



 **FRANA**

Additives in animal feed



Content Part 1

- FRANA & industry associations
- Structure of animal feed
- General information on the EU
- EU Feed legislation
 - Feed additives
 - Feed materials
 - Veterinary medicines
- EU Registration procedure of feed additives
- Impurities
- Quality standards

FRANA/ FEFANA

Interest group for producers and suppliers of additives, premixes and functional ingredients for the animal feed production

- FRANA is the Belgian platform
- FEFANA is the European organisation

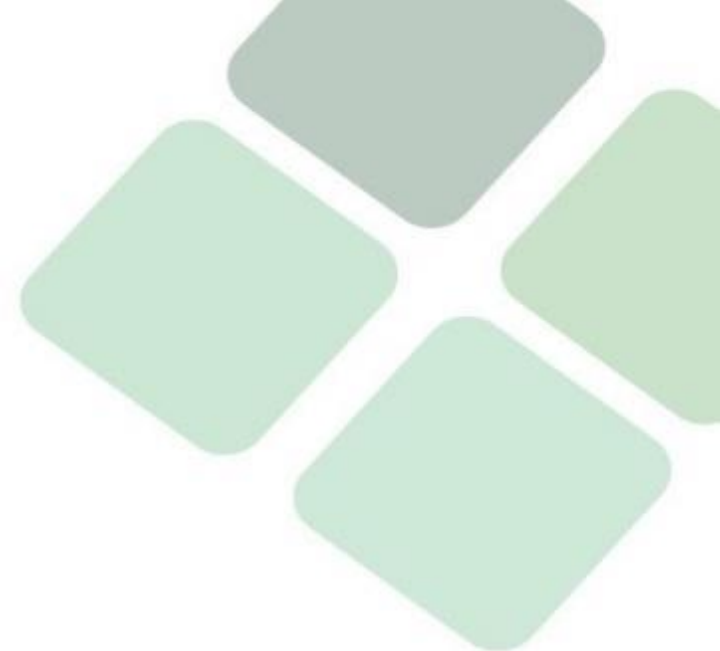


FRANA MEMBERS

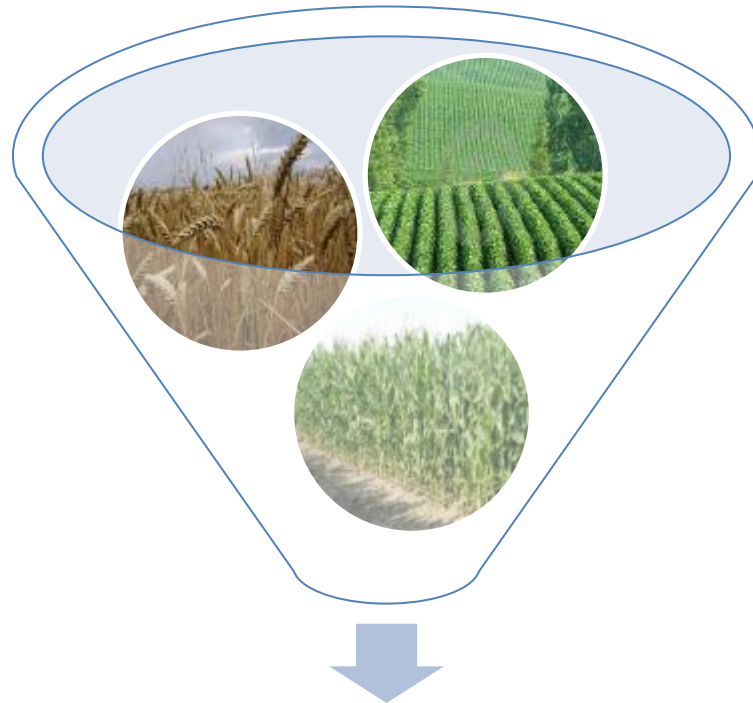


Content Part 1

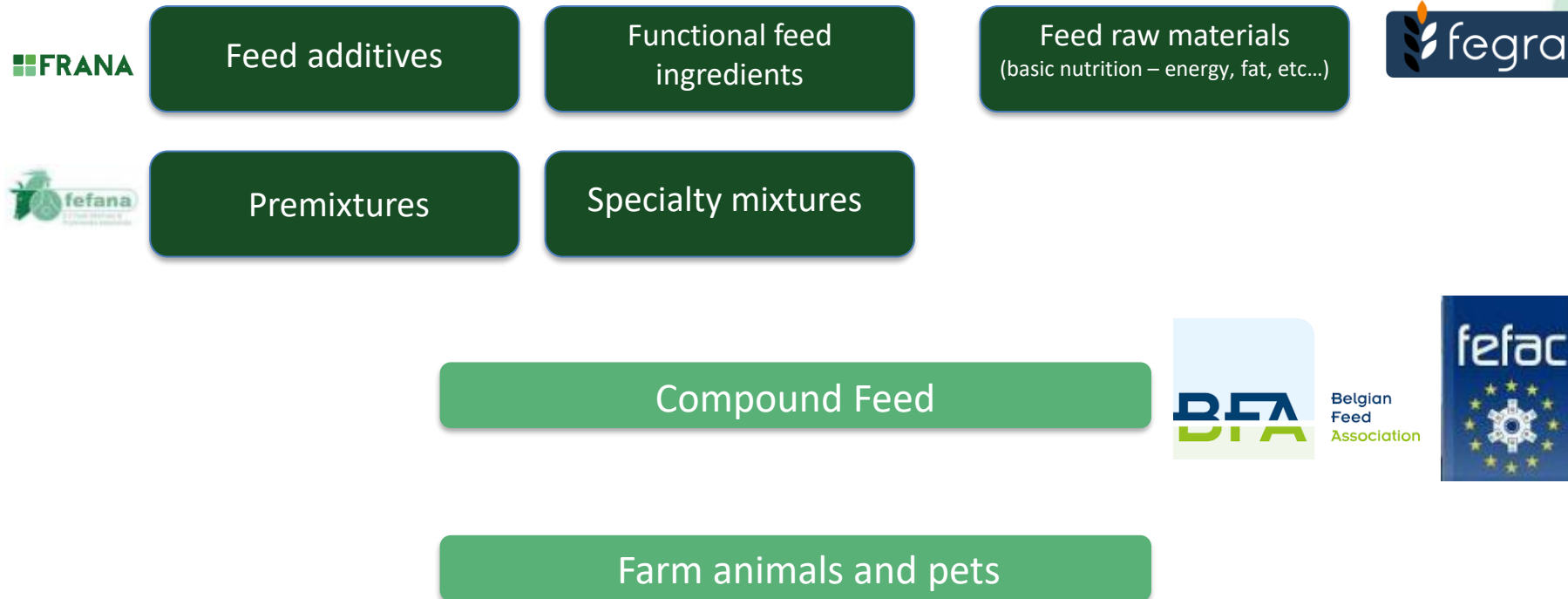
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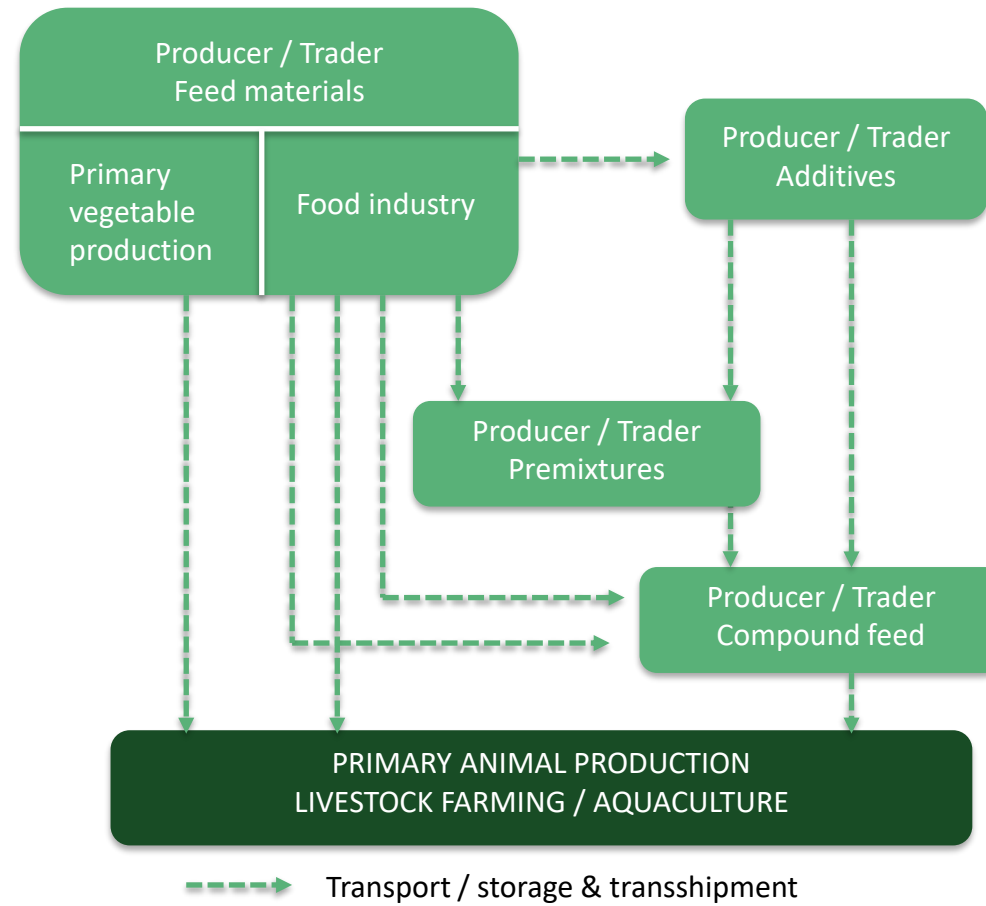
ANIMAL FEED



STAKEHOLDERS IN THE ANIMAL PRODUCTION CHAIN

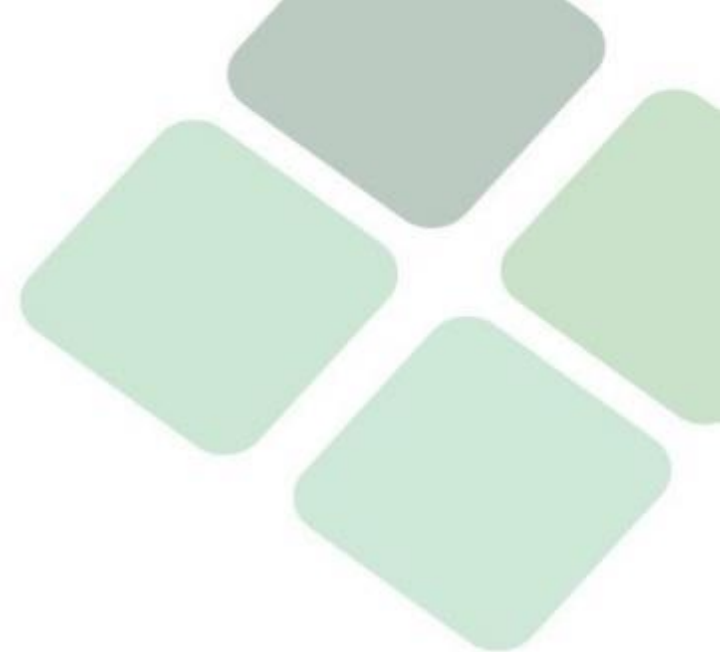


OVERVIEW OF THE FEED SECTOR



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INFORMATION ON EU INSTITUTIONS AND EU LEGISLATION ACTS INVOLVED IN THE EU FEED/FOOD LAWS



- **Legislation acts:**
 - Recommendation (Rec): legally non binding
 - Directive (Dir): to be implemented in national legislation (sometimes late implementation)
 - Regulation (Reg): direct application in all member states
- **EU institutions:**
 - **European Parliament** (705 members, Brussels/Luxemburg/Strasbourg): Dir, Reg
 - elected politicians
 - **Council of the EU** (National government ministers from each member state, rotating presidency) negotiates and adopts EU laws
 - **European Council** (27 members + EU Commission president + own president) - defines the general political direction and priorities of the European Union
 - **European Commission** (27 members, Brussels): Dir, Reg
 - Some legislative competencies (e.g. on food and feed), obtained from Parliament and Council, are executed by the EC via the “Comitology” procedure



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THE USE OF FEEDS AND FEED ADDITIVES IN THE EU

- The legal use of feed and feed additives:
 - Before 2003: authorisation by the European Commission (EC Directive 70/524/EC) based on evaluation by national authorities and SCAN
 - After 2003: regulated at EU level via the European Commission (EC Regulations 1831/2003 and 767/2009) and EFSA (European Food Safety Authority) the independent authority
- Legal acts available on:
 - Feed additives and premixtures
 - Feed materials and compound feed
 - Prohibited feed materials
 - Maximum levels on contaminants/undesirable compounds
 - Feed manufacturing and feed hygiene

**Without authorisation of the additive,
no legal use of the additive/premixture
in EU**

EU FEED LAW DEFINITION OF FEED ADDITIVE / PREMIXTURE

- 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) (see next slide)
- Premixtures:
 - Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals

Feed additive functions

(From Article 5 of Reg. 1831/2003)

The feed additive shall:

- (a) favourably affect the characteristics of feed,
- (b) favourably affect the characteristics of animal products,
- (c) favourably affect the colour of ornamental fish and birds,
- (d) satisfy the nutritional needs of animals,
- (e) favourably affect the environmental consequences of animal production,
- (f) favourably affect animal production, performance or welfare, particularly by affecting the gastrointestinal flora or digestibility of feedingstuffs, or
- (g) have a coccidiostatic or histomonostatic effect.

