

Document code: Security level: Effective date: PRO-0067.03

Public

21/12/2018

Annex 1b MB/40/2018 final 21.09.2018

Prevention and Management of potential Conflicts of Interest

1. Purpose

The management of (potential) conflict of interest situations is a key element of governance and management of every EU institution, body or agency and crucial for maintaining the trust of stakeholders and citizens in its integrity. Effective management of conflicts of interest and assuring legality and regularity of its processes is thus a crucial requirement if ECHA wants to play a pivotal role in ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. For this reason it is vital to ensure ECHA's independence and transparency.¹

In order to achieve this, ECHA has to strike a delicate balance between getting the right expertise to guarantee high quality science-based decision making and at the same time strictly avoiding conflicting interests influencing or seen as influencing the decision-making process. Important tools to achieve this balance are awareness raising, methods for detecting risks to the Agency's integrity, the establishment of clear boundaries for (un)acceptable interests and the appropriate management of conflict of interest situations, including underlying clear procedures. In this, it is not so much a matter of eliminating any possibility of conflict of interest, but of detecting them at an early stage, recording them and handling them appropriately.

2. Scope

This Procedure document applies to the entire ECHA organisation and all of its activities, whether administrative or scientific in nature. The scope thus includes all members, their advisers and invited experts of the ECHA bodies, including the Board of Appeal, the observers participating to their meetings and the statutory staff of the ECHA Secretariat.

For the specific groups below, the general principles of this procedure equally apply, but adaptations are made in view of their specific mandate:

Networks and expert groups

Several networks and expert groups support the Agency in its work. As these networks and expert groups have a balanced composition, and as they are only advisory bodies, the risk of conflicting interests affecting the formal work of ECHA is minimal. However, it shall be a standard practice that the person chairing these meetings requests, when relevant, that any conflicting interests are declared at the start of each meeting and documented in the minutes. Where necessary, ECHA may also impose other preventive measures,

Deleted: ,

Deleted:

Deleted: and networks

Deleted: and any contractors working for the Agency

 $^{^{1}}$ See also recital 95 of Regulation (EC) No 1907/2006 (the "REACH Regulation").



Document code: PRO-0067.03 Security level: Public

21/12/2018 Effective date:

Prevention and Management of potential Conflicts of Interest

including e.g. annual declarations of interest. This latter measure has been implemented for the following expert groups:

- PBT expert group;
- Endocrine Disruptor (ED) expert group;
- Nanomaterial expert group.

Stakeholder observers

ECHA welcomes the attendance of observers of the stakeholder organisations at the meetings of the Committees, the Forum and informal ECHA networks selected by the respective body or network. These stakeholder observers have to comply with the Code of conduct for observers²,

Furthermore, the Rules of Procedure of an ECHA body may foresee the possibility to invite case owners or applicants to participate in a meeting or part of it as observers. As these case owner/applicant observers clearly are attending the meeting to defend the interests of their organisation in a particular dossier, it is unnecessary that they make a declaration of interest. Strict compliance with the applicable Code of conduct shall be enforced³.

Contractors and interim staff

Whenever the Agency is contracting external service providers to support it in its tasks, these contractors are contractually bound by confidentiality duties and to ensure that potential conflicts of interest are avoided. Based on those contractual provisions, the Agency may require external consultants (regardless of the fact whether the person is working intra-muros or not) or interim staff to make a specific declaration of interest with regard to the work performed for ECHA, in case their participation has a qualitative impact on the decision-making at the Agency.

<u>Trainees</u>

The general principles of this procedure apply to the trainees of the Agency, but as they are not given tasks where they would have a qualitative impact on the decision making of ECHA, they are not required to fill out an annual declaration of interest.

Deleted: O

Deleted: As set out above,

Deleted: and need to declare any interest in the cases dealt with by the respective Committee or network at the start of the meeting

Deleted: it shall ensure that

Deleted: Both a confidentiality clause and a conflict of interest clause are included in all such contracts that ECHA concludes.

Deleted: him/her

 $^{^2}$ Code of conduct for observers at ECHA meetings (ED/62/2008). 3 See ECHA Code of conduct for case owners of evaluation draft decisions as observers at meetings of the Member State Committee (ED/89/2013) and ECHA Code of conduct for applicants participating in the Biocidal Products Committee and its Working Groups (ED/104/2013).



Document code: PRO-0067.03

Security level: Public 21/12/2018

Effective date: Prevention and Management of potential Conflicts of Interest

3. Description

3.1. Cooling off periods

All candidates for a position in the Agency (in an ECHA body or in the ECHA Secretariat) are thoroughly screened before appointment.

For the statutory staff, in line with Article 11 of the Staff Regulations, before recruitment, all candidates for a position in the Agency are requested to make a written declaration of interest (based on FOR-0039) in order for the Appointing Authority to be able to assess any potential conflicts of interest in relation to the specific position that may be offered and to take appropriate mitigating measures if necessary.

For certain positions of trust (the position of Executive Director, Director, Head of Unit, permanent member of the Board of Appeal, Accounting Officer or Chairperson of an ECHA Committee), this assessment as required by Article 11 of the Staff Regulations is based on the below mentioned eligibility criteria (see annex 2).

For the members of the ECHA bodies, the pre-recruitment screening is based on the same five specific eligibility criteria.

3.1.1. Generic cooling off periods (before appointment) for key positions: the eligibility criteria (control point 1)

For the positions for which ECHA is the Appointing Authority, it has adopted eligibility criteria (see annex 2) with which candidates for the position of Executive Director, Director, Head of Unit, Committee chair, Accounting Officer, member of the Board of Appeal or member in the Committee for Risk Assessment and the Committee for Socioeconomic Analysis have to comply to be considered for appointment.

