

Collaboration Agreement
Between
The Institute for Health and Consumer Protection of the European
Commission's Joint Research Centre
And
The European Chemical Agency (ECHA)

The Institute for Health and Consumer Protection of the European Commission's Joint Research Centre hereinafter referred to as JRC-IHCP, represented for the purpose of signing this Collaboration Agreement by Mrs. Elke Anklam, in her capacity as outgoing Director and by Mr. Krzysztof Maruszewski as incoming Director,

On the one part,

And

The European Chemicals Agency, (hereinafter referred to as ECHA), represented for the purpose of signing this Collaboration Agreement by Mr. Geert Dancet, in his capacity as Executive Director,

On the other part,

Hereafter referred to individually as "the Party" or collectively "the Parties"

WHEREAS:

1. The mission of the JRC-IHCP is to provide scientific and technical support to EU policies for the protection of the interests and health of European citizens in the areas of food, consumer products and chemicals.
2. The main objectives of the JRC in these areas are:
 - a. To facilitate EU-wide harmonisation and standardisation in the implementation of EU legislation on control of food and consumer products, including the provision of validated analytical methods and tools.
 - b. To develop improved frameworks, systems, databases and tools, including validated non-animal toxicological methods for the safety assessment of chemicals (including nanomaterials) to scientifically underpin the EU legislative process and contribute to international harmonisation.
 - c. To advance and coordinate efforts and activities at the EU-level in preventing and combating Europe's disease-related health burden and foster harmonisation according to best practices.
 - d. To apply the results and insights of behavioural research into the different cycles of the policy making framework and to provide circumspect knowledge to support an evidence-based approach to policy making.

3. The mission of ECHA is to be the driving force among regulatory authorities in implementing the EU's groundbreaking 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 and addresses chemicals of concern.
4. ECHA's strategic aims are to:
 - Maximise the availability of high quality data to enable the safe manufacture and use of chemicals
 - Mobilise authorities to use data intelligently to identify and address chemicals of concern
 - Address scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors
 - Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.
5. The Parties have expressed their mutual desire for cooperation in the field of chemicals, and are for that purpose signing the present Collaboration Agreement. The joint efforts of ECHA and the JRC-IHCP (when appropriate also supported by the JRC Institute for Reference Materials and Measurements, hereinafter referred to as JRC-IRMM) entail working to the mutual benefit of both organisations in the achievement of their objectives and in agreement with their respective missions.
6. The missions and objectives of both JRC-IHCP and ECHA are recognised as complementary by the Parties.
7. There are already a number of on-going collaborations between ECHA and JRC-IHCP.
8. The present agreement does not pre-empt any decision on the publication of calls for proposals from the Parties or the selection of projects thereof.
9. The contribution of the Parties to the collaboration is limited to the resources available within their institutional work programme.

HAVE AGREED AS FOLLOWS:

Article 1 – Objectives of the Collaboration Agreement

The general objective of this Collaboration Agreement is to clarify the roles of the Parties and further strengthen their cooperation in the field of chemicals and the protection of human health and the environment.

Article 2 – Roles of the Parties in the field of chemicals

(a) The objectives of the clarification of the respective roles of the JRC-IHCP and ECHA are to:

- Avoid unnecessary duplication of work and promote an efficient use of the EU resources
- Clarify for the European Commission and other EU institutions the relevant Party for collaboration and requests for information
- Define the fields in which the two Parties are intervening with their specific roles, for a strengthened cooperation

(b) The JRC is the European Commission's science service, whose mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle. It works in close cooperation with policy Directorates-General, and addresses key societal challenges while stimulating innovation through developing new methods, databases, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners. This applies to the chemicals' field.

(c) ECHA is an EU specialised regulatory agency in the field of chemicals., Its tasks are precisely defined in different Regulations (Regulation 1907/2006 "the REACH Regulation", Regulation 1272/2008 "the CLP Regulation", Regulation 528/2012 "the Biocides Regulation", Regulation 649/2012 "the PIC Regulation") and helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. In addition, ECHA provides the Member States and the Institutions of the European Union with the best possible scientific and technical advice on questions relating to chemicals.

