



75th Advisory Forum meeting
Virtual meeting, 1-2 April 2020

EFSA activities on environmental risk assessment (ERA)

↳ **Thematic discussion: Changing
context for ERA**

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Trusted science for safe food

Today's goals

- EFSA's ERA portfolio (snapshot)



- Changing context for ERA



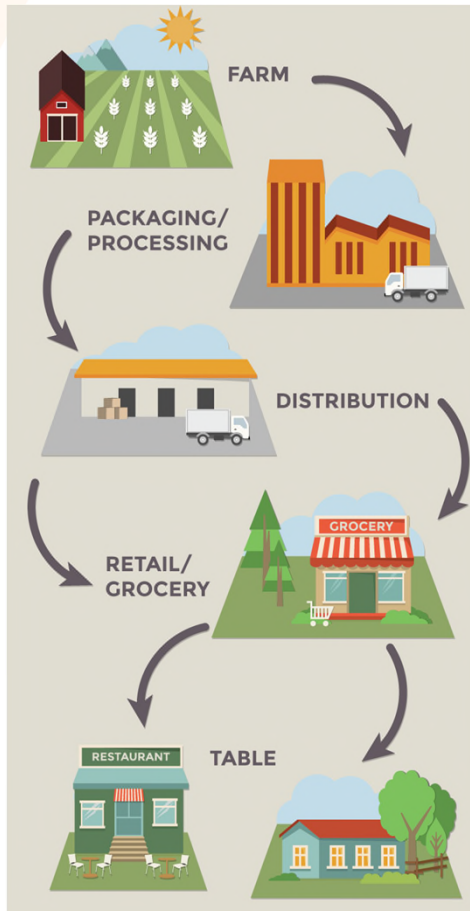
- Collaborative initiatives





EFSA's ERA portfolio (snapshot)

EFSA's remit Simplified



Stressors (agricultural food/feed production)

Animal diseases (zoonotic/non-zoonotic)
 Biological hazards
 Botanicals
 Chemical mixtures
 Contact materials
 Contaminants
 Diet (food/feed)
 Emerging risks
 Endocrine active substances
 Enzymes
 Flavourings
 Feed additives (**FA**)
 Genetically modified organisms (**GMO**)
 Nanomaterials
 Novel foods/feeds
 Plant protection products (**PPP**)
 (active substances)
 Processing aids
 Quarantine plant pests (**QPP**)
 ...

Protection goals

Human health
 Animal health
 Animal welfare
 Plant health

Environment

(biodiversity, ecosystems, ecosystem services, ...)

...

