EFSA activities on environmental risk assessment (ERA)

Thematic discussion: Changing context for ERA

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Today’s goals

- EFSA’s ERA portfolio (snapshot)
- Changing context for ERA
- Collaborative initiatives
EFSA’s ERA portfolio (snapshot)
Protection goals

- Human health
- Animal health
- Animal welfare
- Plant health
- Environment (biodiversity, ecosystems, ecosystem services, ...)

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)
Development of risk assessment tools and data gathering

Assessment of post-market environmental monitoring (PMEM) reports

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

ERA of quarantine plant pests

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

ERA activities Snapshot

PPP

GMO

FA

European Food Safety Authority
Development of risk assessment tools and data gathering

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

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ERA of quarantine plant pests

ERA activities

Snapshot

QPP: Citrus long-horn beetle

QPP: Apple snail
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ERA of quarantine plant pests

ERA activities Snapshot

Cross-cutting
- Protection goals
- Recovery
- Endangered species
- Nano-materials
- Synthetic biology
- Good modelling practices

PPP
- Plants
- Animals (bees, arthropods, reptiles, amphibians, birds, bats, mammals, aquatic organisms)
- Exposure assessment

GMO
- GM micro-organisms
- GM plants
- GM animals
- New genomic techniques
- Synthetic biology
- Gene drive

FA
- Feed additives

QPP
- Plant pests
ERA activities

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

Development of risk assessment tools and data gathering

Assessment of post-market environmental monitoring (PMEM) reports

Development of risk assessment tools and data gathering

GMO: GM plants for cultivation
Development of risk assessment tools and data gathering

Assessment of post-market environmental monitoring (PMEM) reports

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

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

ERA of quarantine plant pests

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

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)?

European Commission

European Parliament

EU Member States (other national food safety bodies)
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

**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

**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
• 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)
**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
• 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
• 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
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  • SHARP Rachel
  • STANCANELLI Giuseppe
  • STREISSL Franz
  • TARRES-CALL Jordi
  • VETTORI Maria Vittori
  • VOS Sybren
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?