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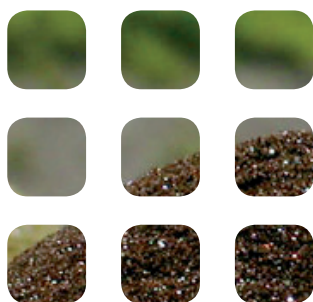
Premixtures

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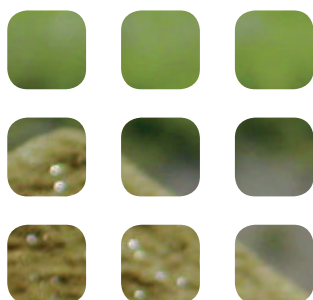
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Preamble

FEFANA is the EU Association of Specialty Feed Ingredients and their Mixtures. With more than 100 members from 28 countries, it represents feed business operators active in the feed chain, such as specialty feed ingredients producers, premixtures manufacturers, users, importers and distributors.

Established in 1963, FEFANA has represented and served the interests of its industry ever since and it is a recognised partner for national, European and international authorities and fellow organizations in the feed and food chain.

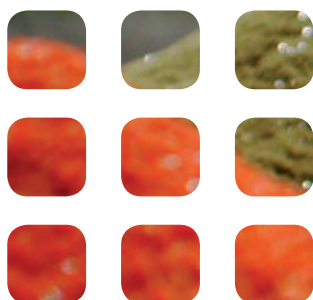
Specialty Feed Ingredients and their Mixtures are fundamental in the livestock chain to ensure balanced feed, thus contributing to animal health and welfare. Quality and safety are at the heart of our business and we believe that innovation and sustainability are key concepts that we will continue to focus on.

With a unique framework, the association is able to draw on the exceptional knowledge of our members, bringing together expertise and science. This is why we are able to provide you with such a valid publication.

The feed premixture industry has developed greatly over the last decades. It is regarded as a key partner for the compound feed industry, farmers and other feed business operators in handling complexity. Just to mention a few: in global sourcing of specialty feed ingredients, in managing many formulations, of safe and smooth handling of ingredients with many different properties. FEFANA is a provider of tailor made solutions and a partner to work on convenient and sustainable feed to food solutions.

In this booklet we would like to provide the up-to-date information about the role of the premixture industry in the feed to food chain.

Didier Jans
FEFANA Secretary General



Introduction

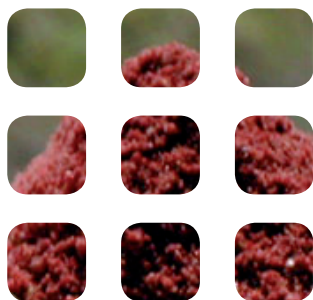
This booklet has been designed and developed by the members of the FEFANA Working Group Premixtures. The aim of this working group is to promote, defend and represent the common and general interests of the European premixture industry.

The different chapters in this booklet aim to draw a picture of the European premixture industry and are based on EU legislation at the time of editing. We aim to update the relevant information as appropriate following changes in legislation.

In particular we start with a description of the various types of premixtures and go on to explain the sourcing and procurement process of premixture ingredients, their formulation, manufacturing, packaging and transport. We then focus on the quality management and safety, and provide information on their physical and chemical characteristics.

We hope you will find this booklet useful and that it will clarify the landscape in which the EU premixture industry is operating.

Peter Fidler
Chairman Working Group
Premixtures



I. THE VARIOUS TYPES OF PREMIXTURES

In the European Union, premixtures are defined as “mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals”. The terms premix, base-mixes, blends, etc, are commonly used as synonyms and reflect the large variety of products.

The use of premixtures is mainly aimed at:

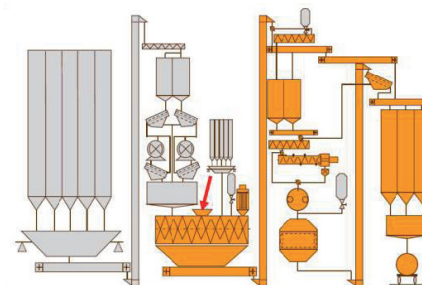
- Reducing the number of ingredients to be supplied, handled and incorporated in the feed mills.
- Ensuring proper homogenisation of the feed additives in the final feed, especially for those additives that are added in very small quantities or that may present specific risks for the animals if not given in the right amount.
- Eventually providing standardised products with sustainable quality and safety to the feed industry.