For the positions for which ECHA is not the Appointing Authority (membership in the Management Board, the Member State Committee, the Biocidal Products Committee and the Enforcement Forum), the same criteria are applied as eligibility guidelines (see annex 2) to which the relevant Appointing Authorities are invited to adhere, with the exception of the Commission when appointing the three Management Board members to represent interested parties.

3.1.2. Specific cooling off periods/restrictions (during mandate) for all positions (control point 2)

Certain competing interests declared lead to an immediate exclusion from the voting in the decision making of the Agency for a specific commercial entity or substance for a period of up to five years. On this basis, an overview of the allowable and non-allowable interests is presented in annex 1.

Agency staff or members of the ECHA bodies who have been employed by or had another professional relationship (e.g. consultancy or legal advice) with a commercial entity, shall not be able to participate in the voting of opinions or decisions which create or modify legal rights or obligations of that commercial entity for a period of five years counted from the end of the employment or other professional relationship.

TEM-0129.01

Uncontrolled copy once printed. Ensure that the right version is in use.

Deleted: <#>General principles¶

Independence and impartiality¶

Independence from all external interests is one of the core values of the Agency. In all of its processes ECHA shall ensure that it is independent from all external interests and that impartial and sciencebased decisions are taken. To achieve this, detailed guarantees and checks need to be implemented in the processes of the Agency. ¶

Transparency¶

Transparency is another core value of ECHA and is strongly embedded in its founding Regulation⁴. Decisions and opinions are formed as openly as possible. For this reason, declarations of interest of the main actors behind ECHA's decision- and opinion-making are made available to the general public.¶

Confidentiality¶
Article 105 of the REACH Regulation imposes on the members of the Management Board, the Committees and the Forum as well as on all staff members of the Agency the duty not to disclose information of the kind covered by the duty of professional secrecy, and this even after their duties have ceased. This confidentiality duty is also included in the respective Rules of Procedure of the ECHA bodies and a written declaration of confidentiality is required (the same applies to the advisors, invited experts and observers)⁵. For the ECHA Secretariat staff also Articles 17 and 19 of the Staff Regulations impose a duty of strict confidentiality. The confidentiality duty shall furthermore also imply that the individuals working for the Agency shall not seek to gain any improper advantages from the information to which they have access and that is covered by the duty of professional secrecy. The management of conflicts of interest is also an element for preventing information leaks.¶

Awareness¶

As the Agency's role is to promote the public interest in an independent and transparent manner with respect for confidentiality rules, it is crucial that the individuals working with the Agency understand that the exercise of public authority comes with certain duties. The Agency shall support these individuals in fulfilling their duties, raise awareness, organise training and set up further implementing procedur ...

Deleted: I

Deleted: as statutory staff member

Deleted: the

Deleted: Management Board

Deleted: MB/45/2013 final

Deleted: To this end, such candidates are invited to fill in a declaration of interest already after inclusion on the list of candidates proposed by the Commission or after their nomination by their respective Member

Deleted: the

Page 3 of 18

Deleted: Management Board

Deleted: Management Board has adopted

Deleted: MB/45/2013 final



Document code: PRO-0067.03
Security level: Public

Effective date: **21/12/2018**

Prevention and Management of potential Conflicts of Interest

Membership of governing boards and permanent scientific advisory bodies

Agency staff or members of the ECHA bodies who have been member of a governance board or permanent scientific advisory body of a commercial entity, shall not be able to participate in the voting of opinions or decisions which create or modify legal rights or obligations of that commercial entity for a period of five years counted from the end of the membership.

Investments and intellectual property

Agency staff or members of the ECHA bodies who hold current investments above 10.000 EUR (or giving right to 5% or more of voting rights) or intellectual property in a specific commercial entity or substance, shall not be able to participate in the voting of the opinion-or decision making with regard to that substance or commercial entity for as long as the investment or intellectual property is kept.⁶

Research funding

Agency staff or members of the ECHA bodies who receive any research funding above 25% of the total research budget from a specific commercial entity shall not be able to participate in the voting of opinions or decisions which create or modify legal rights or obligations of that commercial entity for a period of five years counted from the end of the funding.

Other competing interests declared

Other competing interests declared are assessed case by case and mitigating measures and ad hoc restrictions to participate in the decision making are imposed by the chairperson of the respective ECHA body or the line manager of the staff member.

3.2. <u>Procedure for declaring and assessing all competing</u> <u>interests and for imposing mitigating measures where</u> <u>necessary</u>

The individuals working for the Agency have the duty to **declare** annually all competing interests by submitting and keeping up-to-date a declaration of interest compliant with the form FOR-0039.

The chairpersons of the respective ECHA bodies (for external experts) and the respective line managers (for the staff of the Agency) have the duty to **assess** all competing interests declared and to **impose mitigating measures** where such interest carry a risk of turning into *conflicts* of interest.

3.2.1.

Annual declarations

⁶ For the members of the ECHA bodies, the ECHA management, the Accounting Officer and the Chairpersons of the Committees, current investments above 10.000 EUR (or giving right to 5% or more of voting rights) are even generic cooling off criteria (eligibility criteria) that prevent appointment.

TFM-0129.0

Uncontrolled copy once printed. Ensure that the right version is in use.

Deleted: Preventing conflicts of

Deleted: The first responsibility with regard to preventing conflicts of interest and with respect to confidentiality rules shall lie with the public officials and other individuals working for the Agency. To this effect, they must submit and keep up-to-date declarations of interest compliant with the form FOR-0039.

