

## Review of the Policy for avoiding potential conflicts of interest

### 51<sup>st</sup> Meeting of the Management Board 20-21 September 2018

#### Key messages

With a view of adopting a final text in the December 2018 Management Board meeting, the members are invited to discuss and give feedback on:

- A proposal for revision of the ECHA Procedure for Prevention and Management of potential conflicts of interest;
- A proposal for ECHA guidelines for ensuring the independence of Member State services to be provided to ECHA.

#### Background

The Management Board was informed in its meeting of March 2018 that a revision of the ECHA Procedure for Prevention and Management of potential conflicts of interest is planned for 2018. In its meeting of June 2018<sup>1</sup>, the Board took note and discussed proposed principles<sup>2</sup> for reviewing the policy. In this context, the ECHA Secretariat confirmed that the outcome of the Commission's Internal Audit Service's (IAS) ongoing audit on conflicts of interest and ethics will be taken into account in the review. The discussion was further informed by a report from the Management Board member in the ECHA Conflict of Interest Advisory Committee (CoIAC), which met on 13 June and also discussed the review of the policy.

#### IAS audit on conflict of interest and ethics

In its audit report of 2 August 2018 the IAS makes four audit recommendations and ECHA has set out an action plan to implement those recommendations as follows:

1. The Agency should carry out the following actions to coincide with the next BoA appointment due in 2019 (critical):
  - a. Ensure that the guidelines on the selection and appointment process are updated in line with the rules on Conflict of Interest (CoI);
  - b. Ensure that the Chair of the Board of Appeal (BoA) and the Management Board (MB) are involved in decisions with regard to the BoA and the Registry of the BoA and the relevant decisions are taken at the appropriate authority level;
  - c. Ensure that access rights to confidential documents of the BoA cases are limited to the team who have been subject to the necessary CoI checks.
  - d. Initiate discussions with the Commission Services on the following points to ensure:
    - i. that the vacancy notice for future selection procedures requires a declaration of interest in the application in line with the ECHA DoI;
    - ii. application of criteria for selection;
    - iii. that the roles and responsibilities of the different actors of the selection and appointment process are clearly defined;
    - iv. that the rules are clarified to specify at which stage the assessment of CoI should be performed.

<sup>1</sup> Agenda point B.3 / see also MB/21/2018 final

<sup>2</sup> MB/21/2018

Action plan for this recommendation: To further clarify the roles and responsibilities of the different actors in the procedure, a new document with procedures and practical arrangements for the appointment of the Chairman, two other members of the Board of Appeal of ECHA, their alternates and additional members and their alternates is planned to be agreed between the ECHA Secretariat, the Board of Appeal, the Management Board and the Commission services by end 2018.

The access rights of the case files of the Board of Appeal have been revised to ensure that members declaring a potential conflict of interest no longer have access to the file.

**2. The Agency should:**

- a. Establish a standard way of documenting assessment and review of DoI.
- b. Clarify requirements concerning content of the DoI with all process owners and actors; i.e. whether Agency requires declaration of all interests or declaration of interests that are perceived by the individual as conflicting.
- c. Establish regular monitoring and reporting and set targets in order to follow up on the implementation of the CoI framework.
- d. The CoI policy should provide a clear and realistic description of what circumstances and relationships can lead to a conflict-of-interest situation. The description should also recognise that, while some conflict-of-interest situations may be unavoidable in practice, public organisations have the responsibility to define those particular situations and activities that are incompatible with their role.

Action plan for this recommendation: A standardised template will be created for all the ECHA bodies to document the assessment and review of DoI.

The ECHA CoI policy will be updated to clarify the requirements concerning the content of the DoI and to include increased monitoring and further descriptions of the situations and activities that are incompatible with the role of the Agency.

**3. The Agency should:**

- a. establish a process in order to facilitate compliance with the rules on the remuneration cap for outside activities and improve awareness of the rules;
- b. ensure that the permissions for outside activities are given in compliance with the rules;
- c. ensure that CoI checks are embedded in the administrative inquiries where an internal investigator is nominated.

