

# **SYMPOSIUM: THE ROLE OF INORGANIC MINERALS IN THE FOOD AND FEED CHAIN**

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## **INORGANIC MINERALS AND EU LEGISLATION**

### **INTRODUCTION**

Animal tissues contain inorganic or mineral substances in widely varying amounts. They exist in ash mostly as oxides, carbonates, phosphates and sulphates, so that the percentage of total ash is always higher than the sum of individually determined inorganic elements.

The first demonstration of the nutritional significance of minerals dates back to 1971. It was shown that canaries on a seed diet required a supplement of calcareous earth to be healthy and to produce eggs. Throughout the second and third quarters of the 20<sup>th</sup> century, outstanding advances were made in the understanding of the nutritional significance of minerals. The use of purified diets can demonstrate deficiencies, toxicities or imbalances of certain minerals. The application of molecular biology in the eighties contributed to understanding some of the complex mechanisms by which minerals are safely transported across membranes.

22 minerals have so far been regarded as essential for higher animals.

- There are 7 major macronutrient minerals: calcium, phosphorus, potassium, sodium, chlorine, magnesium and sulphur.
- There are 15 trace elements: iron, iodine, zinc, copper, manganese, cobalt, molybdenum, selenium, chromium, tin, vanadium, fluorine, silicon, nickel and arsenic. The last nine are referred to as new trace elements and their beneficial effects have been demonstrated with laboratory animals reared under very special conditions. Although for some specialists these trace elements have no special relevance in farm animals, the experience with selenium has demonstrated a range of selenium-responsive diseases in farm animals. As techniques continue to be refined, some of these new elements will probably become more relevant.

As regard trace elements, EC legislation regulates all those considered to be essential — iron, iodine, zinc, copper, manganese and cobalt — and also two of the new elements — molybdenum and selenium.

Trace elements are regarded as feed additives, while macrominerals are feed materials.

### **2.- MACROMINERALS**

Macrominerals are regulated by Directive 96/25/EC on the circulation of feed materials. The Annex to the Directive [1] contains a specific chapter listing the more common feed materials used as sources of calcium, magnesium, phosphorus, sulphur and sodium. This list is not exhaustive, so it is possible to use other sources of minerals provided that such materials

circulate under names that are different from<sup>[12]</sup> those listed in the Annex and cannot mislead purchasers as to the real identity of the product offered to them.

Although the use of different feed materials is possible, there are some general requirements that apply. Minerals can be placed on the market only if:

- they are sound, genuine and of merchantable quality;
- they do not represent any danger to animal or human health or to the environment
- they cannot be placed on the market in a manner liable to mislead the user.

While the general labelling requirements are also applicable to macrominerals, certain particulars must be shown on an accompanying document or where appropriate on the packaging, the container or an attached label:

- It is compulsory to declare on the label of a feed material the minerals relevant for the particular feed material. For magnesium sulphate, for example, it is compulsory to declare magnesium and sulphur. This requirement also applies to feed materials not listed in Directive 96/25/EC.

The declaration of the mineral is <sup>[13]</sup>not required in the following cases:

1. if the purchaser has stated in writing that he does not require this information;
  2. pet food subject to a simple physical treatment in quantities less than 10 kg supplied directly to the final user in the same Member State;
  3. certain fresh or preserved feed materials, whether or not subject to a physical treatment, which do not contain additives except preservatives and which are provided by a farmer-producer to a breeder-user established in the same Member State;
  4. by-products of agro-industrial processing with a moisture content greater than 50%
- For two feed materials, it is necessary to indicate the ash insoluble in HCl (calcium carbonate and calcareous marine algae). The above exceptions are also applicable here.
  - In the case of calcium carbonate and sodium chloride, it is possible to add the source of the mineral or to use it instead. For example: "sodium chloride from rock salt" or "rock salt".
  - For dicalcium phosphate, the manufacturing process can be included. This serves to distinguish between organic and inorganic origin.
  - The Directive sets permitted tolerances for declared values of phosphorus, sodium, calcium, carbonate, calcium and magnesium and also for the declaration of ash insoluble in hydrochloric acid. This ensures that even if the declared value is higher than the real content, a minimum level of the mineral is nevertheless guaranteed. For example, in magnesium, for a declared value of 15% or more, the tolerance allowed is 1.5 units. This means that, for a declared value of 16% magnesium, the real content determined in an official inspection cannot be lower than 14.5%.