OTHER EU FEED LAW DEFINITIONS (1)

- (b) 'feed materials' shall mean various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or, after processing, in the preparation of compound feedingstuffs or as substrates for premixtures;
- (e) 'compound feedingstuffs' shall mean mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;
- (f) 'complementary feedingstuffs' shall mean mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;

OTHER EU FEED LAW DEFINITIONS (2)

- (f) ‘daily ration’ means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;
- (g) ‘complete feedingstuffs’ means products as defined in Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition ⁽¹⁾;
- (h) ‘processing aids’ means any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed;

FEED MATERIAL VS. FEED ADDITIVE

- In some cases, there is a grey zone between feed material and feed additive.
- Two “tools” that can be helpful to correctly classify a feed ingredient:
 - COMMISSION RECOMMENDATION of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products
 - Fefana Classification Tool: a questionnaire to determine if the ingredient is a feed material or feed additive, or something else: <https://www.fefana.org/ClassTool/>
- Sometimes, feed materials become feed additives, if the member states and the European Commission decide to change their legal status: e.g. calcium hydroxide, sodium citrate, potassium citrate, mannitol, xylitol and sorbitol will become feed additives by 2028.

EU “CATALOGUE OF FEED MATERIALS” VERSUS “REGISTER OF FEED MATERIALS”

- Content of the register of feed materials is a proposal from the feed sector
- Catalogue is the official, but non exclusive list of feed materials edited by the EU Commission for uniformity of labeling
- EFSA is normally not involved in the safety evaluation of feed materials; however:
 - Feed materials are covered by Feed Hygiene Regulation EC/183/2005;
 - The seller is fully responsible for the safety of the feed for the animal/consumer/user/environment
- In principle a product is listed in either the register of feed additives or in the catalogue/register.

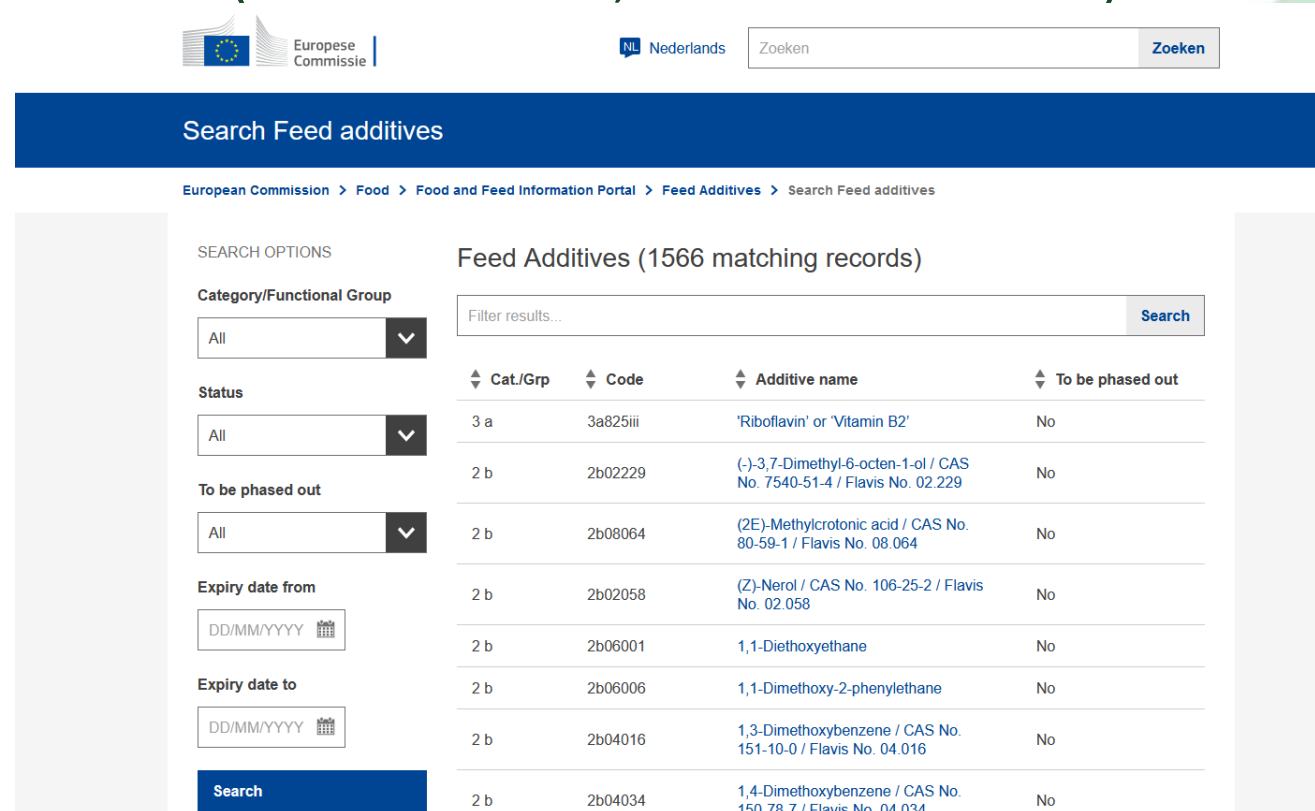
EU “CATALOGUE OF FEED MATERIALS”: Reg. 2017/1017

How it looks like:

4.5.1	Garlic, dried	White to yellow powder of pure, ground garlic, <i>Allium sativum</i> L.	
4.6.1	Manioc; [tapioca]; [cassava]	Roots of <i>Manihot esculenta</i> Crantz, regardless of their presentation.	Moisture if < 60 % or > 70 %
4.6.2	Manioc, dried; [tapioca, dried]	Roots of Manioc, regardless of their presentation, which are subsequently dried.	Starch Ash insoluble in HCl, if > 3,5 % of dry matter
4.7.1	Onion pulp	Moist product obtained from processing onions (genus <i>Allium</i>) and consisting of both skins and whole onions. If obtained from the production process for onion oil, then it mostly consists of cooked remains of onions.	Crude fibre Ash insoluble in HCl, if > 3,5 % of dry matter
4.7.2	Onions, fried	Skinned and crumbed onion pieces which are then fried.	Crude fibre Ash insoluble in HCl, if > 3,5 % of dry matter Crude fat

COMMUNITY REGISTER OF FEED ADDITIVES

(INFORMATIVE; NOT A LEGAL ACT)



The screenshot shows the search interface for the Community Register of Feed Additives. At the top, there is a header with the European Commission logo and the text 'Europese Commissie'. To the right, there is a search bar with the text 'Zoeken' and a 'Zoeken' button. Below the header, there is a blue bar with the text 'Search Feed additives'. Underneath, there is a breadcrumb trail: 'European Commission > Food > Food and Feed Information Portal > Feed Additives > Search Feed additives'. The main content area is divided into two sections: 'SEARCH OPTIONS' on the left and 'Feed Additives (1566 matching records)' on the right. The 'SEARCH OPTIONS' section includes three dropdown menus for 'Category/Functional Group', 'Status', and 'To be phased out', all set to 'All'. There are also two date input fields for 'Expiry date from' and 'Expiry date to', both with a calendar icon. A 'Search' button is located at the bottom of the search options. The 'Feed Additives (1566 matching records)' section features a search bar with the text 'Filter results...' and a 'Search' button. Below this is a table with four columns: 'Cat./Grp', 'Code', 'Additive name', and 'To be phased out'. The table contains eight rows of data, each representing a different feed additive.

◆ 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

<https://ec.europa.eu/food/food-feed-portal/screen/feed-additives/search>

Before April 2023 the register was a pdf-document, now it is an online searchable database.

COMMUNITY REGISTER OF FEED ADDITIVES: EXAMPLES

Characteristics

Conditions of use

Characteristics

Code	3a825iii
Name	'Riboflavin' or 'Vitamin B2'
Other codes	
Category/Functional group (Annex I of Reg. 1831/03)	3a
Category description	3. Nutritional additives
Functional group description	a) Vitamins
Subclassification (old classification)	
To be phased out	No
Footnotes	

Conditions of use

The feed additive is authorised to be used in the following animal category(ies):

All animal species

Reference(s) of Community legal act:

Commission Implementing Regulation (EU) 2023/651 of 20 March 2023

Reference in OJ:

OJ L 81, 21.03.2023, p. 19

Authorisation date: 20/3/2023

Expiry date: 11/4/2033

First entry in the register:

EFSA question nbr:

Authorisation holder:

FEED ADDITIVES VERSUS VETERINARY/ MEDICINAL DRUGS: GENERAL PRINCIPLES

	Feed additives	Veterinary drugs
User/applicant	Feed producer	Veterinarian only
Animals	Healthy animals	Sick animals
Aim of use	Improve productivity	Restore health
Duration of use	Permanently	Temporarily
Safety	No safety risk accepted, severe safety check before authorization	Risk-benefit analysis, waiting periods before consumption of products

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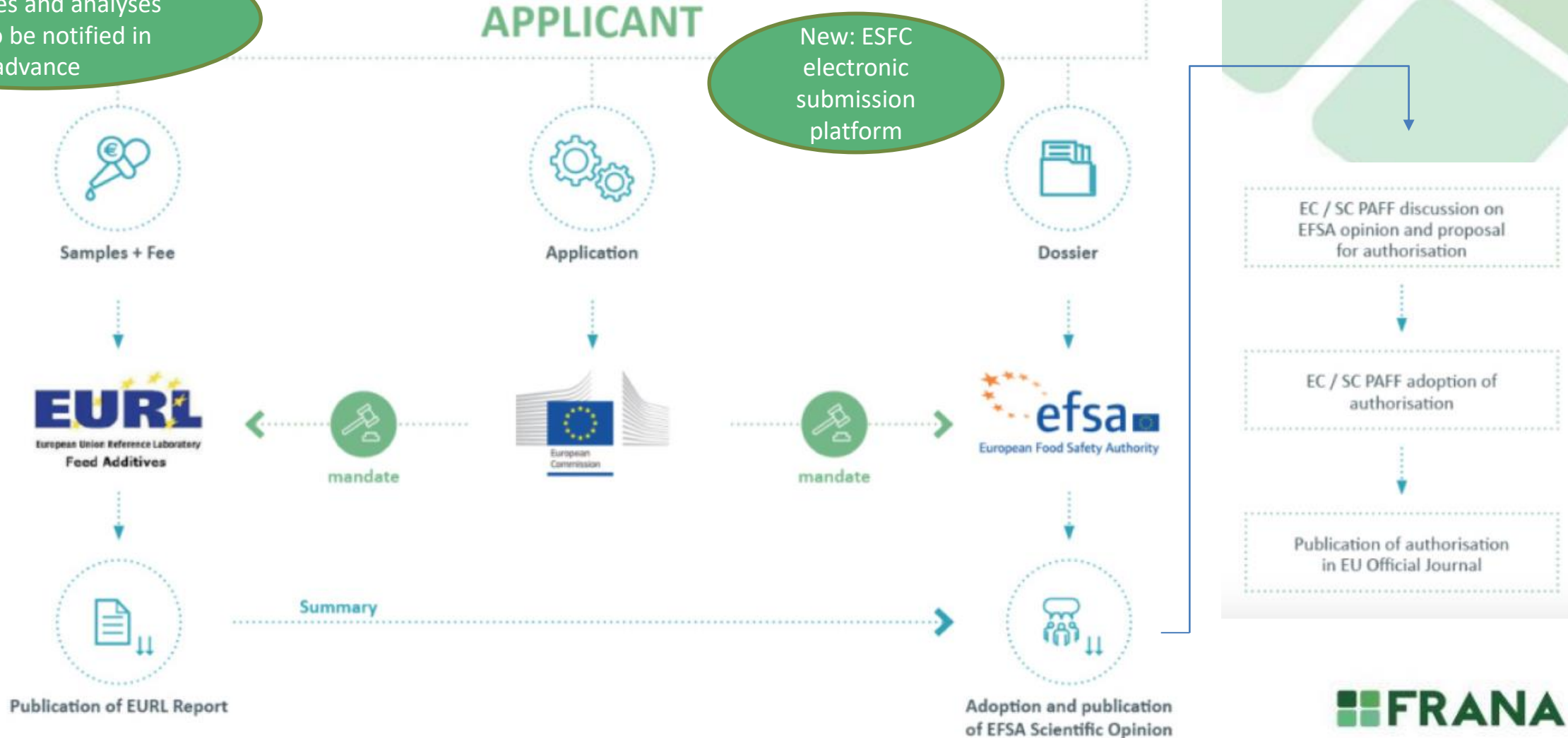
THE AUTHORISATION OF FEED ADDITIVES IN EU

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on “Additives for use in Animal Nutrition”
 - Commission Regulation (EC) 429/2008 on the procedure to be followed for the preparation and the presentation of applications and technical dossiers for authorisation for placing a feed additive on the market.
-
- Procedure for Authorisation
 - Risk Assessment by EFSA (European Feed Safety Authority)

Flow Chart of the Registration Process

New: EFSA Connect portal:
all studies and analyses
need to be notified in
advance

New: ESFC
electronic
submission
platform



EUROPEAN REFERENCE LABORATORY FOR FEED ADDITIVES (EURL-FA)


- Geel (Belgium)
- Regulation (EC) No 378/2005
- Samples of additive (feed/food)
- Assessment of presented methods of analysis
- Testing/Validation needed?
- EURL is assisted by NRLs
- EURL Report to EFSA




EFSA: EUROPEAN FOOD SAFETY AUTHORITY


WWW.EFSA.EUROPA.EU

Other sites EFSA Open EFSA EFSA Journal Connect

 EUROPEAN FOOD SAFETY AUTHORITY

EN English  Calendar

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Multi-country outbreak of *Listeria monocytogenes* linked to fish products

Ready-to-eat fish products, mainly smoked salmon, are the likely source of an ongoing multi-country outbreak of *Listeria monocytogenes*.

