Disclaimer: This document does not present future project calls as part of the EFSA work programme, or any future position of EFSA. It aims to support the development of a roadmap for action and its content can be subject to change.

ANNEX 3

Theme (concept) paper – Building a European Partnership for next generation, systems-based Environmental Risk Assessment

Revised theme paper in light of the comments received from the European Commission (DG SANTE), ENVI Agencies, EU Member States and EFSA's Scientific Committee members in the phases 1 & 2 of EFSA's consultation process

Vision:

By 2022, the European Partnership for Environmental Risk Assessment (PERA) has:

- Brought together partners of relevant sectors across regulatory silos and improved the **cooperation** on regulatory environmental risk assessment (ERA) between these partners.

By 2030, PERA has:

- Facilitated the transition to next generation, systems-based ERA through the co-development of new and complementary **tools** and **methods**, and the sharing of **data** (including their findability, accessibility, interoperability, and reuse) and **expertise**.

Background:

In line with sectoral legal requirements, the ERA of regulated products (such as biocides, chemicals, pesticides, pharmaceuticals, feed additives and genetically modified organisms) is typically performed on a single substance/compound or product basis, for a specific type of use, in the European Union (EU). While the EU has made substantial progress on achieving environmental protection with the exiting ERA paradigm, frameworks for the ERA of single substances/compounds or products are increasingly challenged by the scientific community and society. Such frameworks are claimed to have fallen out of step with **scientific knowledge** and **progress**[1]. Moreover, they are not always in line with new policy targets[2] and society needs[3] that demand for **more sustainable solutions** to protect the environment.

In addition, environmental policies in different sectors have developed independently and at different times, and are implemented by different institutions, leading to inconsistencies between different regulatory frameworks and potential policy gaps. For regulatory ERAs this fragmentation can lead

[1] E.g. https://science.sciencemag.org/content/367/6476/360

[2] E.g. EU Green Deal covering the farm to fork strategy for sustainable food, the chemical strategy for sustainability, the biodiversity strategy, the zero pollution action plan, the circular economy action plan, and the soil thematic strategy

[3] E.g. children striking over climate change, people of Europe demanding for more sustainable food systems

to **inconsistencies** in assessments and decisions across regulated substances/compounds or products.

Today's regulatory ERAs call for a **systems-based approach** that formulate ERA issues/problems and associated protection goals holistically; address the cumulative effects of multiple regulated substances/compounds or products and stressors; analyse upstream and downstream life-cycle implications; evaluate a range of alternative solutions; involve a broad range of stakeholders; and use interdisciplinary scientific approaches. This approach would improve the scientific basis for regulatory ERA and decision-making, create opportunities for new partnerships and enhance cooperation across regulatory silos[4].

Considering the broad array of regulatory ERAs performed under different sectoral regulatory frameworks, there are many commonalities (e.g. hazard assessment, common parameters) for which a more coherent and harmonised approach would be beneficial when characterising environmental risks. Also, next generation ERAs should be designed in a manner that facilitate their integration in EU environmental impact and sustainability assessments, and policy assessments performed by relevant partners in the context of other regulatory frameworks/policies.

Scope and objectives:

The purpose of **PERA** is to provide an overarching platform that:

- Facilitates the transition to next generation, systems-based ERA that addresses new policy targets and society needs;
- Connects relevant partners (e.g. national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society) from various sectors, across regulatory silos, and improves cooperation between these partners;
- Accelerates the development of new/complementary tools and methods, and the uptake of innovative tools and methods for regulatory ERA;
- Promotes and facilitates the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise, and the establishment of a EU-wide cross-disciplinary network of risk assessors and risk managers (e.g. community of practice);
- Improves efficiency and transparency.
- Overcomes the challenges of a fragmented regulatory/policy landscape.

With the instigation of PERA, the "virtual centre of excellence" and platform for the ERA of regulated substances/compounds or products, as suggested by the Scientific Advice Mechanism (SAM) of the Group of Chief Scientific Advisors in 2018 for pesticides[5], will be implemented.

