



COLLABORATION AGREEMENT

COLLABORATION AGREEMENT No. 35173

Between

the European Food Safety Authority with the registered address at Via Carlo Magno 1A, 43126 Parma, Italy represented for the purpose of signing this agreement by Bernhard Url, EFSA Executive Director, duly entitled to sign, (hereinafter referred to as '**EFSA**').

and

The **Joint Research Centre of the European Commission**, represented for the purpose of signing this Agreement by Vladimír Šucha, Director-General of the Joint Research Centre, duly entitled to sign, (hereinafter referred to as '**the JRC**'),

Hereinafter referred to individually as '**the Party**' or collectively as '**the Parties**'.

PREAMBLE

WHEREAS:

It is within the Parties' common interest as well as the public's interest to enhance their co-operation in contributing to protect public health;

Taking note with satisfaction of the on-going co-operation and progress achieved so far on the identification of possible areas of mutual interest concerning an enhanced effort on joint co-operation, it is in the common interest of the Parties to continue and increase co-operation;

EFSA is a decentralised agency of the European Commission, established by Regulation (EC) No 178/2002 (hereinafter the "General Food Law"), whose mission is to provide:

- 1) scientific advice and scientific and technical support for the Union legislation and policies in all fields which have a direct or indirect impact on food and feed safety;
- 2) independent information on all matters within these fields and communicate on risks;
- 3) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;
- 4) scientific opinions on other matters relating to animal health and welfare and plant health;
- 5) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

EFSA aims to provide technical quality of scientific advice issued based on the expertise of its scientific experts and staff and the quality of its science-based information and methodologies, which are grounded on internationally recognised standards. EFSA shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.

As the science and knowledge service of the European Commission, the JRC's mission is to support EU policies with independent evidence throughout the whole policy cycle. Working in close cooperation with other European Commission's Directorates General, in this particular case with DG Health and Food Safety (DG SANTE), the JRC contributes to harmonisation of methods, standards, and practices in support of legislation targeting health and consumer protection. More in particular through its Directorates F and D, the JRC conducts research in the field of health, consumers and reference materials and in the field of sustainable resources.

Through joint efforts of EFSA and the JRC, new approaches can be identified and developed in the areas of risk assessment, thus working to the mutual benefit of both organisations in the achievement of their objectives.

The Parties have expressed their mutual desire to pursue the co-operation in the field of risk assessment related to food and feed safety, animal health and welfare, plant health and nutrition and are for that purpose signing this Collaboration Agreement.

THE PARTIES HAVE AGREED AS FOLLOWS:

ARTICLE 1 – OBJECTIVES OF THIS COLLABORATION AGREEMENT

- 1.1** The general objective of this Collaboration Agreement is to strengthen the cooperation between JRC and EFSA in the field of food and feed safety, animal health and welfare, plant health and nutrition. It also aims to contribute more effectively to understanding and undertaking risk assessment on scientific issues in the field of food and feed safety animal health and welfare, plant health and nutrition. It also aims at ensuring the technical quality of scientific outputs delivered in these fields.
- 1.2** This Collaboration Agreement will, in particular, have the following objectives:
- a) To promote mutual interest and co-operation on food and feed safety, animal health and welfare, plant health, nutrition and environmental issues and
 - b) To deepen the understanding of the economic and social background relating to scientific risk assessment.
 - c) To exchange on common activities on issues related to authorisation procedures foreseen in sectoral food and feed legislation (e.g. genetically modified organisms (GMOs), feed additives or pesticides) for which both Parties have defined tasks.
 - d) To promote the use of alternative methods to protect animals used for scientific studies.
 - e) To foster the development of risk assessment for combined exposure of chemicals and chemical mixtures.
 - f) To encourage collaboration in the areas of collection and use of landscape and environmental data to be used for risk assessment and research on biological and chemical hazards.
- 1.3** In order to fully achieve the objectives of this Collaboration Agreement, the Parties will take inter alia the following actions:
- a) Joint identification of food and feed safety issues to be investigated and development of innovative and cost-effective approaches to improve food and feed safety.
 - b) Joint development of innovative methods, techniques and tools for identification of emerging issues in food and feed safety, animal health and welfare, plant health and nutrition.
 - c) Jointly establish training programs in various areas, for example, on specific topics related to scientific risk assessment through but not exclusively the exchange of staff.
 - d) Identification and creation of new environmental data streams to support the assessment of biological threats to public health, animal health and welfare and plant health.