ERA activities

Snapshot



→ PPP

→ GMO

→ FA

ERA activities Snapshot

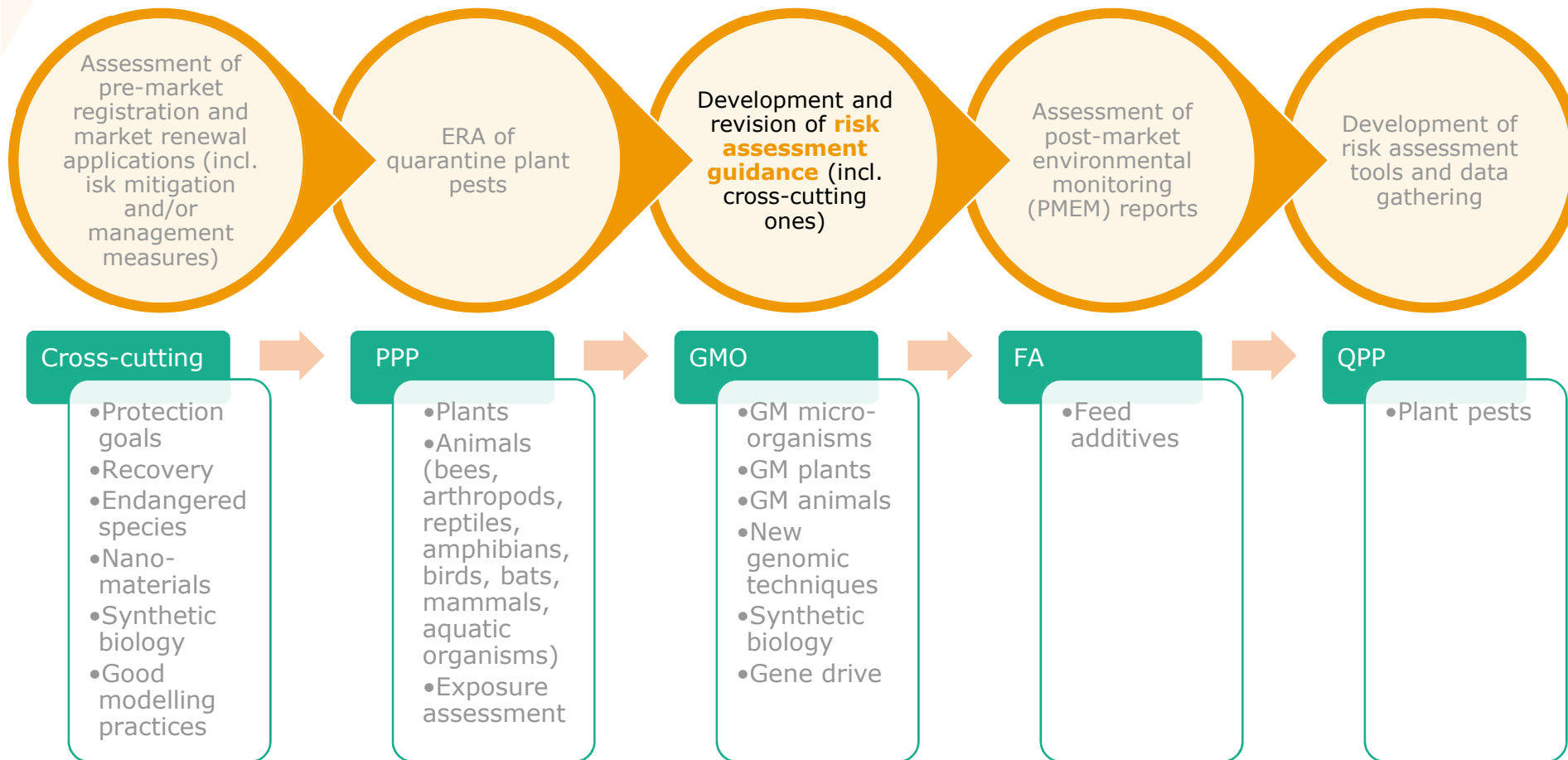


→ QPP: Apple snail



→ QPP: Citrus long-horn beetle

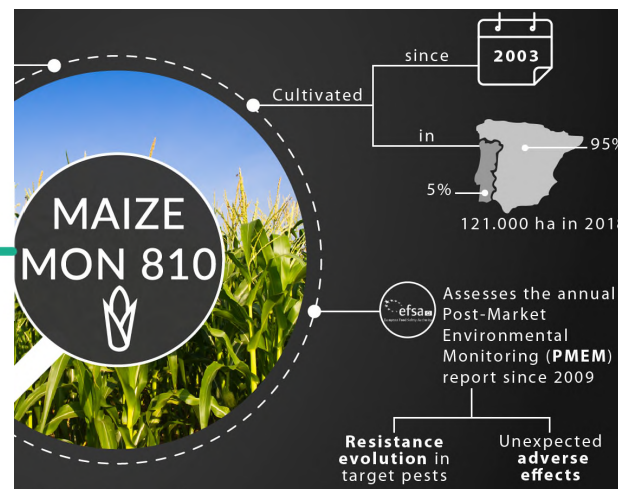
ERA activities Snapshot



ERA activities Snapshot



GMO: GM plants for cultivation



ERA activities Snapshot

Assessment of pre-market registration and market renewal applications (incl. risk mitigation and/or management measures)

ERA of quarantine plant pests

Development and revision of risk assessment guidance (incl. cross-cutting ones)

Assessment of post-market environmental monitoring (PME) reports

Development of **risk assessment tools and data gathering**

Biological RA

Preparedness to risks of **new plant pests**
Integrated **spatial analysis** for biological risk assessment
Wildlife surveillance
Building capacity for **microbiome** assessments