However, manufacturing processes of feed are diverse and new technologies have become available, feeding practices steadily change according to the market trends, scientific progress and economic constraints, new feed additives and functional feed ingredients are entering the market and the regulatory environment is evolving. Therefore, the premixture industry is constantly adapting its offer to the needs of its customers.

Premixtures can take many different forms according to their use or their specific function(s) in the feed.

1. Product forms

Solid premixtures: these premixtures in powder form are usually mixed with the other feed materials in the early steps of the feed production, as close as possible to the mixer, but before any other treatment (such as pelleting, etc). They represent the vast majority of premixtures used on the market.



Picture 1:
Manufacturing flowchart of compound feed. Source: IFF, Braunschweig

Liquid premixtures: in general these liquid premixtures are included after further processing of the feed ingredients (e.g. post-pelleting / extrusion). It is particularly helpful for feed additives which may be sensitive to temperature, moisture or high pressures (e.g. enzymes).

This can also be used to apply flavouring/appetizing substances at the surface of the feed and therefore provide higher palatability.

2. Product functions

Premixtures - in either liquid or solid form - can contain one or more feed additives, with similar or different functions. Basically, the following product types can be defined according to their functions in the feed:

- **Pre-dilution:** They are premixtures of one feed additive with a carrier or carriers, with the aim to dilute the feed additive and then better incorporate it in large amounts of feed materials or potentially in another premixture.
- **Specific blends:** These products are designed to fulfil specific function in feed:
- **Feed additives blends:** These blends are usually premixtures containing additives of the same functional groups (e.g. vitamins, minerals, carotenoids, acids, preservatives, etc...) and which can be used for different types of feeds and potentially different animal species or categories. More than one blend is usually incorporated in the feed mill.

- **Flavour blends:** They are also feed additives blends, but flavouring blends are specifically affected by Intellectual Property aspects. The right combination and balance of the different flavouring compounds can lead to very different results in terms of smell or palatability of final feed. Flavour blends are based on extensive experience, research and know-how that must be protected.
- **Complex premixtures:** Complex premixtures contain a variety of feed additives, which are aimed to cover the nutritional needs and the technological, zootechnical and sensory objectives linked to the particular feed. They are usually the only supply of feed additives in the feed mills.

3. Different constraints

Depending on the type of products manufactured, the need to operate under tight control is increasing and production is becoming more complex due to the following factors:

- **Increasing number of ingredients**
- **Possible chemical interactions between different types of additives leading to**
 - Potential stability issues
 - Potential caking issues
- **Possible physical interactions between the different products leading to:**
 - Potential lack of homogeneity

Therefore, the operators manufacturing premixtures need to implement robust quality systems in their site (further described in other chapters).

In addition, all premixture manufacturers have to strictly follow the general food and feed law and hygiene requirements thereof.

II. SOURCING AND PROCUREMENT

1. Legal, Quality system, Customer requirements

a. *Registered and approved Feed business operators*

Feed business operators shall not operate without a registration or an approval according the European Feed Hygiene regulation. Feed Business operators can only source from registered and / or approved establishments. EU Feed Hygiene Regulation requires that sourcing of feed additives as nutritional additives, zootechnical additives, antioxidants with a fixed maximum content in complete feed, colorants as carotenoids and xanthophylls, is only allowed from approved feed business operators. It is also the case for the use of certain feed materials (biomasses or proteins obtained from micro-organisms). Other feed materials (minerals, carriers, etc), flavouring substances, other technological additives and colorants (other than carotenoids and xanthophylls) are sourced from operators that are properly registered and follow the same strict control regime. For certain feed materials and additives sourced from coun-

tries outside the European Union (third countries), a representative company established in the EU should be identified, declared to national authorities and properly listed. This representative must ensure that the manufacturer in the third country meets at least the hygiene standards in Europe and that the product is compliant with EU legislation.

b. Legal requirements

Maximum levels are set by law to limit as far as possible the presence of undesirable substances and products in animal feed put into circulation within the European Union (EU).

“Undesirable substance” means any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production.

These requirements apply to all products intended for animal feed, including raw materials for feed (basic feed materials and functional feed ingredients), feed additives and complementary feedingstuffs.

Legislation lays down a list of undesirable substances, for which

it sets limit values above which their presence in animal feeds is forbidden or values that should trigger further investigation. These lists are regularly updated in the light of technical and scientific progress.

When these values are exceeded, Member States, in cooperation with the economic operators concerned, must carry out investigations to identify the sources of the substances in question.