3 of 4

EFSA: RISK ASSESSOR

- **EFSA = authority, NOT an administration (Cfr FDA) nor an Agency (Cfr. Federal Agency for the Safety of the Food Chain: FAVV, Brussels)**
One single authority that covers all parts of the food production chain from primary production to consumption: independent, objective and science based risk assessment
- **EFSA = independent authority**
EFSA controlled by Management Board, acting in independent capacity from national authorities

REG. 429/2008: GENERAL GUIDELINES FOR THE PREPARATION OF THE DOSSIER

22.5.2008

EN

Official Journal of the European Union

L 133/1

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 429/2008

of 25 April 2008

on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

(Text with EEA relevance)

CONTENTS OF A TECHNICAL DOSSIER TO BE SENT TO EFSA

- Administrative data and documents
- Section I: Summary
- Section II: Characterisation of the additive
- Section III: Safety of the additive
- Section IV: Efficacy of the additive
- Section V: Post-market monitoring

THE BODY OF THE TECHNICAL DOSSIER

- Section II: Characterisation of the additive
 - Full data on active compounds and impurities
 - Data on stability/manufacturing process
 - Conditions of use
 - EURL official method for analysis
- Section III: Safety of the additive
 - Target species
 - Consumer
 - User
 - Environment
- Section IV: Efficacy
- Section V: Post-market monitoring plan

SECTION II: DATA ON ACTIVE COMPOUND(S) AND IMPURITIES IN THE ADDITIVE

- **Full characterisation (100 % mass balance)**
 - Active compound(s), excipients, impurities,..
 - Chemical formula, CAS/EC/IUPAC number,...)
 - Physical characteristics (pH, viscosity, optical rotation, particle size, dusting potential,...)
- **Impurities** (heavy metals, microbial load, mycotoxins, endotoxins, PCB's, dioxins, impurities from the production process, ...)
- **Methods of analysis of active compound(s)**
 - EURL report

SECTION II: DATA ON STABILITY/HOMOGENEITY/MANUFACTURING PROCESS OF THE ADDITIVE

- Shelf life of the additive
- Stability
 - In premixtures (6 months)
 - In compound feeds (3 months)
 - Stability to processing (e.g. pelleting)
- Homogeneity
 - Tests on the potential for homogeneous distribution in feed/premixtures
- Manufacturing process
 - Flow chart + MSDS of all media/excipients used

SECTION II: CONDITIONS OF USE

To be specified:

- Animal species/categories
- Minimum and maximum dose
- Duration if applicable

SECTION III: SAFETY OF THE FEED ADDITIVE

- One tolerance trial for each target species
 - 10x max. recommended dose + blood chemistry and haematology or 100x overdose without blood analysis (non-GLP)
 - Minimum duration, see table
- Metabolism studies in target species + residues in tissues and products (GLP)
- Toxicological studies in laboratory animals (GLP – Good Laboratory Practice)
 - Pharmacokinetics
 - Acute, sub-acute (90 day), chronic toxicity ► No-observed-effect level (NOEL) and no-observed-adverse effect level (NOAEL)
 - Mutagenicity
 - Reproduction + teratogenicity

SECTION III: SAFETY OF THE FEED ADDITIVE

- Safety for user (GLP)
Inhalation, dermal, eye and skin tests
- Safety for environment
- Attention: for non-food producing animals (e.g. pets) less data are required



SECTION IV: EFFICACY STUDIES

- For zootechnical additives: 3 trials with significant positive results, carried out at minimum 2 different locations for each animal species/category
 - For monogastrics ($P \leq 0.05$)
 - For ruminants and pets ($P \leq 0.1$)
- Short term/long term experiments
- Dose: minimum recommended dose (applicant)
- Intended doses in test diets should be analytically confirmed
- Duration: specified per species

SECTION V: POST-MARKET MONITORING

- Only if required according to the registration (coccidiostats & histomonostats)
- Trace and identify any effects (direct or indirect, immediate, delayed or unforeseen) resulting from the use of the additive on human or animal health or the environment

Transparency Regulation (EU) 2019/1381

- Response to the glyphosate case (some studies showing toxic/carcinogenic results, were not included in the dossier)
- Target: increase the transparency of the EU risk assessment in the food chain, strengthen the reliability, objectivity and independence of the studies used by EFSA
- Published in the Official Journal on 6 September 2019
Applicable since 27 March 2021 (<https://open.efsa.europa.eu/>)

Transparency Regulation (EU) 2019/1381

- Ensuring more transparency
 - Citizens will have automatic access to all studies and information submitted by industry
 - Stakeholders and the general public will also be consulted on submitted studies.
- Increasing the independence of studies
 - All studies will have to be notified to EFSA to guarantee that companies do not hold back unfavourable studies. On the other side, this is not good for innovation in the EU, because innovation is almost always trial and error.
 - Pre-submission advice: EFSA will provide general advice to applicants prior to the submission of the dossier.
 - Commission may ask EFSA to commission additional studies for verification purposes and may perform fact-finding missions to verify the compliance of laboratories/studies with standards
- Strengthening the governance and the scientific cooperation
 - Member States, civil society and European Parliament will be involved in EFSA's activities: represented in EFSA Management Board.
- Developing comprehensive risk communication
 - Ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties.

Generic versus holder-specific authorisations

For most additives, the authorisation is so-called “generic”. Not only the applicant can use the authorisation, but any company can put the additive on the market in the EU, as long as the specifications and conditions in the authorisation are met.

For zootechnical additives, and for additives originating from a GMO plant, the authorisation is “holder-specific”, i.e. linked to the applicant.

EXERCISE 1: How to find an authorisation for a feed additive?

Two options:

- 1) Via the link in the feed additive register
- 2) Via a search in Eur-lex (the database of European legislation): <https://eur-lex.europa.eu>

EXERCISE 2: How to find an EFSA scientific opinion for a feed additive?

Two options:

- 1) Via the EFSA website: <https://www.efsa.europa.eu>
- 2) Google (Scholar): “feed additive” + EFSA + “scientific opinion” + name of the additive

EXAMPLE OF AN AUTHORISATION: L-selenomethionine

Link:

http://data.europa.eu/eli/reg_impl/2014/121/oj

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Selenium in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b815	—	L-selenomethionine	<p><i>Characterisation of the additive</i></p> <p>Solid preparation of L-selenomethionine with a selenium content < 40 g/kg</p> <p><i>Characterisation of the active substance</i></p> <p>Organic selenium in form of L-selenomethionine (2-amino-4-methylselenanyl-butanoic acid) from chemical synthesis</p> <p>Chemical formula: C₃H₁₁NO₂Se</p> <p>CAS number: 3211-76-5</p> <p>Crystalline powder with L-selenomethionine > 97 % and</p> <p>Selenium > 39 %</p> <p><i>Analytical method (1)</i></p> <p>For the determination of L-selenomethionine in the feed additive: high performance liquid chromatography and inductively coupled plasma mass spectrometry (HPLC-ICPMS) after triple proteolytic digestion.</p> <p>For the determination of total selenium in the feed additive: inductively coupled plasma mass spectrometry (ICPMS), or inductively coupled plasma atomic emission spectrometry (ICP-AES).</p> <p>For the determination of total selenium in premixtures, compound feed and feed materials: hydride generation atomic absorption spectrometry (HGAAS) after microwave digestion (EN 16159:2012).</p>	All species	—		0,50 (total)	<ol style="list-style-type: none"> The additive shall be incorporated into feed in the form of a premixture. For user safety: breathing protection, safety glasses and gloves shall be worn during handling. Technological additives or feed materials included in the preparation of the additive shall ensure a dusting potential < 0,2 mg selenium/m³ air. In the directions for use of the additive and premixtures, indicate the storage and stability conditions. Maximum supplementation with organic selenium: 0,20 mg Se/kg of complete feed with a moisture content of 12 %. If the preparation contains a technological additive or feed materials for which a maximum content is set or which is subject to other restrictions, the feed additive manufacturer shall provide this information to the customers. 	28 February 2024

EXAMPLE OF SCIENTIFIC OPINION OF EFSA

Link:

<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6905>

SCIENTIFIC OPINION



ADOPTED: 30 September 2021

doi: 10.2903/j.efsa.2021.6905

**Safety and efficacy of a feed additive consisting of
3-nitrooxypropanol (Bovaer[®] 10) for ruminants for milk
production and reproduction (DSM Nutritional Products Ltd)**

EXERCISE 3: How to find information on an ongoing registration dossier?

1) In EFSA process (risk assessment):

<https://open.efsa.europa.eu>

2) After publication of the EFSA Scientific Opinion: Preparation and vote of the authorisation: go to https://ec.europa.eu/food/horizontal-topics/committees/paff-committees/animal-nutrition_en

Details can be found in the agenda and meeting minutes.

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CURRENT EU - LEGISLATION ON SOME UNDESIRABLE SUBSTANCES IN FEEDINGSTUFFS AND FEEDS (DIRECTIVE 2002/32)

As	2-40	mg/kg
Pb	5-40	mg/kg
F	30-2000	mg/kg
Hg	0,1-0,5	mg/kg
Cd	0,5-10	mg/kg
Aflatoxine B1	0,005-0,02	mg/kg
DON	0,9-12	mg/kg
ZEA	0,1-3	mg/kg
Ochratoxin	0,05-0,25	mg/kg
Fumonisin B1+B2	5-60	mg/kg
Dioxins (PCDD/F-TEQ)	0,75-5	ng/kg
Dioxins + PCBs	1-20	ng/kg
Organochlorines	0,005-2,0	ng/kg



Highest dioxin values for fish oil and fish meal
Lowest value for minerals

Permitted maximum levels depending on feedstuff (feedingstuffs, complete feeds, complementary feed, feed additive, premixture) and on target animal species/category!

(1) Depending on animal species

EXAMPLE

1. Arsenic ⁽¹⁾

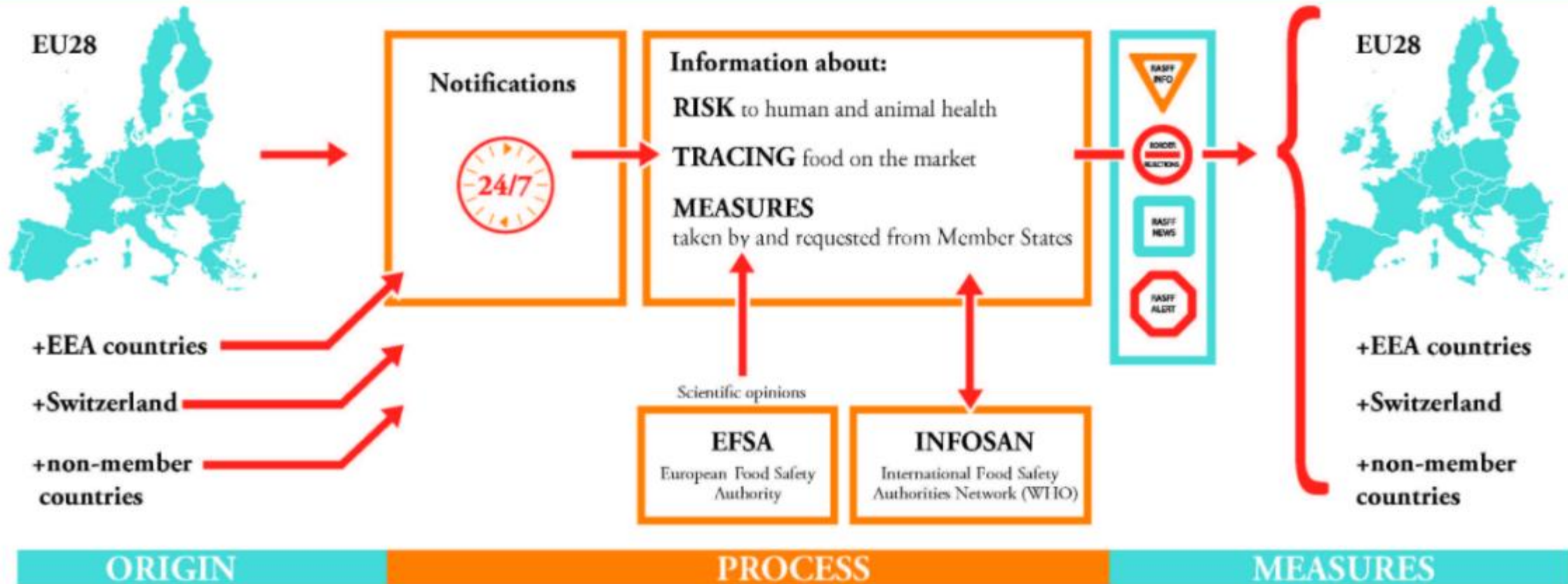
Feed materials	2
with the exception of:	
— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp;	4
— palm kernel expeller;	4 ⁽²⁾
— peat; leonardite;	5 ⁽²⁾
— phosphates, calcareous marine algae;	10
— calcium carbonate; calcium and magnesium carbonate ⁽¹⁰⁾ ; calcareous marine shells;	15
— magnesium oxide; magnesium carbonate;	20
— fish, other aquatic animals and products derived thereof;	25 ⁽²⁾
— seaweed meal and feed materials derived from seaweed.	40 ⁽²⁾
Iron particles used as tracer.	50
Feed additives belonging to the functional group of compounds of trace elements	30
with the exception of:	
— cupric sulphate pentahydrate; cupric carbonate; dicopper chloride trihydroxide; ferrous carbonate; dimanganese chloride trihydroxide	50
— zinc oxide; manganous oxide; cupric oxide.	100

