



Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report

on

Feed

The EGTOP adopted this technical advice at its 3rd plenary meeting
on 29 and 30 June 2011

About the setting of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. These are complex and time consuming exercises, for which a high degree of specialisation is required. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Food.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

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The reports of the Expert group present the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only, at the following webpage:

www.organic-farming.europa.eu

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All Declarations of interest of Permanent group members and Sub-groups members are available at the following webpage:

www.organic-farming.europa.eu

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EXECUTIVE SUMMARY

The expert group for technical advice on organic production (EGTOP; thereafter called ‘the Group’) in replying to point a) of the mandate concerning substances assessment concludes on the basis of the knowledge available in the group and information provided with the dossiers and by the Commission that:

- E 535 Sodium ferrocyanide anti-caking material, should be approved for use as a feed additive in salt for organic animal feed, subject to:
 - a maximum dose rate of 20 mg/kg NaCl (the maximum defined for human food) and
 - a limited time period, in order to provide a legal basis for current practice in the short term and to encourage the adoption of preferred carbonate alternatives longer term.
- E 566 Natrolite-Phonolite anti-caking material should be approved for use as a feed additive in organic animal feed, subject to the limit of 25,000 mg/kg complete animal feed specified in EC Reg. 739/2000.
- E 551a Silicic acid by precipitation anti-caking material should not be approved for use as a feed additive in organic animal feed on the basis of available information about need given the available, more natural alternatives. Further information on this issue should be provided to support the application.
- E 568 Clinoptilolite anti-caking material should be approved for use as a feed additive in organic animal feed, subject to the limit of 20,000 mg/kg complete animal feed and the livestock classes specified in EC Reg. 1810/2005.
- E 237 Sodium formate preservative should be approved for use as a feed additive in organic silage, subject to the outcome of the review of the authorisation of this product under Articles 4 and 7 of Regulation 1831/2003 currently in progress.

If approved:

- it should be considered whether formic and propionic acids should be deleted from Annex VI to Commission Regulation (EC) 889/2008;
- the same restrictions relating to weather conditions and silage quality as currently apply to formic and propionic acids under the organic regulations should apply;
- the concept of ‘difficult’ silages and/or ‘poor’ weather conditions’ that would determine eligibility to use the products should be clarified. Initial dry matter content or sugar content of the forage might be a basis for this.
- Humic acid substances are not currently authorised as a feed additive under EU regulations so they cannot be considered for use as such in organic farming. Their classification as feed material was not considered to be appropriate by the Group, which also noted their current designation as pharmacologically active substances with possible implications for animal health.

In reaching these conclusions, the Group considered that compliance with the organic regulation needs to be assessed according to several criteria which are summarised in Annex 1.

The Group in replying to point b) of the mandate concerning the template for the member states dossier with respect to animal feed materials, feed additives, certain products used in animal nutrition and processing aids, developed the document presented in Annex 2 to this report. This includes a section incorporating the criteria for assessment of consistency with the EU organic regulations. The Group considered that it would be helpful to develop some interpretative guidelines to support the dossier template.

The Group in replying to point c) of the mandate concerning technical aspects of transition to 100% organic feed requirements for non-ruminants concluded that while there are technical solutions that can be implemented in the short to medium term, there is a need for further

research on alternatives and knowledge transfer, a need to reflect on the nature and principles of organic non-ruminant production (whether semi-industrial or extensive), and a need to consider continuing with derogations for a short period limited to specific ages and types of non-ruminants and specific feedstuffs.

1 BACKGROUND

In recent years, several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/2007 concerning the possible inclusion of a number of substances in Annex V and VI to Commission Regulation (EC) No 889/2008.

In relation to feed substances, Germany launched a request concerning E 535 Sodium ferrocyanide, E 566 Natrolite-Phonolite, E 551a Silicic acid in 2007. In the same year, Austria made a request concerning E 568 Clinoptilolite. In 2009 Sweden submitted a dossier concerning E 237 Sodium formate and in 2010 Slovak Republic submitted a dossier on Humic acid substances.

In the light of the changes to organic regulations in recent years, a need has been identified to provide Member States with an improved template with a view to facilitate the elaboration of complete technical dossiers.

In addition the issue of the derogation on 100% organic ingredients for monogastric animal feeds has technical aspects that need to be considered.

The regulatory framework governing animal feed materials and additives is set out in Annex 3 to this report.

For a definition of key terms used in this report, see GLOSSARY.

2 TERMS OF REFERENCE

The EGTOP is asked, in the light of current technical/scientific data and knowledge:

- a) to assess if the use of the following substances:
 - E 535 Sodium ferrocyanide anti-caking material
 - E 566 Natrolite-Phonolite anti-caking material
 - E 551a Silicic acid anti-caking material
 - E 568 Clinoptilolite binder
 - E 237 Sodium formate preservative
 - Humic acid substances feed material

is in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and therefore if they can be authorised in organic production under the EU legislation.

In preparing its final report, the Group may also suggest amendments to the current list in Annex V and VI to Commission Regulation (EC) No 889/2008 as well as take into account possible alternatives to the substances in question. In such cases, the proposal(s) should be accompanied by a brief explanation of the reasons.

- b) to draft the template of the dossier mentioned in Art. 16(3)(b) of Council Regulation (EC) No 834/2007 in relation to feed additives and processing aids and feed materials.

- c) to examine the technical aspects of the transition to 100 % organic feed for non ruminants with a view to provide technical advice for meeting animal's nutritional requirements as stipulated in Art. 14(1)(d)(ii) of Council Regulation (EC) No 834/2007.

