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Directorate B. Multilateral relations, quality policy

B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report

Feed Mandate II

The EGTOP reviewed this technical advice on 31 December 2014 and adopted it at the 10th plenary meeting of 9 October 2014.

About the setting up 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. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

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.

EGTOP Permanent Group

- Keith Ball
- Alexander Beck
- Michel Bouilhol
- Jacques Cabaret
- Roberto Garcia-Ruiz
- Niels Halberg
- Sonya Ivanova-Peneva
- Lizzie Melby Jespersen
- Nicolas Lampkin
- Giuseppe Lembo
- Robin Frederik Alexander Moritz
- Bernhard Speiser
- Fabio Tittarelli

Contact

European Commission - Agriculture and Rural Development

Directorate B: Multilateral relations, quality policy

Unit B4 – Organics

Office L130 – 03/232

B-1049 BRUSSELS

BELGIUM

Functional mailbox: agri-exp-gr-organic@ec.europa.eu

The report of the Expert Group presents 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:

http://ec.europa.eu/agriculture/organic/home_en

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Members of the Group are acknowledged for their valuable contribution to this technical advice. The members are:

Permanent Group members:

- Keith Ball
- Alexander Beck
- Michel Bouilhol
- Jacques Cabaret
- Roberto Garcia Ruiz
- Niels Halberg
- Sonya Ivanova-Peneva
- Nicolas Lampkin
- Giuseppe Lembo
- Lizzie Melby Jespersen
- Robin Frederik Alexander Moritz
- Bernhard Speiser
- Fabio Tittarelli

Sub-Group members:

- Michel Bouilhol
- Jiri Harazim
- Lizzie Melby Jespersen (chair and rapporteur)
- Niels Finn Johansen
- Giovanna Martelli

Secretariat:

- João Onofre
- Luis Martín Plaza
- Louis Mahy
- Stefanie Noe

All declarations of interest of Permanent Group 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), hereafter called “the Group” in their reply to point a) of the mandate concerning assessment of substances concludes on the basis of the knowledge available in the Group, the information gathered and the information provided with the dossiers from the Member states and by the Commission that:

- Lignocellulose as feed material is listed in Reg. (EC) 68/2013 (Catalogue of feed materials) under code: 7.8.1 and therefore allowed as feed material in the EU, but it is not listed in the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003, Annex I: List of Additives as of 12.05.2014, for which reason it cannot be used as a feed additive in the EU. The Group considers that the inclusion of lignocellulose from non-organically grown wood as a feed material in Annex V of Reg. (EC) 889/2008 is not in line with the objectives, criteria and principles of organic farming as laid down in Council regulation (EC) No. 834/2007, because it has not been documented that there is not enough certified organic crude fibre feed materials of a sufficient quality available in the EU. However, it is allowed to use certified organic lignocellulose e.g. from organic fruit trees as a feed material, when processed in accordance with Article 18 of Reg. (EC) 834/2007.
- The use of selenised yeast/selenomethionine produced by *Saccharomyces cerevisiae* (non-GMO inactivated yeast strains) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. Not only the four selenised yeast products currently available on the market, but all selenised yeast products produced by non-GMO inactivated yeasts, which may be approved as feed additives in conventional agriculture in the future, should be included in Annex VI, but only as long as there are no certified organic selenised yeast products available on the market. The group also suggests that the less bioavailable inorganic Se compounds may be phased out in the future.
- The use of mussels and other relevant marine and freshwater invertebrates and byproducts thereof from sustainable fishery and aquaculture is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. They should therefore be included in Reg. (EC) 889/2008, Annex V. Such feed ingredients should be supplied in amounts according to the feeding requirements of the animal species, production type and age group and it shall be secured that heavy metals and blue green algae toxin levels are not exceeded.
- The use of Dicopper chloride trihydroxide (TBCC) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex VI. 3(b) Trace elements. However, supplementation with Cu feed additives in general in organic husbandry should be reduced compared with the maximum limits allowed in conventional production as organic animals have outdoor access a great part of their life, and the upper limits for Cu addition to the feed for piglets is far beyond the need of the animals and may lead to antibiotic resistance of the intestinal and soil bacteria. The Group recommends that specific limits for micronutrient supplementation of the feed of the various organic farm animal species and age groups should be elaborated for all trace elements. It further recommends that the substances already on the list in Annex VI are re-evaluated to allow only the most bio-efficient and least polluting compounds.
- The use of Zinc chloride hydroxide monohydrate (TBZC) as a trace element for organic livestock is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex VI.3 (b). Trace elements. However, just as mentioned for Cu, supplementation with Zn feed additives in general in organic husbandry should be reduced compared with the maximum limits allowed in conventional production, as organic animals have outdoor access a great part of

their life, and the upper limits for Zn addition to the feed is beyond the need of the animals (even when taking the phytate inhibition into account) and may lead to antibiotic resistance of the intestinal and soil bacteria.

The Group recommends that specific limits for micronutrient supplementation of the feed of the various organic farm animal species and age groups should be elaborated for all trace elements. It further recommends that the substances already on the list in Annex VI are re-evaluated to allow only the most bio-efficient and least polluting compounds.

- Due to insufficient information and documentation supplied, the Group considers for the moment that the use of ammonium hydroxide, potassium hydroxide and sodium hydroxide as processing aids for extraction of protein concentrate from alfalfa is not in line with the objectives, criteria and principles of organic farming, because they are not necessary and there are other methods that are more in line with the organic principles. Besides, the production of them is quite energy intensive and their use may create environmental problems. KOH and NaOH cannot be considered processing aids in relation to the organic alfalfa fibre fraction as it will be enriched with K or Na from the concentrate added to the fibre fraction after coagulation of the proteins. The three products should therefore not be included in Annex VI of Reg. (EC) 889/2008.

The Group was further asked by the Commission to give advice on:

- Alignments of terms of the EU feed legislation, Regulation (EC) No. 1831/2003 and Annex VI to Commission Regulation (EC) No 889/2008 as regards the group of vitamins and pro-vitamins
- Suckling period that needs to be respected for different species of animals
- Use of additives or processing aids that are already included in the list of food additives for the same use for feed.
- Use of earthworms or insects as a source of protein.

Re. Alignment of terms of Feed legislation and Annex VI of Reg. (EC) 889/2008: The Subgroup did not have time to deal with alignments of terms of the EU feed legislation and annex VI of the organic regulation (EC) 889/2008 as regards the group of vitamins and pro-vitamins.

Re. Suckling period for different animal species that needs to be respected. The Subgroup did not have the expertise nor the necessary time to give advice on the suckling period that needs to be respected for different species of mammals. However, the Group raised some questions that should be considered in a future evaluation of the subject (included in Annex I).

Re. Use of food additives and processing aids: As regards the use of food additives and processing aids already included in Annex VIII of Reg. (EC) 889/2008 in feed processing the Group concluded that food additives or food processing aids already in Annex VIII, whose use is already authorised for feed in accordance with Reg. (EC) 1831/2003, may be approved if they are used for exactly the same purpose in organic feed processing and production. However, the limit of application shall still be assessed in relation to the animal species and age group the feed is intended for and in relation to animal welfare and environmental aspects. If they are used for different purposes in the organic feed processing and production there should be no automatic approval of food additives or food processing aids already allowed in organic food production.

Re. Use of earthworms and insects as protein source: The Group was of the opinion that terrestrial invertebrates, especially fly larvae and earthworms, constitute a considerable potential for production of high value certified organic protein (meal) for feeding of organic monogastrics. The production is based on low value farm by products or waste products

(e.g. manure) of local origin. Therefore such a production is in line with the principles of Reg. (EC) 834/2007. It is recommended that steps are taken to remove the barriers in the general Feed legislation taking into account the food and feed safety aspects. Restrictions on the growth substrate as regards content of heavy metals, other undesired chemicals as well as pathogens and parasites should also be considered. For the use of fly larvae and earthworms without hygienization (i.e. raw) further research on feed safety aspects in relation to the production process will be necessary and animal welfare aspects for the insect larvae and earthworms should also be considered.

Besides, the Group was asked to give an update of the 2011 EGTOP report on feed as regards the availability of protein feed, in particular essential amino-acids, for monogastrics, and in case of remaining supply difficulties give proposals for new solutions. The Subgroup did not have the relevant experts nor the time for an in depth analysis of the protein feed situation in Europe. In the meantime the Commission has issued a Commission Implementing Regulation (EU) 836/2014, which prolongs the derogation on a maximum percentage of 5 % non-organic protein feed per 12 months to porcine and poultry species, to cover the calendar years 2015, 2016 and 2017. The Subgroup did however, have some proposals for reduction of the need for imported organic soya and dependence on non-organic high quality protein sources:

- Increase the production of soya and other protein crops in Europe
- Increase the use of roughage for other age groups and species, especially for cows making more protein rich feed available for feeding of piglets and poultry.
- Limit further the age groups for which the 5 % non-organic protein feed is allowed.
- Use new sources – e.g. protein concentrate based on alfalfa, alternative protein sources like marine invertebrate meal/silage (e.g. molluscs, crustaceans and echinoderms and their byproducts from fishing/aquaculture industry, terrestrial invertebrates (e.g. insect larvae, earthworms).
- Consider the possibility of allowing meat and bone meal to non-herbivores (pigs and poultry) in conventional as well as in organic animal production in relation to the risk of transferring transmissible spongiform prion transferred diseases (such as BSE and scrapie). Meat and bone meal feed products for organic animals should be of certified organic origin.

1. BACKGROUND

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 16(3)b of Council Regulation (EC) No 834/2007¹ 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 Austria launched a request in 2011 concerning lignocellulose; in 2012 Ireland and Italy made a request concerning selenised yeast (selenium in organic form/selenomethionine produced by *Saccharomyces cerevisiae*). Mussel meal, meal from bivalve molluscs as feed material was requested by Sweden in 2009. Belgium submitted a dossier on dicopper chloride trihydroxide and zinc chloride hydroxide monohydrate in 2013, and France submitted 3 dossiers in 2014 on processing aids for alfalfa/lucerne concentrate.

The Commission has further asked to get advice on alignments of terms of the EU feed legislation, Regulation (EC) No. 1831/2003 and Annex VI to Commission Regulation (EC) No 889/2008 as regards the group of vitamins and pro-vitamins; suckling period that need to be respected for different species of animals; use of additives or processing aids that are already included in the list of food additives for the same use for feed and use of earthworms or insects as a source of protein. Besides, the Commission asked the Group to give an update of the 2011 EGTOP report on feed as regards the availability of protein feed, in particular essential amino-acids, for monogastrics, and in case of remaining supply difficulties to suggest new solutions. Therefore, the Group is requested to prepare a report with technical advice on the matters included in the terms of reference.

For a definition of key terms used in this report, see Glossary in Section 5 of the report.

2. TERMS OF REFERENCE

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

- a) to assess if the following substances are 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 for use as feed (Annex V) or feed additives (Annex VI) in organic production under the EU legislation:
 - Lignocellulose
 - Selenised yeast (Selenium in organic form/selenomethionine produced by *Saccharomyces cerevisiae*)
 - Mussel meal, meal from bivalve molluscs
 - Dicopper chloride trihydroxide
 - Zinc chloride hydroxide monohydrate
 - Processing aids for alfalfa/lucerne concentrate

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.

¹ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.(O.J. L 189 , 20/07/2007, p. 1.)

The Group is further asked to give advice on

- b) Alignments of terms of the EU feed legislation (Regulation (EC) No 1831/2003) and Annex VI to Commission Regulation (EC) No 889/2008, as regards the group of vitamins and pro-vitamins.
- c) Suckling period that needs to be respected for different species of animals.
- d) Use of additives or processing aids that are already included in the list of food additives for the same use in feed.
- e) Use of earthworms or insects as a source of protein.
- f) Update of the 2011 EGTOP report on feed as regards the availability of protein feed, in particular essential amino-acids, for monogastrics. In case of remaining supply difficulties; are there new solutions?

3. CONSIDERATIONS AND CONCLUSIONS

3.1 Lignocellulose

The request (which was only available in German) refers to the possible use of “Lignocellulose” as an individual feed material for production of feed mixtures (Annex V) or as a feed additive (dietary fibre) (Annex VI) of Reg. (EC) 889/2008. Lignocellulose is not authorised in Reg. (EC) 889/2008 as a food additive (Annex VIII) or as a food ingredient of agricultural origin, which has not been produced organically (Annex IX).

Introduction, scope of this chapter

The application dossier describes the feed material “Lignocellulose” as a product consisting of lignin and cellulose from fresh untreated wood (wood fibre) with minimum 55 % crude fibre, crude protein < 1.5%, ashes > 5%, crude fat < 1% and water < 10%. In the dossier two lignocellulose products are mentioned. According to the dossier lignocellulose is chemically defined as lignified cellulose and hemicellulose, while the feed stuff relevant definition is a product, which predominantly consists of lignocellulose (min. 20%), and which is made from raw, untreated wood, that is hygienized and stabilised by drying at 100°C to 91 % DM, after which it is mechanically disintegrated into particle size < 500 µm and perhaps compacted. It may be formulated into flour or into granules of different particle size. No chemicals are used during the processing.

One of the lignocellulose products mentioned in the dossier contains 65% crude fibre and consists solely of non-fermentable dietary fibres. The other lignocellulose product mentioned in the dossier contains 59% crude fibres with a total dietary fibre content of 85% and a lignin content of 30%. In this product the dietary fibres are partly fermentable and partly non-fermentable.

Authorization in general production and in organic production

“Lignocellulose” is listed in Reg. (EC) 68/2013 (the Community Catalogue of feed materials) with the number 7.8.1 and “wood” is listed with the number 7.14.1 with the descriptions and compulsory declaration requirements as shown below.

Number	Name	Description	Compulsory declarations
7.8.1	Lignocellulose	Product obtained by means of mechanical processing of raw natural dried wood and which predominantly consists of lignocellulose	Crude fibre
7.14.1	Wood	Chemically untreated mature wood or wood fibres	Crude fibre

According to Reg. (EC) 767/2009 lignocellulose (7.8.1 and 7.14.1) can be used as feed materials in animal feed, but neither of these two products are listed in the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003, Annex I: List of Additives as of 12.05.2014, for which reason lignocellulose and wood cannot be used as feed additives.

Lignocellulose is also listed in the “GMP+ (Good Manufacturing Practices) Product list” on GMP+ certified feed products under the code 7.034². Lignocellulose is also listed in the German “Positive list of feed materials” under code 12.08.01

Agronomic use, technological or physiological functionality for the intended use

According to the dossier lignocellulose is used as a feed material to cover the physiological requirement for crude fibre/dietary fibre of (mainly) monogastrics (pigs and poultry). Lignocellulose is primarily used in complementary and compound feedstuffs, but it may also be used in production of premixes. The dose of lignocellulose in the feed ration (finished feed) varies between 0.5 and 6 % depending on the animal species, the breed and the age group.