- e) Exchange appropriate scientific and technological information, for example, through conducting occasional seminars and workshops.
 - f) Participate in the execution of on-going programs, projects and related activities of mutual interest to the Parties.
 - g) Carry out research projects directly requested by EFSA, as allowed by JRC competences.
 - h) Identify any other action that they deem appropriate to achieve the objectives of this Collaboration Agreement.
- 1.4** In case of joint projects in accordance with Article 1.3 and without prejudice to obligations deriving from Regulation (EC) No 178/2002 and sectoral legislation, the Parties may, prior to commencing a project and on a case-by-case basis, conclude a specific written agreement (hereinafter referred to as '**the specific agreement**') detailing the specifics of the joint project and which shall in particular cover any necessary technical and legal (including the responsibilities of each Party and intellectual property rights) aspects. The specific agreements shall have the same objectives as detailed in Article 1.2.
- 1.5** The duration of the specific agreements may exceed the duration of this Collaboration Agreement with a maximum of six months provided that the execution of tasks under the specific agreement has started during the duration of the Collaboration Agreement. All provisions of this Collaboration Agreement shall be applicable mutatis mutandis to the specific agreement, unless derogated by specific provisions according to Article 1.6 of this Collaboration Agreement.
- 1.6** If case of conflict between the provisions of the specific agreement and this Collaboration Agreement, the provisions of the Collaboration Agreement will prevail unless the conflicting provision in the specific agreement is introduced by the phrase "*By derogation from the Collaboration agreement ...*" in which case that provision of the specific agreement prevails over the Collaboration Agreement. However, the Parties may not derogate from the following Articles of this Collaboration Agreement: 1.5, 1.6, 2, 3, 6, 9 and 10.

ARTICLE 2 – RESPONSIBILITIES OF THE PARTIES

- 2.1** Each Party will be responsible for its personnel in relation to activities undertaken pursuant to this Collaboration Agreement or the specific agreement. For the purposes of this Collaboration Agreement and the specific agreement, '**personnel**' shall mean all persons associated with one Party, including (i) employees, (ii) guest researchers, (iii) persons under contracts similar to employment contracts and (iv) any other persons whose actions can be reasonably attributed to that Party.
- 2.2** The Parties may exchange personnel if required to pursue activities identified by this Collaboration Agreement under Article 1.3. Such exchange shall be subject the rules and regulations in force at the hosting organisation.

ARTICLE 3 – LIABILITY

- 3.1** Any loss, damage or injury of non-nuclear origin suffered by one Party in connection with the performance of this Collaboration Agreement or the specific agreement shall be borne exclusively by it. If the loss, damage or injury is caused by a person invited by one Party, as described in Article 2.2, the sending Party will be liable for it.
- 3.2** Each Party shall be exclusively liable for any loss, damage or injury of non-nuclear origin caused by its personnel to third parties, arising out of the performance of this Collaboration Agreement or the specific agreements.
- 3.3** 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 personnel in the course of the performance of this Collaboration Agreement or the specific agreement.

ARTICLE 4 – COORDINATION

- 4.1** Each Party shall designate one person to serve as its co-ordinator with responsibility for supervising the implementation of this Agreement. The co-ordinators may nominate other suitable persons to represent them or to attend meetings.
- 4.2** The co-ordinator for the JRC shall be Elke Anklam, Director of JRC-F (elke.anklam@ec.europa.eu).
- The co-ordinator for EFSA shall be Marta Hugas, Chief Scientist of EFSA (marta.hugas@efsa.europa.eu).
- 4.3** All notifications and correspondence under this Collaboration Agreement or the specific agreement shall be sent to the co-ordinators.
- 4.4** Each Party shall notify the other in writing of any changes concerning its designated co-ordinator.
- 4.5** The Parties may establish a Steering Committee to co-ordinate their activities under this Agreement.
- 4.6** If the Parties establish a Steering Committee, the co-ordinators are responsible for organising its meetings.

ARTICLE 5 – REPORTS

The Parties shall consult each other to establish together annual reports detailing the work carried out under this Collaboration Agreement and results obtained.

ARTICLE 6 – FUNDS

- 6.1 All activities conducted pursuant to this Collaboration Agreement or the specific agreement shall be subject to the availability of funds, personnel and other resources as well as to the applicable laws and regulations, policies and programmes of each Party.
- 6.2 Each Party shall bear the cost of any expenditure it incurs relating to the performance of its tasks under this Collaboration Agreement or the specific agreements. There will be no transfer of money between the Parties in connection with this Collaboration Agreement or the specific agreement.
- 6.3 Mission expenses for staff shall be borne by the Party to whom the personnel belongs.