3 CONSIDERATIONS AND CONCLUSIONS

3.1 E 535 Sodium ferrocyanide anti-caking material

Identification of substance, terminology, synonyms

E 535 Sodium ferrocyanide is used as an anti-caking (free-flow) agent in salt (sodium chloride) in animal feed. It is sprayed on the salt in an aqueous solution at a maximum dose of 80 ppm. Sodium ferrocyanide is also known under the names yellow prussiate of soda or sodium hexacyanoferrate and is registered as E 535, EINECS No 237-081-9 and CAS No 13601-19-9.

Authorization in general agriculture or feed/food processing

Its use in animal feed as an anti-caking agent to stop the formation of lumps in salt was authorised by Commission Regulation (EC) No 256/2002 of 12 February 2002 and Commission Regulation (EC) No 1810/2005 with a maximum limit 80 mg/kg NaCl (calculated as ferrocyanide anion).

Sodium ferrocyanide (E 535) is also authorised for use throughout the European Union as an anti-caking agent in salt and salt substitutes for human consumption, pursuant to Directive 95/2/EC with a limit of 20 mg/kg NaCl. In this context it is also allowed for use in salt for human consumption under EU organic regulations.

Technological or physiological functionality for the intended use

Sodium chloride tends to absorb water at a relative humidity of over 75%, leading to secondary crystallisation and the formation of clumps and blocks of salt. The addition of a small amount of E 535 is enough to largely prevent the clumping process. The anti-clumping effect of ferrocyanides is based on two mechanisms: firstly, the growth of NaCl crystals is altered, and secondly, the tendency to absorb and release water is affected. A monomolecular ferrocyanide coating on salt crystals is enough to achieve this effect.

Necessity for intended use, alternatives

The Group recognises that salt is used in livestock feedingstuffs to provide sodium, and that an anti-caking agent is required to prevent the clumping of salt, which can block and damage processing equipment and prevent uniform mixing of ingredients. Sodium ferrocyanide has no direct effect on compound feedingstuffs.

The Group considered whether the positive effect on the flow performance of salt could be achieved by other means:

- Salt could be left out of compound feeds and fed separately by primary producers. However, blocks are normally manufactured from salt which has been treated with this or other additives.
- Other products were identified as having a similar function.
 - Sodium bicarbonate, calcium carbonate and magnesium carbonate are already authorised as feed materials under Annex V to Commission Regulation (EC) 889/2008 and are already used in some countries as a standard alternative in salt for organic processing. However, these are considered by some industry sources to be less effective than sodium ferrocyanide at preventing clumping of salt, as anti-caking

efficacy is influenced by the size of particle of the anti-caking substance (as lower size has better efficacy). These carbonates are also used as primary feed ingredients at levels higher than the salt additives.

- While sodium ferrocyanide is the most frequently used anti-caking agent, the following are also permitted for animal feed, but these are not currently approved in Annex VI to Commission Regulation (EC) 889/2008 :
 - E536 potassium ferrocyanide
 - E538 calcium ferrocyanide
 - E550 sodium silicate
 - E 552 calcium silicate
 - E 554 sodium aluminium silicate
 - E556 calcium aluminium silicate

Materials of origin, methods of manufacture

Sodium ferrocyanide is synthesised from sodium cyanide and iron (II) chloride. The crystalline product is obtained by concentrating the solution. The production process takes place in controlled conditions.

Environmental issues

No environmental risk was identified.

Animal welfare issues

Sodium ferrocyanide is added in trace quantities to salt, not to the compound feeding stuff. The complex ferrocyanide ion is very stable and consequently possesses very low toxicity.

Human health issues

Human health risk has been assessed as part of the process of approving this substance as a feed additive in general agriculture and was not separately reviewed by the Group (ADI 0.0-0.025 mg ferrocyanide per kg body weight).

Food quality and authenticity

Not applicable.

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

Widely used conventionally and is being used inadvertently (i.e. some control bodies and feed compounders appear unaware that it is not currently permitted) in salt used in organic feedstuffs. Although allowed for use in salt for human consumption under EU organic regulations, in some countries (e.g. DE, CH) it is no longer used as carbonates have been the preferred alternatives for many years.

Aspects of international harmonization of organic farming standards

Not applicable.

Further considerations

Taking account of all the issues identified, the Group considered that, if the use of sodium ferrocyanide is to be permitted, the maximum use limit for salt for human consumption of 20 mg/kg NaCl should be applied and the substance should only be permitted for a limited time period to allow the industry to adapt to the available, preferred carbonate alternatives currently permitted under organic regulations.

Conclusion

E 535 Sodium ferrocyanide anti-caking material, should be approved for use as a feed additive in salt for organic animal feed, subject to:

- a maximum dose rate of 20 mg/kg NaCl (the maximum defined for human food) and
- a limited time period, in order to provide a legal basis for current practice in the short term and to encourage the adoption of the preferred carbonate alternatives longer term.

3.2 E 566 Natrolite-Phonolite anti-caking material

Identification of substance, terminology, synonyms

E 566 Natrolite-phonolite is a finely ground stone meal, the stone being of 100% magmatic origin.

Authorization in general agriculture or feed/food processing

This substance is permitted for use as an anti-caking feed additive in animal feed for all livestock categories under Regulation (EC) No 2439/1999 (and as amended by Regulation (EC) No 739/2000) subject to a maximum limit of 25,000 mg/kg of complete feedingstuff.

Technological or physiological functionality for the intended use

The meal is used as a flow modifier in animal feed production. Because it is finely ground, the meal has a large specific surface and the hollow structure of the natrolite – a hollow-bodied mineral belonging to the zeolite family of natural ion exchangers - results in high water adsorption. The addition of 1-2.5% finely ground natrolite-phonolite meal to a compound mineral feed with added molasses improves the speed of release.