Dietary fibre is non-degradable by the enzymes of the stomach and small intestine and reaches the colon undigested, where the fermentable dietary fibres may be degraded by the natural intestinal microflora, while the non-fermentable dietary fibres pass the colon unaltered. The fermentable dietary fibres support a healthy intestinal microflora and the fermentation products, lactic acid and volatile fatty acids, are important for the function and the health of the intestinal environment and support the regeneration of the intestine mucosa (Blaut, 2002), (Back Knudsen and Hansen, 1991), (Sakata et al, 1995), (Roedeiger, 1989). The non-fermentable dietary fibres, which pass the colon unchanged, have a physiologically important swelling capacity, which increases the satiety, regulates the natural feed intake, stimulates the intestinal activity and bowel movement and counteracts constipation. A good intestinal activity causes the fermentable dietary fibres to reach the final part of the colon where they maintain a healthy intestinal flora (Wilfart et al., 2007), (Govers et al., 1999).

² <https://www.gmpplus.org/pagina/4/products-list.aspx>

Necessity for intended use, known alternatives

The dossier claims that there are no alternatives to the use of non-organic lignocellulose from wood. However, the most important source of crude fibre in organic farming is the grazing of the animals or other roughage sources that all organic animals must have access to every day according to Reg. (EC) 889/2008, Article 20. Roughage usually consists of hay or silage of clover grass, alfalfa, maize, cereal or faba bean straw, beet roots or carrots. In the Community Catalogue of feed materials, Reg. (EC) 68/2013 there are also several products listed that may be much more relevant to use as crude fibre sources than non-organic lignocellulose from wood, as they, besides a high content of crude fibres also have other nutritional qualities (e.g. crude fat and/or crude protein) e.g. 2.14.2: Rape seed expeller (product of oil manufacture obtained by processing of seeds of rape. and 6.10.5: Lucerne (alfalfa) meal (product obtained by drying and milling of lucerne). These may also be available in organic quality.

According to the dossier such crude fibre sources have various disadvantages, of which one is that they may be contaminated with mycotoxins due to climate and weather conditions. It is also claimed that suitable organic crude fibre feed products are not available in sufficient quantity, but this is not documented.

Origin of raw materials, methods of manufacture

The lignocellulose in the two commercial products mentioned in the dossier is produced from untreated fresh wood from Germany and Austria, which is dried at 100°C to 9 % moisture after which it is mechanically disintegrated into wood fibres with a particle size of < 500 µm. The commercial lignocellulose products consist of wood fibre flour or granules of max 6 mm and have a density of 350-430 kg/m³. The products are guaranteed to be free from mycotoxins.

Environmental issues, use of resources, recycling

Lignocellulose is produced from fresh raw wood, which is a natural renewable resource. According to the dossier the wood comes from natural forests in Germany and Austria, but in the dossier it is not explained from which kind of tree species the lignocellulose originates. Lignocellulose may also be made from wood from other sources, where it may not be clear whether the trees have been grown without the use of pesticides. This may for example be the case by using waste wood from Christmas tree or fruit tree production. If pesticides are not used no negative impact on the environment is foreseen during production and feeding, though the processing may be more or less energy demanding depending on the energy source and the drying and grinding methods used.

Animal welfare issues

Crude fibres/ dietary fibres have a positive influence on the nutrition and health (Brighenti et al., 1989; Hell et al., 2014). The fermentable dietary fibres support the digestion and health of the beneficial intestinal microflora and the non-fermentable dietary fibres stimulate the bowel movement and prevent constipation. Doses of 0.5%-2% stabilises the intestinal physiology and the natural intestinal microflora, resulting in an antagonistic effect on pathogenic intestinal bacteria and a prophylactic effect on diarrhoea and constipation. Breeding sows are commonly fed to maintain a relatively constant body condition throughout the reproductive cycle and this involves a restriction of feed intake during gestation. Pregnant sows typically receive their whole daily feed in one or two small, concentrated meals which are rapidly consumed. These conditions might not fulfil feeding motivation. Furthermore a low feeding level has been linked

to the occurrence of stereotyped activities (Meunier-Salaün, 2001). Dietary fibre is recognised to exert positive effects on the behaviour of restricted-fed gestating sows (consisting mainly in a reduction of non-feeding activities – including stereotypies - and increase in lying time). In the short term, the greater volume of feed is responsible for a decrease in feeding motivation whilst, in the longer term, both bulk and energy have significant effects (Meunier-Salaün et al., 2001). Highly fermentable fibre (i.e. sugar beet pulp) is capable of maintaining satiety and of stabilising the glucose and insulin blood levels for many hours after feeding (Whittaker et al., 1998), (Leeuw et al., 2004).

Furthermore, diets containing ingredients with a coarse texture and high crude fibre content, (5 – 10 % coarsely grinded straw) reduces or even eliminates stomach ulcers in pigs (Baustad and Nafsta, 1969).

Human health issues

The raw material of lignocellulose is of natural origin and if no pesticides are used during production and no chemicals are added during the processing there should not be any negative influence on human health. However, workers involved in the mechanical grinding, pelleting and packaging should be protected from the dust generated in these processes.

Food quality and authenticity

The lignocellulose products are to be used as ingredients in feeds and not as food for human beings. As they are guaranteed free of mycotoxins there is no risk associated with their use in feed products. There are no legally established upper limits for the content of lignocellulose in feed materials.

Traditional use and precedents in organic production

Lignocellulose is not mentioned in any of the annexes of Reg. (EC) 889/2008, but cellulose is mentioned in Annex VIII, section B: Processing aids for preparation of foodstuffs of plant origin and of animal origin, but only for gelatine production. Wood not treated with chemical products after felling is allowed as substrate for mushroom production (Article 6), Wood shavings are allowed as bedding material for poultry (Article 12.3a) and sawdust and wood chips, not chemically treated after felling are listed in Annex I, “non-organic” fertilizers and soil conditioners. Lignin and cellulose are natural constituents of plants, and are therefore part of the daily feed ration of herbivores as well as of monogastric farm animals.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

Lignocellulose or wood is not authorised for use as feedstuff nor feed additive in Codex Alimentarius – Organically Produced Foods (2013). Neither is it on the National list of allowed and prohibited substances of the US NOP or on the permitted substances list of the Canadian Organic Standard. The IFOAM Norms (2014) does also not mention lignocellulose as feedstuff or feed additive.

Other relevant issues

No other issues identified.

Reflections of the Group / Balancing of arguments in the light of organic production principles

It is well known that natural dietary fibres are important for upholding of the normal intestinal activity and beneficial gut microflora of man as well as animals. It is also documented that higher intake of crude fibres results in a longer lasting feeling of satiation.

Lignocellulose from wood is of natural origin without any added chemicals, but it is not stated in the dossier from which tree species the raw wood material comes, nor if the trees may have been treated with pesticides during growth.

The dossier claims but does not document that there is a lack of organic crude fibre feed materials (e.g. roughage/forage (fresh, hay or silage of clover grass), straw, cereal bran, lucerne and beet pulp etc.) of a sufficient quality in the EU. It is also claimed that such organic feed materials rich in crude fibre may contain mycotoxins. None of the experts in the Group had heard of any lack of crude fibre feed materials in their countries, and mycotoxins are generally not considered a problem if the crop is well harvested, preserved and stored. Besides, drying, hygienisation and grinding/milling of wood for lignocellulose production will most probably require considerably higher energy consumption than drying and grinding of the normally used organic crude fibre materials.

The dossier seems to rely on experiences in conventional pig and poultry production, but according to Reg. (EC) 889/2008 Article 20, 2) and 3) herbivores as well as pigs and poultry must be fed roughage, fresh or dried fodder, or silage every day, so they already get lignocellulose in their daily diet. Besides, organic pigs shall have access to outdoor rooting areas so they get more exercise and spend much more time on searching for feed and on other natural behaviours than conventional pigs, for which reason they will not need a crude fibre product like lignocellulose mixed into their daily feed ration to obtain a satiation effect.

The Group also had some comments to the dossier. First of all the group cannot deal satisfactorily with dossiers presented in languages other than English, because the involved experts are only supposed to be fluent in English. The Group also considers that not all production steps were satisfactorily described in the dossier (wood species, treatment of trees during growing, drying, cooling and milling of the wood). More details are needed on the processing steps to evaluate both the safety of the product and the safety, working environment and environmental impact of the processing e.g. the drying, cooling and milling process and equipment. E.g. indirect drying of lignocellulose would be preferred instead of direct drying for the sake of avoidance of dioxins. For evaluation of feed materials in the future the Group recommends to include a processing flow diagram and a risk assessment of the processing steps based on HACCP plus a detailed description of the processing equipment and conditions as part of the dossier.

Conclusions

Lignocellulose as feed material is listed in Reg. (EC) 68/2013 (Catalogue of feed materials) under code: 7.8.1 and therefore allowed as feed material in the EU, but it is not listed in the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003, Annex I: List of Additives as of 12.05.2014, for which reason it cannot be used as a feed additive in the EU.

The Group considers that the inclusion of lignocellulose from non-organically grown wood as a feed material in Annex V of Reg. (EC) 889/2008 is not in line with the objectives, criteria and principles of organic farming as laid down in Council regulation (EC) No. 834/2007, because it has not been documented that there is not enough certified organic crude fibre feed materials of a sufficient quality available in the EU. However, it is allowed to use certified organic lignocellulose e.g. from organic fruit trees as a feed material, when processed in accordance with Article 18 of Reg. (EC) 834/2007.

3.2 Selenised yeast (Selenium in organic form/selenomethionine produced by *Saccharomyces cerevisiae*)

Compounds of trace elements:

The request concerns selenised yeast. According to Annex I: List of additives of the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003 release 18.07.2014 they are registered with the following code numbers:

- a) 3b8.10 Organic form of Selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 (Selenised yeast inactivated);
- b) 3b8.11 Organic form of Selenium produced by *Saccharomyces cerevisiae* NCYC R397 (Selenised yeast inactivated);
- c) 3b8.12 Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 (Selenised yeast inactivated).

Introduction, scope of this chapter

3b8.10, 3b8.11 and 3b8.12 are organic forms of Selenium (2000-2400 mg Se/kg), mainly in the form of selenomethionine (63 %), produced by different *Saccharomyces cerevisiae* strains. The products are fine tan to light powders with typical yeast aroma. According to Annex I of Reg. 1831/2003, these substances belong to the category 3: Nutritional additives, Functional Group B: Compounds of trace elements.

In the application submitted to the EU Commission a fourth selenised yeast additive, i.e. 3b8.13 Selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 (selenised yeast inactivated) is not mentioned, probably because its authorization as an additive in animal nutrition in the EU was issued more recently by the Commission Implementing Regulation (EU) 427/2013 (08.05.2013).

Authorization in general production and in organic production

The three additives, 3b8.10, 3b8.11 and 3b8.12 have been assessed by EFSA (EFSA 2006 a; EFSA 2006 b; EFSA, 2011) and then authorized as additives in animal nutrition by the following EC Regulations, respectively:

- a) 1750/2006 of 27 November 2006;
- b) 634/2007 of 7 June 2007
- c) 900/2009 of 25 September 2009

The additive 3b8.13 was assessed by EFSA (EFSA, 2012a) and authorized by the EC Implementing Regulation 427/2013 of 8 May 2013.

The three above mentioned EC Regulations (a, b and c) have been amended, as regards the maximum supplementation with selenised yeasts, by Commission Implementing Regulation (EC) 427/2013 of 8 May 2013.

According to the Reg. (EC) 889/2008 only two inorganic forms of Selenium: sodium selenite and sodium selenate are authorized in Annex VI (b): Feed additives, trace elements.

Agronomic use, technological or physiological functionality for the intended use

According to EU legislation, the three additives, 3b8.10, 3b8.11 and 3b8.12 are intended to be used in all animal species as organic selenium sources, and they shall be incorporated in the feed in the form of a premixture. The maximum level of selenium in animal feed is 0.5 mg/kg. The level of selenium via additives currently authorised for use in animal nutrition and with regards to all animal species is 0.20 mg Se/kg of complete feed (measured at moisture content 12%).

Necessity for intended use, known alternatives

Selenium is a naturally occurring element that is essential to human and animal health in trace amounts but is harmful in excess. The major biological functions of selenium are: antioxidant (to prevent oxidative stress), proper thyroid function, maintenance of cellular redox status, and development and maintenance of immuno-competence. The concentration of selenium in plant material is highly correlated with those of the soil in which the plants are grown, but an important factor that may determine selenium-related health problems is the wide ranging ability of different plant species to accumulate selenium. Plants contain many different Se compounds and the main form in non-accumulator species is selenomethionine, but other forms, such as selenocysteine and selenonium have also been described. In most European countries, Se content in grain and forages is low and the regular use of such feeds can lead to deficiency symptoms like myodystrophy, exudative diathesis and depression of productive and reproductive performances (EFSA, 2006a). Subclinical deficiencies of Se may alter the immune response raising animal susceptibility to infectious diseases (EFSA, 2009). As concerns excess, acute selenosis occurs when plants high in Se are consumed in large quantities over a short period or as a consequence of errors in the formulation of the feed. Chronic selenosis ("alkali disease") is related to the ingestion of plants containing 5 – 40 mg/kg feed for weeks or months. The usual clinical signs of chronic selenosis in horses, cattle and swine are: loss of hair, emaciation, hoof lesions and lameness. Consumption of 2 mg/kg of Se has also been shown to cause hoof deformation, hair loss, hypochromic anaemia, increased alkali and acid phosphatase activities in sheep (Levander, 1986 and WHO, 1987 cited by Fordyce, 2005).

Abundant literature (Mahan and Kim, 1996; Knowles et al., 1999; Mahan, 2000; Mahan and Peters, 2004; Fisinin et al, 2008) indicates that Se from selenised yeasts has a high bioavailability and it can be retained in the body or transferred into milk and eggs at higher rates compared to selenite. However, it should be noted that in some of these tests the most evident effects were seen by supplementing Se at a higher level than that authorised in the EU, which is 0.2 mg/kg complete feed (EC Reg. 427/2013). A higher bioavailability corresponds to a significant reduction of Se excretion in swine manure (Mahan and Parret, 1996).

No other form of organic selenium than selenomethionine is presently authorized in the EU as feed additive for livestock. According to the dossier selenised yeasts are not intended to replace inorganic sources of Se, but the organic form of Se is more bioavailable than the inorganic forms and may be added in smaller amounts.

Origin of raw materials, methods of manufacture

Organic selenium is produced by *Saccharomyces cerevisiae*, which through assimilation and metabolism transforms inorganic salts of selenium (non-metal element) added to a culture medium used for its growth into cellular constituents. In this way the yeast becomes rich in selenium. None of the three strains under assessment are genetically modified, and neither is the fourth strain mentioned, and they are all inactivated. The additives mainly contain selenomethionine corresponding to the Se form found in non-Se-accumulator plants. In the dossiers there is a lack of information on the substrate, on which the yeast is grown and on the production method in general. Therefore it cannot be judged if the yeast can be grown in accordance with organic production methods and on a certified organic substrate.

Environmental issues, use of resources, recycling

The use in feed of the three selenised yeasts under assessment does not represent additional risk to the environment compared to other sources of Se for which they substitute, provided that the maximum authorised content of Se in complete feed is respected. In fact, literature-based evidence (Mahan and Parret, 1996) indicates that organic Se is retained at a higher degree than inorganic Se. If smaller quantities of Se are needed to meet the animals' nutritional requirements by the use of selenised yeast instead of inorganic Se as a feed additive, this would reduce the use of Se resources and pollution of the environment in regions where there is no lack of Se in the fields.