Chemical RA

Risk assessment of combined exposure to multiple chemicals; **cumulative** risk assessment
Introducing new approach methodologies (**NAM**) for hazard assessment and risk characterisation

Environmental RA

MUST-B: Holistic approach for the risk assessment of Multiple STressors in Bees
Landscape-based ERA
Non-target Lepidoptera **model**
TK/TD models in aquatic environment
Data collection for **endocrine disruption** assessment for non-target organisms
Critical appraisal forms for ecotoxicological studies



Changing context for ERA

Drivers of change

Examples



- **Science**
 - **Scientific advances (incl. innovation)**
 - Deliver new tools, methods and data relevant for regulatory science
 - **Scientific analyses**
 - Scientific Advice Mechanism [SAM] (2018)
 - EU authorisation processes of PPP – From a scientific point of view
 - European Environment Agency [EEA] (2019)
 - The European environment – State and outlook (2020)
 - “... alarming rate of biodiversity loss, increasing impacts of climate change and the overconsumption of natural resources”
 - Harvey et al. (2020) Nature Ecology & Evolution
 - Roadmap for insect conservation and recovery
 - Science (2020)
 - A cleaner, greener future for chemicals

Drivers of change

Examples



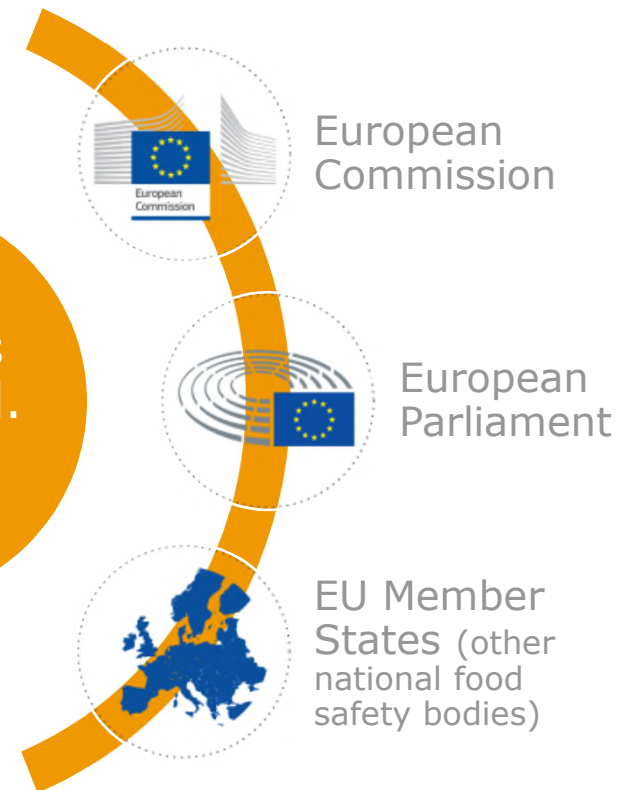
- **Wicked environmental problems**
 - Environmental issues become increasingly complex
- **Societal demands**
 - Citizens of Europe demand more sustainable food systems
 - Children strike over climate change
- **EU policy context**
 - Council conclusions “Towards a Sustainable Chemicals Policy Strategy”
 - Common Agricultural Policy for 2021-2027
 - Biodiversity Strategy for 2030
 - **New Green Deal**
 - Promote sustainable food through the new “Farm to Fork” strategy; Protect biodiversity; Strive to zero pollution; Act on climate change; Move to a circular economy

Risk assessment science in regulatory context

- Regulatory frame



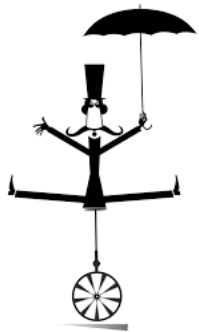
Who mandates EFSA (excl. self-tasking)?



