reviews each case and it has imposed restrictions on several Staff in respect of their post-employment activities to prevent conflicts of interest arising. A **NEW** development since the Court's audit field work in October 2011 is that EMA has extended the application of Art 16 of the Staff Regulations also to trainees, national experts and interims (1 February 2012; EMA/78396/2012). All departing Staff are reminded in writing of their obligations of confidentiality and the need to apply to EMA regarding any post-employment activities whether paid or not for the two year period.

87. EMA draws to the Court's attention that a **NEW** development since the Court's audit field work in October 2011 is that the Joint Committee has issued an opinion, 7/ 2011 of 20 October 2011, which has been made public to EMA Staff. This opinion recognises the right of former Staff to employment after leaving the Agency and the legitimacy of using their skills and experience gained throughout their career. It sets out the compatibility with the interest of the service with regard to specific activities in which EMA Staff may engage after leaving the Agency. The EMA will keep this Joint Committee opinion under review so that the interest of the Agency is assured.

88. Assessment case by case of Staff post-employment activities is in place. The legal basis does not apply for EMA to review post-employment of members of the Management Board or Scientific Committees or experts, none of whom are employed by EMA.

89. EMA is of the view that it adequately manages conflicts of interests, although it acknowledges that there was further room for improvement at the time of the Court's audit field work (October 2011). EMA in particular emphasises the following aspects:

- Notwithstanding the absence of an EU regulatory framework on the handling of conflicts of interests EMA has since its creation implemented the specific legal provisions applicable to the Agency in this field, and, as a result, has complied with the legal requirements. Furthermore, EMA

has over the past 8 years continuously monitored its handling of conflicts of interests, has analysed experience obtained, has looked into lessons learned and taken remedial action whenever necessary. As a consequence, EMA has strengthened the robustness of its handling of conflicts of interests over the past 8 years and has increased transparency in this field (several policies and procedures have been developed and revised over the past 8 years, see above for further information).

- As stated in its policy on the handling of conflicts of interests of Scientific Committees' members and experts, when dealing with conflicts of interests there is a need to find the best balance between ensuring that Scientific Committees' members and experts participating in EMA activities have no interests in the pharmaceutical industry which could affect their impartiality vis-à-vis securing the best possible scientific expertise. Otherwise the problem may shift towards an inferior scientific assessment with negative consequences for the protection of public health and subsequent loss of trust by the general public in EMA's work.
- The Court's audit field work took place in October 2011 and the Court's observations, conclusions and recommendations have been drafted in accordance with the outcome of the audit performed at that time.

Since the Court's audit field work in October 2011 EMA has taken various **NEW** initiatives, addressing already most recommendations made in the Court's Report. EMA thus demonstrates that it takes the issue of management of conflicts of interests very seriously, reviews its policies and the implementation on a continuous basis and takes remedial action whenever necessary. These **NEW** developments relate to:

- A revised EMA policy on the handling of conflicts of interests of Scientific Committees' members and experts which came into effect on 29 September 2011 and was rolled-out during the Court's audit field work in October 2011. The main characteristics of the revised policy are a more robust and transparent system, with stricter requirements in case of direct interests in pharmaceutical industry, stricter requirements for members of decision-making bodies compared to advisory bodies, and stricter requirements for Chairpersons/ Rapporteurs/ other persons in a lead role compared to other members of the scientific fora. Such EMA policy was further revised in 2012 (to give clearer guidance on experts' involvement in academic trials and publicly funded research, to

align restrictions for the different roles in the scientific review process and to tighten the rules on grants from pharmaceutical industry) and became effective on 3 April 2012 (EMA/531078/2010).

- A revised EMA policy on the handling of conflicts of interests of the Management Board came into effect on 3 April 2012 (EMA/MB/64234/2012) in line with the revised policy for Scientific Committees' members and experts.
- Breach of Trust procedures were developed for both Scientific Committees' members/ experts (EMA/154320/2012) (which came into effect on 3 April 2012) and Management Board members (EMA/MB/309079/2012) (which came into effect on 7 June 2012).
- Transparency on conflicts of interests was further increased through the publication online of the declarations of interests of all experts (on 30 September 2011) and their assigned risk level (on 29 February 2012), and through the publication of the declarations of interests of all EMA management (on 29 February 2012).
- On 9 June 2011 EMA adopted rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of EMA employees (EMA/500408/2011) which officially entered into force, following the agreement of the European Commission, on 1 February 2012. These rules were subsequently extended by decision of the Executive Director of 1 February 2012 to trainees, national experts on secondment, interims and visiting experts (EMA/78396/2012).