Animal welfare issues

Selenium is an essential element both for humans and animals and it is used in conventional and organic animal feeding to maintain several basic physiological functions (e.g. thyroid function, immune response, oxidative status) thus contributing to the attainment of a good level of animal health and welfare. In most European countries Se content in grain and forages is low due to low content of Se in the soil, and regular use of such feeds can lead to deficiency symptoms if supplemental Se is not added to the animal diets at appropriate levels as described by EFSA.

Human health issues, food quality and authenticity

Although it is well known that selenium is vital for humans, the present application refers to the use of three selenised yeasts as nutritional feed additives (trace elements) and, as such, they are intended to fulfil the needs of animals and not humans. Se is not expected to result in any modification of the physical properties of meat from animals fed diets enriched with selenised yeasts. Therefore, no effects are expected on human health or food quality.

According to present EU legislation (EC Reg. 427/2013) for reasons of consumer safety, the maximum supplementation level with organic selenium should not exceed 0.20 mg Se/kg of complete feed (moisture 12%).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

According to Codex Alimentarius – Organically Produced Foods (2013), Table 3: Ingredients of non agricultural origin referred to in section 3 of the guidelines, section 3.5: Minerals (including trace minerals), vitamins, essential fatty and amino acids and other nitrogen compounds, such products are only approved in so far as their use is legally required in the food products in which they are incorporated. Codex Alimentarius does not mention any ingredients of non-agricultural origin which are allowed in feed products.

Organic Se-containing feed additives listed in the EU Register of Feed Additives (pursuant to EC Regulation 1831/2003) with the numbers 3b8.10 and 3b8.11, respectively are listed in the OMRI Products list, Web Edition of May 15th, 2014.

The Canadian standard only mentions products derived from sodium selenate or sodium selenite in Section 5.2 Feed Additives and Feed supplements of the Organic Production Systems Permitted Substance Lists CAN/CGSB-32.311-2006 amended 2009, 2011 and reprinted 2011.

Other relevant issues

None.

Reflections of the Group / Balancing of arguments in the light of organic production principles

Owing to its role in many vital functions, Selenium is essential to both humans and animals. Due to insufficient native content of Se in feeding stuffs, Se is usually added to animal diets in order to fulfil nutritional requirements, thus guarantying a good level of animal health and to allow satisfactory performances. The three feed additives under assessment, i.e. 3b8.10, 3b8.11 and 3b8.12, consist of Se-enriched yeasts and are efficacious forms of organic Se characterised by high Se bioavailability. They contain significant amounts of selenomethionine (63% of the Se), a naturally occurring organic form of Se in plants and their uptake is more efficient than inorganic forms of selenium feed additives. Their incorporation into organic animal diets through premixtures is not expected to cause any negative effects on the environment or to the consumer, provided that the maximum limit set up for Se from selenised yeast and total Se in complete feed, as set up by the EU legislation, is respected.

However, according to Reg. (EC) 834/2007, article 20 there are rules specified for production of organic yeast, for which reason selenised yeast should be produced in certified organic quality.

The Group notes that the fourth selenised yeast additive, 3b8.13 contains a higher level of selenomethionine (>70% of the Se), than the three ones requested for inclusion in Annex VI according to the mandate. This selenised yeast is also non-GMO and inactivated just like the other 3 selenised yeast products. Therefore the Group recommends that this additive as well as other selenised yeast products with similar or higher contents of selenomethionine, which may be approved as feed additives in conventional agriculture in the future, should be approved as long as they consist of non-GMO organisms, but certified organic selenised yeast products are to be preferred, if available.

This is the first time that a conventional organically bound micronutrient is authorised in the EU organic regulation, but both yeast and selenium are already authorised for use in certified organic production according to Annex V and VI, respectively. A more efficient uptake of Se in the organic form may be an improvement for the environment as it reduces the excretion of Se in the manure. Besides, an efficient uptake of selenium is very important for the reproduction of animals and the growth of young animals (improves the immune response).

Conclusions

The use of selenised yeast/selenomethionine produced by *Saccharomyces cerevisiae* (non-GMO inactivated yeast strains) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. Not only the four selenised yeast products currently available on the market, but all selenised yeast products produced by non-GMO inactivated yeasts, which may be approved as feed additives in conventional agriculture in the future, should be included in Annex VI, but only as long as there are no certified organic selenised yeast products available on the market. The group also suggests that the less bioavailable inorganic Se compounds may be phased out in the future.

3.3 Mussel meal, meal from bivalve molluscs

The request concerns the use of mussel meal, meal from bivalve molluscs, primarily from blue mussels, *Mytilus edulis* as an alternative for fishmeal in the diet of primarily poultry, but perhaps also for carnivorous finfishes.

Introduction, scope of this chapter

Blue Mussels are a potential source of protein for poultry, pigs and carnivorous fish because of their high content of protein and in particular of the essential amino acids methionine and lysine, which are the amino acids most often in deficit in feed formulations for poultry and pigs respectively (NRC, 1994), (NRC, 1998). The dossier only concerns the use of mussel meal from mussels grown in conventional aquaculture as a replacement for fish meal for organic poultry and perhaps also for carnivorous fish. However, the Group found that the scope of the evaluation should be made broader, since it may also be possible to use cooked, fermented or otherwise preserved mussels. The group also found it relevant to include similar products of sea stars (*Asterias* sp.) as feed in the evaluation, as a Danish research project, “Biofouling and pest animals: sea stars” on the use of these products as protein rich feed ingredients for pigs, poultry and fish has shown promising results, and sea stars are the most important predators of mussels. Sea stars are caught in great amounts and generally considered a useless waste product. (Holtegaard et al, 2008).

Authorization in general production and in organic production

Mollusc meal is registered in the Community Catalogue of feed materials Reg. (EC) 68/2013 under the code no. 10.8.1 with the description: Product produced by heating and drying whole or parts of molluscs including squid and bivalves. Declaration of the product is required for the content of crude protein, crude fat, crude ash, if > 20% and moisture if > 8%. Sea stars are not mentioned in the Catalogue but they may fit under the following code numbers, which also may cover mussels, which are not processed into meal:

10.1.1: Aquatic invertebrates: Whole or parts of marine or freshwater invertebrates, in all their life stages, other than species pathogenic to humans and animals; with or without treatment such as fresh, frozen, dried.

10.2.1: By-products from aquatic animals: Originating from establishments or plants preparing or manufacturing products for human consumption; with or without treatment such as fresh, frozen, dried.

These products can be used as ingredients in animal feed according to Reg. (EC) 767/2009.

According to Reg. (EC) 889/2008, Article 22 (e) as amended by Reg. (EC) 505/2012 products from sustainable fisheries may be used in the processing of organic feed and feeding of organic animals provided that

- (i) They are produced without chemical solvents
- (ii) Their use is restricted to non-herbivores and
- (iii) The use of fish protein hydrolysate is restricted solely to young animals.

According to the consolidated version of the Reg. (EC) 889/2008 it is still allowed to use mussels, sea stars or crustaceans caught in sustainable fisheries to non-herbivores, with the three restrictions mentioned above. Mussels and sea stars caught from mussel aquaculture plants fulfilling the environmental requirements for sustainable mussel production are also considered sustainable fisheries and therefore also allowed.

Agronomic use, technological or physiological functionality for the intended use

Mussels are harvested in marine aquaculture plants or caught in dredge fishing for human consumption, but there are always mussels of a wrong size or with broken shells. These mussels (30 – 40 %) can be used for feed production or as plant fertilisers. Sea stars are a bycatch in mussel fishery but recently targeted fishery of sea stars in the Danish Limfjord has been taken up again in order to reduce a rapidly growing population, which threatens the mussel fishery and with the aim to produce sea star meal for feed also to be used by organic animals. The catch in 2013 was about 1200 – 1500 t (Fiskeritidende.dk, 5. June 2013³).

Necessity for intended use, known alternatives

One of the major problems in the formulation of feed for organic poultry and pigs is the lack of organic feedstuffs of sufficiently high quality as regards the protein content, but even more so as regards the amino acid composition. This is the main reason why fish meal from sustainable fisheries is allowed according to Reg. (EC) 889/2008, article 22 (e). Fish meal is an excellent source of essential amino acids and fatty acids, but fish meal is a limited resource and feeding with fish meal may give meat and eggs a bad “fishy” taste. For these reasons as well as for resource use and environmental reasons utilisation of bycatch, discard and trimmings from sustainable mussel and fish aquaculture and fishing (e.g. mussel waste, sea stars and crustaceans) would be a good alternative to the use of fish meal (EGTOP Aquaculture report A, section 4.2.1).

Mussels and sea stars have a high protein content, comparable with soybean meal or even with fish meal as regards mussel meal, and a high content of the essential amino acids, of which, methionine and lysine are of special importance for feeding of poultry and pigs, respectively. Mussel meal and sea star meal also have a high content of mono- and poly-unsaturated fatty acids. 50 % of the fatty acids in mussels meal are omega 3 (Jönsson and Elwinger, 2009). In the table below is shown some data for the composition of sea stars, sea star meal, mussel meal, soybean meal and fish meal. Because of a very high content of Calcium, sea star meal also has a very high ash content compared to the other protein feed sources, which may make it particularly relevant as feed ingredient in feed for laying hens, which have a high calcium demand, while it can probably only be used in limited amounts to pigs and other types of poultry, unless some of the ash is removed during processing (Holtegaard et al, 2008).

³ <http://fiskeritidende.dk/sostjerne-skal-bruges-til-foder/>

Table 1: Composition of sea stars, sea star meal, mussel meal, soybean meal and fish meal (¹ Holtegaard et al. 2007), (² Nordisk seminarium 23-24. Januar 2007: Muslingemel i stedet for fiskemel i økologisk foder til æglæggende høns, kyllinger og andre husdyr, Tema Nord 2008:536), (³ Johansen, N.F, 2007).

	Sea star ¹⁾	Sea star meal ¹⁾	Mussel meal ²⁺³⁾	Soybean meal ¹⁾	Fish meal ¹⁾
% DM	24.4	93.6	95.3	90	91.6
% OM in DM	58.2	65.3	92.0	93.7	87.0
% ASH in DM	41.8	34.7	8.0	6.3	13.1
% Crude protein in DM	41.8	55.6	65.0	51.2	70.0
% Crude fat in DM	6.1	7.3	16.1	2.4	12.0
Lysine in g/kg DM	25.3	30.6	46.6	31.8	49.6
Methionine in g/Kg DM	7.6	11.3	15.8	6.8	18.8

Origin of raw materials, methods of manufacture

The mussel meal is of animal (aquatic) origin derived from Blue Mussels, a species which is occurring naturally along nearly all coasts in Europe. The present technique for production of mussels is based on ropes kept floating on the surface of the sea down to 5-10 meters by means of floaters. Mussel larvae originating from the naturally occurring population of mussels in the sea will attach to the ropes and within about one year the mussels will have grown to the size of 10-15 cm and can be harvested. Mussels produced by this technique are popularly called "Line Mussels". Other techniques may be developed in the future. The mussels are not fed, but collect the feed themselves, by filtering the seawater. The production method complies very well with the organic principles as stated in Reg. (EC) 834/2007 Artikel 4 (b). Other sources are mussels caught by means of dredge, which is not a sustainable fishing method, as it is very damaging to the sea bottom environment. In table 2 is shown the European catches and aquaculture production of blue mussel (*Mytilus edulis*) for the years 2002 and 2012. The most important blue mussel aquaculture producing countries are Spain and the Netherlands.

Table 2: European catches and aquaculture of blue mussel (*Mytilus edulis*) for the years 2002 and 2012 (FAO FishStat database⁴,

	2002	2012
European blue mussel catches	130,000 t	58,000 t
European blue mussel aquaculture	162,000 t	153,000 t

Mussel meal has been tested as protein feed ingredient and replacement for fish meal in several research projects in Denmark and Sweden, but mussel meal has not yet been used in commercial production of feed products for poultry or pigs.

The processing of mussel meal consists of the following steps (Johansen, 2007):

- Heat treatment (hygienisation)
- Crushing
- Separation of meat/shells

⁴ <http://www.fao.org/fishery/statistics/en>

- Drying and grinding/milling
- Addition of antioxidant (only for conventional feed)
- Packaging

Sea stars may be caught by means of sea star nets or sea star mops, which are both reasonably effective and environmentally friendly sea star fishing tools (Holtegaard et al. 2008). Sea stars have been caught in the Danish Limfjord after the 2nd World War up to 1987 and were processed during the winter period in Fish meal factories by the fjord. The sea star meal was used both as replacement for fishmeal in feed mixtures and as a fertiliser and soil improver (high Ca-content). Since then sea star meal has not been used in commercial production of feed stuffs, but feed experiments with pigs and poultry and test production of sea star meal has recently been started in Denmark again.

The processing method used for production of sea star meal is similar to that used for mussels, except for the crushing and separation step. Another method used for preservation of molluscs and sea stars, which would be allowed in organic farming according to Reg. (EC) 889/2008 is lactic acid fermentation (silage).

Environmental issues, use of resources, recycling

Mussels are filter feeders and are very effective in cleaning the seawater from eating suspended particles (e.g. planktonic algae) hereby increasing the light reaching the sediment surface extending the depth to which ecologically important benthic plants such as sea-grasses can grow (Newell, 2004). One third of the nitrogen ingested is converted into mussel meat, which is removed with the harvested mussels hereby removing nutrients from the sea water. Likewise, removal of sea stars will remove nutrients and recycle them back to the farm land as feed and/or fertiliser/soil improver. The coastal environment will benefit from this (Haamer, 1996). Besides, recycling of these protein rich waste products of high feeding quality as feed for organic non-herbivores will reduce the need for import of organic soybean meal from other continents, hereby contributing to the mitigation of climate change.

Capture of mussels by dredge fishing is not environmentally friendly and therefore not a sustainable fishing method, but it is environmentally friendly to utilise the 30 – 40 % discard from the mussel production that is otherwise a polluting waste product.

Animal welfare issues

Production of mussel meal will help to supply young poultry and piglets with sufficient quantities of high value protein with the needed essential amino acids and fatty acids, hereby reducing problems with cannibalism and feather pecking and at the same time improve the disease resistance. Sea star meal has the same effect when used to egg laying hens as well as being an important supplier of calcium for the egg shell production.

If mussels and sea stars are caught in sea areas with good water quality in accordance with Directive 2006/113/EF/2006, it should be possible to produce mussel or sea star meal with a low content of heavy metals and low risk of contamination with toxins from blue green algae. However, it has been demonstrated, that even if - by accident - the content of toxins in mussel meal from blue green algae should exceed the tolerance limit for human consumption, the health of laying hens is not affected (Jönsson and Holm, 2008). Mussel wastes and sea stars should only be used for feed when coming from sites controlled for micro-algae.

Human health issues

When legal working environment requirements are obeyed there should be no working environment problems involved in the catching and processing of mussels and sea stars.