Necessity for intended use, alternatives

Flow modifiers are required in the production of compounded animal feedstuffs. As the use of compounded feedstuffs has increased in organic farming, so has the need for approved additives. Various stone meals can be used for this purpose, but each has specific characteristics and may be preferred for specific purposes. In addition, sources in close geographical proximity may be preferred for environmental and economic reasons.

Materials of origin, methods of manufacture

The stone is extracted in quarries in certain parts of Europe, finely ground and air sifted. It is a natural mixture of alkaline and alkaline-earth aluminium silicates and aluminium hydrosilicates, principally natrolite (43-46.5%) and feldspar.

Environmental issues

The extraction, use and disposal of natrolite-phonolite do not have any adverse effects on the environment and the substance may be classified as ecologically safe. The reduced transport requirement for locally sourced materials also confers environmental benefits.

Animal welfare issues

The animal health impacts were separately assessed as part of authorisation as a feed additive under Regulation No 2439/1999. This issue was not separately assessed in detail by the Group. According to the information in the dossier, natrolite-phonolite stone meal does not contain any quartz and does not have any adverse side-effects if inhaled during feed production or by animals. It passes through the gastro-intestinal tract of animals. Concerns were raised in discussion about the potential risk of dioxin and/or heavy metal contamination for some sources of this product. The Group considered that these concerns are adequately addressed by the authorisation under the main feed regulations.

Human health issues

Human health risk has been assessed as part of the process of approving this substance as a feed additive in general agriculture and was not separately reviewed by the Group. The dossier supporting the proposal stated that the results of studies of pathological irritant effects on human skin have been negative - the stone meal has been permitted also for use as a medicinal product applied directly to human skin.

Food quality and authenticity

No specific issues identified

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

In organic farming, it is used as stone meal under Commission Regulation (EC) No 889/2008 as a soil improver.

Aspects of international harmonization of organic farming standards

No specific issues identified.

Conclusion

E 566 Natrolite-Phonolite anti-caking material should be approved for use as a feed additive in organic animal feed, subject to the limit of 25,000 mg/kg of complete feedingstuff as specified in EC Reg. 739/2000.

3.3 E 551a Silicic acid anti-caking material*Identification of substance, terminology, synonyms*

E 551a is synthetic, chemically precipitated amorphous silicic acid.

Authorization in general agriculture or feed/food processing

E 551a is permitted for use in animal feed for all livestock categories and all feedingstuffs, without any restrictions on use, by Commission Regulation (EC) No 2439/1999 (and as amended by Regulation (EC) No 739/2000) under the 'binders, anti-caking agents and coagulants' group.

Technological or physiological functionality for the intended use

E 551a Silicic acid, precipitated and dried is used as a carrier of liquid products and as a flow modifier to improve the flow properties of powdered feed. Silicic acids are capable of binding many times their own weight in moisture. This property is exploited in the animal feed and food industries in order to make substances flow freely and maintain them in that condition.

The high absorption and adsorption capacity also makes it possible to transfer oily, semi-solid or paste-like substances into powdery formulations. E 551a is also used in the conventional sector as a carrier for vitamins, fatty acids and aromas. However, the application was for use as an anti-caking material, not as a carrier, and the Group did not consider the merits or otherwise of its use as a carrier.

Necessity for intended use, alternatives

Unlike the colloidal silicon dioxide (E 551b), E551a Silicic acid is currently not permitted for use in organic farming. In conventional feed production, however, E551a differs from E551b mainly in terms of the production process (see below) and the resulting particle size. It is argued by industry sources that it is not always possible to substitute other (currently permitted) silicic acids for E 551a, as they have different technological functions owing to their different physical characteristics (internal surface, absorption capacity and particle size).

Materials of origin, methods of manufacture

E 551a is synthesised by first melting quartz sand, extracted from opencast pits, and sodium carbonate to produce alkaline silicate, in particular sodium silicate. The molten sand is then dissolved under pressure in water to produce an alkaline water-glass solution, which is neutralised with sulphuric acid. The silicic acid is precipitated out as nano-particles during the neutralisation process and extracted from the aqueous suspension using filter presses. The particles tend to agglomerate to larger particles subsequently. Drying, and possibly grinding or granulation, takes place after the filter cake has been washed in water. The final product obtained from this precipitation process still contains about 0.8% SO₃. The final product reaches a purity of about 94% SiO₂ or more.

Environmental issues

According to the information provided in the dossier, the production of synthetically amorphous silicic acids has no adverse effects on the environment and may be classified as environmentally safe. The Group did not carry out a separate environmental assessment.

Animal welfare and human health issues

Like E 551b, E 551a contains no crystalline fractions and so does not pose a danger to health in terms of the occurrence of silicoses. No irritant effect has been noted when silicic acid is applied to the skin and mucous membranes of rabbits. Low toxicity levels have been measured (LD₅₀ 10,000 mg/kg in rats; LC₅₀, 96h in fish above 10,000 mg/l).

Food quality and authenticity

No specific issues identified.

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

No specific issues identified.

Aspects of international harmonization of organic farming standards

No specific issues identified.

Further issues

The Group was concerned that a synthetic form was being added to already approved, more natural forms of silicic acid and that the case for this was not sufficiently made.

Conclusion

The Group does not consider that E 551a Silicic acid by precipitation anti-caking material should be approved for use as a feed additive in organic animal feed on the basis of available information about need given the available, more natural alternatives. Further information on this issue should be provided to support the application.

3.4 E 568 Clinoptilolite anti-caking agent

Identification of substance, terminology, synonyms

E568 Clinoptilolite of sedimentary origin is a finely-ground stonemeal of a natural Na-aluminium silicate. It belongs to the group of zeolites.