Deleted: Before working for the Agency

Deleted: ECHA bodies and ECHA Secretariat¶



21/12/2018

Public

PRO-0067.03

Effective date:

Prevention and Management of potential Conflicts of Interest

According to Article 88(2) of the REACH Regulation, all members of the Management Board and of the Committees and the Forum shall, when taking up their duties, make a written declaration of interest which could be considered to be prejudicial to their independence. Also all members of the Board of Appeal are required to make an annual declaration of interest in writing.

The initial declarations are renewed annually. The secretariat of the respective ECHA body is in contact with members in order to ensure that regular updates are provided. If at any point in time changes occur to the situation of the member's interests, he/she makes an updated declaration without delay.

The respective secretariat of the ECHA body shall enter the declarations of interest in a register, which is also published on the ECHA website.

Upon entry into the service at the Agency, the duty to declare all interests annually which is imposed on the Executive Director by the REACH Regulation is extended to all staff of the Agency. Besides filling in an initial declaration at the start of their employment, all staff members shall thus provide an annual update of this declaration. For the management staff (Executive Director, Directors and Heads of Unit), the permanent members of the Board of Appeal and the chairpersons of the ECHA Committees, these declarations shall be published on the ECHA website.

If at any point in time changes occur to the situation of the staff member's interests, the person involved must update his/her declaration without delay.

3.2.2. Specific declarations

At each meeting the Management Board members and the members of the Committees and the Forum (and their advisors), observers and any experts participating in the meeting are explicitly asked by the chair to declare any interests which could be considered to be prejudicial to their independence with respect to any of the points on the agenda. Such conflicting interests are recorded in the minutes together with the specific mitigating measures imposed (see also chapter 3.3) and made public.

When a Committee member is appointed as Rapporteur or Co-Rapporteur, he or she needs to make for each case a written declaration of absence of conflict of interest in line with Article 87(1) of the REACH Regulation. A member of a Committee is not appointed rapporteur for a particular case if he/she indicates any interest that might be prejudicial to the independent consideration of that case.

The members of the Board of Appeal are required to make an ad-hoc declaration for each specific case before the allocation of that case to them.

If at any point in time the staff member's independence to work on a specific dossier is at risk, the person involved must declare the specific interest in the dossier at hand to the process owner of the process in which he/she operates.

Identifying risk levels and mitigating measures for competing interests declared (control point 3)

ECHA Secretariat

TEM-0129.01

Uncontrolled copy once printed. Ensure that the right version is in use.

Page 5 of 18

Deleted: Subsequently, the respective secretariat and chair shall monitor the declarations regularly to identify potential risks and handle situations of potential conflicting interests in compliance with the present procedure (see further under chapter 3.3.) and specific implementing rules.

Moved down [1]: The respective secretariat shall also undertake sample checks to quarantee the accuracy and completeness of the declarations submitted by the members of the ECHA bodies



Document code: PRO-0067.03
Security level: Public
Effective date: 21/12/2018

Prevention and Management of potential Conflicts of Interest

<u>Upon the receipt of the annually updated declaration of (competing) interests, the respective line manager reviews the content of the declaration and the staff members are classified into two risk levels:</u>

- Staff members that have not declared any competing interests ("clearance list");
- o Staff members that hold one or more competing interests.

The annual declaration of interest of the Executive Director is reviewed by the Chair of the Management Board.

Mitigating measures:

The staff members with the first risk level can be assigned to any task without a further conflict of interest check. For the second group a documented conflict of interest check will be performed each time a new task is assigned in processes that require (conflict of) interest management. The general cooling off periods as defined under chapter 3.1.2 apply to these staff members.

Case-specific conflict of interest checks

The process owners shall, based on a risk assessment, define the processes in the Agency that require interest management. In such processes, conflict of interest checks shall be performed each time a particular staff member is assigned to a role in the process. Such interest checks are performed on the basis of the annual and specific declarations made by the staff members concerned and documented by the process owner. If there is a potential conflict of interest, another staff member shall be assigned, unless appropriate mitigating measures are imposed to guarantee the independent outcome of the procedure (see WIN-0105 Prevention of Conflicts of Interest).

Board of Appeal

The annual declarations of the Board of Appeal members are monitored by its Chair. The Chairman's declarations are monitored by the longest serving member of the Board of Appeal.

Specific, case-related declarations by a member of the Board of Appeal are assessed by the other Board of Appeal members, who shall decide as to the action to be taken.

If a member of the Board of Appeal considers that because of a conflict of interests he/she must not take part in the specific legal proceedings, he/she shall inform the Board of Appeal accordingly. The Chairman may replace that member by an alternate.

Likewise, members of the Board of Appeal may be objected to by any party to the appeal proceedings on the grounds of possible conflicts of interest. In this situation, the Board of Appeal shall decide as to the action to be taken without the participation of the member concerned. For the purpose of taking this decision, the member concerned shall be replaced by an alternate.⁷

Management Board, Committees and Forum

⁷ See Article 90 (5)-(7) REACH Regulation.

TFM-0129.01

 ${\it Uncontrolled\ copy\ once\ printed.\ Ensure\ that\ the\ right\ version\ is\ in\ use.}$

Moved (insertion) [2]

Moved (insertion) [5]

Moved (insertion) [4]

Page **6** of **18**



PRO-0067.03 Document code: Security level: Public

21/12/2018 Effective date:

Prevention and Management of potential Conflicts of Interest

Members who have not submitted the annual declaration of interest shall not take part in meetings of the ECHA body and its working groups or decisions by written procedure.

Upon receipt of the annually updated declaration of (competing) interests, the chairperson of each ECHA body, with the assistance of the ECHA secretariat, shall identify one of the below risk levels for each of the competing interests declared by the members of his/her respective ECHA body:

A ("interest cleared"): no competing interests declared or cleared as not relevant to the work of respective ECHA body

When no competing interests are declared at all or the declared competing interest is classified as not relevant to the work of the respective ECHA body, e.g. because it falls outside the field of activity of ECHA, it is given the risk level A.