Food quality and authenticity

Apparently the high level of essential fatty acids of mussel meal does not increase the nutritional value of eggs, but addition of mussel meal (6 – 7 %) increases yolk pigmentation significantly (Jönsson and Elwinger, 2009; Jönsson et al, 2011), and consumers prefer eggs with dark yellow – orange yolk⁵. Besides, feeding with mussel meal does not give any off-flavour or off-odour of the eggs in contrast to fish meal (Wall et al, 2009). Better flesh colour has also been observed in rainbow trout fed mussel meal in a preliminary study carried out by NIFES in 2013⁶
<http://nifes.no/wp-content/uploads/2014/05/Reserach-news-ENGELSK-enkeltsider.pdf> .

Traditional use and precedents in organic production

Before the amendment of Reg. (EC) 889/2008 by Reg. (EC) 505/2012 the following was specified for fish, other marine animals, their products and by-products in Annex V, section 2.2:

Under the following restrictions: Products origin only from sustainable fisheries and to be used only for species other than herbivores:

- Fish
- Fish oil and cod-liver oil not refined
- Fish molluscan or crustacean autolysates
- Hydrolysate and proteolysates obtained by an enzyme action, whether or not in soluble form, solely provided to young animals.
- Fish meal

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

According to Codex Alimentarius, Organically Produced Foods, third edition (2013) Article B 18: Specific criteria for feedstuffs and nutritional elements, point c): Feedstuffs of animal origin, with the exception of milk and milk products, fish, other marine animals and products derived therefrom should generally not be used or, as provided by national legislation. This means that fish and all marine animals and marine animal byproducts from fishery and aquaculture may be used in feed materials for organic animal production. The use of fish products or products from other marine animals is also not forbidden according to §205.237: Livestock feed of the USDA National Organic Program and The IFOAM Norms (2012) Section 5.6.5.

Other relevant issues

None

⁵ <http://www.thepoulttrysite.com/publications/1/egg-quality-handbook/10/consumer-perceptions-of-egg-quality>

⁶ <http://nifes.no/wp-content/uploads/2014/05/Reserach-news-ENGELSK-enkeltsider.pdf>

Reflections of the Group / Balancing of arguments in the light of organic production principles

It is not possible to evaluate the energy consumption and environmental effect of the processing of mussels, sea stars and other marine invertebrates, because there is no data available. However, harvesting of these animals with the purpose of producing food (mussels, crayfish etc.) and feed ingredients (discards and byproducts from mussel and crayfish production, sea stars etc.) is considered by the Group to be positive for the environment as long as sustainable and environmentally friendly fishing and production methods (aquaculture/fishing gear) are used. It should be possible to use both frozen, cooked, lactic acid fermented and dried (meal) products of relevant marine and freshwater invertebrates as ingredients in feeds for non-herbivores, as long as feed safety (e.g. Salmonella, blue green algae toxins), feed composition in relation to the need of the animals, which the feed is meant for, and environmental aspects are taken into account. Recycling and improved use of food waste products are in line with the organic principles and improving the feed quality as regards essential amino acids and fatty acids for pigs and poultry thereby improving the animal health and welfare is also in line with the organic principles.

Conclusions

The use of mussels and other relevant marine and freshwater invertebrates (e.g. sea stars) and byproducts thereof from sustainable fishery and aquaculture is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. They should therefore be included in Reg. (EC) 889/2008, Annex V. Such feed ingredients should be supplied in amounts according to the feeding requirements of the animal species, production type and age group and it shall be secured that heavy metals and blue green algae toxin levels are not exceeded.

3.4 Dicopper chloride trihydroxide

The request concerns the inclusion of Dicopper chloride trihydroxide ($\text{Cu}_2(\text{OH})_3\text{Cl}$) in Reg. (EC) 889/2008, Annex VI: Feed additives used in animal nutrition, under section 3. Nutritional feed additives, section b: Trace elements.

Introduction, scope of this chapter

According to the dossier dicopper chloride trihydroxide ($\text{Cu}_2(\text{OH})_3\text{Cl}$) is also known as TBCC (tribasic copper chloride). The concentration of Cu is minimum 53% and the Cu purity is min. 90%. Particle size is between 100 μm and 300 μm with an average of 250 μm . The product is dustfree.

Authorization in general production and in organic production

Dicopper chloride trihydroxide (in the following called TBCC) is listed in Annex I: List of additives of the European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003 released on 18.07.2014 with the code number 3b409 as a compound of trace elements. It is authorized in Europe according to Reg. (EU) 269/2012 of 26 March 2012 until 16/04/2022. The α -crystal form of TBCC has been evaluated by EFSA in 2011 (EFSA, 2011).

At present three other forms of copper are authorized in Reg. (EC) 889/2008 Annex VI: Feed additives under 3. Nutritional Additives, Section b: Trace elements. There are no specific additional limits for the use of Cu compounds as feed additives in organic production compared to conventional production.

Agronomic use, technological or physiological functionality for the intended use

According to the dossier TBCC has long been used as a feed trace element in the USA and Canada where it has been marketed since 1996, while it was first authorised in the EU in 2012. However, other Cu compounds have been used as feed trace elements for many years in organic and conventional farming in Europe.

According to the Annex of Reg. (EU) 269/2012 TBCC may be used for all animal species/categories with the following restrictions on the maximum content of Cu in mg/kg of complete feedingstuff with a moisture content of 12%:

- Bovine
 - Bovine before the start of rumination: 15 (total)
 - Milk replacers: 15 (total)
 - Other bovine: 35 (total)
 - Other complete feeding stuffs: 15 (total)
- Ovine: 15 (total)
- Pigs
 - Piglets up to 12 weeks: 170 (total)
 - other pigs: 25 (total)
- Crustaceans: 50 (total)
- Fish: 25 (total)
- Other species: 25 (total)

The additive shall be incorporated into feed in the form of a premixture.

The above mentioned limits for addition of Cu to the feed are too high compared to the need of the animals, especially as regards calves and piglets. In a report of DG Sanco, 'Opinion of the scientific committee for animal nutrition on the use of copper in feedingstuffs', adopted on 19 February 2003, the scientific committee cites various scientific bodies for recommending much lower values:

Pigs: 4 – 10 mg/kg feed (88 % DM)
 Cattle: 9 – 11 mg/kg feed (88% DM)
 Sheep and goats: 5 – 11 mg/kg feed (88 % DM)
 Poultry: 2.5 – 8 mg/kg feed (88% DM)
 Fish: 3 – 5 mg/kg feed (88 % DM)

The Scientific Committee further states that the high level of Cu in the feed (170 mg Cu/kg feed) authorised for piglets does not only cover their nutritional requirements, but also act as an efficient growth promotor (DG Sanco Scientific Committee, 2003).

Necessity for intended use, known alternatives

Copper is an essential micro-mineral for animals, humans and plants, and the availability of trace elements plays an essential role for an optimal maintenance of health and performance of livestock. Copper plays an important role in the regulation of enzyme activities but also in iron metabolism (e.g. iron transport), neutralization of free radicals and the maturation of red blood cells as well as in the bone and cartilage metabolism. Additionally, it has antimicrobial properties and the ability to modulate an immune response in monogastrics, when fed in excess of nutritional requirements (Kampf, 2012).

The total amount of copper ingested by farm animals depends not only on the copper content of the feed, but also on the soil content and availability of Cu, the plant uptake and whether the

water is running in copper pipes or not. The dossier does not document any deficiencies of European soils, but addition of trace mineral mixtures to the feed of livestock is generally accepted in conventional as well as in organic farming.

The use of copper and zinc supplements for pigs has increased as a result of keeping pigs in confinement, depriving them of access to soil, and as a result of the early weaning of piglets. In free range conditions, uptake of soil may account for a considerable amount of copper and zinc (and selenium) (VKM, 2014; Herlin and Andersson, 1996). However, copper uptake may be limited in regions with low soil Cu content or high Mo, Zn, S or Fe content, which inhibits Cu uptake (DG Sanco Scientific Committee, 2003).

Known alternatives to TBCC are the presently (2014) listed copper compounds in Annex VI of Reg. (EC) 889/2008 under ID number 3bE4: Copper:

- basic cupric carbonate, monohydrate;
- cupric oxide;
- cupric sulphate, pentahydrate.

Origin of raw materials, methods of manufacture

Copper is a heavy metal and a limited resource, which comes from mining. About 80 % of all copper extracted comes from sulphide ores and the most important producers are Chile, China, Peru and USA. TBCC occurs naturally as the mineral atacamite in Chile, but it is also formed by the oxidation of other Cu containing deposits, especially under acid, saline conditions (Miles et al, 1998). The TBCC production process usually involves a reaction between an acidic solution of cupric chloride with free hydrochloric acid and copper tetramine dichloride. The chemical reactions required to produce TBCC in the α -crystal form are described in the registration dossier to EFSA.

Environmental issues, use of resources, recycling

It is not clear whether the processing of TBCC is more or less resource demanding or harmful to the environment than the processing of the three copper compounds that are already allowed in organic farming according to Reg. (EC) 889/2008. Neither is it clear whether the copper used for the production comes from mining or from recycling of copper or mixtures of both.

Copper is a heavy metal and therefore accumulates in the soil. The addition of copper to animal feed results in significant copper loads of manure and slurry, resulting in copper pollution of the soil. Application of 170 kg N/ha in manure from piglets, which have the highest Cu content in the feed (max. 170 mg/kg feed) results in an annual application of 2.4 kg Cu/ha corresponding to an increase in the soil content over 20 years of 16.2 mg/kg soil (DG Sanco Scientific Committee, 2003). Excess uptake by some plants results in high Cu concentrations, which are toxic, especially to sheep (NRC, 2005), but also to soil organisms (EFSA, 2012b).

The conditions for authorisation of Cu trace elements in feedingstuffs were stated in Council directive of 23 November 1970 concerning additives in feeding stuffs (70/524/EEC) as amended by Commission Reg. (EC) 1334/2003, which reduces the maximum limits for Cu trace elements in feedingstuffs in order to improve animal production at the same time reducing harmful effects caused by animal excretions and minimise adverse effect on human health and the environment. According to this, the maximum content of Cu in mg/kg of the complete feedingstuff for pigs (other than piglets) was reduced from 125 mg/kg to 25 mg/kg. For sheep the feedingstuffs shall be labelled if the level of copper exceeds 10 mg/kg. Feeding high levels of copper in the diets of piglets may increase the incidence of antibiotic resistance of the gut bacteria as well as the

bacteria in soils, which have been amended with manure from piglets over several years (EFSA, 2012b).

When fed in the amounts needed for micronutrient supplementation with Cu, chelated and complexed minerals (minerals combined with amino acids to form complexes, e.g. cupric methionate) and hydroxy minerals, e.g. TBCC) may have higher bioavailability than copper sulfates and copper oxides, higher stability in feed and greater bioefficacy, which means that TBCC may possibly be used in lower doses and excreted in lower concentration than the presently approved inorganic Cu compounds (Liu et al., 2005; Miles and Henry, 2000; Miles et al, 1998). The use of copper additives in a form which is better taken up by farm animals may thus result in a lower consumption of copper and a lower risk of polluting the environment with Cu. Besides, hydroxy minerals, such as TBCC and high quality chelated minerals like the yeast based ones are generally less toxic than sulphated minerals (Koustos, 2011; Miles et al, 1998).

Animal welfare issues

Cu has numerous essential functions as structural and catalytic component of enzymes, and copper deficiency may lead to various severe deficiency symptoms, e.g. bone abnormalities, impaired immune responses and anemia in poultry) (NRC, 1977). Molybdenum, sulphur and iron can markedly inhibit Cu uptake in ruminants, while in monogastrics there is an antagonistic effect between Cu and Zn and/or Fe (DG Sanco Scientific Committee, 2003). However, as for all trace elements/micro-nutrients, overfeeding with Cu may also lead to toxicity, and sheep (and non-ruminant calves) are particularly sensitive to Cu (DG Sanco Scientific Committee, 2003). Cu excess causes impaired growth and extensive necrosis of hepatocytes and in extreme cases haemolytic crisis leading to kidney, brain and liver damage (EFSA, 2012b).

Feeding elevated levels of copper (125-208 mg/kg feed) may increase the tolerance or the passive or active resistance of the intestinal bacterial community to copper, which again seems to be associated with the selection of antibiotic resistant strains of bacteria (EFSA, 2012b). Selection for copper resistance has been achieved in a bacteria in an animal feeding experiment with young pigs fed 175 mg copper/kg feed (ppm), which is the concentration commonly used for piglets in European conventional pig production. Coselection of macrolide- and glycopeptide-resistant was also demonstrated at this high dose. The use of a 6 ppm dose did not select for any resistance. (Hasman et al., 2006). This means that feeding high levels of copper may make various bacterial strains in the gut of the animals resistant to copper and antibiotics, which again may make curing of severe bacterial diseases in the animals very difficult (Gullberg et al. 2014; DG Sanco Scientific Committee, 2003).

Human health issues

EFSA (2011) considers that there is no substantial difference concerning the deposition of copper in edible tissues and products from copper sulphate and TBCC and therefore concludes that the exposure of consumers to copper from food of animal origin will not be essentially modified by replacement of copper sulphate with TBCC. However, the present high levels for Cu addition to the feed of piglets may lead to too high levels of Cu in the liver of wild animals feeding on the fields with high Cu concentration from the addition of pig manure over many years. Danish laboratory analyses of livers (which accumulates the copper) from deer shot close to big pig farms may have a concentration of Cu above 200 mg Cu/kg liver, and 200 mg Cu is a deadly dose for an adult person (Koplev, 2014).

TBCC is considered a potential irritant to skin and eyes and a potential skin sensitizer for which reason Commission Implementing Regulation (EU) 269/2012 has the provision that for the sake of user safety breathing protection, safety glasses and gloves should be worn during handling. In

its reformulated form TBCC does not contain particles smaller than 50 µm, for which reason significant exposure via inhalation is considered unlikely, also because the dusting potential is low (0.03 g/m³ air) (EFSA, 2011).

Food quality and authenticity

As there is no substantial difference concerning the deposition of copper in edible tissues and other animal products for TBCC compared to the other copper micronutrient compounds, the food quality of animal products should be independent of which form of copper feed additive the animal has ingested.

Traditional use and precedents in organic production

Three other forms of copper are authorized in Reg. (EC) 889/2008, Annex VI, Section 3. Nutritional Additives: b) Trace elements.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

Codex Alimentarius on organic production (2013) states among other things in Article 18 a) and c) that substances used as feed additives may be used only if they are on a positive list established by the competent authority and in line with the national legislation. Besides, feedstuffs of mineral origin, trace elements, vitamins or provitamins can only be used if they are of natural origin. In case of shortage of these substances or in exceptional circumstances, chemically well-defined analogic substances may be used.

According to the US NOP (United States, the National Organic Program) as of September 18 2014, §205.603 Synthetic substances for use in organic livestock production, trace minerals used for enrichment or fortification are allowed, when FDA approved. Cu is listed in the OMRI Products List, updated 08/08/2014, Livestock products under Livestock Feed Ingredients. Copper together with Copper carbonate is listed. These products may be used as feed additives and supplements, but may not be fed in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage in life. They may not be used to stimulate growth or production. (The *OMRI Products List*® is the most complete directory of products for organic production or processing under the U.S. National Organic Program standards, and includes over 3,000 "OMRI Listed®" products).