Recommendation 1

EMA notes the Court's recommendation and would like to emphasise that it is continuously monitoring its handling of conflicts of interests (both from a policy and implementation perspective) and introducing remedial action whenever necessary. Documented evidence to support this statement is referred to in various sections of this Report.

Recommendation 2

EMA notes the Court's recommendation but would like to emphasise that, in line with EMA's Founding Regulation, Scientific Committees' members and experts first need to be nominated after which they need to be included in the European expert list (inclusion is only possible once the nomination form, the declaration of interests and confidentiality undertaking form and the curriculum

vitae have been submitted). Only when this has been completed they may be appointed for involvement in EMA activities, but prior to such appointment an evaluation by EMA of the individual's declared conflicts of interests takes place, resulting, where applicable, in restricted or refused involvement, depending on the nature of the declared interest, the timeframe during which such interest occurred and the type of EMA activity. This shows EMA had already acted upon this recommendation prior to the Court's audit field work in October 2011.
In addition, since 29 September 2011 EMA has introduced a compulsory screening of the declared conflicts of interests of Scientific Committees' members prior to any formal nomination by the Competent Authority, in order to inform the Nominating Authority in advance in case of incompatibility of the declared conflicts of interests with the Scientific Committee membership, or of the extent of the imposed restrictions. In addition, EMA offers to any Nominating Authority the possibility of pre-screening by EMA of any expert prior to the formal EMA evaluation for involvement in an EMA activity.

However, EMA is of the view that further broadening this concept of screening as recommended by the Court is not feasible taking into account the nomination process laid down in EMA's Founding Regulation. Rather EMA considers that full transparency in the field of the handling of conflicts of interests, combined with a robust ex-post control check and a Breach of Trust procedure add more value to a strengthening of the handling of conflicts of interests. EMA has already taken several initiatives along these lines since the Court's audit field work in October 2011, as elaborated upon in various sections of this Report.

Recommendation 3

EMA notes the Court's recommendation and emphasises (as recognised by the Court) that this is outside EMA's direct control. EMA has undertaken everything it can do as per its legal mandate. The initiatives taken by EMA, and already in place at the moment of the Court's audit field work in October 2011, are:
(1) a Memorandum of Understanding (MoU) (EMA/150487/2012) signed between each National Competent Authority and EMA putting explicit responsibilities on the National Competent Authorities on the monitoring of the scientific level and independence of the evaluation carried out

by the National Competent Authorities for services to be provided to EMA. All MoUs were signed by 14 September 2011. In the MoU it is explicitly stated that the National Competent Authorities are responsible for putting in place and maintaining a documented system ensuring that their experts and staff participating at national level in work for services provided to EMA have no financial interests or other interests in pharmaceutical industry which could affect their impartiality. They also have to ensure that any request by the Court of Auditors and/ or the European Anti-Fraud Office to access/ inspect/ audit records on the handling of conflicts of interests can be accommodated within a reasonable timeframe.

(2) at the request of EMA, the agreement reached by Heads of Agencies of the National Competent Authorities at their meeting in July 2011 “that EMA standards will constitute the minimum standards of the conflict of interest with any national variations whenever necessary”.

Recommendation 4

EMA notes the Court’s recommendation and emphasises that clear and objective criteria have already been put in place by EMA prior to the Court’s audit field work in October 2011 and have been strengthened over the past 8 years, most recently in 2012, and are applied consistently through risk mitigation measures (restricted or refused involvement) following evaluation of the declared interests. Reference is made to the Court’s observation number 58 whereby the Court recognises that EMA has the clearest set of assessment criteria and that good practices are applied in EMA for the evaluation of declared conflicts of interests and resulting restrictions, as summarised in Annex VI to this Report.

94. EMA is updating its Code of Conduct, last adopted in 2006, to align to all the recently adopted rules and the guidance of the European Commission on gifts and hospitality.