Authorization in general agriculture or feed/food processing

Clinoptilolite of sedimentary origin is permitted for pigs, chickens and turkeys for fattening and for bovines and salmon at max 20,000 mg/kg complete animal feed (all types) as an additive of the group "Binders, anti-caking agents and coagulants" pursuant to Regulation (EC) No 1810/2005.

Technological or physiological functionality for the intended use

Under normal environmental conditions, Clinoptilolite has a stable crystal structure, with mineral-specific ion exchange and adsorption properties and reversible hydration capacity. The addition of 2% to feed compounds improves flow properties. The physiological and chemical conditions in the digestive system (pH, digestive enzymes, etc.) are not enough to decompose clinoptilolite. Clinoptilolite is not absorbed and is excreted with the faeces.

Necessity for intended use, alternatives

Flow modifiers are required in the production of compounded animal feedstuffs. As the use of compounded feedstuffs has increased in organic farming, so has the need for approved additives. Various stone meals can be used for this purpose, but each has specific characteristics and may be preferred for specific purposes. In addition, sources in close geographical proximity may be preferred for environmental and economic reasons.

E567 Clinoptilolite of volcanic origin is also an option, but was not considered specifically and is not currently approved under organic regulations.

Materials of origin, methods of manufacture

Clinoptilolite of sedimentary origin is a natural Na-aluminosilicate, quarried in Europe. It belongs to the Zeolite group and is mineralogically a clinoptilolite. Clinoptilolite of sedimentary origin can bind water molecules in the zeolite pores. Besides the tightly and loosely bound

zeolitic water there is also external water, which escapes at as low as 30°C in a vacuum. Through contact between the zeolite and ions in an aqueous solution the ions can be absorbed. The specific surface of the zeolite (its size, geometry and energetic characteristics) also influences the ion adsorption. For clinoptilolite this results in mineral-specific ion-exchange and adsorption properties and a reversible hydration capacity.

Environmental issues

The reduction, use and disposal of clinoptilolite have no negative effects on the environment. The mineral rock is very stable and does not decompose in slurries, farmyard manure and litter. Clinoptilolite of sedimentary origin continues to work in slurry, manure and litter with the ion exchange and absorption properties peculiar to the mineral as well as a reversible hydration capacity. Studies have not shown any adverse effects of clinoptilolite of sedimentary origin on soil fauna and the microbial transformation processes. Clinoptilolite of sedimentary origin also has no effects on aquatic fauna and flora, plants - or invertebrates.

Animal welfare issues

The animal health impacts were separately assessed as part of authorisation as a feed additive under Regulation 2439/1999. This issue was not separately assessed in detail by the Group. As with Natrolite-Phonolite (see above), concerns were raised in discussion about the potential risk of dioxin and/or heavy metal contamination (including lead and cadmium) for some sources of this product. The Group considered that these concerns are adequately addressed by the authorisation under the main feed regulations. The conditions in the digestive system and the relatively short time spent in the acid medium are not sufficient to change the lattice structure of clinoptilolite tuff. Clinoptilolite of sedimentary origin is therefore excreted unchanged in the faeces and does not produce any metabolites in the animal.

Human health issues

No specific issues identified.

Food quality and authenticity

No specific issues identified.

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

No specific issues identified.

Aspects of international harmonization of organic farming standards

No specific issues identified.

Conclusion

E 568 Clinoptilolite anti-caking material should be approved for use as a feed additive in organic animal feed, subject to the limit of 20,000 mg/kg of complete feedingstuff and the livestock classes as specified in EC Reg. 1810/2005.

3.5 E 237 Sodium formate preservative (for silage)

Identification of substance, terminology, synonyms

Chemical name(s): Sodium formate

Other names: Formic acid Sodium salt

Trade name: Not applicable

CAS code: 141-53-7

Other code(s): EINECS-No: 2054880

Composition: Chemical formula CHO_2Na

Authorization in general agriculture or feed/food processing

Sodium formate (E237) is approved as a food and feed preservative. Under the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003, an application, in accordance with Article 7, has been submitted for Sodium formate (E237) as an approved feed additive for silage (101st edition (Nov. 2010) European Union Register of Feed Additives), without restrictions on its use. In the same application, a new authorisation was requested, under Article 4, for a new use as a feed additive under the functional group of silage additives.

Technological or physiological functionality for the intended use

Sodium formate can be mixed with formic acid and/or propionic acid and used as a liquid product to produce silage from grass, maize or other crops. However, sodium formate can be found naturally in silage made with formic acid. At pH 4, 60% of total formic acid is in its salt form, with the sodium form predominant.

When used, the feed additive is normally added to the crop to be ensiled at the time of harvesting by suitable application systems and mixed with those feedstuffs. Sodium formate can also be spread as a solid product on the top of the silage in the silage bunker. Normal inclusion is 4.5 kg/t forage when used alone. The inclusion rate is lower when mixed with formic/propionic acid. Sodium formate eases the handling of pure acids that are more corrosive. Corrosion tests using formic / propionic acid with and without sodium formate show that the inclusion of sodium formate significantly lowers the corrosiveness of the acids.

Necessity for intended use, alternatives

There are different types of silage additives available for organic farmers, including formic and propionic acids in pure form, as well as other substances for silage production listed in Annex VI to Commission Regulation (EC) No 889/2008. Acid-based additives can be used for organic farming only when weather conditions do not allow for adequate fermentation. The most commonly used acids are formic acid and propionic acid. The disadvantage with both of these acids is that they corrode. This results in the acids eating into machinery, but most of all they cause a safety risk for persons handling the products. Sodium formate is not critically necessary for organic production, but it eases the handling of and can replace pure acids that are more corrosive and reduces the risk to the operator.