The IFOAM Norms (2014), Article 5.5.6 states that animals may be fed vitamins, trace elements and supplements from natural sources.

Other relevant issues

None

Reflections of the Group / Balancing of arguments in the light of organic production principles

Copper trace elements are needed by all animal groups and hydroxy minerals (TBCC) may have higher relative bioavailability, lower toxicity and higher stability in feed and greater bio-efficacy than traditionally used copper trace elements like copper sulphate and copper oxides. Contrary to copper sulphate TBCC is insoluble in water. This means that it is more resource efficient and the risk of pollution of the environment is lower than for the already approved Cu trace elements in

Annex VI of Reg. (EC) 889/2008, especially if it is administered according to the need of the animals.

The Group also discussed whether TBCC should replace some of the already allowed Cu trace elements instead of just adding to the list, because it is more in accordance with the organic principles than the products already in Annex VI. It was also discussed if organic, chelated Cu compounds should be allowed since they may also have higher bioavailability and lower risk of polluting the environment. However, since there is no dossier on organic Cu compounds and it is not clear how much the manufacturing process influences the environment the Group refrained from giving any recommendations on these issues.

The Group was very concerned about the high limit values for addition of Cu to the feed, which seem to be too high compared to the physiological needs of all animal species, but especially for piglets, which receive at least 35 times as much Cu as their physiological requirement according to DG Sanco scientific Committee, 2003. This over-supplementation leads to increasing concentration of Cu in the soil from manure application, as well as building up of Cu and antibiotic resistance of gut and soil bacteria strains as well as risk of over-supplementation of organic animals with copper as organic animals shall have access to outdoor areas and grazing a large part of their life.

Protection of soils from copper contamination is a priority in organic farming, and has resulted in a quantitative limitation of the use of copper fungicides (see Reg. (EC) 473/2002, recital 7 and 8). Likewise supplementation with Cu feed additives should also be reduced compared to conventional levels. These limitations would also protect against the potential for building up Cu levels in soils that may be toxic to other species, such as sheep as a result of high proportions of ingested minerals being excreted in feces from pigs. The Group has noted that the private standards of Bio Suisse allow only a maximum of 6 mg copper/kg feed for piglet feeds (Böhler et al, 2005), and that production of organic piglets has functioned for many years in Switzerland with this limit.

Conclusions

The use of Dicopper chloride trihydroxide (TBCC) is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex VI. 3(b) Trace elements. However, supplementation with Cu feed additives in general in organic husbandry should be reduced compared with the maximum limits allowed in conventional production as organic animals have outdoor access a great part of their life, and the upper limits for Cu addition to the feed for piglets is far beyond the need of the animals and may lead to antibiotic resistance of the intestinal and soil bacteria.

The Group recommends that specific limits for micronutrient supplementation of the feed of the various organic farm animal species and age groups should be elaborated for all trace elements. It further recommends that the substances already on the list in Annex VI are re-evaluated to allow only the most bio-efficient and least polluting compounds.

3.5 Zinc chloride hydroxide monohydrate

The request concerns the inclusion of zinc chloride hydroxide monohydrate $Zn_5Cl_2(OH)_8(H_2O)$ in Reg. (EC) 889/2008, Annex VI: Feed additives used in animal nutrition, under section 3. Nutritional feed additives, section b: Trace elements.

Introduction, scope of this chapter

According to the dossier zinc chloride hydroxide monohydrate is also known as TBZC (tetra-basic zinc chloride). The specifications of the additive are the following: Total Zn is minimum 54%; zinc chloride hydroxide monohydrate min. 84 % of total Zn; zinc oxide max. 9 %; moisture max. 2 %; starch max.5% (EFSA, 2012c). The particle size is between 100 µm and 300 µm with less than 1 % particles < 50 µm. The product is not dusty.

Authorization in general production and in organic production

Zinc chloride hydroxide monohydrate (in the following called TBZC) is listed in Annex 1: List of additives of the European Union Register of Feed Additives pursuant to Reg. (EC) 1831/2003 released on 18.07.2014 with the code number 3b609 as a compound of trace elements. It is authorized in Europe according to Commission Implementing Regulation (EU) 991/2012 of 25 Oct. 2012 until 15/11/2022. TBZC was evaluated by EFSA in 2012 (EFSA, 2012c).

At present three forms of zinc are authorized in Annex VI of Reg. (EC) 889/2008 under section 3. Nutritional additives; b) Trace elements.

Agronomic use, technological or physiological functionality for the intended use

According to the dossier TBZC has long been used as a feed trace element in the USA and Canada, where it has been marketed since 1996, while it was first authorised in the EU in 2012. However, other Zn compounds have been used as feed trace elements for many years in organic and conventional farming in Europe.

According to the Annex of Implementing Reg. (EU) 991/2012 TBZC may be used for all animal species/categories with the following restrictions on the maximum content of Zn in mg/kg of complete feedingstuff with a moisture content of 12%:

- Pet animals: 250 mg/kg (total)
- Fish: 200 mg/kg (total)
- Other species: 150 mg/kg (total)
- Complete or complementary milk replacers: 200 mg/kg (total)

TBZC shall be incorporated in the feed in the form of a premixture.

Due to environmental concerns, lower levels have recently been proposed by EFSA (2014). These newly proposed total maximum contents are: 150 mg Zn/kg complete feed for piglets, sows, rabbits, salmonids, cats and dogs; 120 mg Zn/kg complete feed for turkeys for fattening; 100 mg Zn/kg complete feed for all other species and categories.

NRC (2012) indicates for pigs a requirement of 50-80 mg Zn/kg feed and Suttle (2010) indicates 24-49 mg Zn/kg feed. More specifically, piglets may need 40-80 mg/kg of Zn in feed with phytate and without phytase (15 mg Zn/kg in feed without phytate), growing pigs require 25-50 mg Zn/kg feed, and breeding pigs somewhat higher than this.

Necessity for intended use, known alternatives

Zinc is a trace element that is essential to all known organisms, and it is the second most abundant trace element, after iron, in most vertebrates. Zinc is required for a variety of basic biological processes, including metabolism of proteins, nucleic acids, carbohydrates and lipids, and it is also involved in more complex processes, such as the immune response, neurotransmission and cell signalling. Dietary zinc has low toxicity to vertebrates. Some of the

most sensitive effects of zinc toxicity are impairment of copper and iron uptake. There are also effects on lipid metabolism and the immune system as zinc is a natural regulator of processes involved in these functions. Water-breathing organisms are sensitive to waterborne zinc with acute toxicity concentrations typically being higher than those for metals such as silver, cadmium and copper but lower than those for manganese and nickel. The relatively high risk of zinc toxicity to aquatic life has led to its inclusion as a “priority pollutant” by the US Environmental Protection Agency (EFSA, 2012c). Clinical signs of Zn deficiency include reduced growth, feed intake and feed efficiency, failure of wounds to heal, thymus atrophy and impaired immune functions (NRC, 2005). Other signs in many species are skin, coat or feather alterations. Zinc bioavailability in feedingstuffs depends largely on its solubility in the intestinal lumen, which in turn is affected by the chemical form of zinc and the presence of specific inhibitors and enhancers of zinc absorption. Dietary phytate (myoinositol hexaphosphate), which is present in plant products (especially cereals and legumes) irreversibly binds zinc in the intestinal lumen and thus inhibits its absorption (NRC, 2005).

Known alternatives are the presently listed forms of Zinc in Annex VI of Reg. (EC) 889/2008 under Id number 3bE6:

- Zinc oxide
- Zinc sulphate monohydrate
- Zinc sulphate heptahydrate;

Origin of raw materials, methods of manufacture

Zinc is a heavy metal and a limited resource, which comes from mining. Over 95% of the world's zinc is produced from zinc blende (ZnS), and 64% of zinc is produced in underground mines. Main producers are China, Australia and Peru. TBZC is produced through a reactive crystallization process in which zinc chloride is reacted with ammoniated zinc chloride and water. The resulting products are zinc chloride hydroxide monohydrate and zinc diammine chloride. To remove zinc diammine chloride, the crude product is rinsed with water prior to the drying step. Some of the zinc diammine chloride is solubilised in this step and is removed by the water, while the remainder is converted to zinc oxide. The level of zinc oxide is less than 9 %. The raw product (without starch) is a colourless salt with low hygroscopicity; it is insoluble in water and organic solvents, but soluble in acids and in neutral ammonium citrate.

Environmental issues, use of resources, recycling

It is not clear whether the processing of TBZC is more or less resource demanding or harmful to the environment than the processing of the three zinc compounds that are already allowed in organic farming according to Reg. (EC) 889/2008. Neither is it clear whether the zinc used for the production comes from mining or from recycling of zinc or mixtures of both. When used in livestock feed zinc from feed additives is unavoidably released into the environment via the faeces, which are applied to the soil as fertiliser in the form of manure, slurry or litter. This may present two main potential risks: zinc accumulation within the topsoil to concentrations posing potential toxic risks to soil organisms and/or leaching of zinc from the soil to surface waters in concentrations posing potential toxic risks to organisms resident in the water column and bottom sediments. When used in aquaculture, zinc may be released directly to the broader aquatic environment around the aquaculture facility or be taken up by fish and then excreted into the environment.

Due to environmental concerns, a lowering of the maximum authorised contents of Zn in complete feed has recently been proposed by EFSA (2014), and just as for Cu it seems that these

limits are set considerably higher than the physiological needs of the animals hereby resulting in a pollution of the soil through manure application. However, the use in feed of TBZC is not believed to represent an additional risk to the environment compared to other authorised sources of Zn for which it substitutes. In fact it may even be safer for the environment than the two zinc sulphate compounds already registered in Annex VI of Reg. (EC) 889/2008 as it, in contrast to them is insoluble in water at neutral to basic pH making leakage to the ground water or surface water less likely, though leaching may take place in acidic sandy soils. Zn in TBZC is at the same time more efficient than zinc oxide making it a resource efficient and environmentally friendly alternative to the already registered Zn additives registered in annex VI, especially when used according to the physiological needs of the animals (Batal et al., 2001), (Cao et al., 2000), (Edwards and Baker, 1999).

Animal welfare issues

Zinc is essential for animals and its use in conventional and organic animal feeding is aimed to maintain several physiological functions thus contributing to the attainment of a good level of animal health and welfare. EFSA (2012c) concludes in its evaluation that zinc from TBZC is as bioavailable as that from the authorised zinc compound, zinc sulphate. Just as for Cu additives, feeding elevated levels of Zn (2425 mg/kg feed compared to 50 mg/kg feed to piglets) significantly increased the tolerance of the population of antibiotic resistant bacteria (Bednorz et al., 2014). The Zn concentration in the feed additive used in this study was more than 10 times higher than the present limit value for pigs, but it is not clear at which exact level Zn may induce multi-resistance in intestinal bacterial strains.

Human health issues

The present application refers to the use of a Zn based nutritional feed additive (trace elements) and, as such, it is intended to fulfil the needs of organic animals. Therefore, no effects deriving from the supplementation of feeds with Zn are expected on human health or food quality, when used in according with the EU regulation.

In its reformulated form, TBZC does not contain particles smaller than 100 µm for which reason significant exposure via inhalation is considered unlikely, but it should be considered as a potential irritant to skin and eyes, and a potential skin sensitiser. Therefore Commission Implementing Reg. (EU) 991/2012 has the provision that for users' safety breathing protection, safety glasses and gloves should be worn during handling.

Food quality and authenticity

As there is no substantial difference concerning the deposition of zinc in edible tissues and other animal products for TBZC compared to the other zinc micronutrient compounds, the food quality of animal products should be independent of which form of zinc feed additive the animal has ingested.

Traditional use and precedents in organic production

Three other forms of zinc are already authorized in Reg. (EC) 889/2008, Annex VI, Section 3. Nutritional Additives: b) Trace elements.

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

Codex Alimentarius on organic production (2013) states among other things in Article 18 a) and c) that substances used as feed additives may be used only if they are on a positive list established by the competent authority and in line with the national legislation. Besides, feedstuffs of mineral origin, trace elements, vitamins or provitamins can only be used if they are of natural origin. In case of shortage of these substances or in exceptional circumstances, chemically well-defined analogic substances may be used.

According to the US NOP §205.603 Synthetic substances for use in organic livestock production as of September 18, 2014, trace minerals used for enrichment or fortification are allowed, when FDA approved.

According to the OMRI Products List, updated 08/08/2014, Livestock products under Livestock Feed Ingredients, TBZC may be used as feed additive and supplement. It may not be fed in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage in life, and it may not be used to stimulate growth or production. (The *OMRI Products List*® is the most complete directory of products for organic production or processing under the U.S. National Organic Program standards, and includes over 3,000 "OMRI Listed®" products).

The IFOAM Norms (2014), Article 5.5.6 states that animals may be fed vitamins, trace elements and supplements from natural sources.

Reflections of the Group / Balancing of arguments in the light of organic production principles

Owing to its role in many biological functions, zinc is commonly added to animal diets in order to fulfil nutritional requirements, thus guaranteeing a good level of animal health and to allow satisfactory performances. Dietary Zinc bioavailability is influenced by the presence of phytate which bonds the element. According to EFSA (2012c), TBZC has the same efficacy (relative bioavailability) as that of zinc sulphate heptahydrate. TBZC is insoluble in water at neutral and basic pH (but soluble at acid pH), which makes it less exposed to leaching than zinc sulphate and it has a considerably higher efficacy (relative bioavailability) than zinc oxide, which may reduce the use of the limited Zn resources. However, concerns regarding induction of multi-resistance in intestinal bacterial strains and environmental pollution due to over-supplementing of Zn in feed additives may make a reduction of the Zn feed additives intake in organic animals advisable, especially because organic animals consume more soil than conventional animals, which are mainly kept indoors most or all of their life.

Conclusions

The use of Zinc chloride hydroxide monohydrate (TBZC) as a trace element for organic livestock is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex VI.3 (b). Trace elements.

However, just as mentioned for Cu, supplementation with Zn feed additives in general in organic husbandry should be reduced compared with the maximum limits allowed in conventional production, as organic animals have outdoor access a great part of their life, and the upper limits for Zn addition to the feed is beyond the need of the animals (even when taking the phytate inhibition into account) and may lead to antibiotic resistance of the intestinal and soil bacteria.

The Group recommends that specific limits for micronutrient supplementation of the feed of the various organic farm animal species and age groups should be elaborated for all trace elements. It further recommends that the substances already on the list in Annex VI are re-evaluated to allow only the most bio-efficient and least polluting compounds.

3.6 Processing aids for alfalfa/lucerne concentrate

The request (which was only available in French) concerns the inclusion of three inorganic processing aids: Ammonia hydroxide (NH_4OH or $\text{NH}_3\text{H}_2\text{O}$), Potassium hydroxide (KOH) and Sodium hydroxide (NaOH) in Reg. (EC) 889/2008, Annex VI: Feed additives used in animal nutrition. These processing aids are to be used to increase the pH to slightly alkaline conditions in order to improve the quality and amount of coagulated proteins in the processing of organic alfalfa into a protein rich concentrate. The three processing aids shall, if approved, probably be listed in Annex VI: Feed additives, under a new section, as there is no section for processing aids in the current or former versions of Reg. (EC) 889/2008.