Action plan for this recommendation: The updated Commission implementing rules on outside activities are presented for adoption by analogy by the Management Board under agenda item A.1. The new rules leave discretion for the authority authorised to conclude contracts (AACC) when assessing applications for professional activities.

The electronic workflow used to submit and decide on outside activity requests will be updated according to the revised implementing rules. Staff will be requested to inform the HR department about their actual annual income received through outside activities.

A CoI check will be embedded in the procedure for administrative inquiries where an investigator is nominated.

**4. The Agency should:**

- a. Consider enhancing its current CoI framework by identifying different risk levels of interests declared with standard criteria and mitigating measures for the assessment and mitigation of risks;
- b. Establish an ex-post control on the DoI checks of the different actors and processes;

- c. Initiate a discussion with the Member States in order to reach a common approach for mitigating the risk for potential CoI for substance evaluation and other operational processes where there is a risk of involvement of third parties similar to substance evaluation.

Action plan for this recommendation: The Agency will update its CoI policy in order to include different risk levels for the interests declared with standard criteria and mitigating measures and to include ex-post controls.

The Agency will initiate a discussion with the Member States in order to reach a common approach for mitigating the risk for potential CoI and depending on the outcome will propose guidelines for the MSCAs on this topic.

## **Review of the Policy for avoiding potential conflicts of interest**

In light of the above audit recommendations and in follow-up to the Management Board discussion on the topic in June 2018, the following main adaptations are proposed to the ECHA policy for avoidance of potential conflicts of interest (see draft text in annex 1):

- Adopt new ECHA guidelines for Member State Competent Authorities on CoI prevention

One recommendation of the Court of Auditors in 2012 already and repeated in audits of the Internal Audit Capability (IAC) and the Internal Audit Service (IAS) recently, is the need for a system to capture potential conflicts of interests at Member State level also, especially for those ECHA decisions which are prepared at Member State level (e.g. substance evaluation). Due to obvious subsidiarity principles, ECHA cannot directly impose conflict of interest measures on the Member States and their staff. Therefore, it is proposed to adopt a concise document with high-level guidelines/principles (see annex 2) that ECHA will invite the Member States to apply when performing work for the Agency. Alternatively, such document can also be annexed to the existing cooperation agreements with the Member States regarding the transfer of fees.

- Include risk levels and clear criteria for assessment of the interests declared in the CoI policy

Whilst this does not require a change in ECHA's current practices, it is proposed, as recommended by the IAS, to more clearly communicate on the assessment criteria and cooling off periods applied for competing interests declared. It could be clarified for instance that:

- a. Interests declared in the public sector can never constitute a conflict of interest
- b. Personal interests declared in an individual company or substance lead to immediate exclusion from any involvement in the decision making with regard to that specific company or substance

All current interests and interests in the past five years in individual companies or substances (e.g. employment, consultancy, membership of governance of scientific advisory boards, research funding above 25% of the total budget, intellectual property, financial investments, etc.) lead to automatic exclusion from the voting in the opinion- or decision making with regard to that specific company or substance.

- c. Clear criteria for the remaining ad hoc assessments

Certain interests declared will always require a case-specific assessment due to the nature of the interest declared or the complexity of the situation. For these assessments, clear up-front criteria would be included in the policy.

- Enhance the eligibility criteria

Firstly, it is proposed that the eligibility criteria, which are a core part of ECHA's policy, could be integrated into the text (as an annex) instead of being laid out in a separate decision (see MB/45/2013 final). Secondly, the scope could be extended to include Committee Chairmen and all ECHA managers. Thirdly, the threshold for exclusion for financial investments in companies

manufacturing, importing, supplying or placing on the market substances or mixtures could be lowered from shares above the value of 100.000 to those above the value of 10.000 EUR (or equivalent to 5% or more of voting rights). Finally, also membership of permanent scientific advisory bodies of companies or interests groups could be added as a criterion and thus excluded (with the exception of time-bound project boards of specific science projects).

