



SUSTAINABILITY



INNOVATION



FEED SAFETY



**ANIMAL HEALTH
AND WELFARE**



SAFE FOOD

Regulation (EC) No 1831/2003 on additives for use in animal nutrition

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CONTENT

REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2003
on additives for use in animal nutrition *(as amended)*

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About FEFANA

<https://fefana.org/>

Our place in the feed & food chain

Manufacturers, traders and premixers of **specialty feed ingredients**



Only 3.5% of the volume
but 10% of the value
of compound feed

→ Total EU turnover =
5 billion Euros



Feed materials
(basic nutrition)



Compound feed

Consumers



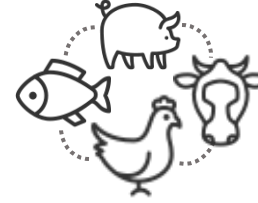
Retailers



Animal products



Animals



Why feed additives?

Safety



Feed preservation
and hygiene



**Protecting
human and
animal health**

Nutrition



Essential nutrients
and optimal
digestibility



**Achieving resource
efficiency and
animal welfare**

Sustainability



Emission and waste
reduction



**Decreasing
environmental
footprint**

Our Industry is...

Globalised



Driven mainly by
European based
Companies



Approx.50%
of worldwide
industry

Innovative



Addressing societal
concerns
(e.g. AMR, welfare)



Solutions
driven

Diverse



High propotion of
EU based SMEs



About 2/3 of
FEFANA
members

About FEFANA

The EU Association representing the industry of Specialty Feed Ingredients and their Mixtures

95 Member companies:
producers, traders, premixers based
in EU, EFTA, UK



Feed additives and other feed
ingredients used for a specific
function (other than basic nutrition)



Represent and promote common
industry interests, engage with EU
institutions and stakeholders for a
fair and competitive market



Regulatory and enforcement
activities promoting feed and food
safety & international collaboration





Introduction to the feed additives legislation

Reg. (EC) No 1831/2003 - Introduction

All animals

Regulation on additives for use in animal nutrition



- Basic law setting rules for authorisation and use of feed additives (and their premixtures) in EU
- Pre-marketing authorisation => **No authorisation/no market** - Principle of a positive list: only what is in the list can be placed on the market and can be used as additive in feed under conditions clearly established (type of feed, level of addition, animals intended to consume the feed, etc...)
- Current Register with about 1560 additives



pets included!



Updated Regulation?

EU Regulations ≈ 10 year turnover

- Better regulation initiative
- Objective: assess if Regulation meets its objectives and the needs of the citizens, businesses and public institutions in an efficient manner

Revision of Reg. (EC) 1831/2003

- 2021 - 2022 IA data collection
 - 3-month internet-based public consultation;
 - Workshop with Competent Authorities (CAs) and stakeholders;
 - Targeted consultations: CAs + stakeholders.
- Drafting & submission of the IA report (EC)

