

DECISION OF THE MANAGEMENT BOARD
RULES OF PROCEDURE FOR COOPERATION OF THE EUROPEAN CHEMICALS AGENCY WITH
THE EUROPEAN FOOD SAFETY AUTHORITY

THE EUROPEAN CHEMICALS AGENCY:

Having regard to 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 (hereinafter, referred to as 'the REACH Regulation'),¹ and in particular to Recital 111, Article 95 and Article 110 thereof,

Having regard to 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 (hereinafter, referred to as 'EFSA'), and laying down procedures in matters of food safety,² and in particular to Article 30 thereof,

Having regard to the Memorandum of Understanding between the European Chemicals Agency (hereinafter, referred to as 'ECHA') and EFSA signed on 20th May 2009, and in particular to Section IV thereof,

After consultation of the Committee for Risk Assessment (hereinafter, referred to as 'RAC') and EFSA, and in agreement with the Commission, pursuant to Article 110(2) of REACH Regulation,

Whereas:

- (1) Both ECHA and EFSA work in the area of assessing the safety of substances.
- (2) ECHA and EFSA may adopt opinions on substances that relate to food safety.
- (3) It is important to ensure cooperation and coordination between ECHA and EFSA, in order to avoid confusion between the respective missions and duplication of work,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Article 1
Aim and scope

Without prejudice to the provisions of Article 30 of Regulation (EC) No 178/2002 and Article 95 of Regulation (EC) No 1907/2006, these Rules of Procedure define the framework for cooperation of ECHA with EFSA with a view to sharing relevant information and ensuring coherence in the work of ECHA and EFSA, in particular on matters concerning substances for which an opinion has been sought in a food safety context.

¹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the 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 No L 136, 29.5.2007, p. 3.

² 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, OJ L 31, 1.2.2002, p. 1-24.

Article 2
Tasks

With reference to matters defined in Article 1, ECHA shall undertake, where appropriate, to:

- a) Exchange relevant information regularly with EFSA, in particular the relevant parts of ECHA work plans, agendas, meeting calendars and public minutes;
- b) Ensure coordination with EFSA, including coordination on communication such as in the event of an emerging risk from chemical substances that may affect or concern human health, environment or food safety;
- c) Inform EFSA when delivering scientific advice, opinions and risk assessments that concern food safety;
- d) Act proactively and on a regular basis to resolve potential sources of conflict between opinions of ECHA and EFSA.

Article 3
ECHA coordinator for EFSA

1. A person of the ECHA secretariat is appointed as a coordinator for the maintenance of close, direct and continuing contacts with EFSA. In the work the ECHA coordinator for EFSA shall consult and inform others in ECHA as appropriate.
2. The ECHA coordinator for EFSA shall forward the information to be exchanged under Article 2 to the relevant Committee secretariat.
3. The ECHA coordinator for EFSA shall identify the need for regular contacts and meetings where appropriate of the Chairs and Secretariats of ECHA Committees and EFSA Scientific Committee and Panels.
4. The ECHA coordinator for EFSA shall keep the records of the information exchanged.

Article 4
Mechanisms for prevention of potential conflicts of scientific opinions

1. Identification of substances that are, or are likely to be, under discussion in both ECHA and EFSA shall be facilitated by exchanging relevant information, such as ECHA's registry of intentions and the Community rolling action plan, as well as EFSA's registry of questions.
2. ECHA shall develop together with EFSA other mechanisms to facilitate early recognition of relevant chemical substances which could be relevant in a food safety context and their impact on the current work of ECHA in particular in cases where the substance has been earlier addressed by either ECHA or EFSA.
3. ECHA facilitates the participation of experts from EFSA in working groups dealing with specific issues when considered appropriate by Committees responsible for setting the working group.
4. ECHA will seek to provide an opportunity for early exchange of views between rapporteurs of its Committees and EFSA's Panels dealing with substances referred to in paragraph 1 where appropriate.

5. When a potential conflict of opinions between the ECHA and EFSA is expected or identified, the possibility of sharing data which has been used as the basis of opinions shall be considered. The principles outlined in Article 6 shall be respected.
6. Where appropriate, ECHA should facilitate an analysis of the methodologies used in preparation of its opinions.

Article 5

Mechanisms for dealing with conflicts of scientific opinions

1. If despite the mechanisms described in Article 4 a conflict of scientific opinions by ECHA and EFSA is identified, the following shall be identified:
 - a) the scientific and/or technical points of conflict;
 - b) the relevant uncertainties in the data and the reasons for the differences in taking them into account;
 - c) the relevant differences in the application of the methodologies used by the ECHA and EFSA.
2. As appropriate, ECHA will arrange joint meetings between experts, rapporteurs and Secretariats of ECHA Committees and EFSA Scientific Committee and Panels, or ECHA may invite EFSA representatives to attend a meeting in order to discuss the specific issue.

Article 6

Confidentiality

ECHA ensures that any data held by it which is not publicly available is shared with EFSA in compliance with ECHA's internal policies on sharing of information with external actors, the confidentiality requirements foreseen in the REACH Regulation and confidentiality provisions in other relevant legislation. When sharing such information, ECHA shall inform the recipients in EFSA of its policies or other specific rules that it deems to apply to this information. In turn, ECHA shall ensure that information received on the basis of this co-operation will be treated in accordance with applicable provisions governing the confidentiality, processing and release of information, respecting EFSA's confidentiality.

Article 7
Final provisions

1. These Rules of Procedure, including any amendments, shall apply from the date they are adopted by the ECHA Management Board. They shall be made publicly available on the ECHA website.
2. ECHA shall carry out a review of these Rules of Procedure by [DATE³] with a view of proposing amendments, where appropriate.

Done at Helsinki, 20/06/2013

For the Management Board
The Chair

signed
Nina CROMNIER

³ Three years from the adoption.