ARTICLE 7 – PROTECTION OF THE RESULTS OF THE COOPERATION

- 7.1. Intellectual Property (IP), and all rights pertaining thereto, created in and for the performance of this 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 this Collaboration Agreement.
- 7.2. Upon termination or expiry of this Collaboration Agreement, Parties shall send each other a declaration including the list of IP which they have created in and for the performance of this Collaboration 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.
- 7.3. 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 this Collaboration Agreement, subject to the maximum achievable extent under the applicable law.
- 7.4. 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.
- 7.5. In case the IP created in and for the performance of this 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.
- 7.6. 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

- 7.7.** In case the collaboration performed under this 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, including external scientific experts, the Parties undertake to respect each other's rights, moral or economic, and to duly acknowledge and reference the authors and contributors.
- 7.8.** 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 this provision shall be considered not only a breach of this Article but also a breach of confidentiality without prejudice to Regulation (EC) No 1049/2001 regarding requests for public access to documents.
- 7.9.** The provisions of this Article shall remain valid and legally enforceable for a period of five years from the date of termination or expiry of this Collaboration Agreement. After the five-year period, the provisions of this Article shall remain valid and legally enforceable for as long as a valid intellectual property right protects the results of the cooperation or if the period has been extended by a separate agreement.

ARTICLE 8 – CONFIDENTIALITY

- 8.1** The Parties undertake to keep confidential any information, documentation, data, reports referred to in Article 5, or any other material communicated to them by the other Party (i) as confidential or (ii) the disclosure of which may clearly be prejudicial to the other Party, until the information legitimately becomes publicly available through other parties or through work or actions lawfully performed outside (not based on activities under this Collaboration Agreement) or has been made available to the receiving Party by another party without any confidentiality restrictions. This confidentiality obligation applies also to information communicated orally when such information shall be kept confidential, for instance in the context of information exchange through seminars and workshops, without prejudice to Articles 38 and 39 of Regulation (EC) No 178/2002.
- 8.2** Confidentiality of information exchanged orally or in writing in connection with this Collaboration Agreement shall be maintained for a period of five years after its expiry or termination. Notwithstanding the foregoing, any Party may indicate when communicating information to the other Party that the confidentiality of such information shall be maintained even after the said five-year period.
- 8.3** A Party that intends to produce any work reproducing or using data exchanged, shall obtain prior permission from the other Party. In case of publications which disclose Member State's specific data, the Parties will request the Member States as well as the owners of this data (if different) for permission and input on such publication. This shall not apply to data legitimately which was made publicly available through third parties or through work or actions lawfully performed outside (not based on activities under this Collaboration

Agreement) or that has been made available to the receiving Party by third parties without any confidentiality restrictions.

ARTICLE 9 – APPLICABLE LAW AND SETTLEMENT OF DISPUTES

- 9.1** This Collaboration Agreement and the Specific Agreement shall be governed by the law of the European Union complemented, where necessary, by the substantive law of Italy.
- 9.2** Parties shall seek to settle any dispute, controversy or claim arising out of or in connection with this Collaboration Agreement through amicable negotiations. Such effort shall be deemed to have failed when one of the Parties so notifies the other in writing.
- 9.3** If the Parties fail to settle their differences through amicable negotiations, each Party may initiate proceedings before the Court of Justice of the European Union in Luxembourg which shall have the sole jurisdiction to decide on any dispute.

ARTICLE 10 – ENTRY INTO FORCE AND DURATION

- 10.1** This Collaboration Agreement shall enter into force on the date of its signature by the last Party and is concluded for a period of 5 years and shall automatically renew at the end of the initial term for successive one-year periods unless terminated in accordance with the following paragraphs. This Collaboration Agreement may be amended only by written agreement signed by the duly authorised representatives of both Parties.
- 10.2** Either Party may terminate this Collaboration Agreement at any time after three months of written notice to the other Party. This shall inter alia be the case where research programmes and budget allocations are no longer compatible with the continuation of the working relationship, procedure or work programme.

ARTICLE 11 – MISCELLANEOUS AND ANNEXES

- 11.1** All provisions of this Collaboration Agreement apply without prejudice to the applicable law, including without limitation Regulation (EC) No 1049/2001 governing the right of public access to documents and the General Food Law. Neither Party can claim any damages or breach of this Collaboration Agreement in cases where the other Party acts according to its obligations resulting from the Union law.
- 11.2** Any personal data included in or relating to this Collaboration Agreement or the specific agreement, including its execution shall be processed by both Parties pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data or any future legislation that will replace it. It shall be processed solely for the purposes of the

performance, management and monitoring of this Collaboration Agreement or the specific agreement by the Director of JRC Directorate F for the JRC and the Executive Director for EFSA, without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in conformity with Union law. The data subject shall have the right of access to her/his personal data and the right to rectify any such data. Should the data subject have any queries concerning the processing of her/his personal data, the data subject shall address them to the Director of JRC Directorate F for the JRC and to the EFSA's Executive Director for EFSA or the Data Protection Officer of each Party. The data subject shall have right of appeal at any time to the European Data Protection Supervisor.

Signed in Brussels on 26 June in two originals in the English language.

For the **European Food Safety Authority**

For the **Joint Research Centre of the
European Commission**

Signature: _____

Bernhard Url, Executive Director
European Food Safety Authority

Signature: _____

Vladimír Šucha, Director General
Joint Research Centre