Introduction, scope of this chapter

The 3 dossiers for Ammonium hydroxide, Potassium hydroxide and Sodium hydroxide give the following information on the substances:

	Ammonium hydroxide	Potassium hydroxide	Sodium hydroxide

Chemical formula/ concentration	NH ₄ OH with 20 % NH ₃	50 % KOH	30 % NaOH
Other names	-	Caustic potash	Caustic soda
Physical properties	Colourless and odourless solution of NH ₃ in water, pungent smell	Colourless and odourless solution	Colourless and odourless solution
Production method	Active substance (NH ₃) in water solution. NH ₃ synthesized from N ₂ + 3 H ₂ → 2 NH ₃ (Haber Bosch process)	Active substance produced by electrolysis of potassium chloride	Active substance produced by electrolysis of sodium chloride
Function	Alkalization (pH regulator) of protein concentrate.	Alkalization (pH regulator) of protein concentrate	Alkalization (pH regulator) of protein concentrate

It is well known that there is a need for protein rich organic feed materials of high quality as regards digestibility and content of essential amino acids, in particular methionine (poultry) and lysine (piglets) for the production of organic monogastric animals. Currently the organic pig and poultry production in the EU is partly relying on import from third countries of organic soya and partly on the derogation allowing 5 % non-organic protein rich feedstuffs in the diet for porcine and poultry species until the end of 2017 (Reg. (EC) 836/2014). Especially the piglets and chickens have a high requirement for such feeds. The usual protein feed materials grown in the EU have a too high content of crude fibre and/or an imbalanced composition of essential amino acids to cover the requirements of the piglets and chicken – i.e. they cannot eat enough to cover their requirement for the limiting amino acid. Therefore easily digestible protein concentrate from organic alfalfa may be an important organic protein feed for such animals.

Authorisation in general production and in organic production

Processing aids and conditions for their use in feeds are not included in Reg. (EC) 1831/2003 on additives for use in animal nutrition, because according to Article 1, 2 (a) they are not considered feed ingredients (see definition of “Processing aid” in the Glossary). Therefore they are not included on the feed label. At present there is no EU legislation governing this type of substance (except for solvents and enzymes) but national legislation may exist which authorises their use and establishes positive lists of processing aids which can be used in industrial processes for specific products. If there is no national regulation governing the processing of a particular feed this does not prevent the use of processing aids, provided that the producer can guarantee that the processing aid is not consumed as a feedingstuff by itself, or 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 (i.e. in accordance with the definition of “processing aids”). This also means that there is no list with legislatively established limits for processing aids for feed. This does not necessarily mean that these substances are safe for feeding of animals. Such a confirmation must be done by the feed business operator based on HACCP principles. However the three processing aids, NH₄OH KOH and NaOH are all listed as food additives in Reg. (EC) 1129/2011 amending annex II to Regulation (EC) 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives with the following E-numbers:

E 527 Ammonium hydroxide

E 525 Potassium hydroxide

E 524 Sodium hydroxide

Ammonium Hydroxide, Food additive E 527: Ammonium hydroxide is approved for use in food in most countries including the European Union as an acidity regulator and technological aid. According to Codex Alimentarius,

<http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=380> NH₄OH is authorised for a wide variety of food categories under the conditions of Good manufacturing Practice (GMP). The EU Food Additives Database only states that it is included in Group I Additives, under hydroxides E524-E528.

https://webgate.ec.europa.eu/sanco_foods/main/index.cfm?event=substance.view&identifier=244. The Joint Expert Committee on Food Additives (JECFA) of the U.N. Food and Agriculture Organization (FAO) and World Health Organization (WHO) recognize ammonium hydroxide as safe for use in a wide variety of foods. (International Food Information Council Foundation: Food Insight)

(<http://www.gvsd.org/cms/lib02/PA01001045/Centricity/Domain/18/Questions%20and%20Answers%20about%20Ammonium%20Hydroxide%20use%20in%20Food%20Production.pdf>)

Ammonium hydroxide has been used in the processing of alfalfa for protein concentrate production for several years and it is widely used in conventional farming for ammonia treatment of straw making the straw more digestible for cattle.

In organic processing ammonium hydroxide is approved for gelatine production according to Reg. (EC) 889/2008 Annex VIII part B: processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production.

Potassium hydroxide, Food additive E 525: KOH is approved for use in food in most countries including the European Union as an acidity regulator and technological aid. According to Codex Alimentarius, <http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=311> KOH is authorised for a wide variety of food categories under the conditions of Good manufacturing Practice (GMP). The EU Food additives database, https://webgate.ec.europa.eu/sanco_foods/main/?event=substance.view&identifier=242 states that KOH is authorised for use as a food additive in processed cereal-based foods and baby foods for infants and young children for pH adjustment with the amount needed. It is also used in cocoa and chocolate products.

The corrosive alkaline properties of potassium hydroxide make it a useful ingredient in agents and preparations for cleaning and disinfection of surfaces and materials that can themselves resist corrosion from alkaline conditions. Therefore KOH (Caustic potash) is also approved in organic farming for such purposes and listed in Reg. (EC) 889/2008, Annex VII: Products for cleaning and disinfection.

Sodium hydroxide, Food additive E 524: NaOH is approved for use in food in most countries including the European Union as an acidity regulator and technological aid. According to Codex Alimentarius, <http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=256> NaOH is authorised for a wide variety of food categories under the conditions of Good manufacturing Practice (GMP). The EU Food additives database, https://webgate.ec.europa.eu/sanco_foods/main/?event=substance.view&identifier=240 states that NaOH is authorised for use as a food additive in jam, jelly and marmalade, sweetened chestnut puree, processed cereal-based foods, baby foods and other foods for young children.

In organic farming NaOH is authorized in Reg. (EC) 889/2008, Annex VIII, Section A: Food additives including carriers for preparation of foodstuffs of plant origin with the restriction: “Surface treatment of “Laugengebäck”. It is also listed in Annex VIII, Section B: Processing aids

and other products, which may be used for processing of ingredients of agricultural origin from organic production for preparation of foodstuffs of plant origin with the specific conditions: Sugar(s) production; oil production from rape seed (*Brassica* spp.). NaOH (Caustic soda) is further listed in Annex VII: Products for cleaning and disinfection.

Agronomic use, technological or physiological functionality for the intended use

Alfalfa protein fractionating process:

According to the dossier Appendix B the protein fractionation starts with a crushing and pressing of the alfalfa in a single screw press max.2 hours after harvest (to minimise degradation of the proteins), generating a green juice with a pH between 5.8 and 6.2 and a fibrous alfalfa fraction. An alkaline solution of NH₄OH with 20 % NH₃ or 50 % KOH or 30 % NaOH is added to the green juice to prevent a drop in the pH, which, according to the dossier, will lead to proteolysis and hereby reduction of the quality (as regards vitamins, protein and pigments) and the quantity of alfalfa protein in the protein concentrate product. The pH adjusted green juice is then coagulated by means of direct steam injection (85°C), after which the protein coagulum is separated from the liquid fraction by means of centrifugal sedimentation. The protein coagulum is dried in a fluidized bed before storage under inert gas or at low temperature (above 0°C). It has a protein content above 50 %. The liquid fraction from the centrifugal sedimentation process is concentrated by means of evapo-concentration to 40-50 % solids before being added to the fibrous alfalfa fraction, which is afterwards dried and pelletized into feedstuff with granules of 6 mm. In conventional protein production the green juice is neutralized or slightly alkalinized (pH 7.5-8.0) before the coagulation with the alkaline solution. According to the dossier the amount of protein concentrate is hereby increased with 24 % on average at normal weather conditions, and the increase will be even higher when harvesting at dry and hot weather conditions (because the proteolysis will go faster).

According to the dossier only ammonia hydroxide has been used commercially as a pH adjuster to alkaline conditions for concentration of the protein fraction from alfalfa, while KOH and NaOH have only been tested for this purpose in laboratory scale.

The dossiers also mention the amounts of the three alkaline substances, which are to be used in the protein concentration process based on a production of 3,700 protein concentrate (8.8 %) from 42,000 t Dry matter (DM) of alfalfa:

	20% NH ₃ / (N)	50 % KOH / (K)	30 % NaOH / (Na)
Kg/t DM	5.7 / (0.7)	6.9 / (2.4)	7.4 / (1.3)

Necessity for intended use, known alternatives

The production of protein concentrate from alfalfa green juice may be carried out without the addition of alkaline pH adjustment before the coagulation of the proteins. The dossier does not mention any alternatives and claims that the addition of an alkaline solution is necessary to obtain a better quality and a higher quantity of the protein coagulum, but this has not been documented in the dossiers.

The protein concentration of leaf proteins of alfalfa green juice (or of other plants) may also be carried out at acidic conditions (pH 3.5-4.0), with anionic and cationic flocculants (Baraniak, 1989) or by means of microbial anaerobic fermentation (Godessart et al, 1987). Pandey and Srivastava (1991) obtained 70 % N and 57.2 % protein on dry weight basis by means of lactic acid fermentation coagulation compared to 60 % N and 53.6 % protein by heat coagulation at

natural pH (pH 5.9) and an in vitro digestibility of 79.3 % of the fermented coagulum compared to 61.8 % for the heat treated coagulum at pH 5.9. Protein concentration by means of lactic acid bacteria even has the advantage that it is carried out by low temperature (35°C) hereby saving energy compared to the coagulation by means of 85°C steam injection. (Pandey and Srivastava, 1991). Horigome et al. (1983) compared the leaf protein coagulation in green juice from alfalfa, and some other plants by heating after adjusting the pH to 4 or to 8-8.5 or without any adjustment (pH about 6). They concluded that in general the leaf protein produced by heating the green juice without any adjustment of pH may be suitable for protein concentrate production because it results in a higher content of true protein and a good nutritional quality. Therefore the adjustment of the pH to slightly alkaline level by means of NH₄OH, KOH or NaOH is not necessary for the production of protein enriched concentrate feed, but the yield may perhaps be higher than without the addition, though this has not been documented in the dossier.

Origin of raw materials, methods of manufacture

NH₄OH consists of the active substance NH₃ in water. Ammonia is synthesized from the gasses N₂ + 3 H₂ -> 2 NH₃ by means of the energy consuming Haber Bosch process. KOH and NaOH are produced by electrolysis of potassium chloride (KCl) and sodium chloride (NaCl) respectively, which are also very energy demanding processes.

Environmental issues, use of resources, recycling

The alkaline substances (NH₄OH, KOH and NaOH) will remain in the soluble phase after the coagulation and therefore only to be found in traces in the final alfalfa protein feed concentrate. Ammonia is highly volatile and will evaporate at the high temperature and alkaline pH. During the process it is condensed with water and used as a nitrogen fertiliser for crops grown on non-organic fields. The waste water from processing of 42,000 t DM of alfalfa is 180,000 m³/year, of which 78,000 (43 %) is ammonia enriched water from the concentration of the fluid fraction after the coagulation of the proteins. The N concentration in the waste water is about 186 g N/m³ corresponding to a production of about 33, 5 t N year.

K and Na will not undergo evaporation but remain in the concentrated liquid which is added to the alfalfa fibre fraction remaining after separation of the green juice. The alfalfa fibre fraction, which is used as animal feed, will have a slightly increased content of potassium from KOH (a relative increase of 10 %) but a much higher content of sodium from NaOH (relative increase of 65 %) compared to standard dehydrated alfalfa.

It is not possible to evaluate the energy consumption for the process but steam injection and dehydration of the protein concentrate as well as concentration of the liquid fraction to 40 – 50 % DM must be quite energy demanding. The production of the alkaline pH regulators is also rather energy intensive.

Animal welfare issues

According to the dossier the use of ammonium hydroxide does not increase the ammonia content of the alfalfa protein concentrate above the level of the concentrate without addition of ammonium hydroxide.

Potassium or sodium hydroxide or salts are not found in the alfalfa protein concentrate fraction, but elevated levels of these salts are found in the fibre fraction which is marketed as feedstuff to herbivores. However, the levels are below the threshold values.

Human health issues

KOH and NaOH belong to the highly hazardous chemicals (hazard class 2) and are very corrosive. Dissolution of sodium hydroxide or potassium hydroxide is highly exothermic, and the resulting heat may cause heat burns or ignite flammables. It also produces heat when they react with acids. KOH and NaOH are to be used in the protein feed concentrate factory and they should be handled there according to the specific working environment regulation for their use. Ammonium hydroxide is also corrosive and a severe irritant and care must be taken when handling the product (staff training). There are no human health risks for the farmers or the people handling the alfalfa protein concentrate or the pelletized alfalfa fibre fraction.

Food quality and authenticity

According to the dossier the use of ammonium hydroxide, potassium hydroxide or sodium hydroxide in the protein coagulation process should increase the quantity and quality of the alfalfa protein concentrate, but this has not been documented.

Traditional use and precedents in organic production

Neither of the three alkaline substances have been used in organic feed production before. However, they are allowed in organic farming and processing for other purposes (as food additives and cleaning and disinfectants).

Authorised use in organic farming outside the EU / international harmonization of organic farming standards

Ammonium hydroxide is not listed in Codex Alimentarius (2013), US NOP (2014) nor in the IFOAM Norms (2014).

Potassium hydroxide is allowed according to the IFOAM Norms (2014) for disinfection and for extraction of seaweed and seaweed products, provided that the minimum amount of solvent necessary is used for extraction.

According to codex Alimentarius (2013) sodium hydroxide is allowed as food additive in cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes excluding bakery ware of yeast leavened breads and specialty breads as well as for pH adjustment in sugar production. The IFOAM Norms (2014) allows sodium hydroxide for sugar processing and surface treatment of traditional bakery products and as a disinfectant. US NOP and Japan allow NaOH for sugar processing, and as a disinfecting agent.

Other relevant issues

At the moment the Danish Organic RDD II research projects (running in the period 2014-2018: *Organic growth with biorefined organic protein feed, fertilizer and energy* (Organofinery) and *Multifunctional perennial high-value crops in organic plant production* (Multiplant) are investigating the possibilities for production of protein concentrate from red clover and other plants by means of lactic acid bacterial fermentation / heat plus acid coagulation of the green leaf fraction followed by separation and testing of the organic protein feed on monogastrics. The first results with protein concentrate from red clover have shown that the yield of concentrate is satisfactory and the amino acid composition of the concentrated protein seems to be better than soya protein in relation to the need of poultry. (Fog and Lübeck, 2014)

Reflections of the Group / Balancing of arguments in the light of organic production principles

Reg. (EC) 834/2007 states in Article 4 a (i) that “Organic production shall be based on the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that use **living organisms and mechanical production methods**”.

There is a great need for production and processing of easily digestible organic concentrated protein of high quality in Europe for feeding of the organic pigs and poultry. The use of alfalfa protein seems interesting, but there are several known alternatives to NH₄OH, KOH and NaOH, which are more in line with the organic principles (necessity for use, environment) e.g. coagulation by means of fermentation with lactic acid bacteria or coagulation without adjustment of the pH.

