EC mandate on new developments in biotechnology applied to animals

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efsa
EUROPEAN FOOD SAFETY AUTHORITY

EC mandate M-2018-0205

"*Mandate*" for an EFSA opinion on new developments in biotechnology applied to animals, including synthetic biology and new genomic techniques

- … *not* a new mandate
- … *but* the continuation of the mandate M-2018-0205
- … *with* adjusted Terms of Reference

EC mandate M-2018-0205 - Background

June 2018

EC mandate (M-2018-0205): Request for an **EFSA opinion on GMOs (microorganisms, plants and animals) developed through Synthetic Biology and their implications for risk assessment methodologies**, covering aspects related to food & feed and environment

October 2018

Step 1: agreement to complete **two opinions** on the evaluation of existing guidelines for their adequacy for the:

- **microbial characterisation** and ERA of **microorganisms** obtained through SynBio (**EFSA SC 2020**)
- **molecular characterisation** and ERA of **GM plants** obtained through SynBio (**EFSA GMO Panel 2021**)

October 2020

Step 2: agreement to complete **two opinions** on the evaluation of existing guidelines for their adequacy for the:

- **food and feed risk assessment** of **GM microorganisms** obtained through SynBio (**EFSA SC 2022**)
- **food and feed risk assessment** of **GM plants** obtained through SynBio (**EFSA GMO Panel 2022**)

December 2022

Step 3: agreement to complete an opinion focusing on new developments in biotechnology applied to **animals**

EC mandate M-2018-0205

EFSA GMO Panel is asked to provide:

I. Knowledge gathering on known cases of animals (and their food and feed products) obtained by new developments in biotechnology

II. An opinion on potential novel hazards/risks from new developments in biotechnology applied to current and near market animals and adequacy of the current EFSA risk assessment guidance, covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact

EC mandate (M-2018-0205) terms of reference

I) Knowledge gathering on known cases of animals (and their food and feed products) obtained by new developments in biotechnology

1. Identify animals and their products obtained by new development in biotechnology described since 2001 including their traits and uses
2. List the techniques and modifications used, including explanation of relevant terminology
3. Identify animals and their products developed since 2001 that are subject to authorisation procedures by international authorities, and the corresponding available risk assessments (e.g. opinions, guidances, authorizations) that exist
4. Collect per case the data and information relevant for risk assessment, and structure it according to the EFSA guidances

EC mandate (M-2018-0205) terms of reference

II) Opinion on potential novel hazards/risks from new developments in biotechnology applied to current and near market animals and adequacy of the current EFSA risk assessment guidance, covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact.

The expected outcome of this activity will be an opinion which:

a) identifies, where possible, novel potential hazards and risks which new developments in biotechnology applied to current or near market animals could pose for humans, animals and the environment compared to conventional breeding or established techniques of genetic modification.

b) determines whether the existing guidelines for risk assessment of genetically modified animals are applicable, fully or partially, adequate and sufficient to risk assess new developments in biotechnology applied to animals.

c) in case existing guidelines for risk assessment are considered not applicable, partially applicable, not adequate or not sufficient, identifies on which specific areas and aspects existing guidelines should be updated, adapted or complemented.

Scope of the mandate

- Focused on new developments in biotechnology, including synthetic biology and **new genomic techniques applied to animals** and their implications for **risk assessment methodologies**.

- Limited to **agri-food-feed products falling within the remit of EFSA**

Agri products: potential GM animals that are farmed but not for food/feed uses, e.g:

- fur animal farms (mink) **???**
- silk farming / sericulture (silkworms) **???**
- insect frass **???**

Food/feed products: potential GM animals that are farmed for food/feed uses, e.g.:

- mammals
- birds
- fish
- insects **???**

Mapping of expertise needed for the WG

Comparative analysis

- ❑ Criteria for the selection of the comparator(s)
- ❑ Comparative analysis of pheno-compo characteristics (e.g. health, physiological and welfare parameters

Molecular characterisation

- ❑ Established and new genomic techniques: general principle & applied to breeding of animals
- ❑ Mutational breeding of animals
- ❑ Off-target mutations
- ❑ Offspring and stability of traits, outcrossing (null-segregants)

GM Food & Feed safety

- ❑ Toxicology
- ❑ Allergenicity
- ❑ Human and animal nutrition

Environmental risk assessment

- ❑ ERA general principles & applied to GM animals
- ❑ Gene transfer in connection to housing/contained use or free ranging (HGT and VGT, linked to persistence and invasiveness)
- ❑ Impact on the receiving environment of mammals, birds, fish (insects?) (effects on TOs and NTOs)
- ❑ Pathogens, infections and diseases

Animal welfare

- ❑ Health & welfare of mammals, birds, fish (insects?)