There are a few macrominerals of animal origin to which relevant veterinary legislation applies, in particular Regulation 1774/2002 laying down rules concerning animal by-products not intended for human consumption and Regulation 999/2001 as regards transmissible spongiform encephalopathies and animal feeding.

The so-called feed ban allows the use of dicalcium and tricalcium phosphate for pets, fur animals and farm animals other than ruminants.

Feedingstuffs containing dicalcium and tricalcium phosphate intended for non-ruminant farmed animals (with the exception of carnivorous fur-producing animals) must comply with the following requirements:

- They must be produced in a processing plant approved by a competent authority in accordance with Regulation (EC) N° 1772/2002. This applies also to petfood.
- The establishment must not prepare feedingstuffs for ruminants, although there are exemptions for home compounders and certain establishments for ruminants;
- Transport must be separate from feed intended for ruminants.
- Storage is prohibited in farms where ruminants are kept, unless the competent authority grants an exemption. This also applies to petfood;
- The labelling and accompanying documents for the feed must indicate: “contains dicalcium/tricalcium phosphate of animal origin — cannot be fed to ruminants”;

The legislation applicable to compound feedingstuffs is Directive 79/373/EEC on the circulation of compound feedingstuffs.

Many trace elements or minerals are incorporated in the daily ration via complementary feedingstuffs or mineral feedingstuffs. Mineral feedingstuffs are in fact a kind of complementary feed composed mainly of minerals and containing at least 40% crude ash.

Apart from the general labelling requirements applicable to compound feedingstuffs, there are some specific requirements relating to the minerals present. Certain particulars must be shown in a space provided on the packaging, the container or an attached label:

1. A description of the compound feed must be given, for example “*complementary feedingstuff*” or “*mineral feedingstuff*”
  2. Except for pet food, the feed material must be declared with an indication, in descending order, of the percentages by weight, with a tolerance of  $\pm 15\%$
  3. Some declarations for the analytical constituents are compulsory depending on the type of compound feed: these declarations refer to the mineral itself, e.g. “*calcium*”, and not to the feed material used to incorporate the mineral into the feed. For the feed material, point 2 above applies.
- In complete feedingstuffs, phosphorus must be declared for fish (except ornamental fish), but this is optional for other species. It is optional to declare calcium, sodium, magnesium and potassium for all species.
  - In mineral feedingstuffs, calcium, phosphorus and sodium must be declared for all animals and magnesium must be declared for ruminants. It is optional to

declare magnesium for animals other than ruminants and sodium for all animals.

- In molassed feed, it is optional to declare calcium, phosphorus, sodium and potassium in all animals. It is compulsory to declare magnesium with a content of  $\geq 0.5\%$  for ruminants, but this is optional for other species.
  - For complementary feedingstuffs other than mineral or molassed feed, it is compulsory to declare calcium (level  $\geq 5\%$ ) and phosphorus (level  $\geq 2\%$ ) for all animals except pets and magnesium (level  $\geq 0.5\%$ ) for ruminants. Other optional declarations are possible for sodium, potassium, magnesium, phosphorus and calcium under certain conditions.
4. For the analytical declarations, the Directive specifies a tolerance where the content recorded is less than the declared content in the case of sodium, potassium, magnesium, phosphorus, calcium and crude ash. Where the variation is in the opposite direction (the declared content is lower than the real content), the total permitted level of those minerals is three times the tolerance permitted in the previous case. For phosphorus, for example, where the declared value is 16% and the analysis demonstrates that the real content is lower, the minimum content permitted is 14.8 %, so the tolerance is 1.2. Where the opposite is the case, i.e. analysis shows that the real content is higher than 16%, the maximum level permitted is 18.6%. The tolerance in this case is three times 1.2
  5. In case of whole grain mixes, the analytical declarations are not required; they may, however, be provided.

In general, Community legislation aims to inform the user about those aspects relevant for ensuring an appropriate diet composition for livestock. For example, the specification of magnesium is relevant for ruminants to prevent some characteristic magnesium-related disorders, e.g. hypomagnesaemia in sheep and cattle.

### **3.- TRACE ELEMENTS**

#### **3.1 Authorisation and labelling**

Community legislation regulates the use of iron, iodine, cobalt, copper, manganese, zinc, molybdenum and selenium.

Regulation (EC) 1831/2003 on additives for use in animal nutrition lays down the conditions for authorisation, labelling and placing on the market of these trace elements. Trace elements belong to the category of nutritional additives. Before Regulation (EC) 1831/2003, trace elements were regulated by Directive 70/524/EEC, which also established a procedure for the authorisation of such additives. Those additives that were placed on the market under this procedure are regarded as existing products in accordance with Article 10 of Regulation (EC) 1831/2003. Those that have been notified and which comply with the requirements in Article 10 will be entered in the Register by 7 November 2005.