RASFF - Rapid Alert System for Food and Feed

- provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed

Classification	Date of case	Reference	Notifying country	Subject	Product Category	Type	Risk decision	
information for follow-up	22/01/2021	2021.0339	Lithuania	too high content of vitamin D3 (3500 IU), cobalt (II) sulfate (0.5 mg) unauthorised and unauthorised feed additives E 324 - ethoxyquin (6.4 mg) and E 312 - dodecyl gallate in complete feed for laying hens from Latvia	feed materials	feed	undecided	Details
information for follow-up	22/01/2021	2021.0340	Belgium	mercury (2.894 mg/kg - ppm) in yeast from Brazil	feed materials	feed	undecided	Details

How does RASFF work



[Notifications list](#)
[New search](#)
[Export to XML](#)
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Notification details - 2021.0340

mercury (2.894 mg/kg - ppm) in yeast from Brazil

Reference:	2021.0340	Notification type:	feed - information for follow-up - company's own check
Notification date:	22/01/2021	Action taken:	informing recipient(s)
Last update:	22/01/2021	Distribution status:	distribution to other member countries
Notification from:	Belgium (BE)	Product:	yeast
Classification	information for follow-up	Product category:	feed materials
Risk decision	undecided	Published in RASFF Consumers' Portal	has never been published

Hazards

Substance / Hazard	Category	Analytical result	Units	Sampling date
mercury	metals	2.894	mg/kg - ppm	12/11/2020

Countries/organisations concerned (D = distribution, O = origin)

[Australia \(D\)](#)
[Belgium \(D\)](#)
[Brazil \(O\)](#)
[China \(D\)](#)
[France \(D\)](#)
[Italy \(D\)](#)
[Singapore \(D\)](#)
[Taiwan \(D\)](#)

Exercise 4: RASFF search

- Try to find a specific RASFF notification.
- Link:

<https://webgate.ec.europa.eu/rasff-window/screen/search>

Content Part 1

- FRANA & industry associations
- Structure of animal feed
- General information on the EU
- EU Feed legislation
 - Feed additives
 - Feed materials
 - Veterinary medicines
- EU Registration procedure of feed additives
- Impurities
- Quality standards

FEED HYGIENE LEGISLATION AND OTHER CONTROL OR MANAGEMENT SYSTEMS, PRIVATE LABELS AND TRADEMARKS (HACCP / EFMC / FAMI-QS / GMP/ ®/™)

8.2.2005

EN

Official Journal of the European Union

L 35/1

I

(Acts whose publication is obligatory)

REGULATION (EC) No 1831/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 12 January 2005
laying down requirements for feed hygiene

FEDERATION EUROPEENNE DES FABRICANTS D'ALIMENTS COMPOSES
EUROPÄISCHER VERBAND DER MISCHFUTTERINDUSTRIE
EUROPEAN FEED MANUFACTURERS FEDERATION



EUROPEAN FEED MANUFACTURERS GUIDE (EFMC)

A COMMUNITY GUIDE TO GOOD PRACTICE FOR THE
EU INDUSTRIAL COMPOUND FEED AND
PREMIXTURES MANUFACTURING SECTOR FOR FOOD
PRODUCING ANIMALS

Version 1.0

January 2007

FAMIqs
European Feed Additives and Premixtures Quality System

FAMI-QS Code of Practice

European Code of Practice for
Feed Additive and Premixture Operators

FRANA

QUALITY

- FCA (Feed Chain Alliance)

- Quality and safety system throughout the whole feed chain
- Belgian platform: www.ovocom.be



- FAMI QS

- Quality and safety system for specialty feed ingredients (feed additives and functional feed ingredients) and mixtures
- Worldwide implemented
- www.famiqs.com



INTERESTING EU WEBSITES

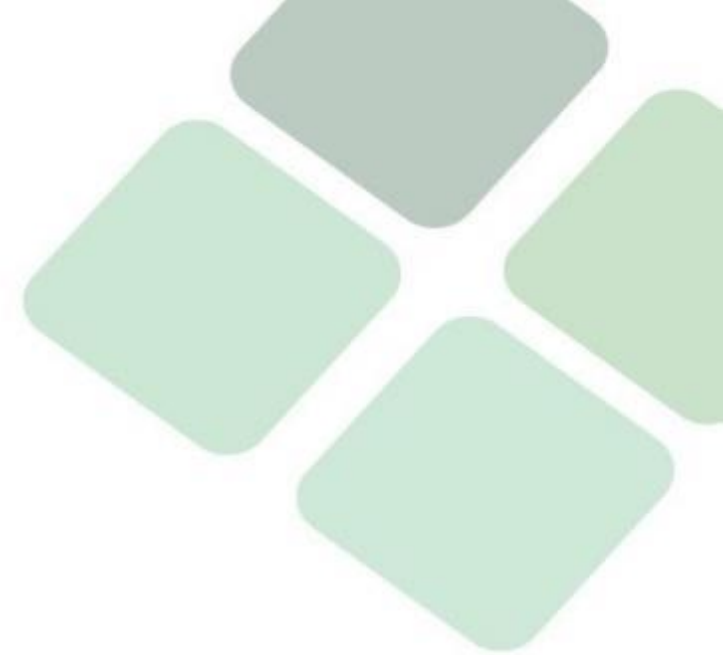
- EFSA: meetings, opinions, guidance documents,...
www.efsa.europa.eu
- EU-legislation: Official Journal of the European Union (including authorisations)
<https://eur-lex.europa.eu/>
- EU- DG SANTE:
https://ec.europa.eu/info/departments/health-and-food-safety_en
- EU-Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) - Section Animal Nutrition: meetings (agenda + minutes)
https://ec.europa.eu/food/animals/committees/sc_animal-nutrition_en
- EU-Parliament:
<http://europarl.europa.eu>
- EU-Council:
<http://consilium.europa.eu>

Content Part 2: feed additives and their use/application



CATEGORIES OF ADDITIVES

- I. Technological additives
- II. Sensorial additives
- III. Nutritional additives
- IV. Zootechnical additives
- V. Coccidiostatics and histomonostatical additives



CATEGORIES OF ADDITIVES

- I. **Technological additives**
- II. Sensorial additives
- III. Nutritional additives
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- V. Coccidiostatics and histomonostatical additives

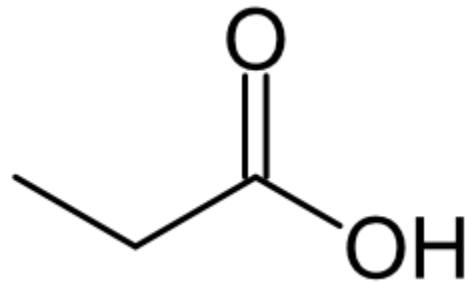
I. TECHNOLOGICAL ADDITIVES

Additives added to the feed for technological reasons

- a. Preservatives
- b. Antioxidants
- c. Emulsifiers
- d. Stabilisers
- e. Thickeners
- f. Gelling agents
- g. Binders
- h. Substances for control of radionucleide contamination
- i. Anticaking agents
- j. Acidity regulators
- k. Enzyme and silage additives
- l. Denaturing agents
- m. Substances for the reduction of the contamination of feed by mycotoxins
- n. Hygiene condition enhancers

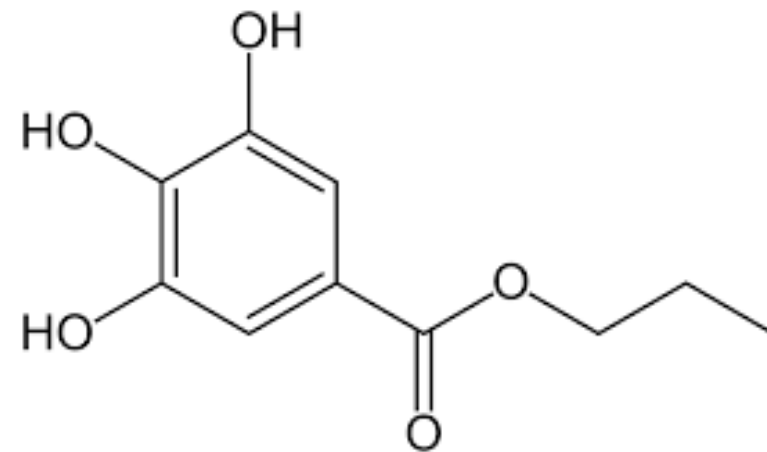
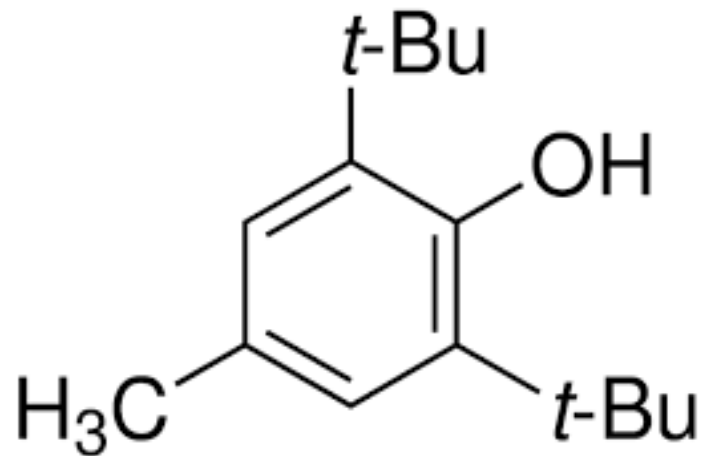
I.A. PRESERVATIVES

- Preservation of feed and premixes
- Mainly organic acids like Fumaric acid, formic acid, propionic acid, lactic acid
- However, they also have a positive effect on animal health and performance and that is (in many cases) why they are added to the feed.
 - If a company wants to claim a positive effect on animal health, it needs to get an authorisation as a zootechnical additive



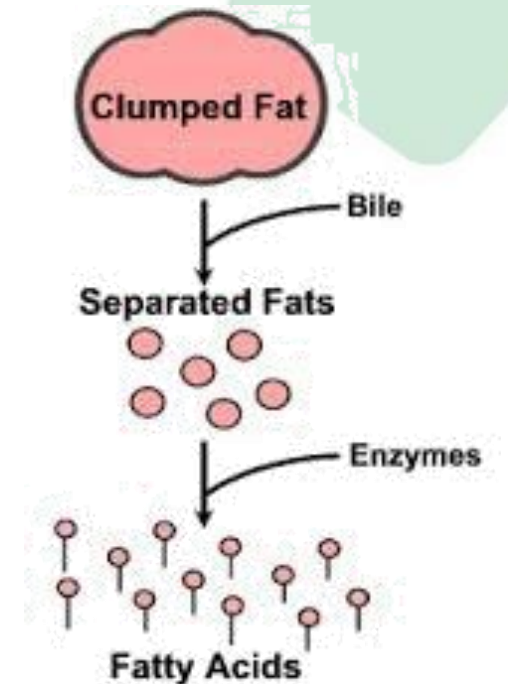
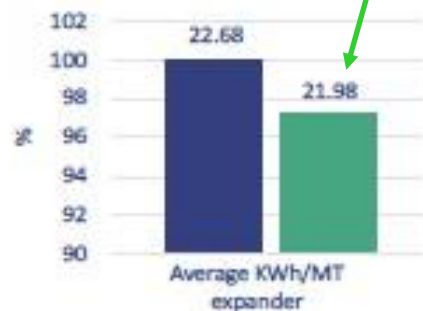
I.B. ANTIOXIDANTS

- Reduce the occurrence and impact of oxidative processes
- e.g. BHT, BHA, Propyl gallate
- But also ascorbic acid and salts (Vit. C), tocopherols (Vit. E)....



I.C. EMULSIFIERS

- Improvement of solubilisation of fat soluble feedstuffs into water or visa versa
- E.g. Lecithin, sorbitol monolaurate
- Can also reduce energy need for pelleting and extrusion



I.D. STABILISERS

- Mostly together in one category with emulsifiers
- E.g. Agar in food
- But also sodium and potassium alginate (petfood)

I.E. THICKENERS

To increase the viscosity of certain compounds
e.g. alginates

I.F. GELLING AGENTS

- Substances which give a feedingstuff texture through the formation of a gel
- E.g. Cassia gum but also alginates....