All interests declared in a (100%) public organisation shall also be given the risk level A.8

Mitigating measures: None. All competing interests that receive the risk level A are considered as not relevant and it clears the respective expert to work on any task assigned to the respective ECHA body, unless he/she has other competing interests that are classified

B ("interests require ad hoc assessment"): competing interest may be relevant to the work of the respective ECHA body under certain specific circumstances

For competing interests declared in the field of "research funding" below 25% of the total research budget; interests in "interest groups"; "other membership, affiliation or position"; "other relevant information" and "interests held by close family members" the identification of potential conflicts of interest can only be performed ad hoc, depending on the exact details and circumstances of the case.

Mitigating measures: the competing interests covered by this risk level have to be reviewed before each meeting against the agenda of such meeting and/or declared ad hoc by the experts themselves in a specific oral declaration at the start of each meeting (minuted). Depending on the exact details and circumstances of the case and based on the following criteria, a decision is made by the chairperson on the possible application of an ad hoc exclusion or restriction:

- Direct interest (e.g. in the company/substance concerned) or indirect interest (e.g. interest of spouse, interest in competitor substance, interest is sectorwide but not related to one company, etc.);
- Amount/percentage of the research funding (below 25%) stemming from a party with an interest in the outcome of the regulatory processes of ECHA;

Deleted: It shall be the task of the respective

secretariat to regularly monitor the annual declarations made by the members and to bring any potential conflict of interest to the attention of the respective chair. The Executive Director shall also be informed of any such cases. On the basis of the type and nature of the potential conflict identified, the chairperson shall decide on the appropriate level of participation in the work of the ECHA body.

Moved up [2]: The annual declaration of interest of the Executive Director is reviewed by the Chair of the

Management Board.¶

⁸ However, Members of the Committee for Risk Assessment or of the Committee for Socio- Economic Analysis shall refrain from voting on proposals for opinion or decision that they have contributed to themselves or that are otherwise stemming from the Member State that has nominated them (based on the principles of good administrative practice where a person shall not review his/her own work and the risk for perception of conflict of interest).



Document code: PRO-0067.03

Security level: Public
Effective date: 21/12/2018

Prevention and Management of potential Conflicts of Interest

- Relevance of the membership, affiliation or position for the regulatory activity under discussion;
- Role of the individual concerned in the regulatory process and availability of alternatives or other experts;
- o Etc.
- C ("interest leads to specific exclusion"): competing interest covered by a general cooling off period

When the declared competing interest is covered by one of the cooling off periods described under chapter 3.1.2 above, it is given the risk level C.

Mitigating measures: for the competing interest covered by a general cooling off period, the expert cannot vote in the opinion- or decision making on this specific substance or company for a duration of five years.

For the competing interests declared orally at the beginning of a meeting, on the basis of the type and nature of the potential conflict identified, the chairperson shall decide on the appropriate level of participation. This applies accordingly for the cases of written procedures in ECHA bodies. As a minimum, such person shall not participate in any voting on the relevant agenda point (see Article 88(3) of REACH). Such person shall also not transfer his/her voting right by proxy to another member, which does not preclude the replacement by an alternate. The member concerned shall also not be appointed as (co-)rapporteur for a particular case if he/she indicates any conflicting interests (see Article 87(1) of REACH).

Additionally, where further steps are deemed necessary, the chair shall at least have at his/her disposal any of the following instruments to mitigate the issue:

- The member concerned can participate in the discussions but shall not participate in the final deliberations on the relevant agenda point;
- The member concerned shall not participate in the discussions or final deliberations on the relevant agenda point;
- The member concerned is to leave the room for the duration of the relevant agenda point;
- The member concerned shall participate only as an expert witness in order to testify and give specialist advice on a specific issue by providing information and replying to any questions;
- In the case that an alternate can be appointed in the pertinent ECHA body, the member concerned may be replaced by his/her alternate for the relevant agenda
- point; Where the Chair is concerned, he/she is to be replaced for the relevant agenda point.
- _____

Moved (insertion) [3]

Deleted: O

Deleted: ¶

Deleted: <#>Mitigating measures for casespecific conflicts of interest¶

Management Board, Committees, Forum¶

The chair will ask members and their advisors as well as invited experts and observers to declare any interests at the beginning of each meeting and any declared interests will be recorded in the minutes.

Moved up [3]: <#>On the basis of the type and nature of the potential conflict identified, the chairperson shall decide on the appropriate level of participation. This applies accordingly for the cases of written procedures in ECHA bodies. As a minimum, such person shall not participate in any voting on the relevant agenda point (see Article 88(3) of REACH). Such person shall also not transfer his/her voting right by proxy to another member, which does not preclude the replacement by an alternate. The member concerned shall also not be appointed as (co-)rapporteur for a particular case if he/she indicates any conflicting interests (see Article 87(1) of REACH).¶

"Additionally, where further steps are deemed necessary, the chair shall at least have at his/her disposal any of the following instruments to mitigate the issue:¶

The member concerned can participate in the discussions but shall not participate in the final deliberations on the relevant agenda point;¶
The member concerned shall not participate in the discussions or final deliberations¶

on the relevant agenda point;¶
The member concerned is to leave the room for the duration of the relevant agenda point;¶
The member concerned shall participate only as an

expert witness in order to testify and give specialist advice on a specific issue by providing information and replying to any questions; ¶

In the case that an alternate can be appointed in the pertinent ECHA body, the member concerned may be replaced by his/her alternate for the relevant agenda ¶

