

FEED REGULATION IN THE EUROPEAN UNION

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Safe feed

Nutritional quality (nutrient content and nutritive value);

Technical quality (physical parameters such as viscosity, density, particle size /distribution, pellet stability, colour etc.);

Safety quality (amount of undesirable substances in the feed);

Ethical quality (presence or animal origin protein sources, GMO plant materials, colorants).

Undesirable substances in feeds

Chemicals: residues of pesticides, herbicides, antibiotics
mycotoxins
environmental contaminants
(metals, PCBs, dioxins, disinfectants etc.)

Biologicals: pathogenic micro-organisms
(*Salmonella*, *E. coli*, *Campylobacter* etc.)
animal origin proteins
moulds

Physicals: glass, plastic, metal and stone particles

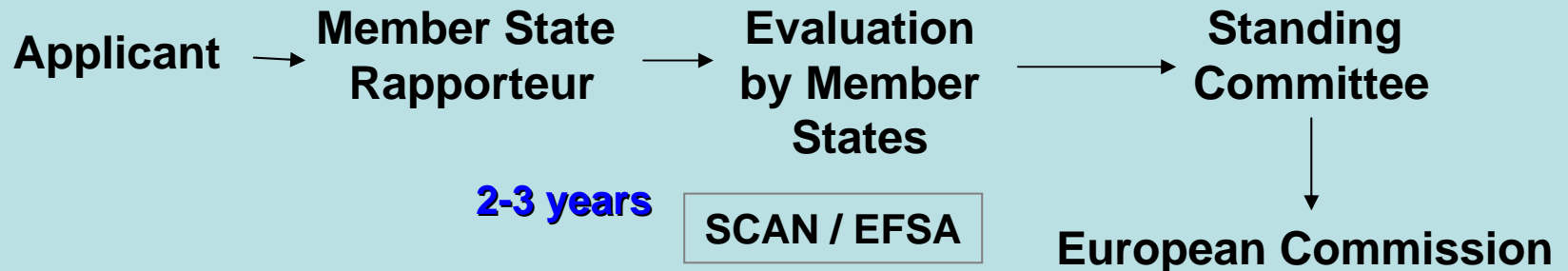
The authorisation of Feed Additives in Europe

Regulation 1831/2003 EC of the European Parliament and of the Council

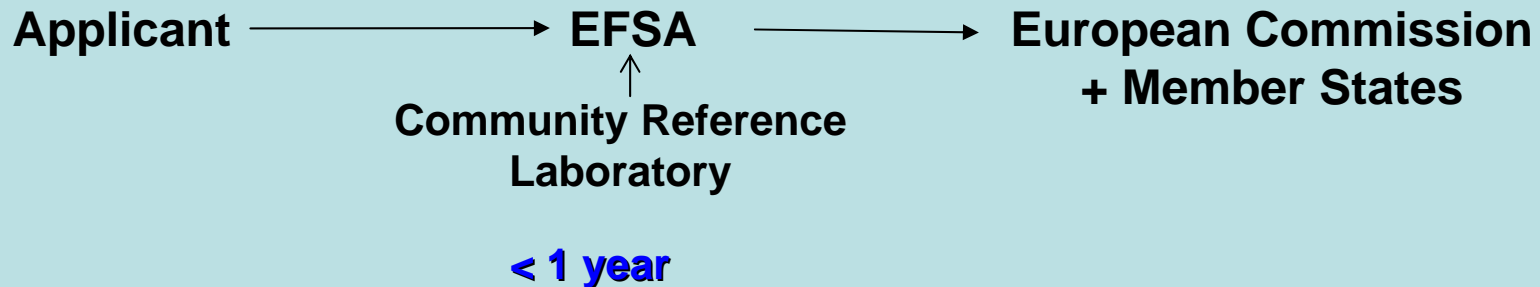
Additives for use in Animal Nutrition

History of the authorisation of feed additives in Europe

Before regulation 1831/2003 EC



After regulation 1831/2003 EC



Regulation 1831/2003 EC

Definition of Feed Additive

Conditions of Authorisation

Categories and functional groups of additives

Process of Authorisation

Other Measures

Definition of feed additives

Substances, micro-organisms or preparations, other than feed materials and premixtures, which are intentionally added to **feed** or **water** in order to perform, in particular, one or more of the functions mentioned in Article 5(3)

Conditions for Authorisation

Article 5

Safe

- for the animals, humans and environment
- does not mislead the consumer and user

Efficacious

Conditions for Authorisation

Efficacy

Favourably affect the characteristics of feed or animal products

Favourably affect the colour of ornamental fish and birds

Satisfy the nutritional needs of animals

Favourably affect animal production, performance or welfare

Have a coccidiostatic or histomonostatic effect

Categories of Feed Additives

Technological (preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, anticaking agents, substances for control radionuclide contamination, acidity regulators, silage additives, denaturants)

Sensory (colourants, flavouring compounds)

Nutritional (vitamins, pro-vitamins, trace elements, amino acids and analogues, urea and derivatives)

Zootechnical (digestibility enhancers, gut flora stabilisers, substances which favourably affect the environment, other zootechnical additives)

Coccidiostats and Histomonostats

Efficacy

Technological/Sensory/Zootechnical

Favourably affect the characteristics of feed or animal products

Sensory

Favourably affect the colour of ornamental fish and birds

Nutritional

Satisfy the nutritional needs of animals

Zootechnical

Favourably affect animal production, performance or welfare

Coccidiostats and histomonostats

Have a coccidiostatic or histomonostatic effect

Process of Authorisation

Technical dossier preparation

Application

Assessment by EFSA /CRL Analytical Methods

Regulation by EC

Technical Dossier

Guidelines for Dossier preparation

- **Chemical Compounds**

Directive 87/153/EEC Annex 1.