- Update of the declaration of interest template and clarify key concepts

Some inconsistency has been found in the filling in of the annual declarations between different populations of ECHA collaborators. For instance it is sometimes questioned if the current employment needs to be filled in if not in conflict with ECHA (e.g. employment at a Member State public authority or an EU institution). This is now clarified together with some other key concepts of the declaration template (see annex 3), such as "public statements", for which the Conflict of Interest Advisory Committee has also issued a recommendation for clarification.

- Introducing ex-post controls, additional reporting to the management and enhancing the audit trail

As recommended by the IAS, strengthening the already existing documentation of the conflict of interest checks performed by the secretariat should give the management more assurance that conflicts of interest will not go undetected. In addition, it is proposed to set up some ex-post controls, including for instance:

- a. an annual ex-post sample check on a small percentage of the annual declarations submitted by members of ECHA bodies and ECHA staff;
- b. an annual ex-post sample check on several closed dossiers to verify if CoI checks were performed and the assessments made were correct.

## Rationale

Firstly, this review was initiated to capitalise on key learnings with regard to policy implementation since the last review in 2014 to ensure that ECHA remains fully compliant with the highest standards of CoI management. Some of these learnings include:

- A need to keep up with the increasing demands placed on public authorities and developments in sister agencies (e.g. enhancing the eligibility criteria);
- A need to clarify towards all collaborators and external audiences what needs to be declared (e.g. declaring an interest vs. having a conflict of interest) and what the consequences are of declaring such interest;
- Clarifications made by CoIAC, e.g. on the definitions of public statements and on the need for RAC and SEAC members to abstain from voting on dossiers stemming from their Member State;

Secondly, the IAS audit report concludes that *"over the years ECHA has heavily invested in this very important process and has developed and implemented a comprehensive set of rules, procedures and IT systems that are in line with the Commission guidelines for agencies on CoI. Although we recognise the ongoing efforts made by the Agency to manage (potential) CoI and improve the internal controls of the processes on ethics, the IAS concludes that in specific areas the current controls to ensure compliance with the rules are neither effective nor efficient."*

The ECHA Secretariat recognises that important weaknesses were identified. Therefore, ECHA welcomes the audit engagement from the IAS and the opportunity to adjust the policies at an early stage when no actual conflicts of interest have yet been identified with regard to the scientific output of the Agency.

Conflict of interest prevention is a crucial aspect of the Agency's governance, as it is vital to ensure its independence and to maintain its reputation as a trusted authority. Therefore, it may be required to invest additional resources to this work, as several of the audit recommendations will require significant additional efforts, e.g. for enhanced monitoring and reporting or in setting up additional controls to administer access rights for thousands of case files.

## Alternative options

In view of the IAS report and ECHA's philosophy for continuous improvement, inaction is not considered an option.

## Drawbacks

There is a risk that the additional measures proposed may not be considered sufficient. On the contrary, there is also a risk that the Agency may face limitations in recruiting qualified personnel for its secretariat and its bodies if the bar would be raised too high, excluding valuable expertise. Therefore, it is crucial to find a workable balance that allows it to draw on knowledgeable experts without running a reputational risk due to conflict of interest situations materialising.

## Attachments:

- Annex 1a: Revised ECHA Procedure for Prevention and Management of potential conflicts of interest (draft)
- Annex 1b: Revised ECHA Procedure for Prevention and Management of potential conflicts of interest (draft) (with tracked changes)
- Annex 2: ECHA guidelines for ensuring the independence of Member State services to be provided to the European Chemicals Agency (draft)
- Annex 3: Revised template for annual Declaration of Interest (draft)

For questions: [bjorn.hansen@echa.europa.eu](mailto:bjorn.hansen@echa.europa.eu) with copy to [mb-secretariat@echa.europa.eu](mailto:mb-secretariat@echa.europa.eu)