Working areas:

The adoption of a **systems-based approach** for next generation ERA will require the implementation of a portfolio of activities clustered in working areas. Each of these working areas

[4] https://ehp.niehs.nih.gov/doi/10.1289/EHP1465
[5] https://op.europa.eu/en/publication-detail/-/publication/5306df12-79b9-11e8-ac6a-01aa75ed71a1/language-en/format-PDF/source-94583924

will cover a set of activities with operational SMART objectives that must be defined by PERA partners.

The following non-exhaustive list of potentially interrelated **working areas** is proposed for PERA:

- Formulating ERA issues/problems and (specific) protection goals holistically to address overall system impacts[6];
- Assessing environmental risks resulting from exposure to regulated substances/compounds or products at relevant levels of biological organisation (individual, population, community, ecosystem) and spatio-temporal scales[7];
- Assessing cumulative environmental effects resulting from exposure to multiple regulated substances/compounds or products, and stressors[8];
- Developing and designing tools and methods (including post-market environmental monitoring) for evaluating the efficiency of risk mitigation measures;
- Monitoring regulated substances/compounds, or products in different environmental compartments and matrices, and along the food/feed chain[9];
- Integrating of pre- and post-registration data of regulated substances/compounds or products, and other environmental monitoring, surveillance and pesticide/pharmacovigilance data[10];
- Comparing environmental risks of regulated substances/compounds or products with a range of alternative solutions;
- Developing more coherent, harmonised and interoperable regulatory ERA approaches;
- Developing a common currency for the assessment of environmental impacts;
- Integrating regulatory ERAs in EU environmental impact and sustainability assessments, or policy assessments performed by relevant partners in the context of other regulatory frameworks/policies;
- Developing and implementing the safe and sustainable by design concepts for regulatory ERA[11];
- Identifying areas where revised or new guidelines are needed for the ERA of future/new candidate (innovative, greener) regulated substances/compounds or products;
- Assessing groups/classes of chemical products for authorisation renewal based on the type of active substance, mode of action, and/or use;
- Implementing the FAIR (findability, accessibility, interoperability, and reuse) principles for digital ERA data;

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6 https://ehp.niehs.nih.gov/doi/10.1289/EHP1465; https://www.sciencedirect.com/science/article/abs/pii/S0273230017301952

7 https://projects.au.dk/almass/; https://link.springer.com/article/10.1007/s10646-018-1962-0; https://www.sciencedirect.com/science/article/pii/S0048969715304939; https://www.sciencedirect.com/science/article/pii/S0048969715308597; https://www.sciencedirect.com/science/article/abs/pii/S0273230017301952

8 Human health effects will be addressed in the SPIDO theme paper on multiple chemicals risk assessment

9 https://science.sciencemag.org/content/367/6476/388

10 https://science.sciencemag.org/content/357/6357/1232

11 https://science.sciencemag.org/content/367/6476/397

- Building on relevant projects;
- Building linkages with relevant/complementary partnerships (e.g. One Health platform[12], EU bee partnership[13], EU Partnership for the Assessment of Risk from Chemicals [PARC][14], EU Partnership for Biodiversity[15]);
- Drawing on experience from related fields, including in non-EU jurisdictions.

Not all working areas and regulated substances/compounds or products proposed in the scope of PERA may be equally relevant for all PERA partners. Moreover, not all PERA partners may be directly involved in regulatory ERAs; instead, they may perform/contribute to environmental impact and sustainability assessments, and policy assessments. Therefore, PERA partners will need to prioritise working areas and type of regulated substances/compounds or products based on their remit. Thus, working areas and specific types of regulated substances/compounds or products may be addressed at different timeframes by different PERA partners.

In this respect, EFSA may focus its initial work on **pesticides**. This will allow EFSA to use this group of substances to pilot and assess the establishment of PERA and evaluate the suitability of the proposed methodology, as well as cooperation with its partners. The work on pesticides will also support the European Commission (EC) in its ambition to reinforce/strengthen the ERA of pesticides, as outlined in the EU farm to fork strategy[16], EU biodiversity strategy[17] and EC report on the evaluation of Regulation (EC) No 1107/2009[18], and of biocides, as outlined in the EU chemical strategy for sustainability. Thereafter, EFSA may consider other relevant regulated substances/compounds or products, including chemical substances/compounds or products regulated by other frameworks in the EU.