According to Regulation (EC) 1831/2003, no person may place on the market, process or use an additive unless:

- (a) it is covered by an authorisation granted in accordance with the Regulation;
- (b) the conditions for use set out in this Regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and
- (c) the conditions for labelling set out in the Regulation are met.

For the authorisation of a new additive, the applicant must submit the application for authorisation to the Commission (the Member state rapporteur has disappeared in the new Regulation). The Commission must inform without delay the Member States and forward the application to the European Food Safety Authority, which is responsible for the risk assessment.

The application for authorisation should include the following information and documents, which must be sent directly to the Authority

- (a) applicant's name and address;
- (b) the identification of the feed additive, a proposal for its classification by category and functional group, in this case trace elements belong to the category "nutritional additives" and the functional group is "compound of trace elements"; the specifications and purity criteria, where applicable, are also required;
- (c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;
- (d) a copy of the studies that have been carried out and any other material available to demonstrate that the feed additive satisfies the criteria laid down in the Regulation;
- (e) proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and the animal species and categories for which the feed additive is intended;
- (f) a written statement that three samples of the feed additive have been sent by the applicant directly to the Community reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex II;
- (g) a proposal for post-market monitoring;
- (h) a summary containing the information provided under points (a) to (g).

The Authority must give an opinion within 6 months; however, this limit can be extended if the Authority asks for complementary information. The Commission must prepare a draft Regulation to grant or deny the authorisation. In this risk management process, the Commission should take into account the opinion of the Authority. When the draft deviates from the opinion, the Commission should provide an explanation. The Commission can also

consider other legitimate factors when drafting the Regulation, in particular those relating to animal health and welfare and benefits to the consumer.

The Community reference laboratory, which is the Joint Research Centre of the Commission, has to prepare a report to evaluate the data submitted by the applicant on the method of detection. This report must be submitted to the Authority, which will verify it.

The requirements for labelling additives or premixtures containing trace elements are listed in Article 16 of the Regulation:

The following information should appear on the label for each additive contained in the material:

- (a) the specific name given to the additive upon authorisation, preceded by the name of the functional group as mentioned in the authorisation;
- (b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article;
- (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;
- (d) where appropriate, the approval number assigned to the establishment or intermediary or the registration number assigned to the establishment.
- (e) directions for use, any safety recommendations regarding use and, where applicable, the specific requirements mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended;
- (f) the identification number;
- (g) the batch reference number and date of manufacture;
- (h) the level of the trace element;
- (i) the expiry date of the guarantee of this level or the storage life from the date of manufacture.

When trace elements are incorporated into compound feed or feed materials, some additional labelling requirements apply. Those requirements are laid down in Article 16 of Directive 70/524/EEC, which continues to apply until the Compound Feed Directive has been revised. The following information must appear on the package, container or label:

- (a) in the case of copper, the name of the additive, e.g. copper sulphate and the level of copper. For other trace elements, this information may be provided but it is not mandatory

Apart from the general requirements applicable to the labelling and placing on the market of trace elements, or feed materials and compound feed there are specific conditions or

restrictions governing the use of such additives that are linked to the specific authorisation and related in some cases to the outcome of the risk assessment.

One of the more important aspects that are clearly linked to the specific authorisation is the maximum level authorised in feed. The permitted maximum levels are calculated on the basis of different parameters:

1. Species or breeds: for example, there are wide differences in susceptibility to copper overload: pigs are highly tolerant, cattle and goats less tolerant and sheep extremely intolerant of copper excess.
2. The type of production: for example, laying hens require higher levels of Zn than fattening chickens.
3. Diet can influence the intake of trace elements. The mineral composition varies between different crops or forages. For example, blood meal contains 2000-3000 ppm of iron while the level in cereals is around 100 ppm. The use of urea to replace protein sources in ruminants results in mineral supplementation because urea does not contain trace elements
4. Local soil and climatic effects: there are soils where copper deprivation occurs due to high concentrations of molybdenum in herbage.
5. The availability to animals. How much can be absorbed from the gut and used by the animals depends on the age, species, intake of the mineral relative to need, chemical form in which the mineral is ingested, and the amounts and proportions of other dietary components with which it interacts metabolically. For example, the presence of fibre and phytate in some plant protein sources reduces the availability of Zn. A high level of cadmium induces either copper or zinc deficiencies.