Recommendation 6

EMA notes the Court’s recommendation and would like to emphasise that the following **NEW** initiatives have been taken since the Court’s audit field work in October 2011:

- A Breach of Trust procedure for Scientific Committees’ members/ experts has been developed and came into effect on 3 April 2012.

- A Breach of Trust procedure for Management Board members has been developed and came into effect on 7 June 2012.
- Article 13 of the Staff Regulations provides for transfer of EMA Staff where spouse employment creates a conflict of interest. At EMA the supplementary SOP/EMA/0101 sets out the procedure to be followed to assess and to mitigate conflict through restricting the work of the conflicted Staff member. Article 9, Annex IX lists the sanctions that may be applied. Article 23, Annex IX provides for suspension of a Staff member. Implementing rules on administrative enquires and disciplinary procedures (EMA 7/20.8, 8 June 2012) govern administrative enquiries. EMA also has a policy on reporting improprieties (EMA/11591/2006, 4 January 2006). Additional rules on breach of trust for Staff would need careful construction not to undermine any of the existing provisions.

Recommendation 7

EMA notes the Court's recommendation but would like to emphasise that at the outset of each meeting Management Board and Scientific Committees' members and experts participating at the meeting are requested to declare any conflict of interest in respect of the agenda points, in addition to the evaluation of the declared interests already done by EMA prior to the start of the meeting. Such declarations of interests are subsequently minuted. As regards the publication of the minutes, Management Board minutes (including a section on declared conflicts of interests) have already been published for several years.

As a **NEW** development, the recording of the declared interests has been further fine-tuned since the Court's audit field work in October 2011 in so far as all restricted involvements put in place vis-à-vis the agenda points of the meeting are now recorded. In addition, on 18 July 2012 EMA has started to make public Scientific Committee meeting minutes (including information on declared conflicts of interests and resulting restricted involvement) in a stepwise approach for all its Scientific Committees. On 18 July 2012 the first PDCO minutes were published, to be followed with the PRAC and COMP minutes in 3Q2012, and all other Scientific Committees' minutes before the end of 2013.

Recommendation 8

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EMA has held 18 training sessions for Staff on the new rules on handling conflict of interest for Staff. In addition, 11 training sessions have been carried out to train managers on the procedures on risk assignment and mitigating actions.

All new Staff are trained on the conflict of interest policy and the Code of Conduct during the introduction training that is offered to all new Staff, interims, trainees and national experts on secondment. Such training is compulsory. Articles 11-26 inclusive of the Staff Regulations and the Code of Conduct are sent to Staff. Staff are asked to confirm that they have read and understood the said articles. In addition, EMA at regular intervals informs the Scientific Committees and other scientific fora on the Agency's handling of conflicts of interests.

98. EMA applies Art 16 of the Staff Regulations whereby all departing or former Staff are required to inform the Agency for a two year period of their post-employment activities. EMA reviews each case and it has imposed restrictions on several Staff in respect of their post-employment activities to prevent conflicts of interest arising. EMA has extended the application of Art 16 of the Staff Regulations also to trainees, national experts and interims (1 February 2012; EMA/78396/2012). All departing Staff are reminded in writing of their obligations of confidentiality and the need to apply to the EMA regarding any post-employment activities whether paid or not for the two year period.

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Recommendation 9

EMA notes the Court’s recommendation and wishes to highlight that all EMA Staff on departure are reminded in writing of their obligations under the Staff Regulations and these obligations are extended by analogy to all trainees, national experts on secondment, interims and visiting experts. The obligation (Art 17 Staff Regulations) to respect confidentiality and the obligation to notify EMA about further employment are both stressed. Departing Staff must acknowledge receipt of this letter and its contents and this confirmation is filed on their personal file.

In line with the process and steps of Article 16 of the Staff Regulations all departing or ex Staff and in addition extended by decision of the Executive Director by analogy to national experts, trainees and interims are required to inform EMA on the details for their paid employment activity after leaving EMA for a period of 2 years. The applications are reviewed by the Joint Committee as provided for in Article 16 and it issues an opinion. The Joint Committee has available to it the details of the previous cases assessed and the restrictions imposed so that consistency in the treatment of cases is applied. In light of this opinion the Executive Director issues his decision. In many cases the scope of action of the ex-Staff member is restricted and contact with EMA Staff is also explicitly restricted.