MEMORANDUM OF UNDERSTANDING BETWEEN THE EUROPEAN CHEMICALS AGENCY AND THE EUROPEAN FOOD SAFETY AUTHORITY

COVER NOTE

Summary:

In view of the intensifying cooperation on issues of common interest, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) are updating their Memorandum of Understanding which was initially agreed in 2009.

ECHA and EFSA cooperate and coordinate their work in accordance with their respective mandates under their founding Regulations and other relevant legal acts. Specific Rules of Procedure between the Agencies were established in 2013 in order to prevent potential conflicts of scientific opinions in the food safety context. The benefits of this cooperation are in the areas of risk and hazard assessment of chemical substances, including application and further development of the methodologies applied, scientific advice, risk communication, data and IT governance, and capacity building.





Memorandum of Understanding between the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA)

The European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), each hereinafter referred to as an "Agency" or jointly as the "Agencies",

Having regard to their respective mandates as set out in their respective founding Regulations (Regulation 1907/2006 for ECHA, Regulation 178/2002 for EFSA),

Having regard to the Common Guidelines on practical arrangements for the sharing of scientific data between the Scientific Committees and Panels of the European Agencies and the Scientific Committees of the Commission of 10 November 2008 ("Common Guidelines on practical arrangements for the sharing of scientific data"),¹

Having regard to the ECHA's Management Board Decision establishing Rules of Procedure for cooperation of the European Chemicals Agency with the European Food Safety Authority ("RoP"),²

Having regard to the joint need, and the related opportunities, to further develop information exchange, scientific-technical cooperation and better mutual understanding between the Agencies,

Having regard to the Common Approach on decentralised agencies³ and various initiatives under the framework of the EU Agencies Network with a view to create efficiencies and synergies between the Agencies,

Whereas:

1. It is within the Agencies' common interest as well as the public's interest to enhance their cooperation in contributing to protect

-

¹ Available at:

https://www.efsa.europa.eu/sites/default/files/assets/ecsharingdataguidelines.pdf

Rules of Procedure for cooperation of the European Chemicals Agency with the European Food Safety Authority, ECHA Management Board <u>Decision 18/2013</u>.
 <u>Joint Statement and Common Approach</u> (Parliament, Council & Commission), 2012.

public health and the environment as well as to the effective functioning of the internal market.

- 2. The Agencies take note with satisfaction of the ongoing cooperation and progress achieved so far under the 2009 Memorandum of Understanding ("MoU")⁴.
- 3. It is important in the common interest of the Agencies to intensify cooperation between them, relating to different topics including the hazard and risk assessment of chemical substances, ensuring the coherence of opinions prepared by their scientific committees and panels, exchange of practices in the area of IT and data governance and analysis and the provision of scientific advice to the Member States and the European Union Institutions as well as facilitating risk communication.
- 4. The cooperation between the Agencies should also facilitate giving clear and concise messages about chemicals and food safety, and thereby increase the confidence of EU citizens in the functioning of the EU legislation for the benefit of human health.
- 5. Established professional linkages between the Agencies should be strengthened, including the possibility for temporary exchange of staff.
- 6. Access to information and data should be made easier to ensure consistency of opinions between the Agencies and facilitate their safety evaluations.

Have reached the following understanding:

I. Purpose of the Memorandum of Understanding

The purpose of this MoU is to enhance the cooperation between the Agencies in order to ensure coherence in scientific methods and opinions and to develop synergies and share knowledge on matters of mutual interest through increased cooperation and, in particular, through active information exchange.

II. Areas to which the MoU applies

In accordance with their respective mandates, co-operation between the two Agencies will relate to the following areas:

- Scientific collaboration and information exchange
- Hazard and risk assessment of chemical substances
- Hazard and risk assessment methodologies for food/ feed and chemical safety
- Development of science-based opinions and advice by the Agencies' scientific committees and panels
- Communication issues related to the areas identified above

⁴ https://www.efsa.europa.eu/sites/default/files/assets/mouecha.pdf

- Exchange of scientific data and experience in developing scientific IT and support tools
- Opportunities for coordinated procurement, joint procurement and shared services
- Opportunities for collaboration on staff recruitment, joint competence development, temporary exchange of staff
- Opportunities for collaboration and synergies in data governance, data analytics, ICT development and ICT systems.