They must then inform the Commission of the outcome of these investigations and the measures taken to reduce the level of the substances or eliminate them.

The use of raw materials (feed materials or additives) that do not comply with these requirements is prohibited, even if diluted in a premixture.

For premixtures there are some specific legal limits defined for undesirable substances as well (e.g. heavy metals, dioxins, coccidiostats, carryovers ...). The rationale for fixing such limits in premixture is to reduce the presence of these contaminants as much as possible, whatever the source, at every level of the feed chain. However, this approach implies additional complexity and responsibilities for premixture manufacturers:

- As the occurrence of these undesirable substances in premixtures is essentially due to the natural presence in these raw materials, sourcing of high quality and reliable ingredients is of real importance;
- Being in the middle of the feed chain, it is the responsibility of premixture manufacturers to ensure that all their products comply with the legal limits whatever the level of additives and carriers used, and that the premixture will not lead to exceeding maximum limits once diluted in compound feed.

c. Quality system

Suppliers to the premixture industry are supposed to have a quality and feed safety system in place, including a HACCP system, where risk assessment and management of supplied ingredients, ensure that these products comply to the applicable legislation and agreed specifications. It is quite common that these suppliers and manufacturers have quality systems implemented like FAMI-QS, GMP+, OVOCOM, UFAS, FEMAS, QS, or similar systems. Mutual recognition between these certification systems is of utmost importance for a good functioning of the internal market.

d. Customer requirements

It is quite common that customers of the premixture industry have the desire for the use of specific feed additives, preparations, carriers or other functional ingredients. These requirements are often related to the preference for certain origins or physical properties. Therefore, premixture manufacturers need to handle a large variety of different ingredients to fulfil their customers' preferences and specific requirements.

e. Sourcing of incoming materials

The approval of good quality suppliers and the selection of excellent ingredients are a key aspect of any operator's quality and safety management system(s). Poor raw materials will result in the production of poor quality finished product and may also compromise the safety of the operator's entire process.

Therefore operators will focus on ensuring that their suppliers and ingredients are of the required quality and standard.

2. Ingredients specifications (feed additives, feed materials used as carriers) and packaging materials

a. *Management requirements for premixture ingredients*

Information shall describe the product to be purchased, including, where appropriate, requirements for approval of purchased product.

Selection and approval of all raw materials shall include their origin, transport, storage, and handling. Any potential hazard associated with ingredients shall be documented.

Each ingredient shall have a written specification, including quality agreement, which is amended when change of documented parameters takes place.

In addition to the analytical characteristics of the ingredient, the specification should include, where appropriate, details of any undesirable substance with which the ingredient may typically be associated, and any other hazards or limitations associated with the ingredient material which have been considered in the operator's HACCP system.

Where appropriate, requirements for analytical monitoring shall be defined.

In case the material is a feed additive imported from outside the European Union, a written confirmation of its compliance with the current EU feed Regulations issued by the supplier is needed.

Documentation is required that these feed additives are produced in compliance with the EU requirements.

Operators have a list of internally approved suppliers and each supplier shall be subject to periodical review.

Premixture operators evaluate and select suppliers based on their ability to supply products in accordance with the operator's requirements. Criteria for selection, evaluation and re-evaluation are established.

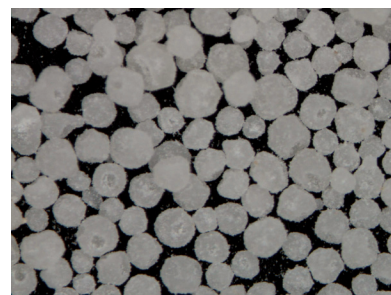
b. *Specifications for packaging materials*

Packaging materials should be suitable for their intended use and in particular they should prevent contamination of the product. A specific chapter of this booklet is dedicated to packaging (Chapter V).

Packaging materials shall not transfer any undesired substances to the products that are packed into it.

3. Specific requirements for premix ingredients

According to European legislation, premixtures of feed additives do not require specific product authorization. They can be manufactured and placed on the market, provided they only contain additives duly authorized (including specific restrictions of use when applicable) and carriers that comply with the EU legislation. The operator shall document that he/she complies with these requirements.



Picture 2:
Particle size: Example of an additive preparation. Microscopic picture of Vitamin D3 beadlets.

a. *Particle size*

Particle size is very relevant for a good distribution in premixtures, but most important for a good distribution in the final feed.