Possible strategic goals for ERA

Ongoing activity/work in progress

- **EFSA 2027 Strategy development**
 - Preliminary considerations on “Future of ERA”
 - To be framed by new **Green Deal goals** and “**Farm to Fork**” strategy



Under current sector-specific regulations

Consolidate & innovate

- By revising current methods
- By integrating new relevant tools, methods, data and expertise
- By sharing data
- By collaborating between relevant actors and key stakeholders

Across all relevant regulations

Foster systems-based approaches & their interoperability

- By integrating
 - Sector-specific ERAs across multiple stressors, across spatial and temporal scales, across policies and regulatory frames, and across regional, national and EU agencies
- Pre- and post-registration data (incl. environmental monitoring and surveillance data)



Possible avenues to advance ERA

Short, medium and long term perspective

Ensure **robust** and **up to date** ERA methodologies

Integrate new tools, methods, data and expertise for **landscape-scale population-level** ERA

Develop and implement methodologies for **cumulative and mixture** risk assessments

Optimise the use of **environmental monitoring and surveillance data**

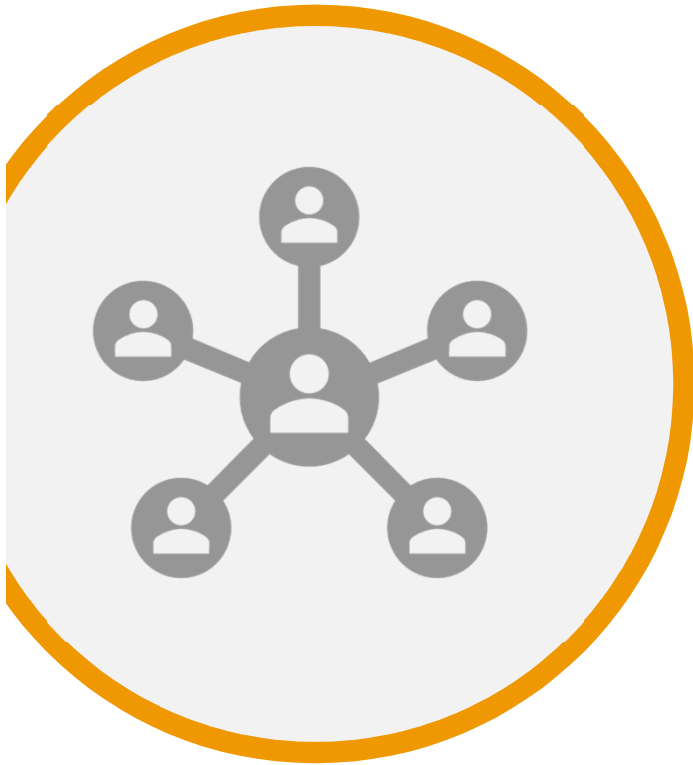
Make **ERAs interoperable** for all regulated stressors and with EU environmental impact and sustainability assessments

Ensure **preparedness** for the next generation of regulated stressors and application technologies

Consider impacts of **(non-regulated) environmental drivers** when framing ERA as part of the problem formulation process

Monitor **new scientific tools, methods and data**, and assess their relevance for ERA, and promote their implementation and integration

Create an **EU collaborative platform** for ERA (virtual centre of excellence)



Collaborative initiatives

Collaborative initiatives

Examples



- **DG SANTE initiative on setting specific protection goals**
 - **ERA of PPP**
 - Series of workshops
 - June 2019
 - **National authorities**
 - September 2019
 - **Stakeholders** (farmer associations, applicants, academia, industry, retailers and non-governmental organisations)
 - February 2020
 - **National authorities and stakeholders**
- **Between EU Member States**
 - **Tasking Grant Framework**
 - e.g. for PPP: EFSA-ANSES, EFSA-BfR and EFSA-BPI

Collaborative initiatives

Examples



- **Between EU Agencies**

- **ECHA-EFSA**

- Hazard identification of **endocrine disruptors** (PPP and biocides) [with technical support from JRC]
 - ERA for **bees** (PPP and biocides)
 - Impact of water treatments on residues of substances in water used as **drinking water**

- **EEA-EFSA**

- Identification of relevant **climate change** scenarios for CLEFSA project (climate change as driver of emerging risks for food/feed safety, plant and animal health, and nutritional quality)

- **EMA-EFSA**

- ERA of feed additives (i.e. **coccidiostats**)