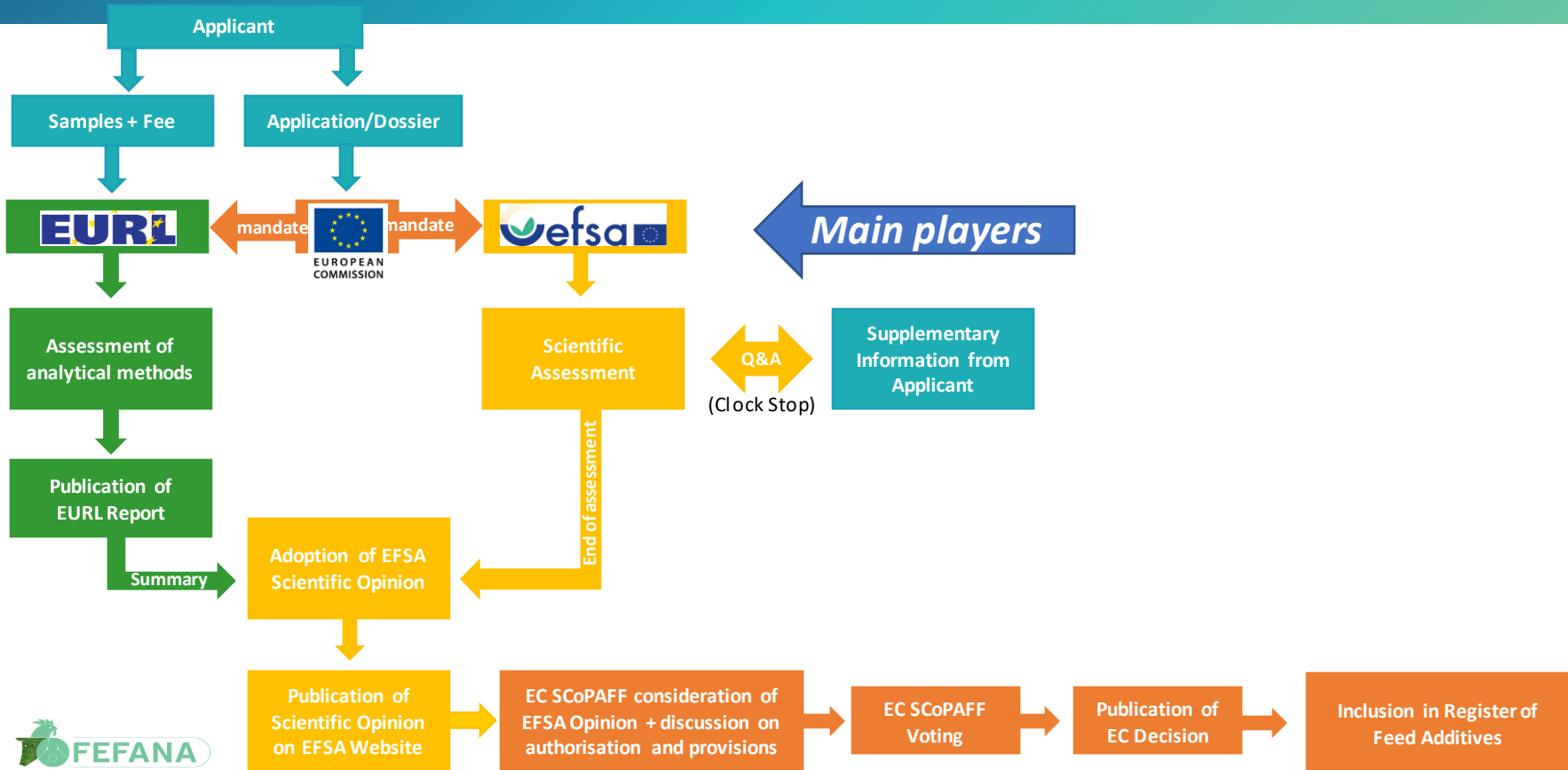


=> In stand-by at the moment!



Authorisation process in a nutshell

Authorisation process in a nutshell





Some definitions and practical aspects

Users of feed additives



- Users = farmers
- Can they use feed additives (and premixtures) ‘as such’ at the farm?
 - **Only if**, as ‘feed business operators’, they are compliant with provisions of Annex II of FHR (Feed Hygiene Regulation (183/2005 as amended))
 - Approved FBO: alpha-number
 - Unless they use silage additives / premixtures of silage additives
 - To be a ‘Registered FBO’ is sufficient

Art. 5(2) of 183/2005: “for operations including mixing of feed for the exclusive requirements of their own holdings **when using additives or premixtures of additives with the exception of silage additives**, feed business operators shall comply with the provisions in Annex II, where relevant for the operations carried out.”

If not: only feed materials and compound feeds

Labels

Labelling of feed additives and premixtures

Article 16

Not compound feed and feed materials

(Regulation (EC) No 767/2009, as amended)

+ amendments on labelling of preparations and premixtures containing them

(Regulation (EU) No 2015/327)

Broiler Grower 0,5% PREMIXTURE for animal feed

Carriers: limestone, wheat middlings

Ingredients:

Vitamins and provitamins

Vitamin A (retinyl acetate, E672)	3 000 000.00 IU/kg
Vitamin D3 (cholecalciferol, E671)	500 000.00 IU/kg
25-hydroxycholecalciferol (3a670a)	12 500.00 mcg/kg
Vitamin E (all-rac- α -tokoferil-acetát) (3a700)	16 000.00 mg/kg
Vitamin K3	800.00 mg/kg
Vitamin B1 (Thiamine mononitrate)	600.00 mg/kg
Vitamin B2 (Riboflavin)	1 600.00 mg/kg
Pantothenic acid (calcium-D-pantothenate)	3 600.00 mg/kg
Vitamin B6 (pyridoxine hydrochloride) (3a831)	1 000.00 mg/kg
Vitamin B12 (cyanocobalamine)	5.00 mg/kg
Vitamin C (ascorbic acid) (E300)	40 000.00 mg/kg
Niacin (vitamin PP) (3a314)	12 000.12 mg/kg
Folic acid (3a316)	400.00 mg/kg
Biotin (vitamin H)	60.00 mg/kg
Choline chloride (3a890)	35 000.00 mg/kg
Betaine hydrochloride	30 000.00 mg/kg