## IRON

Iron is the most abundant trace element in the body and its value as a dietary constituent has been recognised for over 200 years. It interacts with Cu, Mn, Zn and P.

It is important to note that copper deficiency results in hepatic iron accumulation. In general, for farm livestock, the iron supply is rarely critical except in the first few weeks of life when the production of haemoglobin increases (approx. 60% of iron is present in the body as haemoglobin). The legislation takes into account the special case of anaemia in piglets when pigs are housed in concrete (so they do not have access to soil rich in iron): as piglets can ingest only mother's milk, the requirements are set in mg/day. Pet animals, in particular carnivorous pets such as cats and dogs, also demand higher levels of iron.

The maximum levels permitted in mg/kg of complete feed (except for piglets)<sup>1</sup> are:

- a. Ovine: 500 (total) mg/kg of the complete feedingstuff
- b. Pet animals: 1 250 (total) mg/kg of the complete feedingstuff
- c. Piglets up to one week before weaning: 250 mg/day, other pigs 750 99m
- d. Other species: 750 (total) mg/kg of the complete feedingstuff

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<sup>1</sup> All the references to maximum contents or levels are calculated for the maximum content of the element in mg/kg of the complete feed with a moisture content of 12%.

## **COBALT**

Cobalt deficiency *per se* has never been clearly demonstrated in monogastric species and horses, which have lower dietary requirements for vitamin B<sub>12</sub>. Non-ruminant species cannot incorporate cobalt in its physiologically active form and must obtain cobalt via Vitamin B<sub>12</sub> from feed. For ruminants, deficiency occurs when the dietary cobalt is inadequate for synthesis of sufficient vitamin B<sub>12</sub> by the rumen microorganisms. Cobalt deprivation is in many cases linked to soil characteristics: for example, soils rich in manganese depress cobalt uptake in pasture. Heavy liming also reduces plant-available soil cobalt.

The maximum content laid down in the legislation is 10 ppm. The Directive applies this level to all animals but it is in fact relevant only for ruminants.

## **COPPER**

Copper is essential for growth and haemoglobin formation and also for the prevention of a wide range of clinical and pathological disorders. Another important aspect is the antagonisms between copper and molybdenum. Extensive copper-deficiency areas, affecting both crops and livestock, have been discovered throughout the world. High levels of molybdenum in soils cause copper deprivation in ruminants in pasture or those fed on silage from these areas. The opposite applies when the level of molybdenum is too low: this may cause copper poisoning.

Copper is also an iron antagonist and the interaction between copper and molybdenum is also related to levels of sulphur. For this reason, the labelling has to inform users that levels lower than 20 ppm may cause copper deficiencies in cattle-grazing pastures with high levels of molybdenum and sulphur.

The growth-promoting effects of copper are very important in pigs. The legislation has authorised levels of 170 ppm for piglets up to 12 weeks. For growing and finishing pigs, no significant growth effects have been demonstrated, so that the maximum content is 25 ppm.

The high ability of calves to absorb copper along with the high copper storage ability of their livers means that toxic levels are quickly reached, so milk replacers and other feeds for calves should contain low levels of copper (15 ppm). For ovines, there is a narrow margin of safety between nutritional requirements and toxic levels. For this reason, the maximum level is reduced to 15 ppm as well. Some breeds of sheep are even more sensitive to copper, so the legislation specifies that the label of the compound feed must warn the user about the possibility of copper intoxication for certain breeds if the level exceeds 10 ppm.

For other species or types of production, the maximum authorised level is 25 ppm, except for crustaceans, which have higher requirements: 50 ppm

## **IODINE**

The iodine requirements have been re-examined by the European Food Safety Authority. For the moment, the maximum authorised level is 10 ppm except for equines (4 ppm) and fish (20 ppm). The Commission is examining the report of the European Food Safety Agency with a view to deciding on a possible change in iodine levels. Nevertheless, it is clear from the report that additional information is required before any complete revision of the appropriate levels.

## **ZINC**

In all species, zinc deprivation is characterised by retardation of growth, skin lesions and abnormalities in hair, wool or feathers and decreased efficiency of feed utilisation.

The maximum authorised contents are 150 ppm for the majority of species, except for fish and milk replacers (200 ppm) and pet animals (250 ppm).

Large areas of zinc-deficient soils exist in many countries, which can cause zinc deprivation in grazing animals. Cereal-based diets and diets containing soya, lupin and cotton-seed meals also cannot be relied on to provide sufficient zinc for poultry because of the chelating effects of phytate. Zinc bioavailability is also influenced by high amounts of copper and iron in the diet. In general, however, livestock exhibit considerable tolerance to this trace element.

