European Food Safety Authority

# Session 47

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European Food Safety Authority

# Assessment of feed additives that improve the diet utilisation in the European Union

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## Part I

Authorisation of feed additives in the European Union

## Part II

Assessment of feed additives that belong to the functional group ‘Digestibility Enhancers’

## Miscellanea

# Feed additives in the EU

**In order to be placed on the EU market, feed additives need to undergo an authorisation procedure as established in the Regulation (EC) No 1831/2003**

# Feed additives in the EU

**Feed Additives:** Substances, micro-organisms or preparations, other than feed material and premixtures intentionally added to feed or water in order to:

- ✓ Favourably affect the characteristics of feed, animal products and the colour of ornamental fish and birds
- ✓ Satisfy the nutritional needs of animals
- ✓ Favourably affect the environmental consequences of animal production
- ✓ Favourably affect animal production, performance or welfare
- ✓ Have a coccidiostat or histomonostatic effect

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## Feed additives categories

- ✓ Technological preservatives, antioxidants, emulsifiers, stabilisers, thickeners, silage…
- ✓ Sensory colourants, flavouring compounds.
- ✓ Nutritional vitamins, trace elements, amino acids, urea
- ✓ Zootechnical additives digestibility enhancers, gut flora stabilisers, substances which favourably affect the environment, other zootechnical additives
- ✓ Coccidiostats and histomonostats

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**In order to obtain the authorisation an additive has to be basically**

Safe and efficacious

# Feed additives in the EU

## Conditions for the authorisation (1/2)

### Safety

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## Conditions for the authorisation (2/2)

**Efficacy** The claim(s) made by the applicant should be demonstrated

- ✓ Technological preservatives, antioxidants, emulsifiers, stabilisers, thickeners, silage…
- ✓ Sensory colourants, flavouring compounds
- ✓ Nutritional vitamins, trace elements, amino acids, urea
- ✓ Zootechnical additives digestibility enhancers, gut flora stabilisers, substances which favourably affect the environment, other zootechnical additives
- ✓ Coccidiostats and histomonostats

