# Risk analysis and the cooperation between risk assessors and risk managers

## The Role of the European Commission & Comitology

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**Animal nutrition and veterinary medicines**

**Regulation (EC) No 178/2002 of the European Parliament and the Council**

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

(General Food Law Regulation)

# *What is feed?*

*Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals*

*Feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feedingstuffs.'*

# *An integrated approach to food safety ("from the farm to the fork")*

*"This Regulation shall apply to all stages of production, processing and distribution of food and feed" (Article 1(3))*

*Including feed and feed production*

# *A system based on risk analysis*

*"(…) food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure." (Article 6(1))*

*Risk analysis is:*

*Risk assessment: "Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner" (Article 6(2))*
*+*
*Risk management: "Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority (…), other factors legitimate to the matter under consideration and the precautionary principle where (…) relevant" (Article 6(3))*
*+*
*Risk communication: interactive exchange of information among all stakeholders*

## *Risk assessment*

*Target species*

*Consumer*

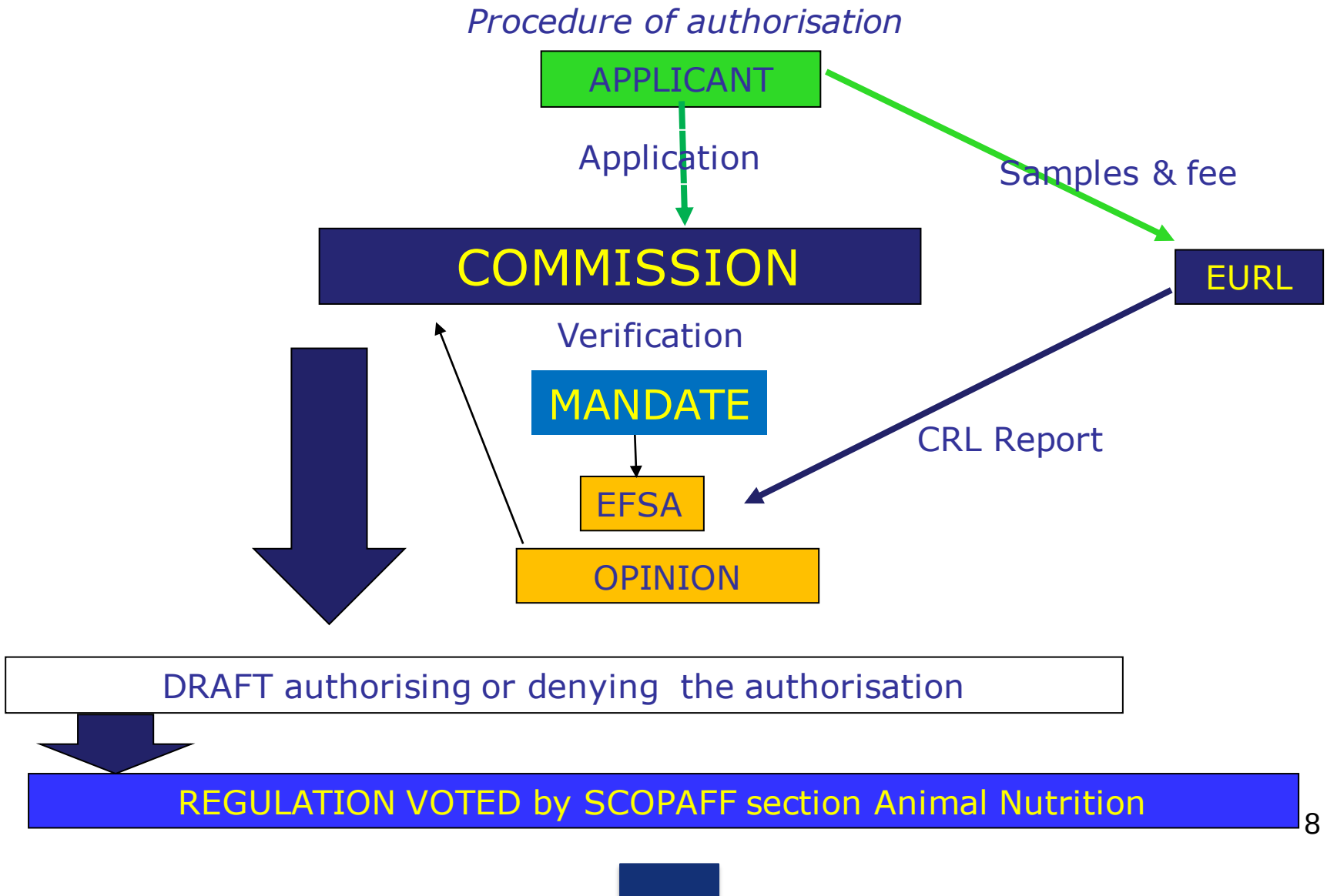
*User*

*Environment*

## *The European Food Safety Authority (EFSA) (Articles 22-49)*

- *Provides scientific advice and scientific and technical support for the EU legislation and policies in all fields which have a direct or indirect impact on food and feed safety*
- *Provides independent information on all matters within these fields*
- *Communicates on risks*

*Independent from the risk manager*


Procedure of authorisation
APPLICANT
Application
Samples & fee
COMMISSION
EURL
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MANDATE
CRL Report
EFSA
OPINION
DRAFT authorising or denying the authorisation
REGULATION VOTED by SCOPAFF section Animal Nutrition

# Post EFSA opinion: Comitology

***Standing Committee on Plants, Animals, Food and Feedsection Animal Nutrition***

> ***Article 9*** *Within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft Regulation to grant authorisation or to deny authorisation.*