Collaborative initiatives

Examples



- **EU bee partnership discussion group**
 - **Trigger**
 - MEP request to ensure sustainable pollination and beekeeping in EU (at 2017 bee week event on data collection & sharing)
 - **Scope**
 - Bee health assessment (honeybees first and then other bees)
 - **Goals**
 - Improve data collection, management and sharing (harmonisation/standardisation)
 - Develop tools for the assessment of bee health (holistic manner)
 - Engage with stakeholders
 - **Partners**
 - Beekeeper associations, conservation organisations, farmer associations, plant protection and veterinary medicine industry, risk assessors, scientists and veterinarians

Collaborative initiatives

Examples



- Proposal for an EU collaborative platform on ERA
 - Main goals
 - While building on existing regulatory frames and involving risk managers
 - Facilitate **cooperation** on current and future ERA challenges/needs
 - **Bring** all relevant actors and key stakeholders **together**
 - Promote **exchange** of relevant ERA and monitoring data, knowledge and expertise
 - **Validate** new tools and methods and **promote** their **uptake** in regulatory science;
 - Bridge gaps in **regulatory science**
- ↳ Create a virtual centre of excellence for regulatory science
- ↳ Advance ERA and ensure preparedness

Collaborative initiatives

Examples



- Proposal for an EU collaborative platform on ERA
 - Scope
 - Relevant **actors** (including risk managers) and key **stakeholders**
 - Commission services
 - EU agencies
 - EU Member States (national authorities)
 - Policy makers
 - Scientists
 - Non-governmental organisations
 - Applicants
 - Civil society
 - **Regulated stressors** associated with agricultural food/feed production

Collaborative initiatives

Examples



- Proposal for an EU collaborative platform on ERA
 - Plan
 - 2020
 - Outsource roadmap development
 - Incl. feasibility assessment
 - 2021 and beyond
 - Actions driven by roadmap outcomes



Take home messages

Take home messages



- **ERA is in EFSA's remit**
 - Regulated products associated with agricultural food/feed production (i.e. PPP, GMO, FA)
 - QPP
- **Changing context for ERA**
 - New Green Deal and "Farm to Fork" strategy
 - Possible avenues to advance ERA
- **Proposal for an EU collaboration platform on ERA**
 - Outsource roadmap development

Thank YOU

- **EFSA colleagues**

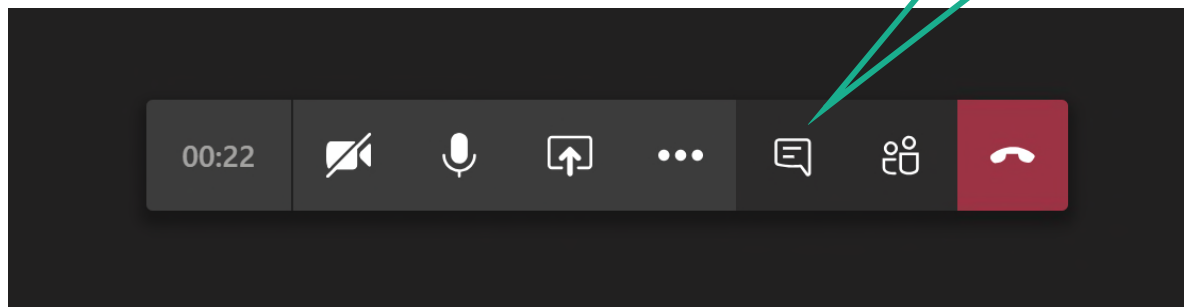
- EGSMOSE Mark
- IPPOLITO Alessio
- MAGGIORE Angelo
- NOUGADERE Alexandre
- PADOVANI Laura
- RIOLO Francesca
- RORTAIS Agnès
- SCHOONJANS Reinhilde
- SHARP Rachel
- STANCANELLI Giuseppe
- STREISSL Franz
- TARRES-CALL Jordi
- VETTORI Maria Vittori
- VOS Sybren



Questions



If you wish to take **the floor to speak**, please indicate this in the **meeting chat** by simply using the wave emoji





Points for thematic discussion

Discussion points



1. Do you see added value in the establishment of an EU collaborative platform for ERA?
2. Do you see cooperation opportunities and challenges?
3. Are you aware of relevant existing collaborative partnerships and those that are under development?
4. Do you have suggestions for developing the roadmap for the creation of an EU collaborative platform on ERA?