Ingredients with low particle size have in theory more chance to be mixed homogeneously. On the other hand, such ingredients, also depending on many other factors (moisture, electrostatic charges, particle size distribution and shape, etc...), may have more tendency to cake and be more difficult to process. Finally, such ingredients may give rise to occupational health concerns, especially when they have inherent toxicity or sensitizing properties, high dusting potential and particle size in the thoracic or pulmonary fractions (<50 or <10 microns respectively).

Coarse ingredients give less homogeneity, are usually less dusty and do in general flow better.

Here the industry has to find the best compromise.

In a lot of cases the premixture industry will and has to apply pre-blending steps, depending on the physical properties of the used ingredients and the desired flowing properties, as well as to the applied amounts to be weighed and dosed.

b. *pH*

Ingredients can have a wide range of pH values because of

their chemical properties or the way they are processed.

Some additives are more or less sensitive to high or low pH values in a premix, especially if there is free moisture present.

c. *Moisture*

Moisture levels especially in carriers are very relevant, as they can highly contribute to total moisture levels in premixtures.

In general free moisture in premixture will affect stability and can also lead to microbial contamination, as well as increasing the chance on mold formation.

High moisture levels can also have negative effect on flowability and can more easily generate lumps in a premixture.

d. *Bulk density*

Bulk density of ingredients, in relation to the particle size, is a relevant parameter in order to achieve sufficient homogeneity. Carriers with lower bulk density will achieve a higher separation between active particles in premixtures, depending on the amount of carrier present. In addition a consistent and constant bulk density of ingredients will lead to a more constant performance of dosing, weighing and packaging equipment and therefore to a more constant final product.

e. *Reactivity*

Reactivity of ingredients is often related to their properties and to their environment.

Higher moisture levels in the ingredients used, more or highly water-soluble ingredients, or very fine particle sizes (more surface contact possible) will increase the chance of unwanted reactions.

These unwanted reactions can also be strengthened by high or low pH values in moister environments. Sensitivity to high temperatures is also an important parameter for ingredients intended to be further used in harsh feed manufacturing processes (pelletizing, extrusion, etc).

Sensitivity to light and oxygen is especially relevant to define storage and packaging conditions.

f. *Contaminants*

Basically, premixtures should not contain levels of contaminants that impose a risk to feed or food safety or affect the expected quality.

Inclusion of premixtures in feed according to the instruction on the label or guide documents should not lead to any undesired contamination of this feed.

Therefore it is appropriate to agree, besides legally defined limits for premix, also on limits that are only defined for the ap-

plicable feeds for which the premixture is intended.

Most commonly known contaminants are heavy metals like lead, cadmium, arsenic and mercury, as well as dioxins and dioxin-like PCB's, but also physical impurities as well as microbiological contamination shall be avoided. Unexpected contamination from the supply chain is limited by sourcing of known and certified suppliers and manufacturers, as well as by means of selection of reliable transport (to avoid cross-contamination).

g. *Solubility in water*

For certain applications it is important to have total solubility of ingredients (e.g. milk replacers, liquid feeds, etc). If a product is water soluble as defined by its chemical properties; concentration and temperature of water influence the solubility. However, the formulation of the product is also important (e.g. granulation/particle size); feed additives in different preparations forms or with added anti-caking can have different solubility than the straight feed additive as such.

h. *Hygroscopicity*

Hygroscopic ingredients can attract water, and make the premixture subject to lumping, discolouring or chemical reactions during process-

ing or during storage. This will occur faster in warmer circumstances with a high relative humidity and depending on the raw materials used.

i. *Shelf life*

Ingredients shall have a suitable shelf life when received, so that levels and quality can be guaranteed up to the end of shelf life of the premixture.

j. *Flowability*

Ingredients are selected and assessed on their flowability as well. This important aspect will be further developed in Chapter VIII on Physical and chemical characteristics.

k. *Dustiness*

Dusty products may give rise to occupational health concerns and may give rise to a risk of dust explosions.

In conclusion, ingredients for premixtures are selected based on different criteria, often in mutual agreement between Sourcing and Procurement, Operations, Formulation and Quality Assurance.