***For particular cases this period can be extended***

# Post EFSA opinion: Comitology

(17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. Therefore, the authorisation of an additive should be granted by the Commission.

REGULATION 1831/2003

# Post EFSA opinion: Comitology

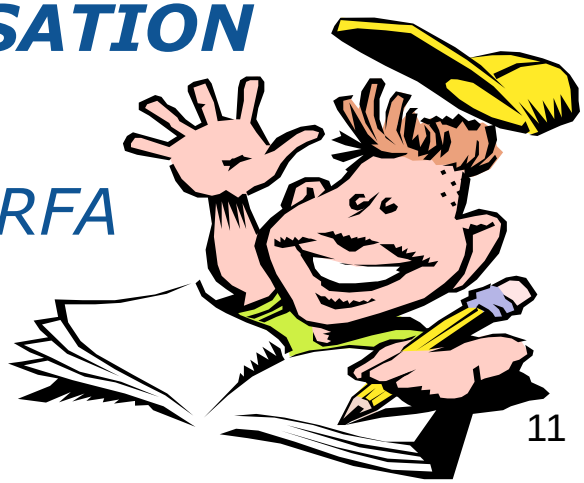
***EFSA opinions***

*Favorable opinion ⟶ discussion/s and proposal of draft Regulation at SCOPAFF for vote*

***REGULATION OF AUTHORISATION***

*PUBLICATION on OJ*

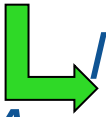
*REGISTRATION on EURFA*



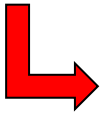
# Post EFSA opinion: Comitology

*Inconclusive/negative opinion ⟶ discussion/s at SCOPAFF and in case, request for new data to applicant, with the possibility to withdraw the application.*

*New data sent to Commission (copy to EFSA). A new mandate to EFSA. (Regulation 178/2002)*



*New EFSA opinion: positive discussion/s on Annex at SCoFCAH* ***REGULATION***



*New EFSA opinion: negative discussion/s at SCoFCAH* ***REGULATION of denial***

# Post EFSA opinion: Comitology

***The Standing Committee on Plants, Animals, Food and Feed***

- *Composed of representatives of the 27 EU Member States (EFTA (NOR, ISL), Switzerland)*
- *Adoption of Implementing Regulation proposed by the European Commission and voted (Qualified Majority/Unanimity)*
- *Oversight by European Parliament and (Council of Ministers) Lisbona Treaty*

# EU feed legislation

*Regulation 178/2002 (General Food Law)*
*Feed materials (Regulation 767/2009)*
*Feed additives (Regulation 1831/2003)*
*Feed Hygiene (Regulation 183/2005)*
*Medicated Feed (Directive 90/176) (Regulation (EU) 2018/……..)*
*Official controls (Regulation 882/2004) (Regulation (EU) 2017/625)*
*Undesirable substances (Directive 2002/32)*
*GM food and feed (1829/2003) and traceability of GMOs (1830/2003)*
*Animal By-products (1069/2009)*
*Catalogue of feed material (Regulation 68/2013)*
*Status of certain products (Regulation 892/2010)*
*Guidelines for the distiction between feed material, feed additives, biocide products and veterinary medicinal products (Recommandation 2011/25)*
*….*


# *Thank you*