Deleted: Board of Appeal¶

Moved up [4]: Specific, case-related declarations by a member of the Board of Appeal are assessed by the other Board of Appeal members, who shall decide as to the action to be taken.¶

If a member of the Board of Appeal considers that because of a conflict of interests he/she must not take

Deleted: ECHA Secretariat¶

Moved up [5]: The process owners shall, based on a risk assessment, define the processes in the Agency that require interest management. In such processes, conflict of interest checks shall be performed each time a particular staff member is assigned to a role in the process. Such interest checks are performed on the



PRO-0067.03

Public

Effective date:

21/12/2018

Prevention and Management of potential Conflicts of Interest

3.3. Additional controls

3.3.1. Mitigating measures for conflicts of interest of a general nature and breach of trust (control point 4)

FCHA hodies

Any false declaration, wilful omission or refusal to declare interests or any other failure to comply with this procedure may be seen as a breach of trust towards the Agency. The same applies for any persistent conflict of interest which seriously hampers the functioning of the ECHA body.

The respective chair of the ECHA body can decide on remedial actions to address an alleged breach of trust. In case the remedial actions do not bring the expected outcome, the chair in consultation with the Executive Director shall send a formal notification to the Appointing Authority¹⁰ stating the nature of the problem.

The respective Appointing Authority is responsible for adopting any formal decision as a consequence of a (potential) conflict of interest when they are informed of a situation which may be detrimental to the Agency. Such decision may vary from a letter of reprimand to the request or duty to resign or the revocation of the nomination / appointment.

The members of the Board of Appeal may not be removed from office unless there are serious grounds and only by decision of the Commission, after obtaining the opinion of the Management Board.

In case the Executive Director is not satisfied with the remedies put in place by the chair or by the Appointing Authority, he/she shall inform the ECHA body concerned of this fact in its next meeting and have it noted in the minutes of the meeting.

Anyone affected by a decision of the chair of an ECHA body to implement remedial actions can request the Chair of the Management Board for a review of such decision. The Chair of the Management Board, in consultation with the Executive Director, shall decide on the follow-up, with the possibility to consult the Conflicts of Interest Advisory Committee.

ECHA staff

Any persistent conflict of interest that may hamper the proper functioning of an ECHA staff member in his/her current function shall be assessed by the respective line managers and escalated towards the Appointing Authority for decision if necessary. Where necessary,

 10 For the Management Board the appointing authority is either the European Council (for the members nominated by the Member States), the Commission or the Parliament (Article 79 REACH Regulation). The appointing authority for the Member State Committee, the Biocidal Products Committee and the Forum are the respective Member States (Article 85(3) and 86 REACH Regulation and Article 75(2) BPR), while for the Board of Appeal, the Committee for Risk Assessment and the Committee for Socio-economic Analysis the appointing authority is the ECHA Management Board or the Committee in the case of co-opted members.

TEM-0129.01

Uncontrolled copy once printed. Ensure that the right version is in use.

Deleted: Identifying and handling potential conflicts of interest

Deleted: <#>General assessment criteria¶

The interests to be assessed shall include all private interests in the field of activity of the Agency, and more in particular employment, consultancy, legal representation or advice; membership of a governing body or scientific advisory body; other memberships and affiliations; research funding; investments; intellectual property; public statements and positions and any other interests that may interfere (or may be seen as interfering) with the work of the Agency (see FOR-0039, declaration of interest form). \P When assessing whether certain of the above interests held by an individual working for the Agency are to be considered as constituting an actual or perceived conflict of interest, the following minimum criteria shall be taken into account:¶ Not only personal interests, but also all relevant interests held by close family members (i.e. members of the same household: spouse, partner and dependent children) need to be considered; Not only current interests, but also those that existed during the last 5 years preceding the assessment shall be considered (with an exception for investments, intellectual property and interests held by close family members for which only current interests are of relevance);¶ All financial investments in a commercial entity that amount to a value above 10,000 EUR per company or shares, stocks or comparable amounting to a voting right of 5% or more in a company (notwithstanding their financial value) are to be

considered.¶ On this basis, an overview of the allowable and

non-allowable interests is presented in the annex.

Deleted: Besides these minimum criteria, the assessor (chair of ECHA body, line manager/process owner for ECHA staff) shall take into account the other elements of the case, including the importance of the interest declared, the role of the individual holding the interest, $\,$ specific mitigating measures and controls imposed, the importance and impact of the decision or opinion to be drafted, the availability of alternates or other experts, etc.¶



Document code: PRO-0067.03 Security level: Public 21/12/2018 Effective date:

Prevention and Management of potential Conflicts of Interest

appropriate mitigating measures will be implemented (e.g. change in task description, move to another position in the interest of service, etc.)¹¹. The Appointing Authority shall have the possibility to consult the Conflicts of Interest Advisory Committee before deciding on the action to take.

Any false declaration or wilful omission of potential conflicts of interest, as well as the refusal to declare interests may result in disciplinary action under the Staff Regulations.

3.3.2. Post-employment declarations

Members of the ECHA bodies, staff members of the Agency, members of networks or expert groups, observers and third parties working with the Agency shall be required, even after their duties have ceased, not to disclose information of the kind covered by the duty of professional secrecy¹².

When a staff member leaves the service at ECHA, he/she shall continue to be bound by the duty to behave with integrity and discretion as regards the acceptance of certain appointments or benefits. They shall be reminded of their duties under the Staff Regulations and shall duly sign a document regarding integrity, discretion and confidentiality.