I.G. BINDERS / ANTI CAKING AGENTS

- Substances which increase the tendency of particles of feeding stuffs to adhere
- E.g. Clinoptilolite, Bentonite, sodium alginate, potassium alginate

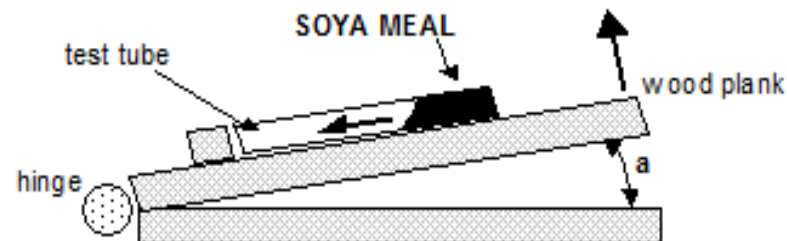
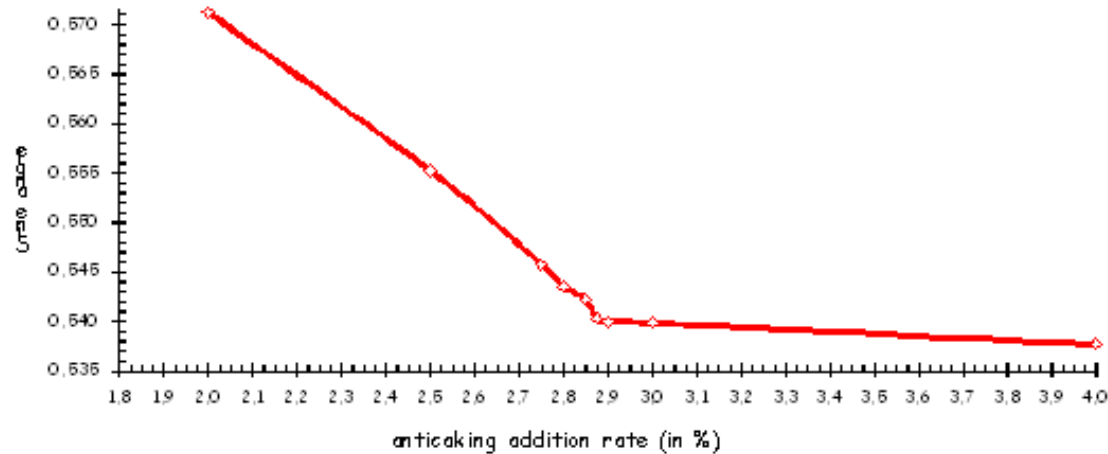
I.H. SUBSTANCES FOR CONTROL OF RADIONUCLIDE CONTAMINATION

Substances that suppress absorption of radionuclides or promote their excretion

e.g. bentonite and ferric ammonium hexacyanoferrate

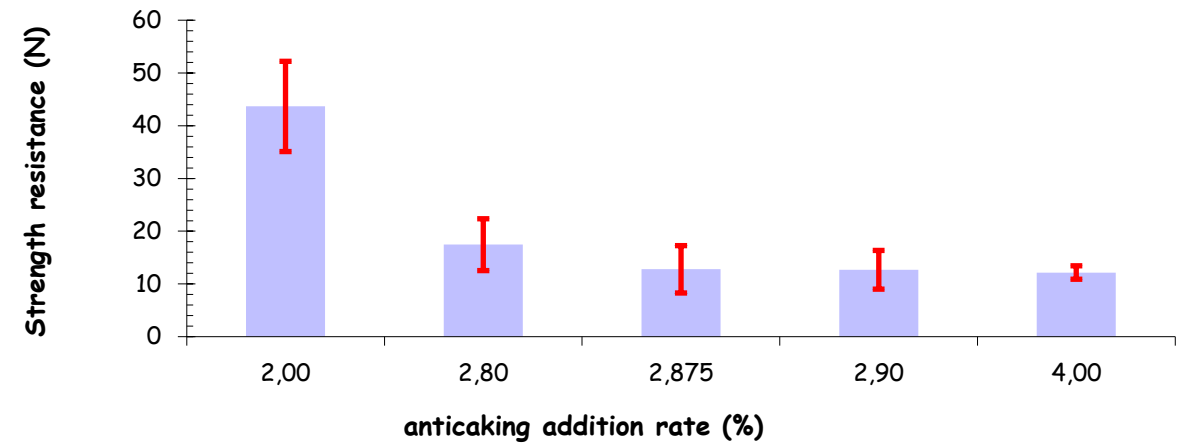
I.I. ANTICAKING AGENTS

Effect on flowability of a product (e.g. Clinoptilolite, Bentonite, Fe sodium tartrates)



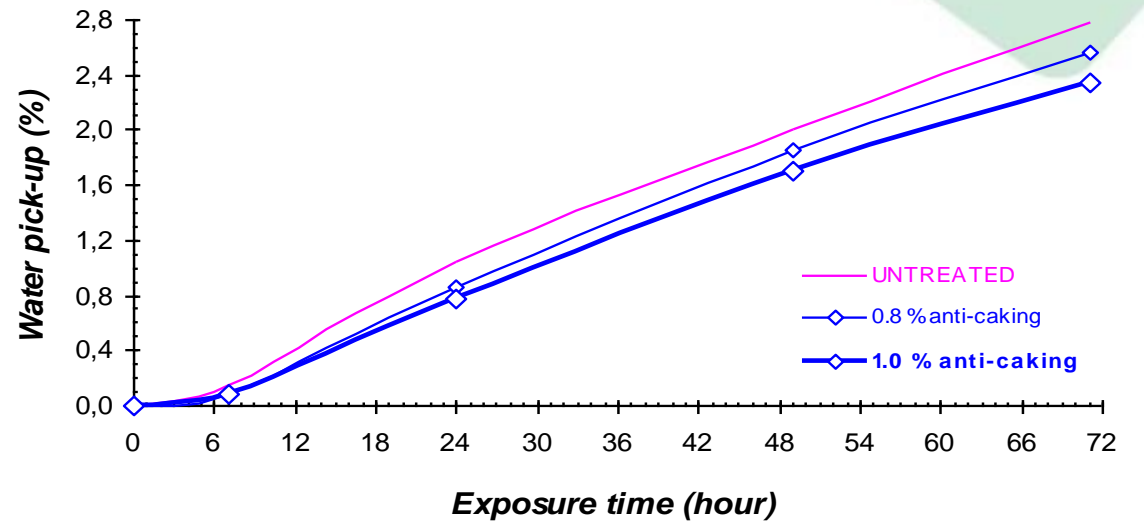
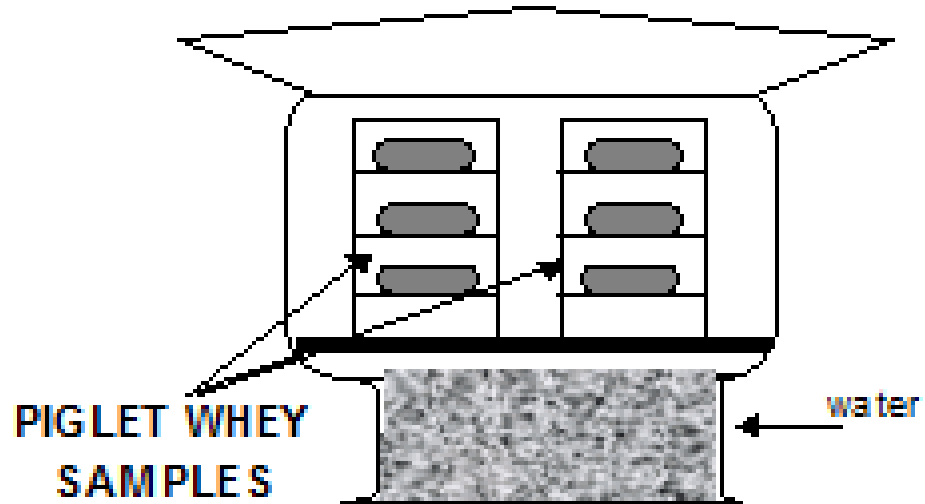
I.I. ANTICAKING AGENTS

Effect on reducing of caking



I.I. ANTICAKING AGENTS

Effect on hygroscopicity



I.J. ACIDITY REGULATORS

- Mainly acids regulating the pH of feeds
- E.g sodium bisulphite, some acids/hydroxide, phosphates
- Mainly used in petfood

I.K. SILAGE ADDITIVES

- To control the fermentation of mainly corn and grass silages but also CCM (corn cob mix) or ensiled whole grains
- Can be organic (acids) based, microbial based, enzyme based or combined



I.L. DENATURANTS

- Substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials
- No products on the list

I.M. SUBSTANCES FOR THE REDUCTION OF THE CONTAMINATION OF FEED BY MYCOTOXINES

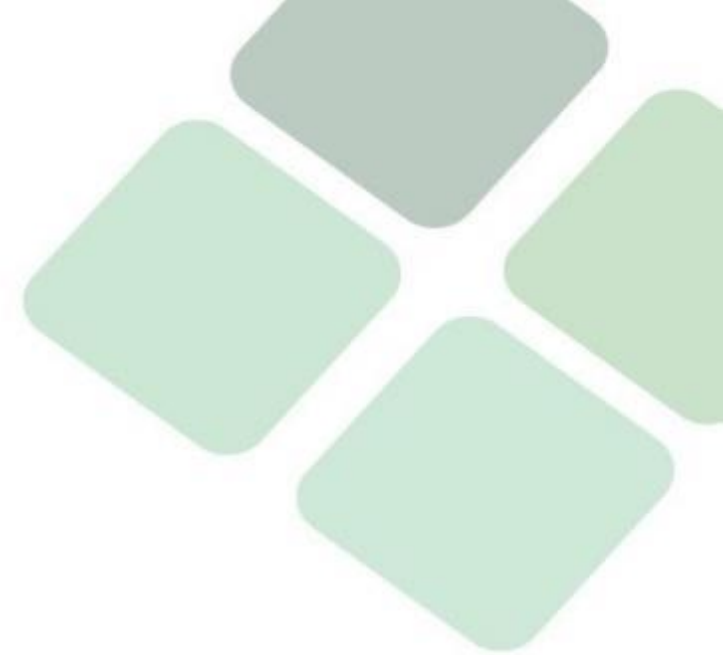
- To reduce the effect of toxins formed by moulds in the field stage or when not correctly stored (too hot, too wet...)
- Can be based on absorption (clay, yeast cell wall) or degradation (enzyme)
- When max levels for mycotoxins exist, these levels have to be respected: these products aim to reduce the effect of contamination which should be always below the maximal levels

I.N. HYGIENE CONDITION ENHANCERS

- Substances or, when applicable, microorganisms which favorably affect the hygienic characteristics of feed by reducing a specific microbiological contamination
- For the reduction of (pathogenic) microorganisms e.g. Salmonella
- Examples:
 - * formic acid
 - * sodium formate
 - * *Pediococcus acidilactici*

CATEGORIES OF ADDITIVES

- I. Technological additives
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- III. Nutritional additives
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II. Sensorial additives

Substances by which the organoleptic properties of a feed or the visual characteristics of animal derived food products are changed and/or ameliorated.

a. Colorants

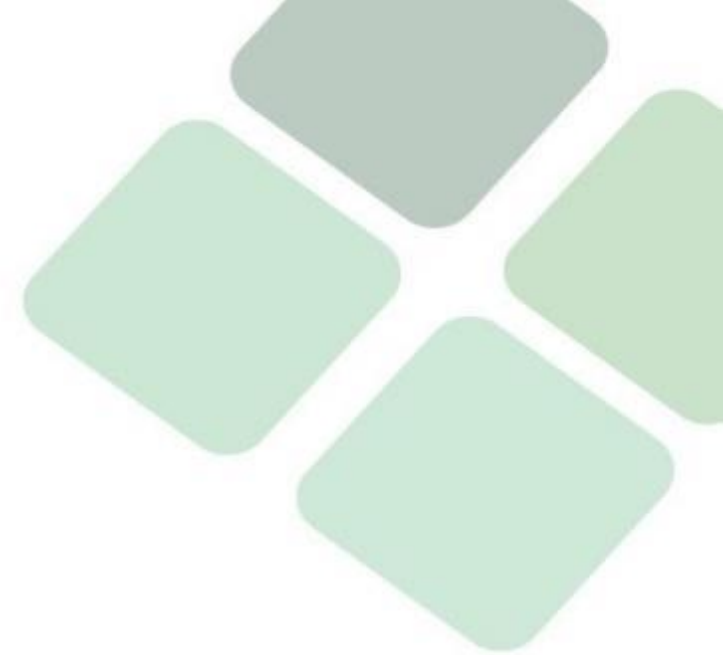
- Substances that add or restore colour of feedingstuff
- Substances which, when fed to animals, add colour to food of animal origin, e.g. astaxanthin, canthaxanthin, caratenoids
- Substances which favourably affect the colour of ornamental fish or birds

b. Sensory additives: flavouring compounds

- A lot of them from “prehistory” – bit by bit sorted out.