Materials of origin, methods of manufacture

The process for synthesising the main polyol product is based on the reaction, at relatively low temperature and pressure, between butyraldehyde or acetaldehyde and formaldehyde in alkaline environment. Sodium formate is a by-product from this production. The reaction is done batch-by-batch in a rustproof reactor. In the subsequent separation steps the sodium formate is crystallized, purified and dried.

Environmental issues

Sodium formate is biodegradable: (BOD₂₈/COD 86% (OECD 306); COD 240 mg/h (O₂); Zahn-Wellen 100%). Sodium formate does not accumulate in organisms. Sodium formate has a low toxicity for aquatic organisms (EC₀ > 1000 mg/l (daphnia); EC_{10/18 h} 10600 mg/l /bacteria); EC_{50/48 h} 790 mg/l (algae); LC_{50/96h} > 1000 mg/ml (fish)).

Animal welfare issues

No specific issues identified.

Human health issues

Sodium formate is irritating to eyes and might irritate skin. If the product is inhaled it can irritate respiratory tracts and cause coughing and breathing difficulties. If swallowed irritations of the mucosae in the mouth, throat, oesophagus and intestinal tract can occur. Usual precautions for handling chemical products should be followed. Sodium formate makes the acids easier to handle. Compared to the pure acids already approved for organic silage production, sodium formate contributes a smaller safety risk.

Food quality and authenticity

No specific issues identified.

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

No specific issues identified.

Aspects of international harmonization of organic farming standards

No specific issues identified.

Further considerations

The review of feed additive regulations currently in progress may restrict use of this additive and acids to 'difficult' silages. There is also a need for a clearer definition of the relevant 'weather conditions' for these additives in the organic regulation, which could be based on dry matter content or any definition of 'difficult' silages that may be adopted. Any use of sodium formate for silage making should be restricted to the same conditions as currently applied to acids. There is a case that if permitted, sodium formate should eventually completely replace the use of acids in organic farming given the operator safety and other risks associated with the acids.

Conclusion

E 237 Sodium formate preservative should be approved for use as a feed additive in organic silage, subject to the outcome of the review of the authorisation of this product under Articles 4 and 7 of Regulation 1831/2003 currently in progress.

If approved:

- it should be considered whether formic and propionic acids should be deleted from Annex VI to Commission Regulation (EC) 889/2008;
- the same restrictions relating to weather conditions and silage quality as currently apply to formic and propionic acids under the organic regulations should apply.

- the concept of ‘difficult’ silages and/or ‘poor’ weather conditions’ that would determine eligibility to use the products should be clarified. Initial dry matter content or sugar content of the forage might be a basis for this.

3.6 Humic acid substances - feed material

The original application received was for the assessment of humic acid substances (HAS) as a feed *additive*. As they are not approved under general feed regulations as a feed additive (see below), consideration in this context was not possible, and the mandate requested the Group to consider their use as a feed *material*. The Group considered that the information presented was more consistent with the use of HAS as a feed additive for prophylactic treatment, that the direct nutritional value was unclear, and therefore that consideration of their use as feed material was not appropriate. The assessment below reflects this.

Identification of substance, terminology, synonyms

Humic acid substances (HAS) are a group of natural high-molecular-weight macromolecules composed of aromatic rings forming a very complex structure in the presence of phenolic, hydroxyl, phenolic hydroxyl, ketonyl, quinone, semiquinone, carboxyl, carbonyl and alkoxy groups. The humic acids are often complexed with a mixture of compounds (especially metals). Functional groups of humic acids are capable of ion exchange reactions. Ability to form chelates in the presence of carboxylate and phenolate groups is important in regulating bioactivity of metal ions and pH adjustment.

Authorization in general agriculture or feed/food processing

Humic acids are not currently authorised as a feed additive. This product would need approval under EC Regulation 1831/2003 before it can be considered for possible inclusion in Annex VI of Regulation 889/2008. Humic acids and their sodium salts are, however, identified as pharmacologically active substances with no maximum residue level and no restrictions on use under Regulation 37/2010 and Annex II of Regulation 2377/90.

Technological or physiological functionality for the intended use

Humic acids are used in horses, ruminants, swine and poultry at oral doses level of 500 to 2000 mg/kg body weight for the treatment of diarrhoea, dyspepsia, and acute intoxications. They exert a protective action on the mucosa of the intestine and have antiphlogistic, adsorptive, antitoxic and antimicrobial properties. They are not used in humans (Committee for Veterinary Medicinal Products). An EFSA scientific assessment of human use of humic acids as a food supplement (EFSA journal 2009 1147:1-36) concluded that the bioavailability of iron, chromium selenium or other minerals from their humic acid/fulvic acid chelates might be limited or even absent, whereas the possibility that the source may reduce the bioavailability of the metals and nutrients from other sources in the diet cannot be excluded.

Necessity for intended use, alternatives

Although a wide range of advantages have been claimed for humic acids as a feed additive, the Group found that the evidence provided was insufficient to support these claims. A detailed evaluation of the claims would need to be carried out as part of the registration process as feed additive.

Materials of origin, methods of manufacture

As natural organic compounds, HAS are derived from biological, chemical and microbial decomposition of organic matter (especially plants). HAS exist from trace quantities in sandy soils to abundant amounts up to 40 wt.% in peat and brown coal, soil, well water and others. Where transformed organic matter reaches a point of stability under constant conditions, humus is formed in considerable extent. The Group did not have sufficient information or technical expertise to comment on the process of extraction.