Furthermore, when leaving the Agency service, former ECHA staff have to notify the Agency for a period of two years any new occupational activity they intend to engage in. If that activity is related to the work carried out by the staff member during the last three years of service and could lead to a conflict with the legitimate interests of the Agency, the Appointing Authority can, if needed, either forbid the former staff member from undertaking it or give its approval subject to any conditions it thinks fit (Article 16 Staff Regulations). For the senior management of the Agency, the outcome of such decisions is published on the ECHA website for full transparency.

3.3.3. Ex-post controls (control point 5)

The respective secretariat of each ECHA body shall undertake sample checks to guarantee the accuracy and completeness of the annual declarations submitted by the members of the ECHA bodies.

Each year the ECHA Secretariat shall undertake a number of ex-post reviews of conflict of interest checks performed. To that end, it shall verify for a number of randomly selected case files whether conflict of interest checks were performed according to this procedure and its implementing rules.

An ex-post review shall be mandatory with regard to the concerned case file(s) when an actual conflict of interest is discovered. Similarly, if the person concerned by an established

Moved (insertion) [6] breach of trust was involved in an opinion- or decision-making procedure, the Agency may Deleted: I

TEM-0129.01

Uncontrolled copy once printed. Ensure that the right version is in use.

Page 10 of 18

Moved down [6]: If the person concerned by an established breach of trust was involved in an opinionor decision-making procedure, the Agency may carry out an ex post review of the person's activities and contributions to the Agency's output.

Deleted: Ex-post review¶

Deleted: After work for the Agency has ended

Moved (insertion) [1]

Deleted: also

¹¹ For the regular members of the Board of Appeal (who are also ECHA staff) the provisions of Article 90 of the REACH Regulation will apply.

12 See e.g. Article 105 of the REACH Regulation and Article 12 of ED/62/2008.



PRO-0067.03 Public

21/12/2018

AICALS AGENCY Effective date: 21/
Prevention and Management of potential Conflicts of Interest

carry out an ex post review of the person's activities and contributions to the Agency's output.

3.3.4. Conflicts of Interest Advisory Committee

A Conflicts of Interest Advisory Committee is established as an advisory body in the context of this Procedure. It is available to the Management Board, the Committees and the Forum as well as to the Executive Director for advice on matters related to (potential) conflicts of interest of individuals staffing the Agency or members of its bodies. It is composed of the Head of the Legal Affairs unit of the Agency, Chair, of a person designated by the Management Board and of an outside expert designated by the Executive Director for its competence in the field of conflicts of interest.

The Executive Director can consult the Conflicts of Interest Advisory Committee in all stages of the process of handling a potential situation of conflicting interests, to seek their advice on the individual case at hand. The chair of any of the ECHA bodies can also request the Executive Director to consult the Conflicts of Interest Advisory Committee. On request of the Executive Director, possibly prompted by the chair of an ECHA body, the Conflicts of Interest Advisory Committee issues a reasoned advice, without prejudice to the decision-making powers of the Agency body requesting it.

For issues related to the Board of Appeal, the Management Board has established a standing working group. This working group can also provide advice on issues related to (potential) conflicts of interest. Where necessary and as appropriate, the working group may ask the Chair of the Management Board to consult the CoIAC in order to guarantee consistency in the application of conflict of interest criteria within the Agency.

3.4. Further implementation

As the legal representative of the Agency and responsible for the daily management of the Agency, the Executive Director shall adopt implementing rules to this procedure, containing the detailed rules for preventing and handling conflicts of interest. He/she shall regularly report on the implementation of the procedure to the Management Board and in the annual activity report of the Agency.

The ECHA bodies shall include detailed provisions for the implementation of this procedure into their respective Rules of Procedures, Codes of Conduct and working procedures. Where necessary and if applicable, the chair may decide to impose the same requirements on the regular members of working groups established by the respective ECHA bodies.

The staff of the ECHA Secretariat shall further comply with all other obligations that are imposed on them by the Staff Regulations (see Articles 11 to 19) and its implementing rules.

4. Flowchart

N/A



PRO-0067.03

Public

Effective date:

21/12/2018

Prevention and Management of potential Conflicts of Interest

5. Definitions

Term or abbreviation	Definition	
Breach of trust	Any false declaration, wilful omission or refusal to declare interests or any other failure to comply with the agency's conflict of interest policy.	
CoIAC	Conflicts of Interest Advisory Committee	
Conflict of interest	There is a conflict of interest where the impartiality and objectivity of a decision, opinion or recommendation of the Agency, including its bodies, is or might in the public perception be compromised by an interest held by, or entrusted to, an individual working for the Agency.	
ECHA body	The ECHA bodies shall include the Management Board, the Member State Committee, the Risk Assessment Committee, the Committee for Socio-economic Analysis, the Biocidal Products Committee, the Enforcement Forum and the Board of Appeal.	
ECHA Secretariat	The ECHA Secretariat works under the leadership of the Executive Director and provides technical, scientific and administrative support for the Committees and the Forum and ensures appropriate coordination between them. It shall also undertake the work required of the Agency under the procedures for pre-registration, registration and evaluation as well as preparation of guidance, database maintenance and information provision (Article 76.1(g) of REACH)	
Process owner	A process owner is a person (staff member of the ECHA Secretariat) designated by the Executive Director, responsible for the efficient and effective functioning of the process and has the necessary authority to take action or make decisions with an impact on the process performance. In general, the process owner ensures that proper action is taken with respect to the implementation, maintenance, control and improvement of the process.	