Overarching areas

- ❑ Classical breeding of mammals, birds, fish (insects?)
- ❑ Animal trials for comparative analysis - experimental design and statistical analysis
- ❑ Offspring and stability of traits, outcrossing (null-segregants)

1. Current knowledge on NGTs animals

NGTs applied to animals are mainly used for:

Food purposes: farmed animals
- ❑ cattle (hornless cattle; heat-resistant cattle)
- ❑ pigs (porcine reproductive and respiratory syndrome-resistant pigs)
- ❑ fish (yield-enhanced/fast-growing tilapia)
- ❑ birds (gene-edited hens to end cull of male chicks)

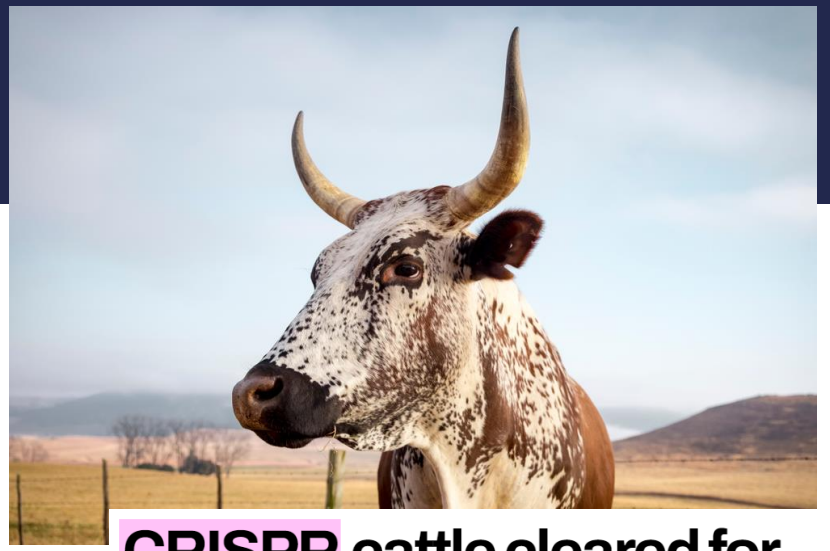
Environmental control: NGT-based gene drive applications
- ❑ insects, especially mosquitos and some invasive species

Research on human diseases e.g.:
- ❑ mice: disease models for a gene therapy (cancer and genetic diseases)
- ❑ pigs: donor of organs to be transplanted into human patients (no transplant rejection)
- ❑ rats and monkeys still at the early R&D (model human diseases)

Potential case studies

Gene-edited cattle produce no horns

New technique could eliminate the need for painful dehorning

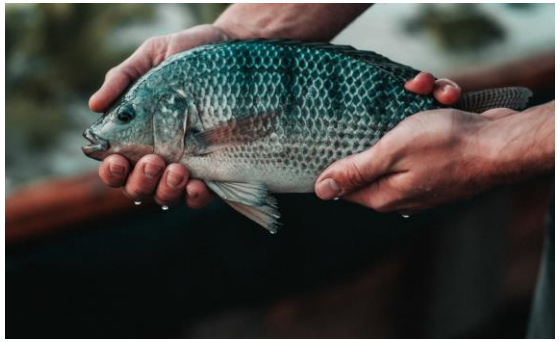


CRISPR cattle cleared for the first time by FDA

The animals carry a gene that helps them beat the heat.

AquaBounty gets Argentina go-ahead for edited tilapia

Transgenic salmon producer AquaBounty and its majority owner, Intrexon, today announced that their jointly developed gene-edited line of tilapia, FLT 01, has been exempted from GM regulation in Argentina.