Trace elements

Selenium (sodium selenite) (Se, E8)	80.00 mg/kg
Iron (iron sulphate monohydrate) (Fe, E1)	16 000.00 mg/kg
Copper (Copper sulphate pentahydrate) (Cu, E4)	3 000.00 mg/kg
Manganese (Manganese oxide) (Mn, E5)	20 000.00 mg/kg
Zinc (Zinc oxide) (Zn, E6)	20 000.00 mg/kg
Iode (Calcium-iodate anhydrous) (I, E2)	400.00 mg/kg

Coccidiostats and histomonals

Salinomycin-sodium (Salinomax 120G) (E766) 14 000.00 mg/kg

Digestibility enhancers: Endo-1,4-beta-glucanase EC 3.2.1.4 (4a1602i) 16 000.00 U/kg Endo-1,3(4)-beta-glucanase EC 3.2.1.6 (4a1602i) 14 000.00 U/kg Endo-1,4-beta-xylanase EC 3.2.1.8 (4a1602i) 54 000.00 U/kg Endo-1,4-beta-xylanase EC 3.2.1.8 (4a1607) 60 000.00 FXU/kg Serin-protease EC 3.4.21. (4a13) 3 000 000.00 PROT/kg 6-phytase EC 3.1.3.26 (4a18) 200 000.00 FYT/kg

Antioxidants: Butylated hydroxytoluene (BHT)(E321) 7 000.00 mg/kg

Instructions for use: For broiler feed. Inclusion rate in complete feed: 0.5%.

Precautions: Withdrawal period: 1 day. Dangerous for equines and turkeys. This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g.tiamulin) can be contraindicated. Can cause allergic reactions. For use in feed rich in non- starch polysaccharides (mainly beta-glucans and arabinoxylans). For use in feed containing more than 0,23 % phytin-bound phosphorus. Keep in dry and cool place ! Other information on material safety data sheet.

Scope

Ensure a high level of protection of the whole chain



Definitions

Article 2

'Feed additives': **Substances, micro-organisms** or **preparations**, other than feed material 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)

Substances

(usually a chemical)

ZnO

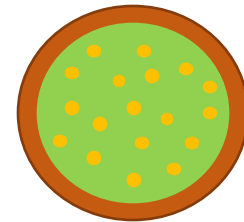
Micro-organisms

(Preparations of organism(s))



+ ingredients

Preparations



Active substance
encapsulated in a beadlet
But also 'simple' mixtures

Feed additives are a type of feed

Regulation (EC) No 178/2002 (GFL) 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 (as amended)

‘feed’ (or ‘feedingstuff’): any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals



All feed additives are feed, but all feeds are not feed additives

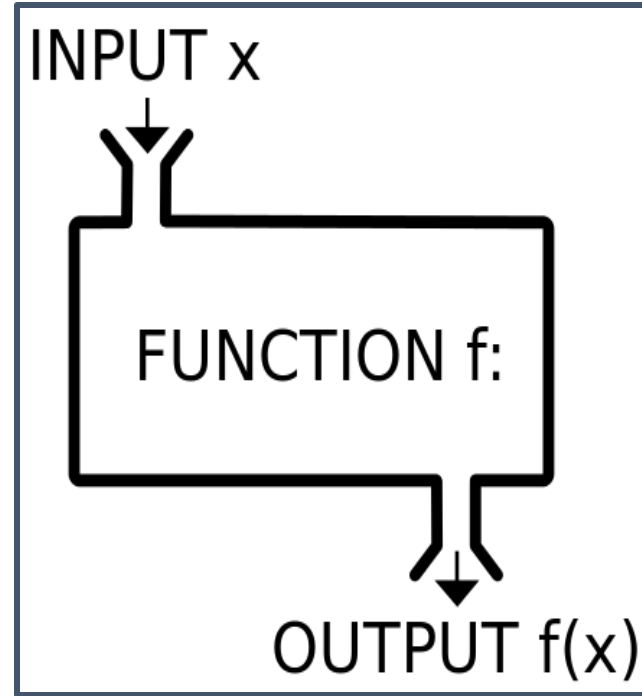
Functions/efficacy of feed additives



Feed additives →

Feed, water, animal →

Performance, animal welfare, food quality,
nutritional needs, appearance feed,
environment, etc. →



Functions of feed additives (a)

Article 5(3)

- (a) favourably affect the characteristics of **feed**

Preservatives

Antioxidants

Flavourings

Functions of feed additives (b, c)

Article 5(3)

- (b) favourably affect the characteristics of **animal products**
- (c) favourably affect the **colour** of ornamental fish and birds



Carotenoids



Other
colourants

Functions of feed additives (d)