- **Enzymes and micro-organisms**

Opinion of the Scientific Committee on Animal Nutrition (SCAN) 22 October, 1999

Scientific Assessment by EFSA

Assessment on the data presented in the dossier

Verify the CRL report

6 months deadline (extended if more information is needed)

CRL Analytical Methods Evaluation

Regulation 378/2005 EC

Samples of additive (+ premixtures and complete feed)

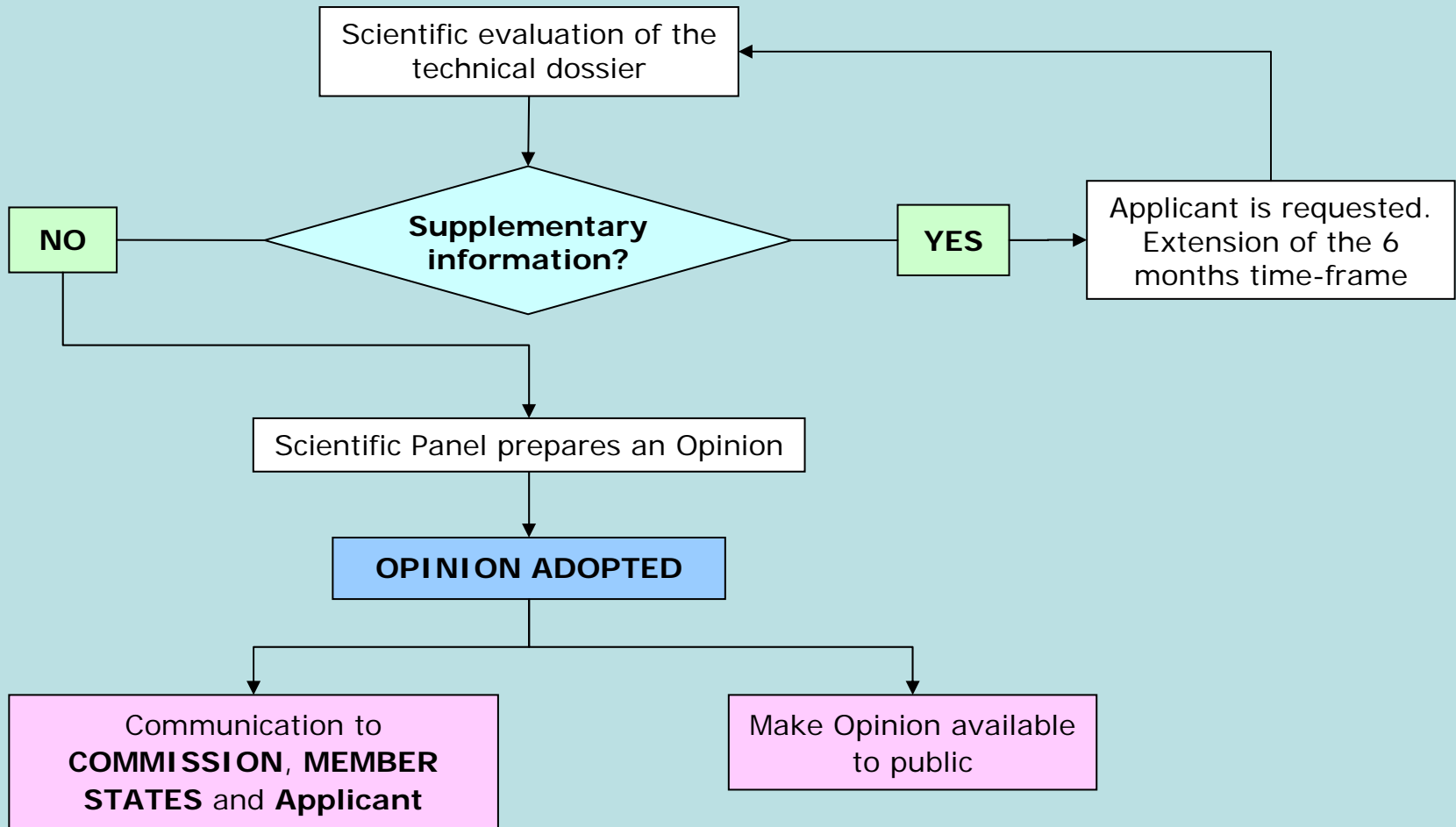
Assessment of methods of analysis

Testing/validation needed?

CRL is assisted by National Reference Laboratories

Report to EFSA within **3 months (can be extended)**

Procedure for EFSA Opinion Delivery



Community Authorisation

EFSA Opinion

EC - Draft Regulation authorisation, 3 months

Standing Committee (EC + Member States)

Authorisation of the additive for 10 years

Holder specific/generic

Other Measures

Existing products – Notification

Re-evaluation by 2010

Modification authorisation

Renewal authorisation

Confidentiality/data protection

Other Measures

**Phasing out of Coccidiostats and Histomonostats
by 31 December 2012**

Prohibition of Antibiotics on 31 December 2005

Traceability

Traceability of feed components and complete feeds (178/2002/EC)

All charges of the feed components have to identified according to producer and origin

All complete feed have to identified according to producer and origin even at farm level