## **MANGANESE**

Manganese has effects on cartilage development, blood clotting, lipid and carbohydrate metabolisms and reproduction.

In general, manganese deprivation is largely confined to poultry species. However, it may occur in ruminants reared on maize silage or on diets with high contents of iron, calcium, phosphorus and potassium.

The maximum authorised content is 150 ppm, except for fish (100 ppm).

## **MOLYBDENUM**

This element is mainly known for its interaction with copper. This is explained above in the section on copper. The maximum authorised content is 2.5 ppm

## **SELENIUM**

For many years, selenium was known only for its toxic effects. Not until 1957 was it discovered that selenium plays an essential physiological role in animals. Selenium is necessary for growth and fertility and for the prevention of a variety of diseases that show a variable response to vitamin E, e.g. muscular dystrophy in calves and lambs. The dietary requirement for selenium must be adjusted to vitamin E, which has a complementary action. The maximum authorised content is 0.5 ppm. The high toxicity of selenium calls for proper use and management.

### **3.2 Conditions for establishments using additives belonging to the functional group “compounds of trace elements”**

Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene applies from 1 January 2006 and replaces Directive 95/69/ EC.

This Regulation lays down general rules for feed hygiene, conditions and arrangements for ensuring the traceability of feed and conditions and arrangements for the registration and approval of establishments.

As regards feed hygiene requirements, operators carrying out activities other than those related to primary production must follow a permanent written procedure or procedures based on HACCP principles. This applies to those manufacturing compounds of trace elements.

The Regulation requires the approval of establishments by the competent authorities where such establishments carry out one of the following activities:

- (1) manufacturing and/or placing on the market of all compounds of trace elements;
- (2) manufacturing and/or placing on the market of premixtures prepared using copper and selenium compounds.

Where other establishments are concerned, feed business operators must notify the appropriate competent authority of any establishments under their control so that they can be registered.

#### **4. Presence of undesirable substances in additives and trace elements**

Directive 2002/32/EC on undesirable substances in animal feed establishes maximum limits for undesirable substances in feed materials, additives, premixtures of additives and compound feed. The maximum limits need to be revised on the basis of updated scientific risk assessments. This Directive introduced the possibility of establishing maximum limits not only for compound feed but also for additives.

Minerals and trace elements are sometimes the origin of feed contamination with undesirable substances. Depending on the origin of the mineral or the manufacturing process, the product can be contaminated with various heavy metals, for example mercury in calcium carbonate, or other highly toxic substances, such as dioxins in calcium sulphate.

Directive 2002/32/EC sets specific levels of certain undesirable substances for the following minerals.

<b>UNDESIRABLE SUBSTANCE</b>	<b>MAXIMUM LEVEL IN PRODUCTS INTENDED FOR ANIMAL FEED, IN MG/KG (PPM) RELATIVE TO A FEEDINGSTUFF WITH A MOISTURE CONTENT OF 12 %</b>
1. Arsenic	— Phosphates 10 — Calcium carbonate 15 — Magnesium oxide 20 — Mineral feedingstuffs 12
2. Lead	— Phosphates 15 — Calcium carbonate 20 — Mineral feedingstuffs 15

3. Fluorine	<ul style="list-style-type: none"> <li>— Phosphates 2 000</li> <li>— Calcium carbonate 350</li> <li>— Magnesium oxide 600</li> <li>— Complementary feedingstuffs containing <math>\leq 4</math> % phosphorus 500.</li> <li>— Complementary feedingstuffs containing <math>&gt; 4</math> % phosphorus 125 per 1 % phosphorus.</li> </ul>
4. Mercury	— Calcium carbonate 0.3
5. Cadmium	<ul style="list-style-type: none"> <li>— Phosphates 10</li> <li>— Mineral feedingstuffs 5</li> </ul>
6. Dioxin (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs))	Minerals listed in the Annex to Council Directive 96/ 25/EC of 29 April 1996 on the circulation and use of feed materials 1.0 ng WHOPCDD/ F-TEQ/ kg

The EFSA's Scientific Panel on Contaminants in the Food Chain has adopted two opinions on cadmium and lead on 2 June 2004. On the basis of these opinions, it is advisable, among other things, to establish maximum limits for lead and cadmium in all additives belonging to the functional group trace elements and also for premixtures of such additives. The Commission is examining this issue and a proposal will be presented for adoption.