Article 5(3)

- (d) satisfy the nutritional needs of animals

Vitamins

Amino-acids

Trace
minerals

Functions of feed additives (e)

Article 5(3)

- (e) favourably affect the **environmental consequences** of animal production



Phytases



Urine pH

Functions of feed additives (f)

Article 5(3)

- (f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs

Probiotics

Enzymes

Organic
acids

Functions of feed additives (g)

Article 5(3)

- (g) have a coccidiostatic or histomonostatic effect



Coccidiostats



Histomonostats

Categories and functional groups



Definition of categories

Article 6

1. Technological additives: any substance added to **feed** for a technological purpose

Preservatives, Antioxidants, Emulsifiers, Stabilisers, Thickeners, Gelling agents, Binders, Substances for control of radionuclides, Anticaking agents, Acidity regulators, Silage additives, Denaturants, Mycotoxin contamination reducers

Colourants, Flavouring compounds

2. Sensory additives: any substance, the addition of which to **feed** improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals

Vitamins and vitamin-like Trace elements
Amino acids, Urea and derivatives

3. Nutritional additives

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

4. Zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment

Substances intended to kill or inhibit protozoa

5. Coccidiostats and histomonostats



Types of authorisations

Non-holder specific additives

- FBO should ensure compliance of the composition/identity of their product with the feed additive authorisation (+ all aspects of the FHR)
 - Quality control is the responsibility of the placer on the market
- Applicants?
 - Single companies
 - Two or more companies

FEFANA authorisation consortia are typical examples of multi-applicants applications

Holder specific additives

- Categories 4 and 5, and 1, 2, and 3 in case of GM
- Only the applicant(s)/authorisation holder can place the additive on the market (+ their customers/representatives)
- Applicants?
 - Single companies (most applications)
 - Two or more companies
 - Each participant receives a holder specific authorisation for the same product

Non-holder vs holder specific additives

3	a	Vitamins, pro-vitamins and chemically well-defined substances having similar effect	3a890	Choline chloride <div style="border: 1px solid red; height: 20px; width: 100%;"></div>
4	a	Digestibility enhancers	4a11	Preparation of endo-1,4- β -xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (ATCC PTA 5588) (Holder of the authorisation Danisco Animal Nutrition) [Piglets (weaned) and pigs for fattening]

Fermentation products / Micro-organisms

1	k	2 – Microorganisms		<i>Lactobacillus buchneri</i> KKP. 907
3	c	Amino acids, their salts and analogues	3c3.6.1	L-arginine produced by <i>Corynebacterium glutamicum</i> (ATCC 13870) [All species]
3	b	Compound of trace elements	3b8.11	Selenomethionine produced by <i>Saccharomyces cerevisiae</i> NCYC R397 (Selenized yeast inactivated) [All species]

Additives after 10 years...

'Following the provisions of Art. 14 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted'

Renewal ongoing, additive remains authorised until assessment is finished and decision is taken

- No application for renewal of authorisation submitted one year before expiry date
- Authorisation will expire at expiry date



Feed additives Register

EU register of Feed Additives

- The Register has only informative purposes and does not replace Community legal acts concerning the authorisation of each additive entered in the Register
- The legal acts are the only legal basis for the placing on the market and use of the additives

European Commission > Food > Food and Feed Information Portal > Feed Additives > Search Feed additives

SEARCH OPTIONS

Category/Functional Group
All

Status
All

To be phased out
All

Expiry date from
DD/MM/YYYY

Expiry date to
DD/MM/YYYY

Search

Clear filters

Feed Additives (1563 matching records)

Filter results... Search

Cat./Grp	Code	Additive name	To be phased out
3 a	3a825iii	'Riboflavin' or 'Vitamin B2'	No
2 b	2b02229	(-)-3,7-Dimethyl-6-octen-1-ol / CAS No. 7540-51-4 / Flavis No. 02.229	No
2 b	2b08064	(2E)-Methylcrotonic acid / CAS No. 80-59-1 / Flavis No. 08.064	No
2 b	2b02058	(Z)-Nerol / CAS No. 106-25-2 / Flavis No. 02.058	No
2 b	2b06001	1,1-Diethoxyethane	No
2 b	2b06006	1,1-Dimethoxy-2-phenylethane	No
2 b	2b04016	1,3-Dimethoxybenzene / CAS No. 151-10-0 / Flavis No. 04.016	No
2 b	2b04034	1,4-Dimethoxybenzene / CAS No. 150-78-7 / Flavis No. 04.034	No

THANK YOU!

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FEFANA asbl
FEFANA is the united voice of the specialty feed ingredients business in Europe.