6. Records

Record name	Security level	Comments
Declarations of interest of members of ECHA bodies	Public	
Declarations of interest of ECHA managers	Public	
Declarations of interest of ECHA staff	Restricted	



Public

Effective date:

21/12/2018

PRO-0067.03

Prevention and Management of potential Conflicts of Interest

Record name	Security level	Comments
Declaration of commitment and of confidentiality of members of ECHA bodies	Restricted	
Declaration of confidentiality of ECHA staff	Restricted	
Specific declarations of interest related to a point on the agenda of a meeting of an ECHA body, as recorded in the minutes	Public	
Specific declarations of interest by an ECHA staff member related to a specific dossier, as recorded in the case file	Dependent on the case file concerned	

7. References

Associated document code	Document name		
REACH 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		
Biocidal Products Regulation (BPR)	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products		
Regulation (EC) No 771/2008	Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency		
Staff Regulations	Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union		
MB/11/2008 amended by MB/21/2013	Code of Good Administrative Behaviour for the staff of the European Chemicals Agency		
MB/11/2012 final	Code of conduct of the Management Board of the European Chemicals Agency		
MB/12/2012 D final	Implementing rules on the conduct of administrative inquiries and disciplinary proceeding		
MB/38/2012/D (2) final	Terms of Reference of the ECHA Conflicts of Interest Advisory Committee		
MB/40/2012 final (1) final	Rules of Procedure for the Committee for Risk Assessment		
MB/40/2012 (2) final	Rules of Procedure for the Committee for Socio-economic Analysis		



Document code: Security level: Effective date: PRO-0067.03 Public 21/12/2018

Prevention and Management of potential Conflicts of Interest

Associated document code	Document name	
MB/51/2012 final	Rules of Procedure for the Management Board	
MB/14/2013 final	Rules of Procedure for the Member State Committee	
MB/25/2013 final	Rules of Procedure for the Biocidal Products Committee	
MB/31/2013 final	Rules of Procedure for the Forum for Exchange of Information on Enforcement	
MB/45/2013 final	Eligibility criteria and guidelines for the ECHA bodies	
MB/62/2013	Implementing Rules to the EU Staff Regulations on Outside activities and assignments	
ED/62/2008	Code of conduct for observers at ECHA meetings	
ED/159/2012	Guidance on gifts and hospitality	
ED/08/2013	General Principles and Guidance for Committee Members of the European Chemicals Agency	
ED/43/2013	General Principles and Guidance for members of the Forum for Exchange of Information on Enforcement of the European Chemicals Agency	
ED/89/2013	ECHA Code of conduct for case owners of evaluation draft decisions as observers at meetings of the Member State Committee (MSC)	
ED/104/2013	Code of conduct for applicants participating in the Biocidal Products Committee and its Working Groups	
ED/13/2014	Rules on the secondment of national experts to the European Chemicals Agency (ECHA)	
ED/28/2014	Guidance for filling in the declaration of interest	
BoA/02/2010	Code of conduct of the (regular/alternate/additional) members of the Board of Appeal of the European Chemicals Agency	

8. Annexes

Annex 1 - Overview of allowable and non-allowable interests

Annex 2 - Eligibility criteria



PRO-0067.03 Document code: Security level:

Public

Effective date: 21/12/2018 Prevention and Management of potential Conflicts of Interest

Annex 1 - Overview of allowable and non-allowable interests

Full exclusion applied (before appointment)

Specific restriction applied for 5 years for specific substance or company concerned (during mandate)

Allowable interests: no exclusion nor restriction

Interests subject to case-by-case assessment

External experts		ECHA staff		
Management Board members	Committees and Forum members	Additional and alternate members of the Board of Appeal	Regular members of the Board of Appeal – ECHA managers – Accounting Officer – Committee chairpersons	Other ECHA staff
Non-allowable i	nterests			
Current employment (in a position of relevant importance) by, or holding a position in a governing body (whether paid or unpaid) of, a commercial enterprise with an interest in the field of activity of the Agency.				Under the Staff Regulations for EU officials, all ECHA staff members have to receive the approval of the appointing authority for any outside activity or assignment, regardless whether the activity is paid or unpaid.
Current active membership of, or employment by (in a position of relevant importance), an association or other body (except a body established under public law serving a public interest) which can be considered an interest group with an interest in the field of chemicals management.				
Current personal contractual obligations with a commercial entity or an interest group with an interest in the field of activity of the Agency.				
Current investments above 10.000 EUR (or giving right to 5% or more of voting rights) in a commercial entity manufacturing, importing, supplying or placing on the market substances or mixtures subject to the authority of the Agency.				Current investments above 10.000 EUR (or giving right to 5% or more of voting rights) in a commercial entity (with regard to that commercial entity for as long as the investment or intellectual property is kept)
Past employment by (in a position of relevant importance), or holding a position in a governing body or permanent scientific advisory body (whether paid or unpaid) of, a commercial enterprise with an interest in the field of activity of the Agency within the past two years when the individual concerned has a potential conflict of interest of a general nature that would lead to multiple exclusions of the individual from the meetings of the ECHA body concerned, from rapporteurship or from the decision-making of the Board of Appeal.				



Document code: PRO-0067.03

Security level: Public

ENCY Effective date: 21/12/2018

Prevention and Management of potential Conflicts of Interest

Past active membership of, or employment by, an association or other body (except a body established under public law serving a public interest) which can be considered an interest group with an interest in the field of chemicals management within the past two years when the individual concerned has a potential conflict of interest of a general nature that would lead to multiple exclusions of the individual from the meetings of the ECHA body concerned, from rapporteurship or from the decision-making of the Board of Appeal.

Past employment or another professional relationship (e.g. consultancy or legal advice) with a commercial entity for a period of **five years** counted from the end of the employment or other professional relationship (with regard to a substance manufactured or placed on the market by that commercial entity)

Past membership of a governance board or permanent scientific advisory body with a commercial entity for a period of **five years** counted from the end of the membership (with regard to a substance manufactured or placed on the market by that commercial entity)

Current intellectual property in a specific commercial entity or substance (with regard to that substance or commercial entity for as long as the intellectual property is kept)

Research funding above 25% of the total research budget received from a specific company for a period of five years counted from the end of the funding (with regard to a substance manufactured or placed on the market by that commercial entity)

Allowable interests

Interests outside the regulatory field of activity of ECHA, with no restrictions.