CATEGORIES OF ADDITIVES

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III. NUTRITIONAL ADDITIVES

- A. Vitamins, provitamins and chemical well defined substances having similar effect
- B. Compounds of trace elements
- C. Amino acids, their salts and the analogues
- D. Ureum and its derivatives

III.A. VITAMINS, PROVITAMINS AND CHEMICAL WELL DEFINED SUBSTANCES HAVING SIMILAR EFFECT

Supplementation of the feed with vitamins to cover the requirements as raw materials have limit content



III.A. VITAMINS, PROVITAMINS AND CHEMICAL WELL DEFINED SUBSTANCES HAVING SIMILAR EFFECT

- What are levels in feed materials?
 - Variation in raw materials
- How much should we add?
 - Requirement – basal level in compound feed from feed materials
- Limitations by law?
 - Max levels for trace elements, some vitamins (per species)
 - Defined in EU legislation (e.g. 767/2009)
- In pure form or via premix?
 - Depending on practical situation in factory (e.g. dosing system, storage capacity) larger volumes can be dosed directly, small volume mainly via premix

III.A. VITAMINS, PROVITAMINS AND CHEMICAL WELL DEFINED SUBSTANCES HAVING SIMILAR EFFECT

- Requirements of the animal?
 - Depending on age, production stage, etc
 - Several research institutes publish requirements:
 - CVB (NL)
 - INRA (FR)
 - NRC (USA)
 - Others, private companies, etc

III.A. VITAMINS, PROVITAMINS AND CHEMICAL WELL DEFINED SUBSTANCES HAVING SIMILAR EFFECT

SWINE¹⁾

Category/Phase	Duration	Vit. A	Vit. D ₃ ²⁾	25(OH)D ₃ (Hy+D) ³⁾	Vit. E ⁴⁾	Vit. K ₃ (Menadiolone)	Vit. B ₁	Vit. B ₂	Vit. B ₆	Vit. B ₁₂ ⁵⁾	Niacin	D-Panto themic acid	Folic acid	Biotin	Vit. C ⁶⁾	Choline	β-Carotene
		IU	IU	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg
Fattening pigs																	
Pre-starters	< 5 kg	10000-20000	1800-2000	0.05	100-150 ⁸⁾	8-10	3.5-5.5	10-15	6-8	0.05-0.07	60-80	30-50	1.5-3	0.2-0.4	100-200	500-800	
Starters	5-30 kg	10000-15000	1800-2000	0.05	100-150	5-6	3-5	10-15	6-8	0.04-0.06	35-55	25-45	1.5-2.5	0.2-0.4	100-200	250-400	
Growers	30-70 kg	7000-10000	1500-2000	0.05	80-100	2-4	2-3	7-10	2.5-4.5	0.03-0.05	20-40	25-45	1-1.5	0.15-0.3		150-300	
Finishers	70 kg to market	5000-8000	1000-1500	0.05	80-100 ⁸⁾	2-4	1-2	6-10	2-3.5	0.03-0.05	20-40	25-45	0.5-1	0.1-0.2		100-200	
Breeders																	
Replacement gilts		10000-12500	1800-2000	0.05	80-100	1.5-3	1-2	6-10	3.5-5.5	0.03-0.05	20-30	15-30	3.5-5.5	0.3-0.5	200-300	250-500	
Sows		10000-15000	1500-2000	0.05	100-150 ⁸⁾	4.5-5	2-2.5	6-10	3.5-5.5	0.03-0.05	25-45	30-55	3.5-5.5	0.5-0.8	200-300	500-800	300 ⁹⁾
Boars		10000-15000	1500-2000	0.05	100-150	4.5-5	1-2	6-10	3.5-5.5	0.03-0.05	25-45	20-30	3.5-5.5	0.5-0.8	200-500	500-800	



¹⁾ Added per kg air-dry feed. ²⁾ Local legal limits of Vitamin D₃ activity higher than 3% then add 5 mg/kg feed for each 1% dietary fat. ³⁾ For feed. ⁴⁾ For optimum meat quality: additional 150 mg/kg feed. ⁵⁾ For lactation total 250 mg/kg feed. ⁶⁾ Use upper level when cobalt is supplied. ⁷⁾ Recommended in stress condition and to enhance reproductive performance (ascorbic acid monophosphate) for reducing losses during processing. ⁸⁾ per day immediately after weaning until confirmed conception.

Recommendations

HORSES & OTHERS

Category/Phase	Vit. A	Vit. D ₃	Vit. E	Vit. K ₃ (Menadiolone)	Vit. B ₁	Vit. B ₂	Vit. B ₆	Vit. B ₁₂	Niacin	D-Panto themic acid	Folic acid	Biotin	Vit. C ¹⁾	Choline	β-Carotene
	IU	IU	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg	mg
Foals, 1st year²⁾	25000-30000	4500-5500	250-500	8-12	20-25	20-30	15-20	0.15-0.3	25-50	20-30	15-20	2-3	500-750	300-400	
Leisure horses³⁾	35000-45000	3500-4500	500-1000	8-12	40-55	30-40	25-35	0.35-0.95	55-85	45-65	25-35	15-20		600-900	
Race horses⁴⁾	65000-85000	6500-8500	1000-2000	11-22	70-110	70-85	40-65	0.55-0.95	110-200	50-90	45-65	15-20	1000-2000	1000-1400	
Mares & stallions⁵⁾	65000-85000	6500-8500	1000-2000	11-22	70-110	70-85	40-65	0.55-0.95	110-200	50-80	45-65	15-20	1000-2000	1000-1400	400-600 ⁶⁾
Rabbits⁷⁾	8000-12000	800-1200	40-60	1-2	1-2	3-5	2-3	0.01-0.02	40-60	10-15	0.2-0.5	0.1-0.2 ⁸⁾	150-250	600-900	10-20
Nink & Innes⁹⁾	10000-15000	1500-2000	100-200 ⁸⁾	1-2	20-50 ⁸⁾	10-20	10-20	0.03-0.06	20-40	8-20	0.6-1	0.3-0.8	100-200		

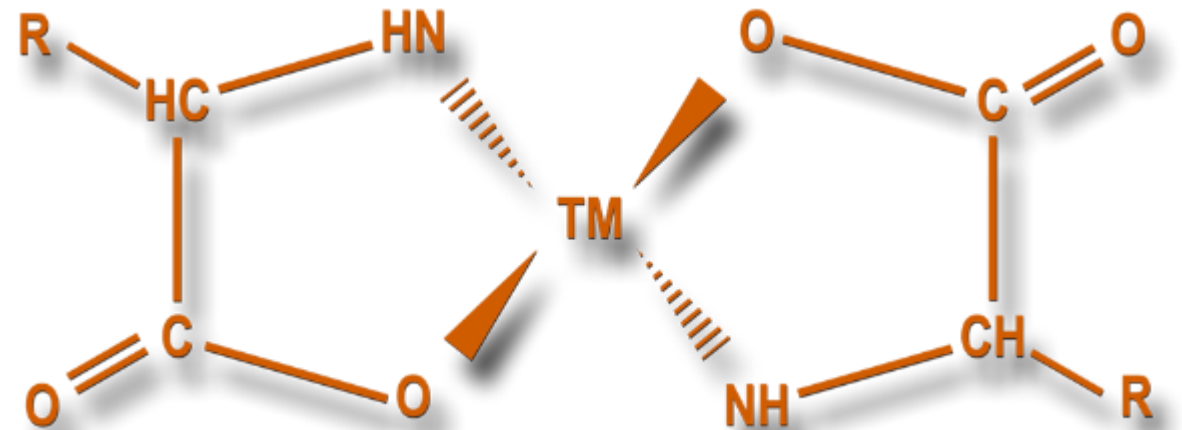
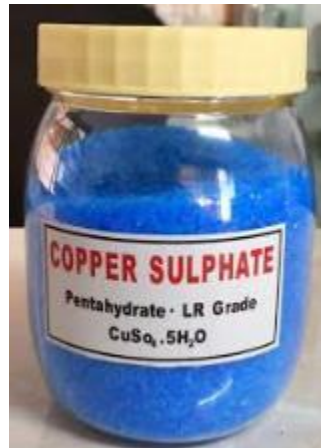
¹⁾ Added per animal per day, based on average weight of 250 kg. ²⁾ Added per animal per day, based on average weight of 550 kg. ³⁾ Added per kg air-dry feed. ⁴⁾ Dietary fat higher than 3%: additional 5 mg/kg feed for each 1% dietary fat. ⁵⁾ When feeding raw fish: additional 50 mg/kg feed. ⁶⁾ For fur production rabbits: 0.6 mg/kg feed. ⁷⁾ Recommended in stress condition and to enhance reproductive performance in brooders. ⁸⁾ Use ROVIMAX[®] STAY-ON[®] (ascorbic acid monophosphate) for reducing losses during processing. ⁹⁾ From 4 weeks before until 10 weeks after parturition.



OPTIMUM VITAMIN NUTRITION

III.B. TRACE ELEMENTS

- Inorganic versus organic
- Inorganic: e.g. sulphates, oxides, chlorides and hydroxychlorides of Fe, Mn, Zn, Cu,....
- Organic: chelates (proteinate, glycinate,...)



III.B. TRACE ELEMENTS inorganics and organics

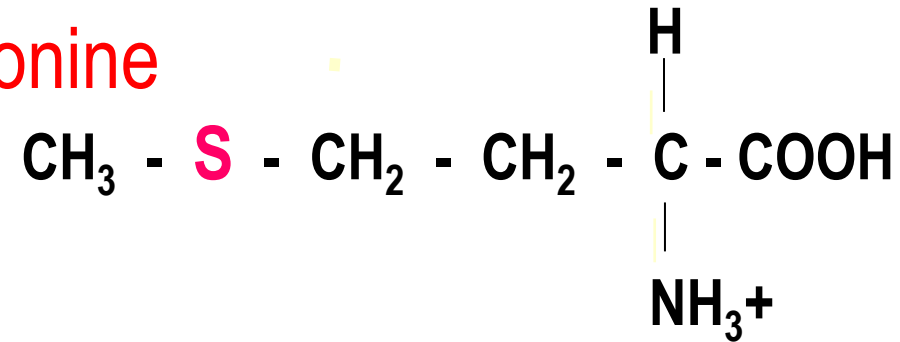
	Inorganic	Organic	Hydroxy
Developed	1950's	1970's	1990's
Bond	Ionic (weak)	Covalent (strong)	Covalent (strong)
Ligand	Non-carbon	Carbon	Hydroxy (non-carbon)
Examples	Oxides, sulphates	Chelates	Hydroxy TM

Special cases where mineral is built in completely in the molecule

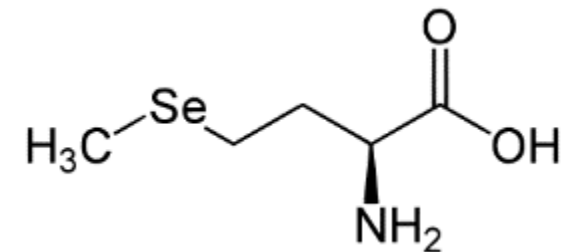
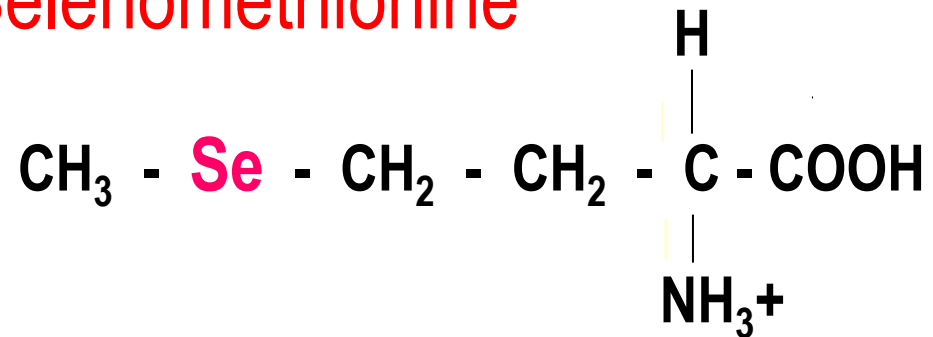
- Ca iodate
- Sodium selenite
- Se yeast containing selenomethionine and preparation of selenomethionine