# Who is Who

Applicant

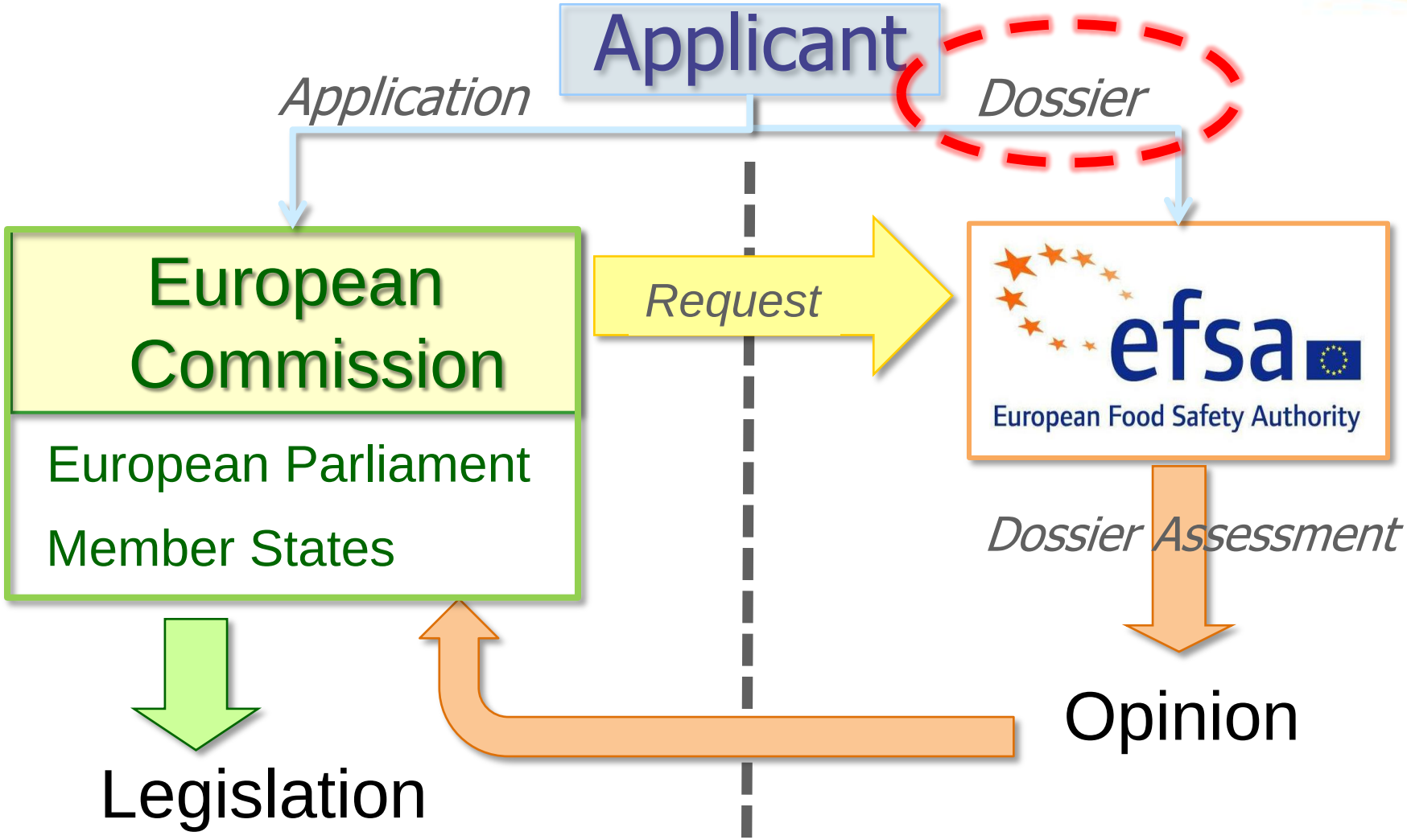
**The requestor**

European Commission

**Risk Manager**

**Risk Assessor**

# Feed additives in the EU



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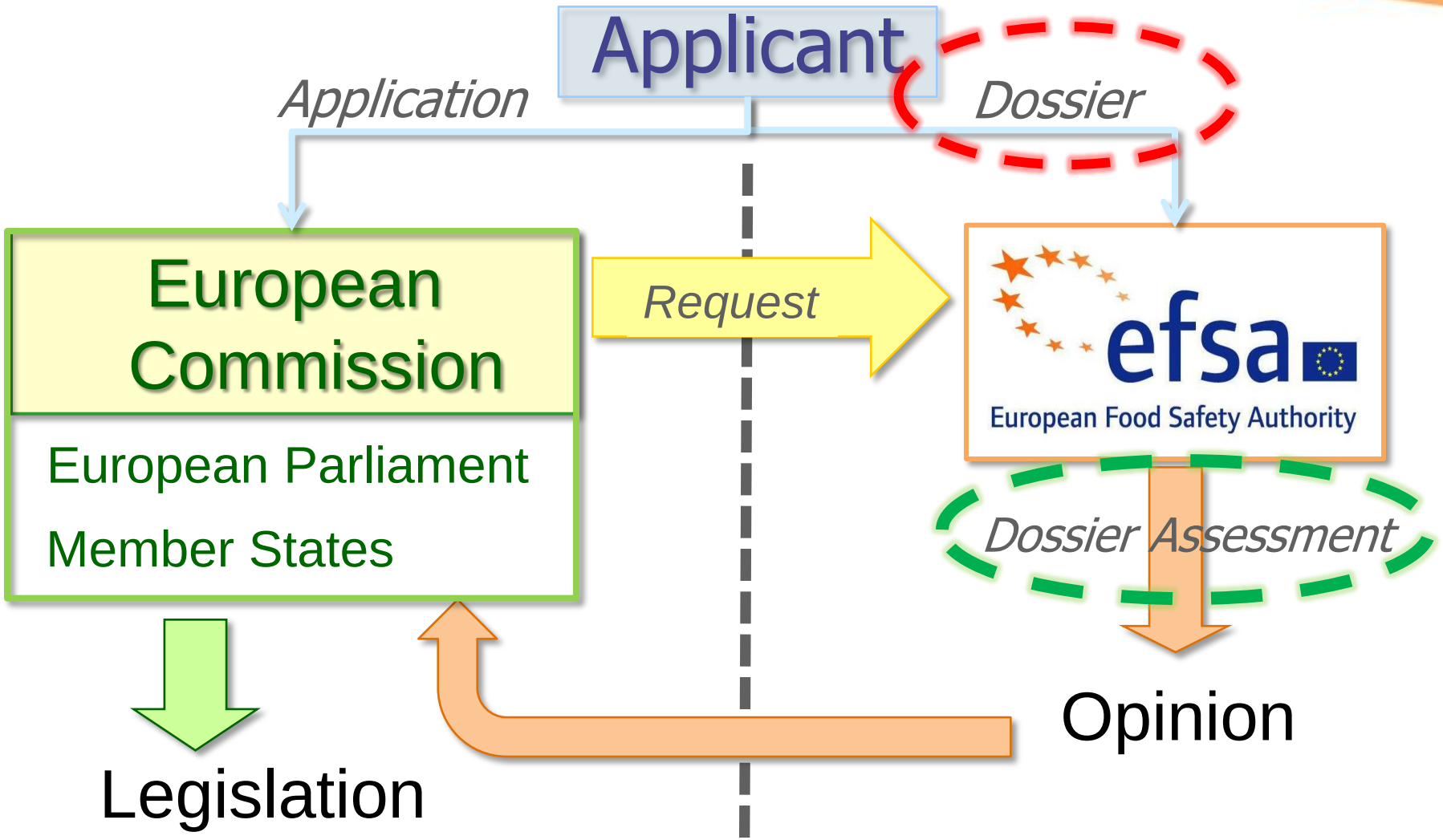
# The Dossier