Environmental issues

No specific issues identified, but humic acids are widespread in the environment.

Animal welfare issues

As a recognised pharmacologically active substance, there are potential impacts on health and welfare, which would need further consideration as part of any possible authorisation as a feed additive.

Human health issues

No specific issues identified (but see above).

Food quality and authenticity

No specific issues identified.

Consistency with objectives and principles of organic production, as well as criteria and general rules laid down in Council Regulation (EC) 834/2007

See summary table in Annex 1 to this report.

Traditional use and precedents in organic production

No specific issues identified.

Aspects of international harmonization of organic farming standards

No specific issues identified.

Further considerations

Humic acid substances were not considered by the Group to be a feed material and would need authorisation under EU feed regulations for use as a feed additive. If used as a veterinary treatment in organic production, their use should be curative, not prophylactic, in accordance with organic principles. Curative use is also consistent with EMA scientific opinion (EMA, 1999) that no MRL needed to be defined as humic acids are used only for infrequent and non-regular treatments.

Conclusion

Humic acid substances are not currently authorised as a feed additive under EU regulations so they cannot be considered for use as such in organic farming. Their classification as feed material was not considered to be appropriate by the Group, which also noted their current designation as pharmacologically active substances with possible implications for animal health.

3.7 Template for dossier in relation to feed additives, processing aids and feed materials

The Group developed the template presented in Annex 2 to this report. The Group considered that it would be helpful to develop some interpretative guidelines to support the dossier template. The template presented in Annex 2 to this report includes in part B a checklist incorporating the criteria for assessment of consistency with the EU organic regulations.

There was some debate within the Group about whether it was necessary to identify and assess all the inputs used in the process of manufacturing the feedstuff or feed additive under consideration, potentially even the chemical reactions involved. While some agreed with this position, others argued that relevant safety and environmental issues are considered as part of the additives authorisation process in place under Regulation 1831/2003, and that we are relying, and should rely, as much as possible on this process as it would not be possible to duplicate this work within EGTOP.

3.8 Technical aspects of transition to 100% organic feed for non-ruminants

The Group considered various technical aspects of the transition to 100 % organic feed for non ruminants with a view to provide technical advice for meeting animal's nutritional requirements as stipulated in Art. 14(1(d)(ii) of Council Regulation (EC) No 834/2007. The following technical issues were identified:

- A balanced supply of methionine and lysine remains a key problem for monogastrics.
- Attempts to address this at current levels of semi-industrial production intensity can result in excess of other amino acids leading to potential health and environmental problems, especially for young animals (piglets, chick broilers, and chick turkeys) and laying hens.
- Failure to provide sufficient amino acids can lead to a severe welfare problem from feather pecking/cannibalism. This problem is mainly specific to layers and not other monogastrics, although it can affect other poultry up to 28 days old and pigs up to 3 months old. Other factors including housing, rearing and breeding can also contribute to the feather-pecking problem in poultry.
- Other welfare/environmental problems may be caused by the excess levels of other amino acids present in the diet as a result of trying to achieve minimum levels for the critical amino acids. This can lead to breathing problems, hock burn and potential pollution risks due to N surpluses.
- Organic soybean cake is rich in methionine and lysine but there is currently high reliance on imports. However, there are initiatives to increase European production even in northern Europe.
- While fishmeal and yeast are permitted options that are used, they are non-agricultural products and not relevant to the 100% organic feed discussion.
- Conventional potato and maize protein are the main sources currently used to balance rations but these are not available organically – if organic potatoes or maize were to be processed for protein, a market would need to be identified for a significantly larger quantity of starch as a by-product¹
- A number of different potential feed sources, including for example triticale and rapeseed, have been identified by Nicholas et al. (2007) in a review of the issue. However, these ingredients are only available in relatively small quantities and in many cases feed

¹ E.g. 100 kg of maize produce only 9 kg of gluten and about 90 kg of starch

manufacturers lack the storage capacity to store these ingredients as well as the main ingredients such as wheat and therefore prefer not to use them.

- For some ingredients, such as sunflower or rapeseed, the restrictions on processing them as organic mean the quality of the end product makes them less suitable for use in feed cake.
- Protein extract from alfalfa, might also be a suitable alternative source and legumes are recommended in crop rotations. Hemp seed is another possibility.
- Proposals for novel feed materials, including (farmed) organic mussel/molluscs meal², fly larvae grown on organic animal manure³ and micro/macro algae⁴ are under development. Earthworms could also be an option⁵. However, despite these advances, there will still be a time lag before these products are commercially available.
- There is a need to consider whether the same performance standards as for conventional production should be used as a basis for organic mono-gastric production and ration formulation. A more extensive approach could reduce required concentrations of methionine and lysine.
- There is a need to review breeds, or to initiate breeding of genotypes, that would be suited to a more extensive approach while remaining economically viable and sustainable, but it needs to be recognised that in many case suitable breeds are not currently available and that there could be a significant time lag before new, more suitable breeds, can be produced.
- The actual protein requirements of systems and breeds used in organic production should be reviewed. For example, Spanish research indicates that the nutritional requirements of Iberico pig are much lower than standard breeds. For French Label Rouge table birds such information already exists.
- There is a need to consider how more nutritional benefit can be obtained from the rangeland, including through more diverse management of the land to encourage invertebrates and other beneficial nutritional components (ORC, 2011). This may require a different model of production contrasting with the semi-industrial approach of some current organic production systems.
- Many of the options identified could be implemented now or within a few years with appropriate knowledge transfer and some additional research, but it may be that a derogation for very specific classes of mono-gastrics⁶ should be retained. However, a new derogation

² Mussel meal should be regarded as an organic feed ingredient. Under current Danish developments, the mussels will be produced in the sea, but under controlled conditions, and certified organic. Mussel meal is mechanically separated from the shell and dried and without chemicals added.