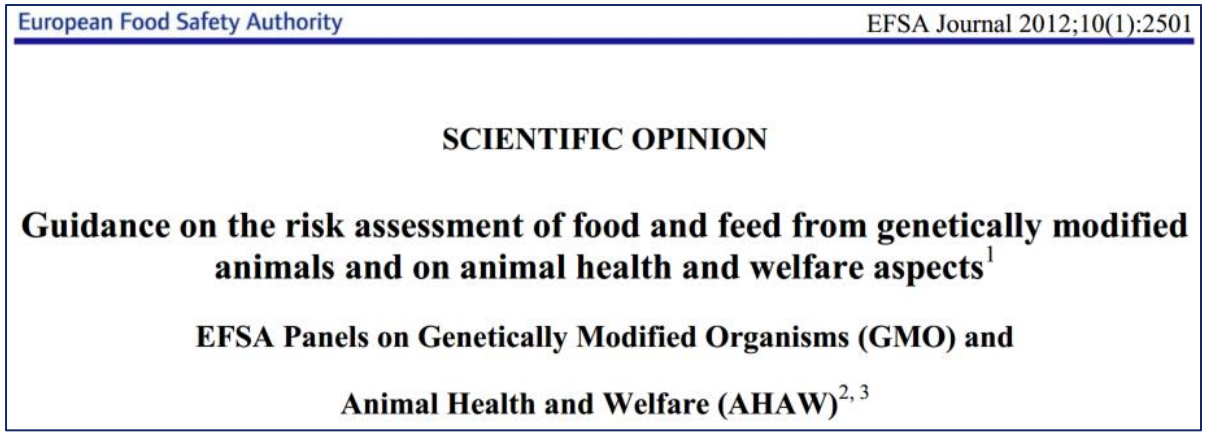
Agreement targets disease-resistant gene-edited pigs

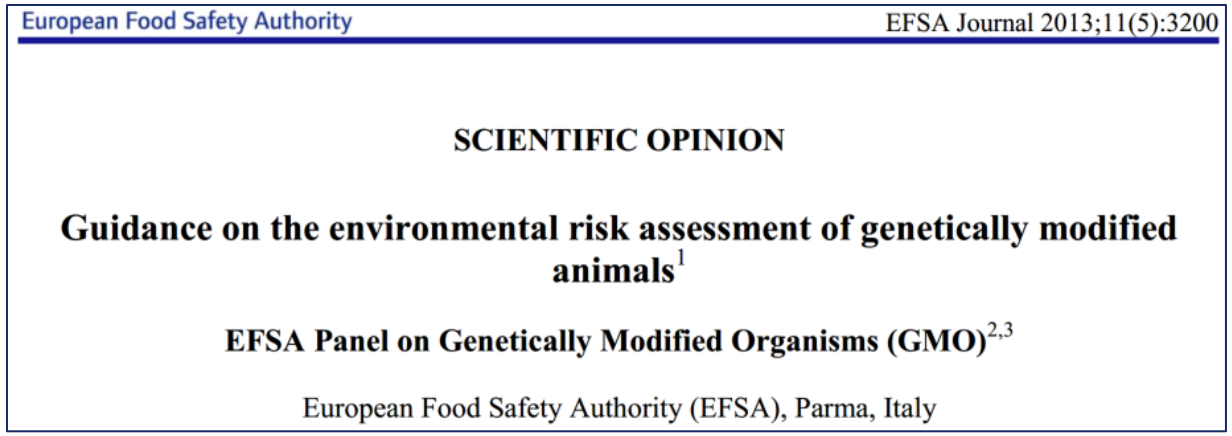
Researchers and commercial partners to continue collaboration on developing pigs resistant to Porcine Reproductive and Respiratory Syndrome.

Photocredits: Shutterstock

2. Aim of the Scientific opinion

- 1. to identify potential novel hazards/risks from new developments in biotechnology applied to current and near market animals
- 2. to assess the adequacy of the current EFSA risk assessment guidance covering all aspects of molecular characterisation, food feed safety & welfare and environmental impact





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