(d) The Parties have a common interest in providing scientific and technical support to other customer entities.

(e) In order to achieve this objective, the JRC-IHCP and ECHA commit to:

- inform each other when appropriate about requests for technical and scientific advice and support from Commission's services on chemicals
- support each other when possible in delivering this technical and scientific advice and support
- deal with these requests in line with the following principles:
 - the provision of general scientific support is performed by the JRC-IHCP, as intended in its mission and work programmes, with possible support from ECHA on request and agreement
 - tasks under ECHA's responsibility are those that fall within its remit according to the REACH and CLP Regulations, such as reporting on REACH and CLP activities, or those that are associated with topics of ECHA work programmes or long-term strategic objectives, with possible support by JRC-IHCP on request and agreement
 - any questions relating to emerging issues such as nanomaterials, mixture toxicity and endocrine disruptors which are of relevance for JRC-IHCP and ECHA's work may for certain matters be considered as a joint effort between ECHA and JRC-IHCP and included in the Cooperation Programmes (article 4.3)
- cooperate closely to ensure that the requests for technical and scientific advice from the Commission's services are addressed to the Party which is better placed to undertake the support
- cooperate where appropriate in providing technical input for EU contribution to OECD chemicals activities
- Consider to involve the relevant Institutes of the JRC in the implementation of the Collaboration Agreement, such as the JRC-IRMM for nanomaterials.

Article 3 – Joint Coordination Group and cooperation coordinator

(a) The Parties agree to establish a Joint Coordination Group (JCG) to review once a year the goals and monitor the progress of the cooperation process outlined by the Parties. The JCG is composed of the Director of JRC-IHCP, of the Director of Regulatory Affairs of ECHA, and at least two other members designated by each of the Parties.

(b) Each Party shall nominate one Cooperation Coordinator.

(c) The Cooperation Coordinators organise the Secretariat of the JCG and ensure the day to day follow-up of the cooperation. The Cooperation Coordinators are informed of the status of the projects and actions by the persons responsible, and take necessary actions to identify and solve possible problems. In addition, the coordinators present to the JCG an annual report on the implementation of the Collaboration Agreement.

Article 4 – Strengthening of the cooperation

4.1 Specific objectives of the cooperation

(a) Each Party has a broad and specialised experience in the field of chemicals and exchanges between the teams would benefit to each of the Parties. In addition, common activities concerning capacity building would be beneficial for both Parties.

(b) Further to these exchanges of information and common capacity building, the Parties have an interest in developing common projects, or involving each other in their projects.

(c) Cooperation based on information on chemicals detained by the two Parties would benefit the Parties, as long as compliance with the rules on the protection of data and information held by the Parties remains assured. The Parties commit to facilitate this access, taking into account that it may be necessary to sign individual Security Declarations prior to granting this access (to be elaborated in more details at a later stage).

4.2 Cooperation on the annual and multiannual work programmes

(a) The Parties agree to consult each other on their draft annual and multiannual work programmes before they are submitted for approval by the relevant bodies. The conditions of this consultation are defined by the Joint Coordination Group and are implemented by the Cooperation Coordinators.

(b) The Parties agree that the actions which are approved by the Joint Coordination Group in the Cooperation Programme are mentioned when necessary in the annual work programme of each Party.

4.3 Cooperation Programme

(a) The Joint Coordination Group defines the topics which are of interest for the cooperation.

(b) The Parties agree on the Cooperation Programme. This Cooperation Programme which includes projects and actions is maintained by the Cooperation coordinators and amended whenever necessary to take into account new projects and actions agreed by the Parties, and agreed changes in existing projects and actions. To that effect both institutions will exchange each year before the summer their first draft work programme for the next year.

(c) In case of joint activities covered by the present Collaboration Agreement, the Parties may, prior to commencing a project and on a case by case basis, conclude a specific written agreement detailing the specifics of the joint project and which could in particular cover any necessary technical and legal (including the responsibilities of the Parties and intellectual property rights) aspects.