III.B. TRACE ELEMENTS inorganics and organics

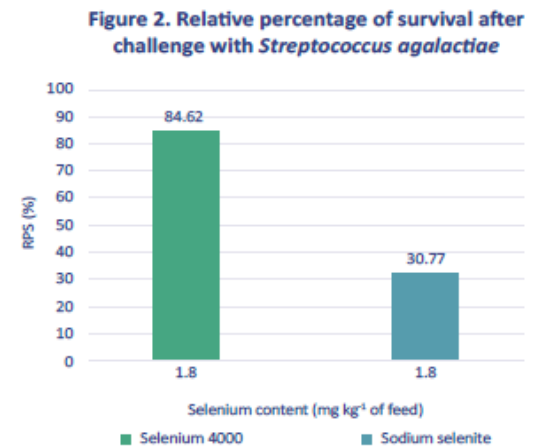
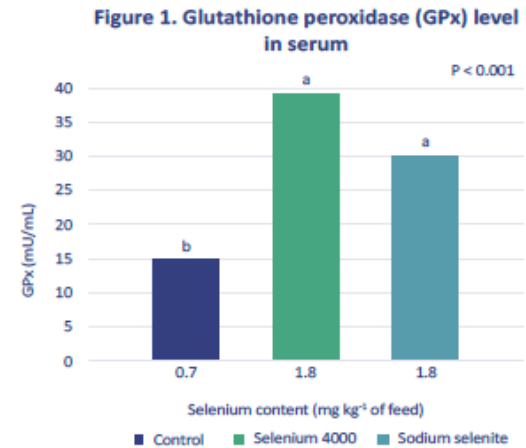
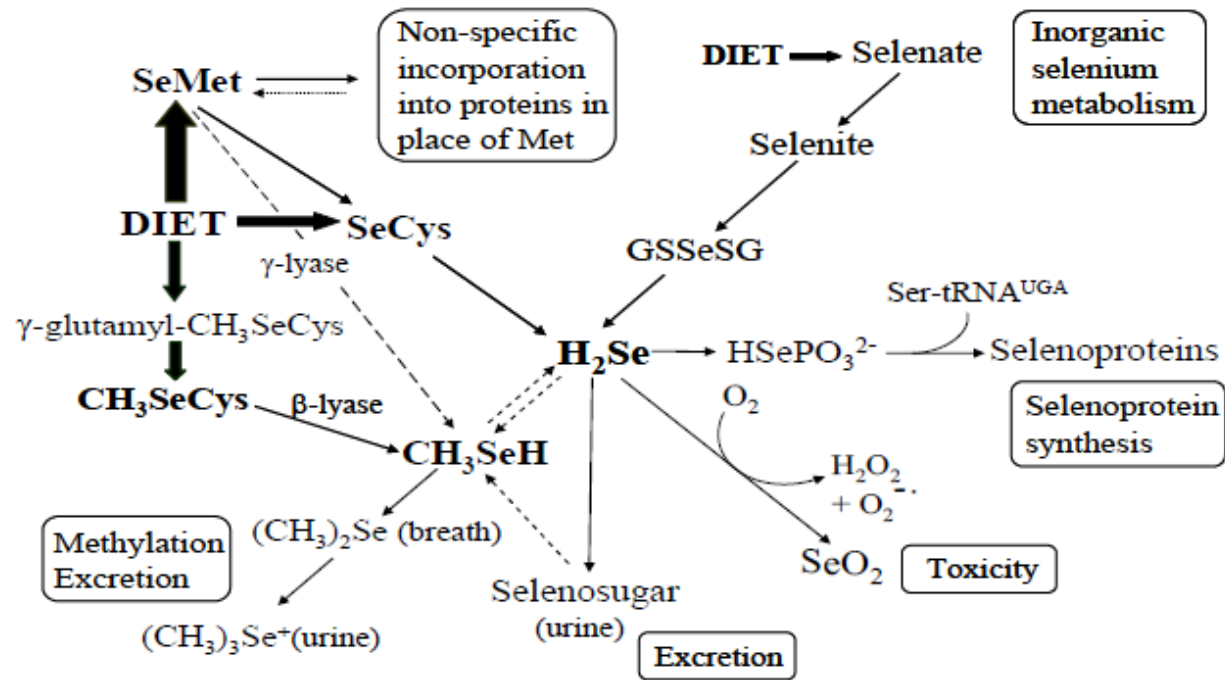
Methionine



Selenomethionine



III.B. TRACE ELEMENTS Selenomethionine



III.C. AMINO ACIDS, THE SALTS AND ANALOGUES OF THEM

- Animals need amino acids as building blocks for protein
- In total 20 amino acids are needed
- Essential: can not be synthesised by animal, should be added via feed
- Non essential: can be synthesised by the animal itself and are not needed via the diets, provided there is enough N

Essential	Conditionally	Non Essential
Lys		Gly
Thr		Ser
Met	Cys	Pro
Trp		Asp
Val		Asn
Ile		Ala
Leu		Glu
His		Gln
Phe	Tyr	Arg

III.C. AMINO ACIDS, THE SALTS AND ANALOGUES OF THEM

- Animal need a certain amino acid (AA) profile
- Expressed as ratio to the first limiting (Lys) > Ideal protein concept

In piglets:

100% Lys

65% Thr/Lys

60% Met+Cys/Lys

22% Trp/Lys

70% Val/Lys

(INRA, 2013)

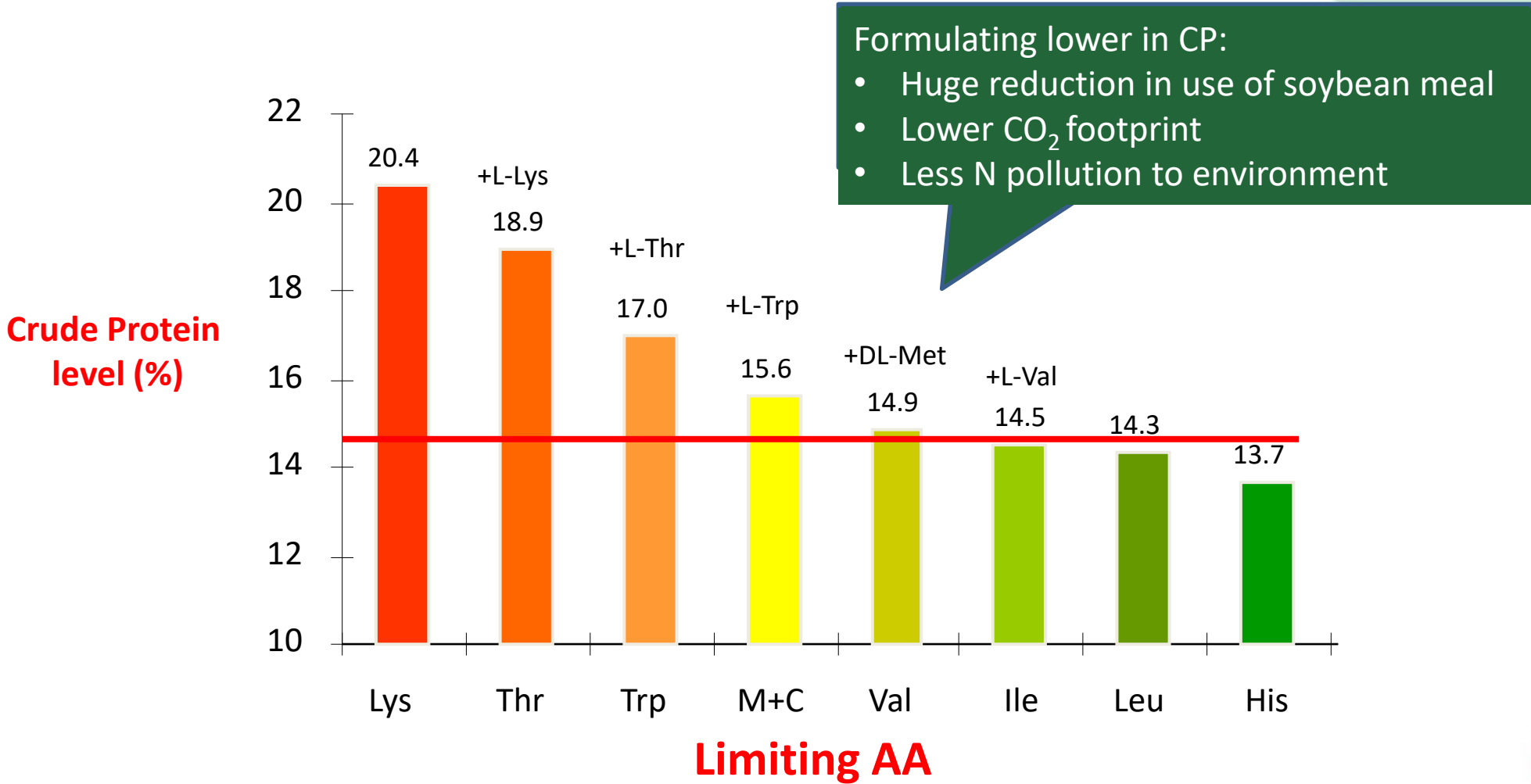


Liebig's barrel

III.C. AMINO ACIDS, THE SALTS AND ANALOGUES OF THEM

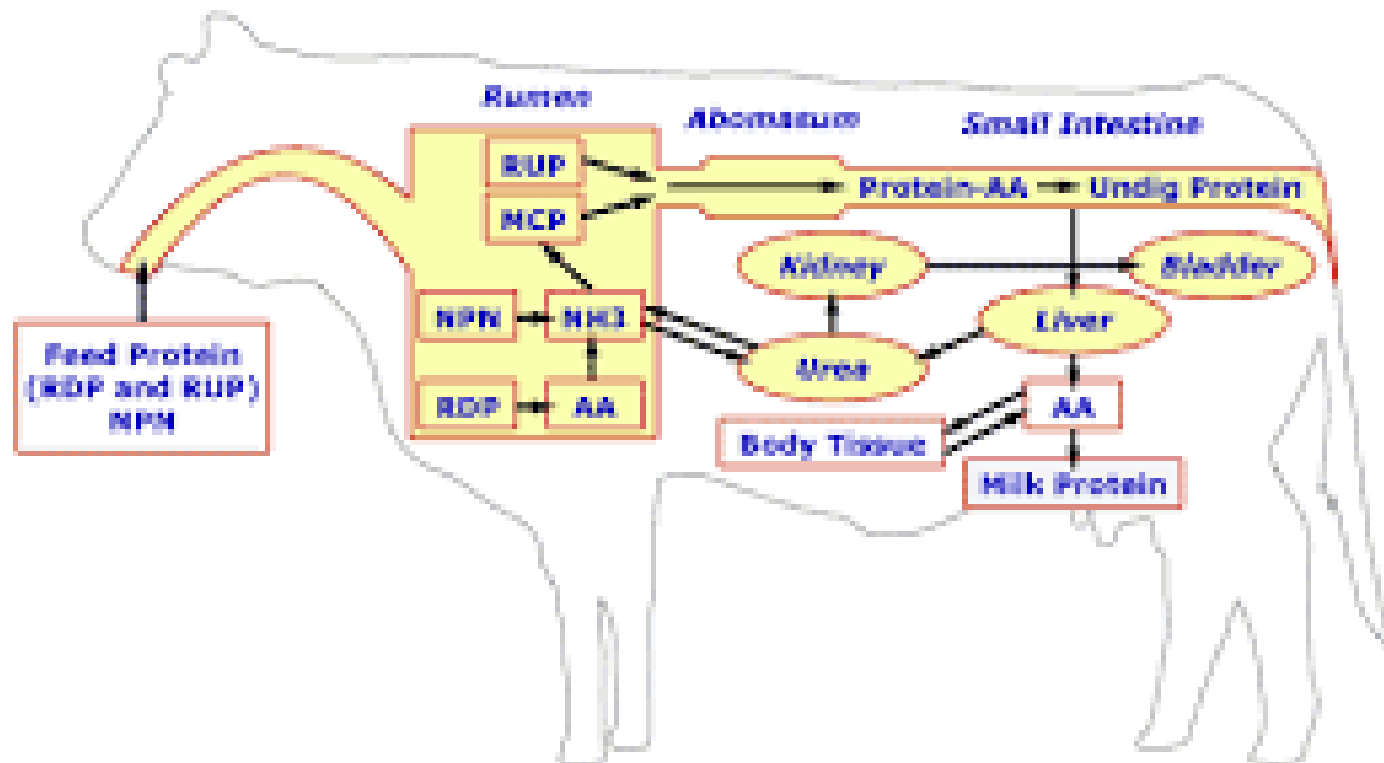
- Example with a pig grower diet (0.85% SID Lys, 9.5 MJ/kg NE), based on Wheat, Soybean and rapeseed meal
- In a formula without free AA, all AA should come from protein feedstuffs (first red bar)
- If you add the first limiting AA (in this case lysine), the protein can drop till it reaches the requirement of the next limiting (threonine), etc.
- The more AA are added, the more precise the ideal AA profile can be covered and the lower the CP (crude protein) level

III.C. AMINO ACIDS, THE SALTS AND ANALOGUES OF THEM



III.D. UREUM and its derivatives

Ruminant application: ureum-N is transformed into microbial N (so low value N transformation into amino acids (protein) with high nutritional value



CATEGORIES OF ADDITIVES

- I. Technological additives
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- IV. Zootechnical additives**
- V. Coccidiostatics and histomonostatical additives

IV. ZOOTECHNICAL ADDITIVES

- a) Digestibility enhancers
- b) Gut flora stabilisators
 - Micro-organisms (probiotics) – bacterial or yeast
 - Other, chemical defined substances which, by addition to the animal, have a positive effect on the gut flora
- c) Substances with a positive effect on the environment:
 - One product: 3-nitrooxypropanol (3-NOP): reduction of methane by dairy cows and heifers
- d) Other zootechnical additives
 - a) Essential oils
 - b) Organic acid (mixtures)

IV.A. DIGESTIBILITY ENHANCERS - ENZYMES

Enzymes are added to diets to improve digestibility of feed materials and improve availability of nutrients.