The generation of large volumes of ammonia wastewater when using ammonium hydroxide is critical and NaOH and KOH have not been tested in commercial scale protein concentrate production, – besides these two products leave either K or Na in the alfalfa fibre fraction which may influence its feeding value and its organic status.

Conclusions

Due to the insufficient information and documentation supplied, the Group considers for the moment that the use of ammonium hydroxide, potassium hydroxide and sodium hydroxide as processing aids for extraction of protein concentrate from alfalfa is not in line with the

objectives, criteria and principles of organic farming, because they are not necessary and there are other methods that are more in line with the organic principles. Besides, the production of them is quite energy intensive and their use may create environmental problems. KOH and NaOH cannot be considered processing aids in relation to the organic alfalfa fibre fraction as it will be enriched with K or Na from the concentrate added to the fibre fraction after coagulation of the proteins. The three products should therefore not be included in Annex VI of Reg. (EC) 889/2008.

4. QUESTIONS FROM THE COMMISSION

4.1 Alignments of terms of the EU feed legislation (Regulation (EC) No 1831/2003) and Annex VI to Commission Regulation (EC) No 889/2008, as regards the group of vitamins and provitamins.

This issue was not dealt with by the Subgroup, due to lack of any background information concerning the question and due to time constraints.

4.2 Suckling periods that need to be respected for different species of animals

Currently suckling period and milk feeding are dealt with in Reg. (EC) 834/2007 and Reg. (EC) 889/2008 which state the following:

Reg. (EC) 834/2007, Article 14.1. d (vi): Suckling mammals shall be fed with natural, preferably maternal milk ;

Reg. (EC) 889/2008, Article 20.1: Feed meeting animals' nutritional requirements:

“All young mammals shall be fed on maternal milk in preference to natural milk, for a minimum period of three months for bovines including *bubalus* and bison species and equidae, 45 days for sheep and goats and 40 days for pigs”.

The Subgroup had not received any background material nor did it have the time and expertise needed among its members for giving scientifically based recommendations on this subject. However, some issues were raised, which should be dealt with in a mandate on this issue. They are included in Annex 1.

4.3 Use of additives or processing aids that are already included in the list of food additives for the same use in feed.

The requirements for use of food additives and processing aids in organic food production are stated in Reg. (EC) 889/2008, Article 27 and Annex VIII, while the requirements for use of feed additives are stated in Reg. (EC) 889/2008, Article 22 and Annex VI, stating that feed additives must have been approved under Reg. (EC) 1831/2003. The Group considers that food additives or food processing aids already in Annex VIII, whose use are already authorised for feed in accordance with Reg. (EC) 1831/2003, may be approved, if they are used for exactly the same purpose in feed processing and production. However, the limit of application shall still be assessed in relation to the animal species and age group the feed is intended for, and in relation to animal welfare and environmental aspects. If they are used for different purposes in the organic feed processing and production there should be no automatic approval of food additives or food processing aids already allowed in organic food production for such use.

4.4 Use of earthworms or insects as a source of protein

Legal barriers for the use of earthworms and insects as protein feed

Insects or earthworms produced for either human consumption or use in animal feed will be subject to the requirements of the EC General Food Law, Regulation 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. This prohibits food or feed being placed on the market if it is unsafe or unfit for human or animal consumption.

The legislation which forms barriers to the use of earthworms and insects as protein feed to non-herbivores can be divided into two parts:

- 1) Legislation that deals with the production, labelling and marketing of feed in general and from animal products.
- 2) Legislation laying down restrictions on the substrates used for the rearing of insects or earthworms.

Legislation restricting production and marketing of insects and earthworms as feed

Producers and distributors of insect or earthworm products will be subject to Reg. (EC) 183/2005 on feed hygiene, which requires feed businesses to be registered and approved following an on-site visit. Business operators are also required to implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles. Furthermore, products containing insect or earthworm protein would have to adhere to regulation EC 767/2009, which set out requirements for the labelling of feed.

Terrestrial invertebrates are listed in Reg. (EC) 68/2013 with the code number 9.16.1 and the description: “Whole or parts of terrestrial invertebrates, in all their life stages, other than species pathogenic to humans and animals; with or without treatment such as fresh, frozen, dried”. Insect larvae and earthworms are terrestrial invertebrates so they are registered as feed materials in the EU.

However, Reg. (EC) 999/2001 (consolidated version) laying down rules for the preservation, control and eradication of certain transmissible spongiform encephalopathies, Article 7, 1 and 2 states, that the feeding to ruminants of protein derived from animals shall be prohibited and that this prohibition shall be extended to animals other than ruminants and restricted in accordance with Annex IV. According to Annex IV of Reg. (EC) 999/2001 as amended by Reg. (EU) 56/2013 feeding with hydrolysed protein from parts of non-ruminants or from ruminant hides and skins, fish meal and blood products from non-ruminants are allowed to be used in feeds for non-ruminant farmed animals, and processed animal protein (PAP) other than fishmeal is allowed for aquaculture animals. However, this allowance cannot be extended to cover pig and poultry feed because there are no valid diagnostic methods able to detect the presence of pig or poultry material in animal feed, and intra-species recycling and forced cannibalism is prohibited according to Reg. (EU) 56/2013. Nevertheless, it is probable that once valid diagnostic tests become available, the use of PAP from insects or earthworms in pig and poultry feed will also be re-authorized (FAO, 2013).

The requirements of Directive EC 2002/32/EC on Undesirable Substances in Animal Feed and the EU Animal By-Products Regulation (EC) 1069/2009 must also be met, According to Article 31 of Reg. (EC) 1069/2009 animal by-products and derived products used for feed must be processed with steam sterilisation or another process guarantying similar sterilisation before they can be fed to animals. Under this regulation, aquatic and terrestrial invertebrates that are not

pathogenic to humans and animals are classed as category 3 material and are therefore suitable for feeding to farmed animals when sterilised in accordance with Article 14 and 31.

Legislation laying down restrictions on the substrate used for production of earthworms and insects

Some earthworm species (e.g. *Eisenia fetida*) and maggots of some fly species (e.g. House fly) naturally grow in untreated manure, but present maggot farming in Europe predominantly uses abattoir waste as a substrate rather than manure, and the fly species grown is *Calliphora* (Smith and Pryor, 2013). This production approach is certainly inappropriate for animal feed production according to Reg. (EC) 1069/2009, as it states that manure, non-mineralised guano, digestive tract content, animal byproducts collected during the treatment of waste water and in slaughter houses are Category 2 materials, which may not be fed to farmed animals and reared earthworms and insects are considered farmed animals according to the definition of Reg. (EC) 1069/2009 (see definitions). Category 2 materials may only be used for manufacturing of organic fertilisers or soil improvers, transformed into biogas or applied to land without processing if the competent authority considers that they do not present a risk for the spread of any serious transmissible disease. Catering waste is a Category 3 material, but is currently prohibited as feed for farmed animals, other than fur animals.

If any revised legislation determines that the substrates on which insects or earthworms are reared have to be category 3 material of Reg. (EC) 1069/2009 it is likely that production of feed from earthworms and insects may become uneconomic. Additionally, Reg. (EC) 767/2009 states among other things that apart from being safe the “Feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited. The list of such materials is set out in Annex III” (Article 6.1) of Reg. (EC) 767/2009, and among the prohibited materials listed in Annex III are:

1. Feces, urine and separated digestive tract content resulting from the emptying or removal of digestive tract, irrespective of any form of treatment or admixture.

Therefore it appears that under the current regulations, it is not possible to grow earthworms or maggots of flies on manure or catering waste, but waste products from bioethanol production (e.g. wheat protein, maize and barley hulls) are listed in the Catalogue of Feed Materials (EC 68/2013) and thus could be used as a substrate on which to rear flies.

An overview of the relevant legislation for use of earthworms and insects can be found in Annex II.

Production of insect larvae

One of the major advantages of the invertebrates is that they can utilise a whole array of different byproducts or waste materials as growth substrate and hereby recycle low-value nutrients into high value protein feed to be used again in the food production, but at the moment the EU legislation prohibits this as the insect larvae or earthworms shall be reared on feed materials listed in the EU feed catalogue (Reg. (EC) 68/2013), and be of feed grade standard, which leaves no space for recycling of most of the cheap and relevant by-products that are available in organic quality (e.g. manure, abattoir and catering waste).

A method for large scale production of house fly larvae based on manure as growth medium has been developed in Serbia and Denmark. Manure from poultry seems to be the most suitable type of substrate for the process. First step is the production of fly eggs, which is carried out in an insectarium. The fly eggs are collected daily and are transported to the larvae production plant. Immediately after having placed the manure in the production device, fly eggs are added on top

of the manure. Within 24 hours the eggs hatch and become larvae. The larvae migrate into the entire mass of manure. At a temperature of 30°C the larval state takes about 5 days, in which period the fly larvae consume the entire mass of manure. After the process the manure has turned into humus and the larvae have increased their bodyweight by 300 times. Just before the larvae pupate, the humus and the larvae are separated. Fly larvae normally migrate out of their substrate to pupate. From 1000 kg of manure (30 % dry matter) about 70 kg of larvae are produced. After drying and milling of the larvae the 70 kg are reduced to about 14 kg of larvae meal. (Johansen and Hinge, 2007?).

Use of the Soldier fly instead of House Fly would increase the efficiency of the process, but in the northern part of Europe the Soldier Fly is regarded as an invasive species, and therefore it cannot be used there.

Food safety aspects

Potential safety hazards of insects as food and feed are highly contextual and often species dependent. These hazards include a variety of contaminants that can potentially affect an earthworm or insect over its lifecycle. These may include heavy metals, mycotoxins, pesticide residues, pathogens, natural toxins, allergens, processing contaminants and veterinary residues (Spiegel et al, 2013). The risk of transmitting pathogenic bacteria, parasites or chemical residues from manure to the animals eating the larvae or earthworms has hindered the use of this substrate despite it being the natural medium for growing of these invertebrates.

Transmission of *E. coli*, *Campylobacter* or *Salmonella* has been investigated in the Danish project, Integrated larvae production for feed in organic egg production (BIOCONVAL) where fly larvae were grown on poultry manure for 5 days. The tests showed that the fly larvae reduced these pathogenic bacteria faster than if the manure was composted without them. However, to remove all bacteria a disinfection treatment (e.g. heating) will be necessary (Fischer et al, 2014). Undesired chemical substances may not be inactivated by heat treatment but can instead be avoided by proper selection and testing of the relevant substrates. It has been shown that the content of environmental pollutants such as dioxin or PCB may be higher in the fly larvae than in the rearing substrate indicating that some accumulation occurs, but the level reached in the larvae did not exceed the limit for feedstuffs. When these larvae were fed to egg laying hens, no difference in the dioxin level was observed between hens receiving fly larvae and hens which had not received any (Nordentoft et al., 2014).

Content of nutrients in fly larvae and fly larvae meal

Poultry, piglets and fish have a high need for high quality protein feed and sulphur containing amino acids. To fulfil these requirements fishmeal is often included in the diet, but fish meal is a limited resource, for which reason it is important to find suitable alternatives. The question is whether fly larvae or earthworms can replace fishmeal? In table 2. and 3 below is shown the nutrient content in house fly maggot meal, fresh meal worms, dried earthworms, non-dehulled soya meal and low protein fishmeal (as in trimmings)

The content of crude protein in house fly maggot meal and fresh meal worms is similar to non-dehulled soya and low-protein fish meal like fish meal of trimmings, while dried earthworms have a higher content of crude protein. In general the content of the essential amino acids, Lysine, methionine and Cysteine is also lower than fish meal in house fly maggot meal and meals worms but on level or higher than soya meal except for cysteine. Dried earthworms have the highest content of lysine and methionine of them all.

Table 2. Nutrients in house fly maggot meal, fresh meal worms. Dried earthworms, non-dehulled soya meal and low protein fishmeal (Feedipedia Animal resources information system by INRA, Cirad and FAO www.feedipedia.org as of 23.112014)

	House fly maggot meal^o	Meal worm, fresh	Earthworm, dehydrated¹⁾	Soya meal (non-dehulled)	Fish meal (low protein)
DM %	92.4	42.2	90.8	87.9	92.5
Crude protein, % DM	50.4	52.8	61.0	51.8	48.4
Fat, % DM (Ether extract)	18.9	36.1	8.6	2.0	10.3
Crude fibre % DM	5.7	-	3.2	6.7	-
Ash, % DM	10.1	3.1	9.4		35.2
Energy, MJ/ kg DM	22.9	26.8	21.4	19.7	19.0
Calcium g/kg DM	4.7	2.7	5.4	3.9	79.3
Phosphorus g/kg DM	16.0	7.8	10.2	6.9	39.8

1) Data from FAO's Animal Feed Resources Information System (1991-2002), datasheet currently under revision in Feedipedia: www.feedipedia.org

Table 3. Important essential amino acids in house fly maggot meal, fresh meal worms, dried earthworms, non-dehulled soya and low protein fishmeal (Feedipedia: www.feedipedia.org)

In % protein	House fly maggot meal	Meal worm	Earthworm, dehydrated ¹⁾	Soya meal (non-dehulled)	Fish meal (low protein)
Lysine	6.1	5.4	7.4	6.1	7.0
Methionine	2.2	1.5	4.0	1.4	2.6
Cysteine	0.7	0.8	1.0	1.5	1.2

1) Data from FAO's Animal Feed Resources Information System (1991-2002), datasheet currently under revision in Feedipedia: www.feedipedia.org

Reflections of the Group:

The system for production of fly larvae or earthworms based on manure is in accordance with the principles of Reg. (EC) 834/2007:

- A low value product (manure) is converted into a high value protein rich feed product without the use of any synthetic means.
- The organic farmers get access to an organic protein rich feed ingredient of high quality, which helps achieving the goal of 100 % organic feeding.
- The "in-farm" production of feed from manure is in accordance with the principle of using local resources.
- Animal welfare of poultry and pigs will be improved because of better nutrition .
- If processed into a protein rich meal the feed product is also safe for the animals.

However, the system is not in accordance with the present EU legislation on feed. Further research is needed to document the feed safety aspects of feeding with fresh maggots, larvae or earthworms, which would be most natural for poultry and pigs, as well as other feed and food safety aspect plus animal welfare aspects of insect and earthworm farming for feed purposes.

Conclusion

The Group is of the opinion that terrestrial invertebrates, especially fly larvae, meal worms and earthworms, constitute a considerable potential for production of high value certified organic protein (meal) for feeding of organic monogastrics. The production is based on low value farm by-products or waste products (e.g. manure) of local origin. Therefore such a production is in line with the principles of Reg. (EC) 834/2007. It is recommended that steps are taken to remove the barriers in the general Feed legislation, taking into account the food and feed safety aspects. However, restrictions on the growth substrate as regards content of heavy metals, other undesired chemical contaminants as well as pathogens and parasites should be considered. For the use of fly larvae and earthworms without hygienization (i.e. raw), further research on feed safety aspects in relation to the production process will be necessary and animal welfare aspects for the insects and earthworms should also be considered.