³ The methods of fly larvae production in Denmark have not yet been finalised. The larvae can be produced on large scale using known methods and the production can be certified organic. The larvae, whether they are used directly (alive) or processed into meal constitutes a very valuable feedstuff, high in energy, protein, essential amino-acids and fatty acids. An "on farm" solution would be preferable, feeding the larvae to the animals (poultry) directly, but this raises questions concerning hygiene that need to be resolved through further research before the production process can be finalised. The research will be conducted in the next 2-3 years.

⁴ Dried products of both micro algae (*Spirulina*) and macro algae are produced under controlled conditions and can probably be certified organic. There is still a lot of research to be done concerning processing of the algae, nutritional value and hygienic aspects. Algae do not have as high a nutritional value as mussels and fly larvae. Macroalgae have a considerable content of carbohydrates that are not very metabolizable for monogastrics and may therefore require processing before using as a feed ingredient.

⁵ It was reported in the discussion that trials with earthworms in France has led to concerns about heavy-metal concentration, but the substrate (e.g. FYM or household waste compost) needs clarification as a potential explanation

⁶ The Group did not have sufficient time to consider the detail of how such derogations might be applied. One suggestion was that the derogations should be limited to the following age ranges: chickens 0-4 weeks, turkeys 0-4 weeks, piglets 3-8 weeks, and layers 18-32 weeks, although the case was also made that for piglets the age

period should be relatively short, e.g. 2-4 years, so as to keep farmers, research institutes and the industry motivated.

Conclusion

The Group concluded that while there are technical solutions that can be implemented in the short to medium term, there is a need for further research on alternatives and knowledge transfer, a need to reflect on the nature and principles of organic non-ruminant production (whether semi-industrial or extensive), and therefore a need to consider continuing with derogations for a short period limited to specific ages and types of non-ruminants and specific feedstuffs.

range should be 6-12 weeks. However, concerns were also raised about the practical problems that might arise in policing this. It was also suggested that the derogation should be limited to specific classes of feed (all fish and marine animals and their by-products, plant protein extracts, yeasts, molasses, powders and extracts of plants, spices and herbs, seaweed meal), but this needs to be consistent with organic principles. However, many of these products are not of agricultural origin and therefore cannot be organic in terms of the regulation and potentially fall outside the scope of the 100% organic feed requirement in any case.

4 LIST OF ABBREVIATIONS

CAS	Chemical Abstracts Systematic names
EGTOP	Expert Group for Technical Advice on Organic Production
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Commercial Chemical Substances
EMA	European Medicines Agency
HAS	Humic acid substances

5 REFERENCES

Nicholas, P.; A. Sundrum and S. Padel (2007) Guidance notes to operators including recommendations in relation to nutrient supply. Deliverable 4.3. EEC 2092/91 (ORGANIC) Revision - Research to support the revision of the EU Regulation on organic agriculture SSPE-CT-2004-502397. University of Wales, Aberystwyth

ORC (2011) Position paper on 100% organic feed for monogastrics. Organic Research Centre, Newbury

EMA (1999) Humic acids and their sodium salts. Summary Report EMEA/MRL/554/99-FINAL. Committee for Veterinary Medicinal Products.

For list of regulations, see Annex 3.

6 GLOSSARY

Feed (or feedingstuff) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals (Source: EU Reg. 178/2002 Art. 3 pt 4).

Feed additives means 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) (Source: EU Reg. 1831/2003; Art. 2a):

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 (Source: EU Reg. 1831/2003; Art. 2h)

Feed materials means products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures; (Source: EU Reg. 767/2009; Art. 2g)

Feed intended for particular nutritional purposes means feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC.

Annex 1: Overview of compliance with organic regulations

Substance	E535 Sodium fer- rocyanide	E566 Natrolite- Phonolite	E551a Silicic acid	E568 Clinop- tilolite	E237 Sodium formate	Humic acids
Criterion						
Role?	Anti-caking agent	Anti-caking agent	Anti-caking agent	Anti-caking agent	Preservative	Feed material (additive)
Nutritional value?	None	None	None	None	None	Not clear
EU-authorised?	Yes	Yes	Yes	Yes	Yes as a preservative	No, but listed as a PAS ¹
Restrictions (for animal feed)?	Only for salt max 80 mg/kg NaCl	25000 mg/kg for all stock	None	20000 mg/kg for specific livestock	Under review as feed additive	Not authorised as an additive
Natural (not chemically synthesised)?	No	Yes	No	Yes	No	Yes
Traditional input?	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
GMO?	No	No	No	No	No	No
Growth promoter?	No	No	No	No	No	No
Synthetic amino acid?	No	No	No	No	No	No
Natural milk replacer?	No	No	No	No	No	No
Agricultural origin?	No	No	No	No	No	No
Organic? (if relevant)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Land-based?	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Internal? (on farm)	No	No	No	No	No	No
Pasture access?	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Minimise additives?	No	No	No	No	No	No
Essential? (need demonstrated)	No, but more effective than alternatives	No, but regional applicability	Yes, where particle size critical	No, but regional applicability	No, but safer than acids for difficult silage	No

Species appropriate?	Not applicable	Not applicable				
Environmental impacts?	No	No	No	No	No	No
Animal health/welfare impact?	No	No	No	No	No	Pharmacologically active
Human health impacts?	No	No	No	No	Yes, but safer than acids	Potentially
'Misleading' subst./processes?	No	No	No	No	No	No
Careful processing?	Yes	Yes	Yes	Yes	Yes	No
Solvent extracted?	Not applicable	No	No	No	No	No
Food quality/authenticity?	None identified	None identified				

¹ pharmacologically active substance

Annex 2: Template for dossiers concerning the request to amend Annex V and VI of Commission Regulation (EC) No 889/2008

Part A

DOSSIER CONCERNING THE REQUEST TO AMEND ANNEXES V and VI concerning feed materials, additives/processing aids and certain substances used in animal nutrition of Commission Regulation (EC) No 889/2008

Articles 16.3 b and 21 sec. par. of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."