(d) The formalisation of these projects and actions does not prevent informal cooperation and contacts between the staff members working for the Parties, which is encouraged.

(e) The Parties agree to have the right to mention non-confidential and non-sensitive aspects of the Cooperation Programme in public meetings where appropriate

Article 5 - Responsibilities of the Parties

(a) Each Party is responsible for its own personnel in relation to activities undertaken pursuant to this Collaboration Agreement.

(b) When it is necessary for staff members from the JRC-IHCP or ECHA to participate for brief periods in carrying out projects or activities implemented by the other Party, the Parties shall conclude a separate agreement as regards the secondment of their staff to address the regulation of their mutual rights and obligations, the conditions of the cooperation provided by said staff member and the terms under which the JRC-IHCP and ECHA authorise their staff member to participate. Staff members involved in exchange programmes and projects shall comply with the rules and working conditions of the host institution.

(c) The host Party will assist, as much as possible, in meeting the personal and professional needs of the visitor, including access to facilities within the context of the Regulations in force at the host site.

Article 6 – Liability

(a) Any loss, damage or injury suffered by one Party in connection with the performance of this Collaboration Agreement shall be borne exclusively by it.

(b) Each Party shall be exclusively liable for any loss, damage or injury caused to third parties, arising out the performance of the Collaboration Agreement.

(c) Each Party shall indemnify the other Party for all liability in respect of any action for damages brought by third Parties and caused by their respective personal

Article 7 – Protection of the results of cooperation

(a) Intellectual Property (IP), and all rights pertaining thereto, created in and for the performance of the present Collaboration Agreement shall belong to the Party whose Personnel created it. The owning Party shall have the right to use, exploit, assign or dispose of such IP at its own will and discretion, unless otherwise provided for in the present Collaboration Agreement.

(b) Upon termination or expiry of the present Collaboration Agreement, Parties shall send each other a declaration including the list of IP which they have created in and for the performance of the present Agreement. Parties agree to grant each other rights of access and use for such IP on non-exclusive, royalty-free and non-transferable basis for internal and non-commercial purposes only.

(c) Parties shall put in place appropriate means to ensure their ownership of or rights in such IP to the extent necessary for the exercise of their duties and obligations under the present Collaboration Agreement, subject to the maximum achievable extent under the applicable law.

(d) In case the owning Party decides to waive or abandon its rights in such IP, or decides not to protect such IP, whether patentable or not, it undertakes to inform the other Party of its decision. The other Party may decide to pursue the protection of such IP by itself, in its own name and through its own means. For this end, Parties undertake to sign an Assignment Agreement particular to the IP concerned.

(e) In case the IP created in and for the performance of the present Collaboration Agreement cannot be clearly or reasonably separated between the Parties, or if the Parties have mutually contributed to the creation of the IP, or if it is evident that the IP created by the Parties have merged to such an extent that different parts cannot exist independently of the other, then such shall be considered as a jointly-owned IP.

(f) Neither Party can dispose of, license, assign, or transfer such jointly-owned IP to third-parties without the prior written consent of the other Party in the absence of a particular joint-ownership agreement. Following the coming into existence of a jointly-owned IP, the Parties undertake to conclude a particular Joint-Ownership Agreement to govern the terms and conditions pertaining to rights, duties and obligations of the Parties concerning the jointly-owned IP.

(g) In case the collaboration performed under the present Collaboration Agreement leads to the creation of results in the form of scientific, technical or academic publications, conference proceedings, reports, and similar written work authored through the involvement of the Personnel of both Parties, the Parties undertake to respect each other's rights, moral or economic, and to duly acknowledge and reference the authors and contributors.

(h) Neither Party can publish, disseminate, make publicly available, or disclose to a third party any result of the cooperation without prior written consent of the other Party on the manner, timing and contents of such disclosure. Consent for the foregoing may not be unreasonably withheld. Any breach of the present provision shall be considered not only a breach of the present Article but also a breach of confidentiality.