Opportunities:

Systems-based approaches are not new and have gained broad interest in the international scientific community. However, a systems-based ERA for regulated substances/compounds or products has not yet been developed and thus integrated in regulatory assessments. In recent years, the EU has made substantial efforts towards the development of a holistic and integrated risk assessment approach of multiple stressors in bees (MUST-B)[19,20] that could serve as a model case study for the further advancement of regulatory ERA.

The European Green Deal announced the development of a chemical strategy for sustainability in 2020, which will require the EU Agencies and scientific bodies to move towards a process of "one substance – one assessment". This will overcome some of the challenges of a fragmented regulatory/policy landscape.

PERA will provide an overarching platform that can:

12 https://onehealthplatform.com/home
13 https://www.efsa.europa.eu/en/supporting/pub/en-1423
14 https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf
15 https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/european_partnership_for_rescuing_biodiversity_to_safeguard_life_on_earth.pdf
16 https://ec.europa.eu/info/sites/info/files/communication-annex-farm-fork-green-deal_en.pdf
17 https://ec.europa.eu/info/sites/info/files/communication-annex-eu-biodiversity-strategy-2030_en.pdf
18 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_report_2020_en.pdf
19 https://www.efsa.europa.eu/en/topics/topic/bee-health
20 https://b-good-project.eu/about; https://www.poshbee.eu/

- Improve interagency cooperation on regulatory ERA and other types of assessment, and cooperation between risk assessors and managers, and other relevant partners at European, national and regional level;
- Advance and harmonise regulatory ERAs, across regulatory silos;
- Address new policy targets, the "one substance – one assessment" concept, and society needs;
- Co-develop new/complementary tools and methods, and implement innovative tools and methods for regulatory ERA;
- Improve the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise;
- Identify current and emerging ERA needs, and bridge ERA gaps;
- Identify, prioritise and promote research and innovation needs for regulatory ERA, and align research and innovation in ERA with EU/national Research & Innovation investments to improve coherence and reduce overlap between national and EU funding in ERA research;
- Build linkages with relevant/complementary partnerships and projects.

Cooperation:

PERA will facilitate the advancement of regulatory ERA by promoting cooperation with relevant partners (such as national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society).

PERA will also build linkages with relevant/complementary partnerships and projects, such as the new European Partnership for the Assessment of Risks from Chemicals (PARC)[21] to be launched under Horizon Europe in 2022. The innovative research projects to be supported by this partnership will focus on human health aspects, but are expected to include environmental aspects that are relevant for regulated ERA, in particular in the areas of environmental media monitoring and sources of human exposure to chemicals.

The European Commission launched in mid-September a €1 billion call for research and innovation projects that respond to the climate crisis and help protect Europe's unique ecosystems and biodiversity. The Horizon 2020-funded European Green Deal Call, has 8 thematic areas including area 6: Farm to fork, area 7: Biodiversity and ecosystems and area 8: Zero-pollution, toxic-free environments that aim to launch large consortia to work on these issues.

***Impact for EFSA and other PERA partners**:*

- Strengthen interagency cooperation on ERA for regulated substances/compounds or products and other types of assessment, and cooperation with national competent authorities/agencies, EU Member States, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society;
- Harmonise regulatory ERAs, across regulatory silos;

[21] https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf

- Facilitate the development of new/complementary tools and methods, and uptake of innovative tools and methods for the further advancement of ERA within the context of regulatory science;
- Improve the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise;
- Deliver rapid methodological improvements, foster data sharing and make better use of available expertise for the ERA of specific groups of regulated substances/compounds, or products to demonstrate the value of PERA;
- Pave the way for the transition to next generation, system-based ERA that addresses new policy targets, including the "one substance – one assessment" concept, and society needs, that aim to better protect the environment and halt biodiversity loss (including farmland biodiversity);
- Position EFSA and other PERA partners as important partners for the implementation of next generation ERA in regulatory science at EU level, and internationally;
- Increase researchers' interest in regulatory ERA and science.