European Union Policy / Regulatory Framework

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GMO Food & Feed

General aspects

- Prior authorisation scheme: only EU authorised products on EU market
- Strict separation between risk assessment and risk management
  - Risk assessment → European Food Safety Authority (EFSA)
    - GMO applications → EFSA GMO Panel
  - Risk management → European Commission & Member States
    - Authorisation: European Commission
    - Enforcement: Member States
- No animal applications received so far
- NGT (GnEd) animals = GM (GE) animals (CJEU 2018)

Legal framework

Major building blocks:

- Deliberate release Directive 2001/18/EC
- GM Food & Feed Regulation (EC) No 1829/2003
  - GM Food & Feed Implementing Regulation (EU) No 503/2013 (plants only)
- GM traceability & labelling Regulation (EC) No 1830/2003
- GMM Contained Use Directive 2009/41/EC

Supplemented by implementing rules, recommendations and guidelines

GM animals used in contained facilities / laboratories

- MS competence
- Contained Use Directive 2009/41/EC applies to GM microorganisms
  - including animal cells in culture
- MS flexibility to lay down national legislation for GM animals used in research
  - National reports: gene drive mosquito research

Release of living GM animals

- Other than food / feed use:
  - GM insects for control of vector borne disease, nature conservation / restauration, de-extinction, GloFish®
  - ➔ Deliberate Release Directive 2001/18/EC
- Food / feed use:
  - GM animal husbandry in EU holdings, GM fish in EU aquaculture
  - ➔ GM Food & Feed Regulation (EC) No 1829/2003

Import of food/feed derived from GM animals

- Possible examples: non-EU origin GM salmon, NGT (GnEd) tilapia

➔ GM Food & Feed Regulation (EC) No 1829/2003

- Specific traceability and labelling conditions apply (R 1830/2003)
  - Traceability from first stage of placing on the market through all subsequent stages
  - Written information: ‘contains or consists of GMO(s) (+ unique identifier(s))’
- Labelling
  - ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’

Import of non-edible products from GM animals

- Leather from GM cattle, “spider silk” for GM silkworms
- Do not fulfil the definition of ‘GMO’ → not in scope of GMO legislation

➔ Other legislation (standard animal health requirements) may apply

Procedural aspects – application

- Submission through e-Submission Food Chain (ESFC) platform to a national authority within whose territory the release is to take place
  - Purpose and scope, all relevant data, studies and analysis of the results
  - Monitoring plan, detection method, labelling proposal
  - Indication of confidential information
  - Reference material & detection method
- Transfer to EFSA for
  - Completeness check of dossier
  - Publication non-confidential dossier
  - Risk assessment

Procedural aspects – risk assessment

- Risks to environment, human health and animal safety
- Minimal aspects to be covered (Deliberate Release Directive):
  - Molecular characterisation
  - Persistence / invasiveness – selective advantage / disadvantage
  - Potential gene transfer
  - Environmental impact (incl. specific techniques used for management of the GMO)
  - Effects on human & animal health and biogeochemical processes

Procedural aspects – EFSA risk assessment guidance documents

- Specific guidelines applicable to animals:
  - Guidance on the environmental risk assessment of genetically modified animals
  - Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects
  - Guidance on Risk Assessment for Animal Welfare
- Generic guidance documents available at:
  - https://www.efsa.europa.eu/en/methodology/guidance

Procedural aspects – EFSA risk assessment

- Current GM food/feed assessment (based on plant risk assessment)
  - Literature review
  - Molecular characterisation
  - Comparative analysis
  - Food/feed safety assessment (if applicable)
  - Environmental risk assessment
  - Monitoring plan
- Additional aspects for GM animals:
  - Animal welfare

Procedural aspects – risk management

- European Union Reference Laboratory for GM Food & Feed
  - Certified reference material and validation detection method
- Authorisation decision
  - Based on EFSA Scientific Opinion (30d public comment period)
  - Vote in Standing Committee → adoption by College of Commissioners → publication
  - Ten-year validity → renewal
- Enforcement
  - Member States competent authorities
  - Zero-tolerance for GMO not authorised in the EU
  - Traceability and labelling (labelling threshold for processed products)

Ongoing work

- EFSA mandate on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques) M-2018-0205
  - Knowledge gathering: external scientific report "New Genomic Techniques (NGT) in animals and their agri/food/feed products"
  - Opinion on potential novel hazard & risks from new developments in biotechnology applied to current and near market animals and the adequacy of the current EFSA risk assessment guidance, covering all aspects of molecular characterisation, food & feed safety, welfare, and environmental impact: final output expected by 30 June 2025
- Mandate to EURL GMFF on detection of GM / NGT animals

Thank you

European Commission