(i) Provisions of the present Article, and the rights, duties and obligations stipulated therein, shall remain valid and legally enforceable during the term of the present Agreement and for a period of five years from the date of its termination or expiry unless otherwise extended in a Separate Agreement.

Article 8 - Access to information detained by other Party

(a) The Parties commit to facilitate each other's access to information they detain on chemicals. However, the conditions of this access can be defined to minimise the workload for the Party holding the information, in particular by providing an access in the premises of the Party detaining the information.

(b) Access of JRC-IHCP staff to information originating from ECHA's information systems shall respect the conditions defined by ECHA's Management Board decision concerning the access of Member States Competent Authorities, Mandated National Authorities and the Commission to these databases. ECHA may specify and communicate more detailed requirements and specifications for the treatment of information originating from its information systems for individual projects. Unless otherwise indicated, information contained in ECHA's information systems shall be treated as non-classified, sensitive information.

Article 9 – Funding

(a) The activities conducted pursuant to this Collaboration Agreement shall be subject to the availability of appropriate funds, persons and other resources as well to the applicable laws and regulations, policies and programmes of each Party.

(b) Each Party shall bear the cost of any expenditure it incurs relating to the performance of its tasks under this agreement.

(c) Mission expenses for staff shall be borne by the Party to whom the staff belongs

(d) The JRC-IHCP shall be eligible to participate in ECHA's requests for scientific and technical support and to receive financial support if such studies are beyond the JRC's institutional work programme. Similarly work undertaken by ECHA for the JRC outside its own work programme could also be subject to financial support.

(e) Service Level Agreements are authorised between the Parties.

Article 10 – Confidentiality

The Parties undertake to keep confidential any information, document or other material communicated to them as non-classified, sensitive or the disclosure of which may be prejudicial to the other Party, until or unless the content legitimately becomes publicly available or under express consent of the other Party.

All exchange of non-classified, sensitive information between the JRC-IHCP and ECHA shall be in accordance with the respective security provisions applied by the Parties for such exchanges.

Confidentiality of information exchanged orally or in writing in connection with this Collaboration Agreement shall be maintained for a period of at least five years after its expiry or termination. Notwithstanding the foregoing, confidentiality of third party information held by either of the Parties and exchanged through this Collaboration Agreement shall be maintained for an indefinite period of time, unless otherwise agreed. For other information, any Party may indicate when communicating information to the other Party that the confidentiality of the information shall be maintained even after the said five-year period.

Article 11 – Applicable law and settlements of disputes

This Agreement shall be governed by European Union law supplemented as appropriate by the substantive law of Belgium.

The Parties shall do everything possible to settle amicably any dispute arising between them during implementation of this Collaboration Agreement. Such effort shall be deemed to have failed when one of the Parties so notifies the other in writing. In that case, each Party may initiate proceedings before the General Court of the European Union in Luxembourg.

Article 12 – Entry into force and duration

This Collaboration Agreement shall enter into force on the date of the last signature. This Collaboration Agreement may be extended or amended only by written agreement signed by the duly authorised representatives of both Parties.

The Collaboration Agreement shall be concluded for a period of three years which shall be renewable.

If a Party believes that the Collaboration Agreement can no longer be executed effectively or appropriately, it shall consult the other Party. Failing agreement on a solution, either Party may terminate the Collaboration Agreement by serving three months' written notice.

13.12.2012 Helsinki

Date and place

**Institute for Health and Consumer
Protection of the European Commission's
Joint Research Centre**

Signed

Elke Anklam
Director JRC-IHCP (up to 31.12.2012)
Incoming Director JRC-IRMM (from 01.01.2013)

Signed

Krzysztof Maruszewski
Director JRC-IRMM (up to 31.12.2012)
Incoming Director JRC-IHCP (from 01.01.2013)

13.12.2012 Helsinki

Date and place

European Chemicals Agency

Signed

Geert Dancet
Executive Director