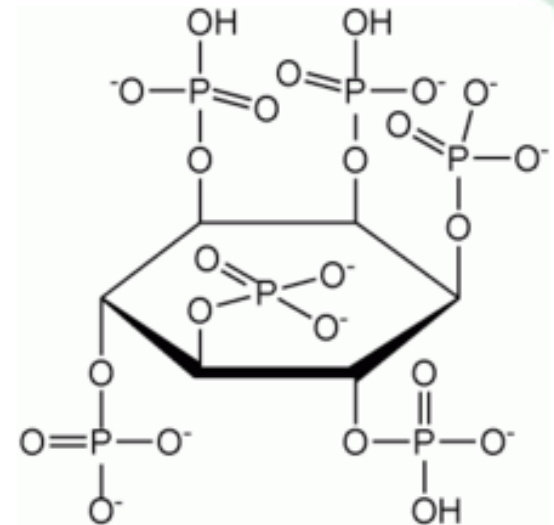
- Cereals such as wheat, rye and barley, for example, contain long, complex carbohydrate molecules known as non-starch polysaccharides (NSPs), for which animals such as pigs and poultry do not produce the necessary digestive enzymes
- E.g. cellulase, β -glucanase, Xylanase
- Increase efficiency, better raw material utilization, lower cost



IV.A. DIGESTIBILITY ENHANCERS - ENZYMES

Enzymes are added to diets to improve digestibility of feed materials and improve availability of nutrients.

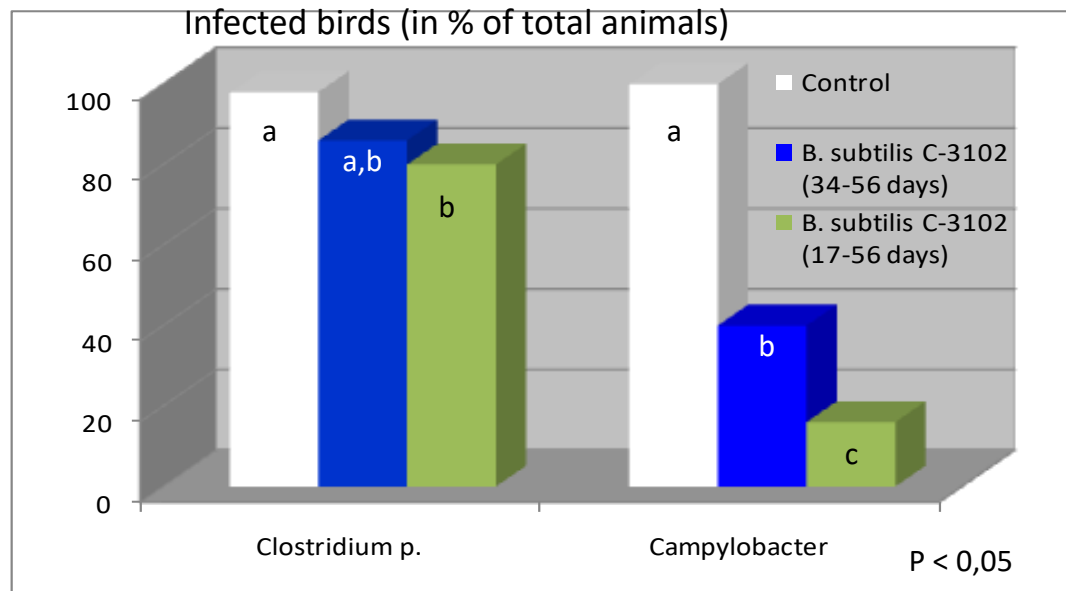
- In vegetable feedstuffs, P is bound in phytate, which is unavailable for the animal
- By adding phytase to the diet, this phytate bound P is made digestible and available for the animal
- Benefits: higher P efficiency, less pollution to the environment, better performance of animals



Phytate

IV. B. GUT FLORA STABILISERS (PROBIOTICS)

- Probiotics are added to diets to improve microbial balance and improve gut health.
- Increase number of beneficial bacteria (lactobacilli, bifido bacteria) and lower amount of pathogens



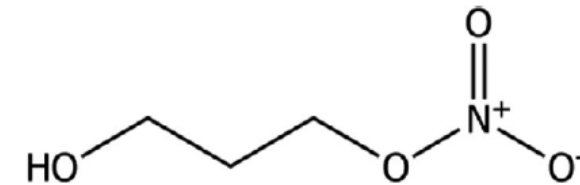
Group	Log 10 value per g faeces		
	Entero-bakterien	Clostridium perfringens	Campylo-bacter
Control	7,21	3,15	6,23
B. subtilis C-3102 (34.-56. day)	6.45***	2,94	4.20***
B. subtilis C-3102 (17.-56. day)	6.88**	2.57***	3.77***

*= P < 0.05, **= P < 0.01, ***= P < 0.001

Maruta et al. (1996)

IV.C. SUBSTANCE WITH A POSITIVE EFFECT ON THE ENVIRONMENT

- A lot of products have positive effect on the environment but are not registered as such e.g. enzymes/phytase, free amino acids, ...
- First additive in this functional group: 3-NOP as first methane inhibitor for ruminants (published in April 2022)



- **Benefits:**
higher N&P efficiency, less pollution to the environment

IV. D. OTHER ZOOTECHNICAL ADDITIVES

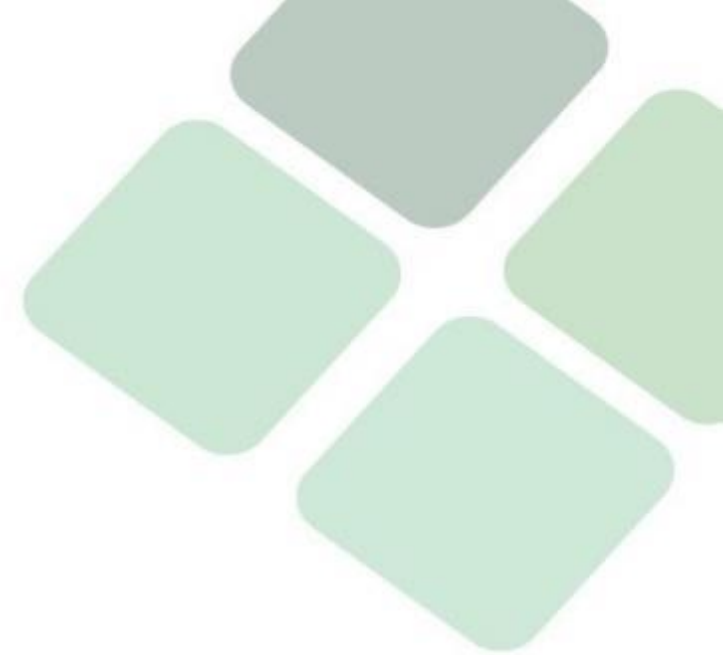
Other additives which do not fit the previous categories but of which the aim is to improved the technical performance of animals.

Examples:

- Potassium diformate (4d800), benzoic acid (4d210), => improvement of performance parameters: weight gain or feed gain ratio
- Ammonium chloride (4d7): reduction of urinary pH
- Canthaxanthin (4d161g): stabilisation of reproductive performance
- Essential oil blends

CATEGORIES OF ADDITIVES

- I. Technological additives
- II. Sensorial additives
- III. Nutritional additives
- IV. Zootechnical additives
- V. Coccidiostatics and histomonostatical additives**



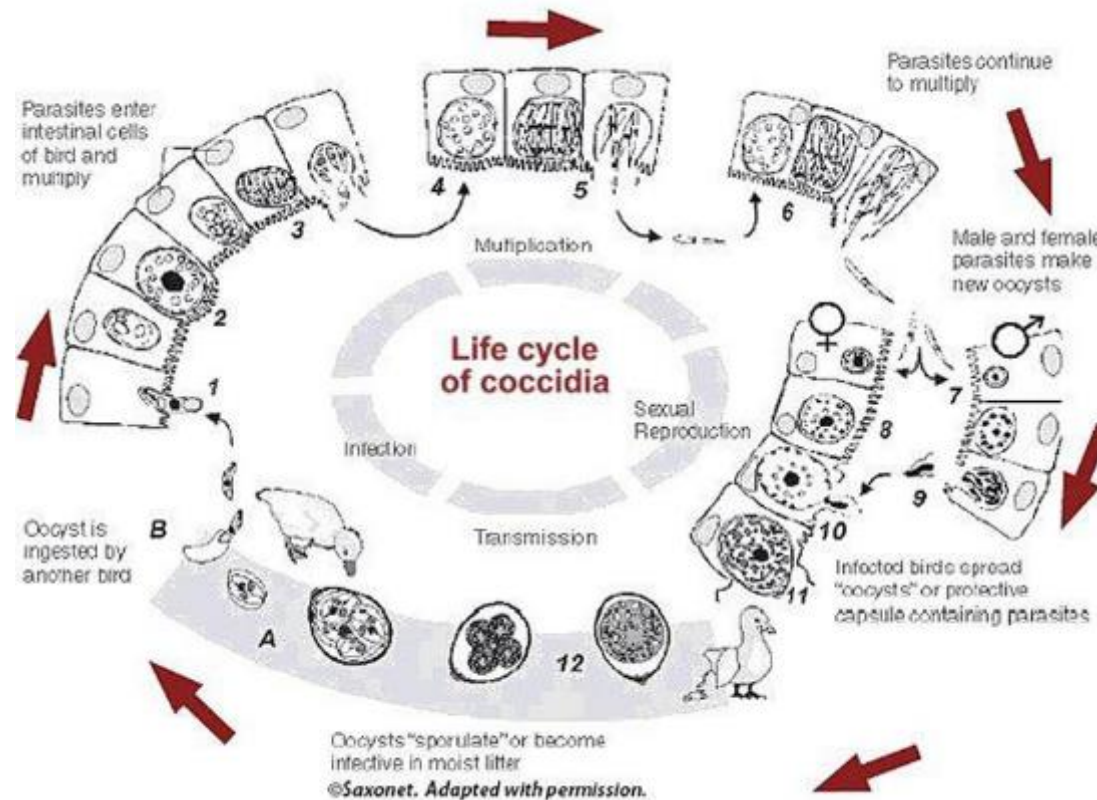
V. COCCIDIOSTATICS AND HISTOMONOSTATICAL ADDITIVES

- a. Coccidiostatics
- b. Histomonostats

With the current review of the feed legislation, it could be that they will be put under the veterinarian legislation – this is however not going to happen before end of 2025

COCCIDIOSTATS

Products added to the feed to reduce coccidiosis caused by protozoa in poultry.

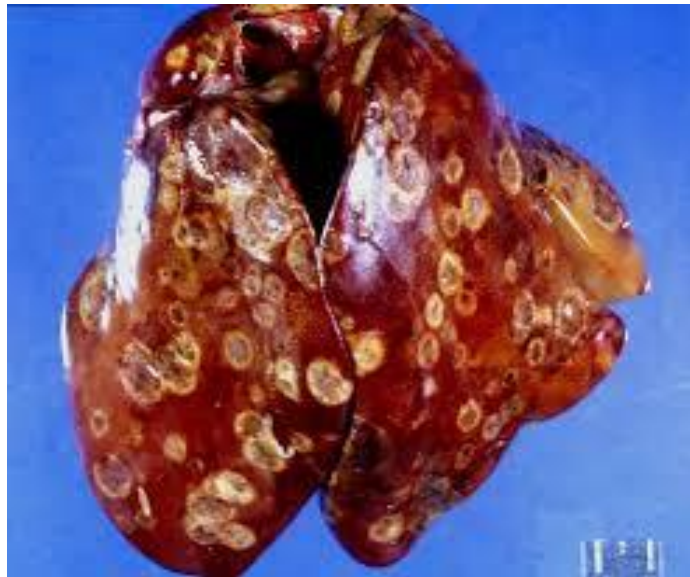


ANTICOCCIDIALS IN EU

Brand Name	Compound	Company	Dose (ppm)	WT (d)	Authorised until
Robenz	Robenidine HCl	Zoetis	36	5	25/02/2030
Deccox/Avi-Deccox	Decoquinat	Zoetis	30-40	0	20/12/2031
Avatec	Lasalocid A sodium	Zoetis	90	3	06/06/2033
Elancoban	Monensin sodium	Elanco	100-125	1	Under revision
Maxiban	Narasin/nicarbazin	Elanco	80-100	0	Under revision
Nicarbazin	Nicarbazin	Elanco (Phibro)	125	1	Under revision
Monteban	Narasin	Elanco	60-70	0	Under revision
Clinacox	Diclazuril	Elanco	1	0	Under revision
Monimax	Monensin/nicarbazin	Huvepharma	80-100	0	30/07/2030
Sacox	Salinomycin sodium	Huvepharma	50-70	0	09/11/2027
Stenorol	Halofuginone	Huvepharma	2-3	3	04/02/2034
Coxidin	Monensin sodium	Huvepharma	100-125	1	Under revision
Coxiril	Diclazuril	Huvepharma	0.8 -1.2	0	04/02/2025
Coxam	Amprolium hydrchloride	Huvepharma	125	0	14/12/2031

HISTOMONOSTATS

- Products to fight histomoniasis (blackhead disease) in poultry
- At this moment no additives registered



Sustainability and animal welfare



Sustainability and animal welfare

Through innovation, the Specialty Feed Ingredients Industry continuously and intensively contributes to limiting the environmental impact of animal farming activities.

Role of Specialty Feed Ingredients	Benefits for sustainable animal farming
Improve feed digestibility	By-products from food industry can be used as feed ingredients Reduce the excretion of nutrients (nitrogen, phosphorus and trace elements)
Improve feed efficiency	Reduce emission intensity of milk, meat and eggs Reduce the excretion of nutrients
Preserve feed	Limit the spoilage of feed, hence reducing feed losses
Decrease emission	Reduce greenhouse gas emission, such as ammonia and methane from farms.
Stimulate longevity	Less replacement of reproductive animals

(Source: Fefana)

QUESTIONS?



FRANA MEMBERS