This MoU may be implemented through specific projects jointly agreed by the relevant units of the Agencies. With the consent of both Agencies, cooperation can be extended to any other matter falling within their mutual interest.

III. Mutual consultation

The Agencies undertake to, where possible and appropriate:

- (a) consult each other regularly and endeavour to keep each other informed on strategic matters of common interest for the purpose of achieving their respective objectives, and to ensure coordination in regard to matters falling within the mutual interest of the Agencies
- (b) consult each other in the event of an emerging risk from chemical substances that may affect or concern human health, environment or food or feed safety
- (c) consult each other when delivering scientific advice and risk assessments that concern food/feed safety and the safety of chemicals, biocides and pesticides
- (d) share in advance their draft annual work and grants & procurements plans for the year ahead, with the view to identify synergies between activities leading to cooperation

In particular, EFSA might need to make use of ECHA's substance data (and possibly vice versa) and expertise when preparing its opinions, in accordance with the respective applicable legal requirements. Two examples of areas where this might apply are i) (biocide) substances used in food contact materials and food additives and ii) substances used in plant protection products.

IV. Common approach on conflict of opinions

Without prejudice to the provisions on conflicting opinions set out in the Agencies Founding Regulations⁵, reference is made to the RoP establishing more detailed mechanisms for prevention of potential divergences of opinions. In particular, the Agencies will coordinate the submission of pesticide dossiers for approval and classification purposes in order to avoid overlap and contradiction without prejudice to the respective applicable legislation.

V. Capacity building, synergies, and stakeholder engagement

The Agencies undertake to, where possible and appropriate:

⁵ In particular, Article 30 of Regulation (EC) 178/2002 and Article 95 of Regulation (EC) 1907/2006.

- (a) consider opportunities for joint communication activities on issues of common interest and stakeholder outreach (e.g. joint press releases, briefings, publications, online communications)
- (b) facilitate a pilot programme for temporary staff exchange or a joint trainee programme
- (c) cooperate on public procurement or recruitment exercises, in particular under the framework of the EU Agencies Network.

VI. Information exchange and data governance

Both Agencies acknowledge that they are data-driven organisations handling highly complementary sets of data and facing common challenges. Therefore, the Agencies intend to cooperate on:

- (a) Exchanging/accessing data needed for their regulatory purposes without prejudice to the respective applicable Union legislation;
- (b) Strengthening data and IT governance practices;
- (c) Increasing efforts to harmonise data formats;
- (d) Exchanging knowledge on IT development;
- (e) Exploring the application of modern technologies (e.g. artificial intelligence, machine learning and data mining).

Exchange of information between the Agencies may take place for the purpose of and in accordance with the provisions of this MoU, the RoP and the applicable Union legislation. Each Agency shall designate one staff member as its coordinator for the maintenance of close, direct and continuing contacts, in line with the RoP and with a view to ensuring the application of the provisions of the present MoU.

VII. Confidentiality of information

Each Agency will ensure that information received on the basis of this MoU will be treated in accordance with applicable laws and regulations governing the processing and release of information, including the RoP. Sharing of information shall safeguard the legitimate rights of third parties, including their intellectual property rights. When exchange of data that is not publicly available takes place, confidentiality requirements shall apply as provided in the Agencies' founding Regulations, the RoP, or other relevant legislation. The Agencies will respect each other's confidentiality policy. Unauthorised use and processing of data provided by a third party for the benefit of another party shall not be allowed.

VIII. Divergences of interpretation or implementation

The Agencies undertake to make the best efforts with a view to resolving any divergence that may arise in the implementation of this MoU.

IX. Amendments

This MoU may be amended by the mutual written consent of the Agencies at any time.

X. Termination of the MoU

This MoU may be terminated by either Agency giving at least three months' written notice, or by mutual written agreement.

XI. Entry into force

This MoU enters into force upon signature by both Agencies and repeals the previous MoU signed on 20 May 2009.

Signed at Berlin in duplicate on 29 November 2017,

For the European Chemicals Agency	For the European Food Safety Authority
[signed]	[signed]
Geert Dancet Executive Director	Bernhard Url Executive Director