General information on the request

Nature of the request	<input type="checkbox"/> Inclusion <input type="checkbox"/> Deletion <input type="checkbox"/> Change of disposition
Request introduced by	[Member State] Contact e-mail:
Date	

Please indicate if the material provided is confidential

Requested inclusion/deletion/amendment

Name of additive / substance	Primary use/conditions

1. Identification

Common name
Name(s) of active substance
Other names
Trade names

CAS ⁷ No. (if appropriate)
IUPAC ⁸² Name (if appropriate)
E.C Additive Identification No (if appropriate)
Other code(s)

2. Characterisation

Chemical formula/composition of active substance (if appropriate)
Concentration of active substance
If preparation, other components
Physical properties
Origin, inputs and production method of the active substance
Method(s) of analysis

3. Specification of use

Material/additive category
Material/additive functional group
Species groups

⁷ Chemical Abstracts Systematic Names

⁸ International Union of Pure & Applied Chemistry

Minimum or maximum rate according to species group (if appropriate)
Application route

4. Status

Authorization in general agriculture or food processing

Historic use
Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable)

5. Reasons for the inclusion, withdrawal or amendments,

Specify in which Annex the inclusion, withdrawal or amendments is requested

V VI

Explain the need for the proposed feed material or additive change
What alternative solutions are currently authorised or possible?
Is there any traditional use or precedents in organic production?

6. Consistency with objectives and principles of organic production

Please use the check list in part B to this Annex to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

7. Other aspects

Environment
Animal health and welfare
Human health
Food quality and authenticity
Ethical
Socio-economic

8. Annexes

9. References

Part B

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulations

Criterion	Specific articles in Reg. 834/2007	Yes/No/Not applicable	Brief qualification
What is role of material/additive?	Art. § 5 k) & art.14 § 1. d) iv)		
Is it EU-authorized?	Art. 1 § 4.		
What restrictions (for animal feed) apply?	General regulation & Art. 16 § 2. e)		
Does it have nutritional value?	-		
Is it natural (not chemically synthesised)?	Art. 4, b) & c).		
Is it a traditional input or does it have organic precedence?	-		
Is it a GMO?	Art. 9		
Is it a growth promoter?	Art. 14 § 1. d) v).		
Is it a synthetic amino acid or vitamin?	Art. 14 § 1. d) v).		
Is it a natural milk replacer?	Art. 14 § 1. d) vi).		
Is it of agricultural origin?	Art. 14 § 1. d) iv).		
Is it produced organically?	Art. 14 § 1. d) i) & iv).		
Is it land-based?	Art. 4 - a) & b) & Art. 5 g).		
Is it produced internally (on farm)?	Art. 14 § 1. d) i).		
Does it involve pasture access?	Art. 14 § 1. d) iii).		
Does it minimise use of additives?	Art. 7 b) & Art. 16 § 2. a) et e) i).		
If an additive, is it essential (need demonstrated)?	Art. 7 b) & Art. 16 § 2. a) et e) i).		
Is it species appropriate?	General regulation & art. 16 § 3.		
Does it have negative environmental impacts?	Art. 3 a) i) & art. 4 c) iii).		
Does it have negative animal health/welfare impacts?	Art. 5 h) & art. 14 e) i).		
Does it have negative human health impacts?	Art. 3 b) & c) &		
Does it involve 'misleading' substances/processes?	Art. 7 c) & Art. 18 § 4.		

Annex 3: EU legislation governing feed materials, additives and processing aids

Organic regulations

- Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91
- Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (Annexes V & VI).

Feed additives

- Commission Regulation (EC) No 2439/1999 on the conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' in feedingstuffs Repealed by Commission Directive 2003/57/EC.
- Commission Regulation (EC) No 739/2000 amending Regulation (EC) No 2439/1999 on the conditions for the authorisation of additives belonging to the group 'binders, anti-caking agents and coagulants' in feedingstuffs. Repealed by Commission Directive 2003/57/EC.
- Commission Regulation (EC) No 256/2002 of 12 February 2002 concerning the provisional authorisation of new additives, the prolongation of provisional authorisation of an additive and the permanent authorisation of an additive in feedingstuffs
- Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition for the new rules on the authorisation, supervision and labelling of feed additives
- Commission Regulation (EC) No 1810/2005 concerning a new authorisation for 10 years of an additive in feedingstuffs, the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs
- 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
- Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council
- European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 Appendixes 3b & 4. Annex : list of additives revision 115 Released 08 April 2011.

Feed materials

- Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, amending European Parliament And Council Regulation (EC) No 1831/2003
- Commission Regulation (EU) No 454/2010 on transitional measures under Regulation (EC) No 767/2009 of the European Parliament and of the Council as regards the labelling provisions for feed
- Commission Regulation (EU) No 242/2010 creating the catalogue of feed materials. Repealed by Commission Regulation (EU) No 575/2001.

Pharmacologically active substances

- Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Repealed by Regulation (EC) No 470/2009 of the European Parliament and of the Council
- Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
- Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Food additives

Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners. Repealed by regulation (EC) No 1333/2008 of the European Parliament and of the Council.