4.5 Update of the 2011 EGTOP report on feed as regards the availability of protein feed, in particular essential amino-acids, for monogastrics. In case of remaining supply difficulties, Are there new solutions?

Regulation (EC) 889/2008, as amended by Commission Implementing Regulation (EC) No 836/2014, Article 43 states the following as regards protein feed supply for monogastrics:

“Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply and where farmers are unable to obtain protein feed exclusively from organic production, the use of a limited proportion of non-organic protein feed is allowed for porcine and poultry species.

The maximum percentage of non-organic protein feed authorised per period of 12 months for those species (porcine and poultry) shall be 5 % for calendar years 2015, 2016 and 2017.”

The problem is that at the moment there is not enough protein feed with the right amino acid composition for certain age groups of pigs and poultry, and a large part of the organic protein feed used is imported soya from overseas markets, which is not in line with the organic principles (i.e. environmentally and climate friendly). However, if the animals do not get protein feed of the right composition their health and welfare will be threatened, which may lead to increased feather picking, reduced growth and other animal health and welfare disturbing symptoms.

The Subgroup did not have the time and the relevant experts to deal in depth with this subject but listed the following possibilities to reduce the need for imported organic soya and dependence on non-organic high quality protein sources:

- Increase the production of soya and other protein crops in Europe.
- Increase the use of roughage for other age groups and species, especially for cows making more protein rich feed available for piglets and poultry.
- Limit further the age groups for which the 5 % non-organic protein feed is allowed.
- Use new sources – e.g. protein concentrate based on alfalfa, alternative protein sources like marine invertebrate meal/silage (e.g. molluscs, crustaceans and echinoderms and their byproducts from fishing/aquaculture industry, terrestrial invertebrates (e.g. insect larvae, earthworms).
- Consider the possibility of allowing meat and bone meal to non-herbivores (pigs and poultry) in conventional as well as in organic animal production in relation to the risk of transferring transmissible spongiform prion transferred diseases (such as BSE and Scrapie). However, meat and bone meal feed products for organic animals should be of certified organic origin.

Some scientific project and reports dealing with this subject were identified. They are enclosed in Annex III

4.6 Problems with interpretation of Reg. (EC) 889/2008 Article 22 a.

When dealing with the question concerning allowance of ammonium hydroxide, potassium hydroxide and sodium hydroxide as processing aids for production of an enriched protein fraction from alfalfa (see Section 3.6) the Group discussed Article 22a of Reg. (EC) 889/2008 in detail. The reasons for this discussion were the following:

- 1 There is and has not been a section for processing aids in Annex VI: Feed Additives similar to section B of Annex VIII on products for production and processing of food, so should the Group suggest such a section.
- 2 After the amendment of Reg. (EC) 889/2008 by Reg. (EC) 505/2012 there are no longer any non-organic plant products listed in Annex V of the regulation, so the question was, if the fibre fraction of certified organic alfalfa should be put in Annex V, if the processing

aids (NH₄OH, KOH or NaOH) used for the protein extraction were not approved for inclusion in Annex VI, because they end up in the fibre fraction hereby making it ‘non-organic’. Otherwise the alfalfa fibre fraction of the certified organic alfalfa would be considered non-organic, which would seem to be a waste of an otherwise good organic feed product for herbivores.

Article 22a on the ‘Use of certain products and substances in feed’ states the following:

‘For the purposes of Article 14(1)(d)(iv) of Regulation (EC) No 834/2007 only the following substances may be used in the processing of organic feed and feeding organic animals:

(a) non-organic feed materials of plant or animal origin, or other feed materials that are listed in Section 2 of Annex V (= Other Feed Materials than Feed materials of mineral origin, which are listed in Section 1), provided that:

(i) they are produced or prepared without chemical solvents; and

(ii) the restrictions laid down in Article 43 (max. 5 % non-organic protein feed for pigs and poultry) or Article 47(c) (exceptions in catastrophic circumstances) are complied with’

The sentence ‘non-organic feed materials of plant or animal origin, or other feed materials that are listed in Section 2 of Annex V’ is not clear, At the moment there are only two fermentation (by-)products from inactivated or killed microorganisms in Annex V, Section 2 but more materials, e.g. of plant origin could be added in Section 2. When reading the sentence it may be interpreted as if non-organic feed materials of plant (or animal) origin cannot be used, as none are listed in Annex V.

This interpretation is actually confirmed when reading Reg. (EC) 834/2007 Article 14 (1)(d)(iv) and in particular Article 16 (1) (c+d).

Reg. (EC) 834/2007, *Article 14 on ‘Livestock production rules’* says under (1)(d)(iv): *‘non organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under Article 16’.*

and

Reg. (EC) 834/2008 Article 16 on ‘Products and substances used in farming and criteria for their Authorisation’ says under (1)(c+d):

‘1. The Commission shall, in accordance with the procedure referred to in Article 37(2), authorise for use in organic production and include in a restricted list the products and substances, which may be used in organic farming for the following purposes:....

(c) as non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition;

(d) as feed additives and processing aids’

According to Article 16 all non-organic feed materials from plant, (animal and mineral) origin, which are to be used in organic farming shall be authorised and included in a restricted list by the Commission. However, since the amendment of Reg. (EC) 889/2008 by Reg. (EC) 505/2012 there has not been a list of authorized non-organic feed materials of plant or animal origin in Annex V of the regulation. Therefore it seems that according to Reg. (EC) 834/2007, Article 14 and 16 no non-organic protein feed materials of plant and animal origin are currently authorized for feeding of organic monogastrics.

The Group recommends the Commission to solve this contradiction between Reg. (EC) 834/2007 and Reg (EC) 889/2008 as soon as possible⁷.

MINORITY OPINIONS

None

4.7 LIST OF ABBREVIATIONS / GLOSSARY

The following definitions from Reg. (EC) 1831/2003, Article 2.2 are used in the report:

Feed hygiene means the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use.

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) of Reg. (EC) 1831/2003.

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 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.

The following definitions from Reg. (EC) 1069/2009, Article 3 are used:

Animal by-products: means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen (Reg. (EC) 1069/2009).

Farmed animal: means a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes; b) equidae.

⁷ The Commission considers that there is no contradiction between Council Regulation (EC) No 834/2007 and Commission Regulation (EC) No 889/2008 as regards the use of non-organic protein feed of plant or animal origin. Although not included in a restricted list, such material is actually authorised through Article 43 of Regulation (EC) No 889/2008, for porcine and poultry species, until 2017.

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REGULATION (EC) No 767/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives.

REGULATION (EC) No 183/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 January 2005 laying down requirements for feed hygiene

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

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

COUNCIL REGULATION (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (Consolidated version).

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COMMISSION REGULATION (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements.

COMMISSION REGULATION (EC) No 473/2002 of 15 March 2002 amending Annexes I, II and VI to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, and laying down detailed rules as regards the transmission of information on the use of copper compounds.

COMMISSION IMPLEMENTING REGULATION (EU) No 991/2012 of 25 October 2012 concerning the authorisation of zinc chloride hydroxide monohydrate as feed additive for all animal species.

COMMISSION IMPLEMENTING REGULATION (EU) No 836/2014 of 31 July 2014 amending 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.

COMMISSION IMPLEMENTING REGULATION (EU) No 427/2013 of 8 May 2013 concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 as a feed additive for all animal species and amending Regulation (EC) 1750/2006, (EC) No. 634/2007 and (EC) No 900/2009 as regards the maximum supplementation with selenised yeast.

COMMISSION IMPLEMENTING REGULATION (EU) No 505/2012 of 14 June 2012 amending and correcting 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.

COMMISSION IMPLEMENTING REGULATION (EU) No 269/2012 of 26 March 2012 concerning the authorisation of dicopper chloride trihydroxide as feed additive for all animal species.

DIRECTIVE 2006/113/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2005 on the quality required of shellfish waters.

DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 May 2002 on undesirable substances in animal feed.

COUNCIL DIRECTIVE 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs.

ANNEX 1:

Questions to consider in a mandate on Suckling periods that need to be respected for different species of animals

- Definition of natural milk: Is natural milk defined as milk from the same species or is it fresh milk in contrast to milk replacement? And should it be required that it is from the same species?
- All new-borne mammals must be fed colostrum, preferably directly from the mother but otherwise from other mother-animals, preferably from the herd (e.g. frozen colostrum) within the first 6 hours after the birth for the sake of raising the immune defence of the new borne calf/kid/lamb/foal/piglet. Is it necessary to state this in the organic regulation?
- How long time should the mother and offspring minimum be together seen from an animal health and welfare point of view of both mother and offspring?
- Should the use of milking aunts after the minimum weaning period be required for a certain period of time for socializing of the young mammals?
- Are 40 days enough for piglets, considering the risk of diarrhoea of the piglets by weaning?

Two reports have been identified which deal with the subject, but they are in Danish and Dutch respectively:

- Arbejdsgruppen om hold af svin (2010): Arbejdsgrupperapport om hold af svin, Dec. 2010.
- Wageningen UR Livestock Research (2011): Scheiden van dieren. Rapport 428.

ANNEX II:**Feed: Relevant legislation**

The regulations listed here are of high relevance to earthworm and insect feed products placed on the European market. The list is not exhaustive (after Münke and Halloran, 2014).

	Regulation	Full name of regulation	Purpose	Notes
1	1069/2009	EC Reg. 1069/2009 laying down health rules as regards animal byproducts and derived products not intended for human consumption and repealing Reg. (EC) 1774/2002 (Animal byproducts Regulation)	<ul style="list-style-type: none"> Establishes strict health rules for the use of animal byproducts, so as to ensure a high level of health and safety. In particular it inhibits intraspecies recycling; Sets out the measures to be implemented for the processing of animal byproducts; Establishes a classification of animal byproduct materials (Categories 1, 2 & 3) 	<ul style="list-style-type: none"> Under EC Reg. 1069/2009: <ol style="list-style-type: none"> 'animal' means any invertebrate or vertebrate animal; 'farmed animal' means (a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes; (b) equidae; Insects used as feed would be considered under Category 3. Category 3 material comprises the following animal byproducts, (for a full description please refer to the summary of EC Regulation 1774/2002 under A) below the table). Includes a ban on the use of manure and catering waste for feeding of farm animals, including insects and earthworms
2	32/2002	DIRECTIVE 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed	The Directive lays down a list of undesirable substances, for which it sets limit values above which their presence in animal feeds is forbidden (see Annex I to the Directive). This list is regularly updated in the light of technical progress.	

3	68/2013	EC Reg. 68/2013 on the Catalogue of feed materials	<ul style="list-style-type: none"> • To support livestock farmers who normally do not analyse the feed materials they use. • Facilitates the implementation of EC Reg. 767/2009 	Voluntary, materials not listed does not imply that they are barred from use. Feed materials used, but not listed must be registered under the Feed Materials Register
4	142/2011	EC Reg. 142/2011 Implementing Reg. (EC) 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and Implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive.	<ul style="list-style-type: none"> • To simplify the procedure of labelling and marketing feed, while guaranteeing a high level of protection for animal health and welfare, as well as public health. • This Regulation covers feed, i.e. any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. 	<ul style="list-style-type: none"> • Includes Processed Animal Proteins (PAP): Animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X so as to render them suitable for direct use as feed material or for any other use in feedingstuffs (see B below). Only animal byproducts which are Category 3 material or products which are derived from such animal byproducts, other than Category 3 materials, referred to in Article 10(n), (o) and (p) of Reg. (EC) 1069/2009 may be used for the production of processed animal protein. • If insects are considered a Category 3 materials shall comprise the following animal byproducts (a) carcasses and parts of animals slaughtered.
5	767/2009	EC Reg. 767/2009 on the placing on the market and use of feed, amending European Parliament and Council Reg. 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC, 96/25/EC and Commission Decision 2004/217/EC	<ul style="list-style-type: none"> • Helps to provide information to users concerning the content of the feed purchased for livestock and other animals 	<ul style="list-style-type: none"> • Implemented though EC Reg. 68/2013
6	183/2005	EC Reg. 183/2005 laying	<ul style="list-style-type: none"> • Establishes general 	

		down requirements for feed hygiene	rules governing feed hygiene, conditions and arrangements ensuring traceability of feed as well as conditions and arrangements for registrations and approval of establishments	
7	999/2001 & 56/2013	<p>EC Reg. 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies</p> <p>EC Reg. 56/2013 amending Annexes I and IV to Reg. (EC) 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies</p>	<ul style="list-style-type: none"> Establishes rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies in animals in order to protect human and animal health 	<ul style="list-style-type: none"> Created after the BSE outbreak of 1994. Under EC Reg. 56/2013 processed animal proteins (PAPs) from non-ruminant animals and feedingstuffs containing such PAP have now been reauthorized for feeding aquaculture species. However, this does not include insects or earthworms.

A) According to EC Reg.1774/2002 Category 3 feed material comprises the following animal byproducts:

- parts of slaughtered animals which are fit for human consumption but are not intended for human consumption for commercial reasons;
- parts of slaughtered animals which are rejected as unfit for human consumption but are not affected by any sign of a communicable disease;
- hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse and were declared fit for human consumption after undergoing an ante mortem inspection;
- blood obtained from animals declared fit for human consumption after undergoing an ante mortem inspection, other than ruminants slaughtered in a slaughterhouse;
- animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;
- former foodstuffs of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects;
- raw milk originating from animals that do not show any signs of a communicable disease;
- fish or other sea animals, except sea mammals, caught in the open sea for the purpose of fishmeal production, and fresh by-products from fish from plants manufacturing fish products for human consumption;
- shells of eggs originating from animals that do not show any signs of a communicable disease;
- blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from healthy animals;
- catering waste other than category 1.

B) According to EU Reg. 142/2011 'processed animal protein' means animal protein derived entirely

from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (including blood meal and fishmeal) so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including petfood, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen.

ANNEX III:**Scientific projects and reports on the availability of protein feeds, in particular essential amino acids for organic monogastrics.**

The 3 year CORE Organic II project, ICOPP (Improved Contribution of local feed to support 100 % Organic feed supply to Pigs and Poultry. The project was finalised on September 30, 2014.

See:

<http://www.organicresearchcentre.com/icopp/?page=home>

http://www.orgprints.org/21763/1/Nelder%20OAH%20proceedings_2012.pdf

<http://www.orgprints.org/25217/1/frueh-2014-Eiweissversorgung.docx.pdf>

- Gittins, J.; Cottrill, B. and Wheeler, K. (2014): 100% Organic Diet Mixes for Monogastrics – Impacts on UK Production. Defra Project OF0397.
- Rahmann, Gerold (2014): Ganz oder gar nicht!: pro 100-Prozent-Biofütterung. Ökologie und Landbau, Band 170, Heft 2, Seiten 20-21 (in German).
- Stephanie Witten, Hans Marten Paulsen, Friedrich Weißmann, Ralf Bussemas (2014): Praxisbefragung zur Aminosäurelücke und praktische Möglichkeiten zur Verbesserung der Eiweißversorgung der Monogastrier in der Fütterung im Ökologischen Landbau. Thünen Working Paper 23 (in German).