- **Section I:** Summary of the dossier
- **Section II:** Identity, characterisation and conditions of use; Methods of analysis
- **Section III:** Studies concerning the safety of the additive
- **Section IV:** Studies concerning the efficacy of the additive
- **Section V:** Post-market monitoring plan

# Feed additives in the EU



# Feed additives in the EU

## Scientific Assessment of the information

Chair of the FEEDAP Panel
**Andrew Chesson**

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Paul Brantom
Francesca Caloni
Pier Sandro Cocconcelli
Joop de Knecht
Noël Dierick
Mikolai Antoni Gralak
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Sven Lindgren
Anne K. Lundebye Haldorsen
Alberto Mantovani
Miklós Mézes
Derek Renshaw
Maria Saarela

## Part I

Authorisation of feed additives in the European Union

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# Digestibility enhancers

**Zootechnical additives:**

Any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment

- ✓ Digestibility enhancers,
- ✓ Gut-flora stabilisers,
- ✓ Substances which favourably affect the environment,
- ✓ Other zootechnical additives

# Zootechnical additives

## Digestibility enhancers

"Substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials"

Enzymes

Other types of additives with different mode of action

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# Digestibility enhancers - Enzymes

- **Section II - Identity**

**Description of the additive in terms of**

# Digestibility enhancers - Enzymes

## ✓ Section II - Identity

### Description of the additive in terms of

**Composition**
*Enzyme activity*
*Carriers*
*Batch to batch variation*

**Purity**
*µ contamination*
*Mycotoxins*
*Heavy metals and AS*
*Production strain*
*Spent medium*

**Production strain**
*Id. and deposition number*
*Genetic modification*
*Toxins*
*Antibiotic production*

**Physico-chemical properties**
*Shelf-life*
*Stability in premixtures and feed*
*Homogeneity*

**Conditions of use**

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# Digestibility enhancers - Enzymes

## ✓ Section III – Safety (1/4)

## Safety for the target species

### Tolerance studies

To provide a limited evaluation of the short-term toxicity of the additive for the **target animals**

- Multi-fold overdose of the product
- Monitoring of the health status, performance, gross pathology and blood haematology and chemistry

# Digestibility enhancers - Enzymes

## ✓ Section III – Safety (2/4)

## Safety for the consumer

### Toxicological tests

To evaluate the safety for the consumer of food products derived from animals fed the additive and containing residues of the additive or its metabolites

- Set of Genotoxicity-mutagenicity studies
- Sub-chronic oral toxicity study

Test substance: fermentation product

# Digestibility enhancers - Enzymes

## ✓ Section III – Safety (3/4)

## Safety for the user/worker

The additive has to be safe for those people handling the additive or feed containing the additive

- Irritant capacity skin and if negative on the eye
- Skin sensitisation
- Enzymes are considered respiratory sensitisers

Test substance: the additive

# Digestibility enhancers - Enzymes

## ✓ Section III – Safety (4/4)

## Safety for the environment

The additive must be safe for the environment

- Normally, no risks for the environment are expected from the use of enzymes
- Products produced by a GMO, special attention should be paid to the presence of recombinant DNA in the final product

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# Digestibility enhancers - Enzymes

## ✓ Section IV – Efficacy (1/2)

Efficacy shall be demonstrated in 3 studies showing positive effects on relevant parameters

How it should be demonstrated:

- three *in vivo* long term studies
- two different locations (1 in th
- target categories/species
- performance paramet (zootechnical)
- minimum recomm d dose

However…

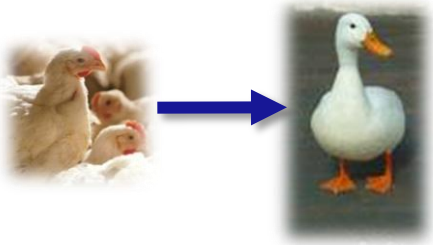
# Digestibility enhancers - Enzymes

## ✓ Section IV – Efficacy (2/2)

a) Phytases: Efficacy can be demonstrated in short-term studies

b) Extrapolation: Efficacy can be extrapolated directly from major to minor species physiologically related (tolerance)

Mode of action



Dose

# Digestibility enhancers - Enzymes

**OPINION**

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## Miscellanea

# Community register of feed additives

http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

# FEEDAP Guidance

**Guidance documents provide detailed guidance to the applicants in the preparation and presentation of feed additives dossiers**

# Miscellanea

Technological

Sensory

Nutritional

Zootechnical

Coccidiostat

Tolerance/efficacy

Consumer/User

Environment

Minor species

Microbial studies

Food additives

Re-evaluation

# Miscellanea


## Experts

http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/efsa_locale-1178620753812_1178712806106.htm

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# Thanks for your attention

Questions?