Past interests, for which a period of 5 years or more has passed, with no restrictions.

Past employment by, or holding a position in a governing body or permanent scientific advisory body (whether paid or unpaid) of, a public organisation (including e.g. national competent authorities). 13

Current investments below 10,000 EUR per commercial entity, with no restrictions (except if these investments would amount to voting rights of 5% or more in such commercial entity).

Current non-active membership/affiliation or past active membership/affiliation in an organisation relevant to the regulatory field of activity of ECHA for which a period of five years has passed, with no restrictions. Current and past active membership or affiliation in organisations not relevant to the regulatory field of activity of ECHA, with no restrictions.

Past interests of members of the same household, with no restrictions.

Interests subject to a case-by-case analysis, taking into account all the specific elements of the case

All current and past interests related to **research funding below 25%, memberships, affiliation and positions and close personal relationships** (beyond those with the members of household).

¹³ However, Members of the Committee for Risk Assessment or of the Committee for Socio- Economic Analysis shall refrain from voting on proposals for opinion or decision that they have contributed to themselves or that are otherwise stemming from the Member State that has nominated them (based on the principles of good administrative practice where a person shall not review his/her own work and the risk for perception of conflict of interest).



Document code: Security level: Effective date: PRO-0067.03 Public 21/12/2018

Prevention and Management of potential Conflicts of Interest

Annex 2 – Eligibility criteria for candidates for membership in the ECHA bodies and for key positions in the ECHA Secretariat¹⁴

Group 1: Candidates for membership in the Committee for Risk Assessment, the Committee for Socio-economic Analysis or additional or alternate members of the Board of Appeal have to comply with the five eligibility criteria a) - e) below to be considered for appointment by the ECHA Management Board.

Group 2: For the candidates for membership in the Management Board, the Member State Committee, the Biocidal Products Committee, the Enforcement Forum (group 2), with the exception of the Commission when appointing the three Management Board members to represent interested parties, the relevant appointing authorities are invited to respect the ECHA Conflict of Interest Policy and to adhere to the below five guidelines for eligibility a) – e) when appointing members to such ECHA bodies.

Group 3: candidates for the position of Chairmen of the ECHA Committees (MSC, RAC, SEAC, BPC), Accounting Officer or for the position of Executive Director, Director, Head of Unit or permanent member of the Board of Appeal have to comply with the eligibility criteria d) – e) below to be considered for appointment. The first three criteria a) -c) are not relevant for the candidates for the above positions and do not apply, as they become ECHA staff members and they will have to comply with the Staff Regulations for EU officials, and in particular the obligation to receive the approval of the appointing authority for any outside activity.

- a. Candidates being currently employed by (in a position of relevant importance), whether paid or unpaid, a commercial entity with an interest in the field of activity of the Agency or an association or other body (except a body established under public law of a Member State serving a public interest) which can be considered as an interest group with an interest in the field of chemicals management shall not be appointed. Appointed members of the Committees of the Agency shall resign from the Committee before they enter into service in any such enterprise.
- b. Candidates being an active member of, or holding a position in a governing body or permanent¹⁵ scientific advisory body of a commercial entity with an interest in the field of activity of the

¹⁴ The scope of the eligibility criteria shall be limited to duty-holders and interest groups under the REACH, CLP, Biocides and/or PIC Regulation as appropriate taking into account the mandate of the respective ECHA body. The eligibility criteria apply equally to the interests held by members of the candidates' household (i.e. the spouse and dependent children) if significant interests are at stake that would potentially lead to multiple exclusions of the candidate from the meetings of the ECHA body, the decision making of the Agency or from rapporteurship.

¹⁵ As opposed to ad hoc or temporary project boards



PRO-0067.03

Public

Effective date: **21/12/2018**

Prevention and Management of potential Conflicts of Interest

Agency or an association or other body (except a body established under public law of a Member State serving a public interest) which can be considered as an interest group with an interest in the field of chemicals management shall not be appointed. Appointed members shall resign from the Committee before they enter into service in any such association.

- c. Candidates who personally have contractual obligations with a commercial entity or interest group with an interest in the field of activity of the Agency after having been appointed as members, shall (a) withdraw from current contracts and (b) refrain from entering into any new contracts with such commercial entities or organisations.
- d. Candidates who currently hold investments above 10.000 EUR in a commercial entity manufacturing, importing or supplying substances or mixtures subject to the authority of the Agency, including holding of stocks and shares, stock options, equity, bonds, partnership interest in the capital of such undertaking, one of its subsidiaries or a company in the capital of which it has a holding or entitling to a voting right of 5% or more in such commercial entity, shall not be appointed. This is without prejudice to financial interests held through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements, provided that these investments are broadly diversified and the candidate has no influence on their financial management.
- e. Candidates who were within the past two years employed by (in a position of relevant importance), or held a position in a governing body or permanent scientific advisory body (whether paid or unpaid) of a commercial entity with an interest in the field of activity of the Agency or an association or other body (except a body established under public law of a Member State serving a public interest) which can be considered as an interest group with an interest in the field of chemicals management (or an active member thereof) shall not be appointed when the candidate has a potential conflict of interest of a general nature that would potentially lead to multiple exclusions of the individual from the meetings of the ECHA body, the decision making of the Agency or from rapporteurship.

Deleted: 100.000

Deleted: 20