III. FORMULATION OF PREMIXTURES

Formulation is a critical step in the delivery of a premixture. Although some standard branded blends are used for specific purposes, in practice, premixture manufacturers usually handle hundreds of different specific formulations, which are often exclusive and tailor-made for each customer. Therefore, formulators should take into account many different parameters in order to define the right composition of a blend:

- Types of premixtures and purpose of use
- Nutritional aspects
- Physical and chemical characteristics of the ingredients
- Choice of suitable carrier(s)
- Handling properties
- Production constraints
- Safety aspects
- Regulatory requirements
- Specific requirements of the customer
- Economic and logistic aspects

1. Product types

Premixtures can serve different purposes and can exert several functions in feed, so the complexity and particular features of the formulation exercise depends on the type of premixture and its purpose:

- “Pre-dilutions” are aimed at facilitating the use and handling of a specific feed additive, in particular its homogeneous mixture in specific blends, complex premixtures or compound feeds
- Specific blends have specific functional objectives in the final feeds or can be used in different complex premixtures
- Complex premixtures contain different types of additives and minerals, and are usually pursuing different objectives

a. Pre-dilutions

These “pre-dilutions” are simple mixtures of one feed additive, either as pure active substance or as a formulated preparation, and usually a single carrier. They may be required for additives that are incorporated in small amounts in the feed or premixtures in order to guarantee a good homogeneity in the end-product. This may also be a regulatory requirement for some feed additives in order to avoid the risk of overdose in compound feed.

Basic nutritional blends containing several nutritional additives (vitamins, trace elements) can also be prepared in advance for later use in the formulation of different complex premixtures with the same basic nutrients’ levels, in order to improve production throughput and reactivity of supply.

Formulation is usually not complex; the choice of the carrier depends on the particular characteristic of the feed additive(s). For liquid/oily forms of additives, a carrier with good adsorption properties will be required, while for additives in solid form, a carrier with similar particle size distribution and shape will be selected. The carriers used for these blends are usually neutral materials of mineral (e.g. calcium

carbonate) or plant origin (e.g. wheat middlings). However, possible interactions with the carrier should be anticipated, including the presence of free-water activity (e.g. in carriers of plant origin) for water soluble and sensitive additives.

b. Specific blends

These blends are designed to fulfil a specific function in the feed. The following types of formulation can be cited as examples:

- **Antioxidant blends** are composed of feed additives aimed at protecting feed, and primarily unsaturated fats and oils, from oxidation. Antioxidants are not equally efficient on different feed materials, but combination of several antioxidants usually provides synergy (1+1=3). Hence the formulation of the blend depends on the specific ‘mode of action’ of each additive and the composition of the final feed, based on a specific balance defined by experience. As these substances are very reactive the carriers are usually neutral.
- **Acidity regulator blends** are composed of organic and/or inorganic acids. The primary functions of these blends are buffering capacity and preservation of the feed. It is of utmost importance to formulate them in a proper way

- so as to better exploit synergies between the different acids. Usually, these blends do not contain carriers or only in small amounts.
- **Flavouring blends** formulation is based on an important level of knowledge, research and experience on the interactions between the different molecules, in order to get the proper smell and taste for the different animal species and categories, in the different types of target feed. This is why it needs a high level of protection (Intellectual Property) to ensure constant innovation. The use of carriers depends on the type of flavouring blends; they are usually based on plant feed materials, salt or sweeteners. Liquid blends are also available for specific applications.
 - **Vitamin blends** are formulated on the basis of nutritional levels of vitamins. The nutrient level is defined in accordance with the target animal's allowances and potency of the products. The different vitamin forms are then selected and mixed. The carriers are most often inert, usually of mineral or plant origin.
 - **Trace elements blends** are formulated on the basis of nutritional levels of trace elements. The nutrient level is defined in accordance with animal's allowances and the different trace elements compounds or preparations are then mixed (taking into account of interactions, linked to e.g. water content) usually with a mineral carrier(s).
 - **Other specific blends** are usually formulated on the basis of the regulatory limitations (minimum / maximum dose) of the products (e.g. for enzymes) and are based on the knowledge of the feed composition and animal species and categories of destination.
- c. Complex Premixtures*
- These products are formulated on the basis of the type of animal species/categories, as well as the type of feeds to be produced. The formulation takes into account different parameters:
- The **nutritional requirements** of the target animal (see below). Industry recommendations also usually take into account the know-how regarding the behaviour and possible losses of the different feed additives during manufacturing, storage and further process into feeds;
 - The **technological requirements** based on production constraints, either for the premixtures itself (e.g. specific particle size required for good mixing in the target compound feed, presence of antioxidants to increase the shelf life of the premixture or to limit the degradation of other

components; anti-caking agents to avoid the chemical interaction between different components of the premixtures, improve flowability or limit compaction in silos or when stacking bags, etc...) or of the final feeds (e.g. binders to ensure proper manufacturing of pellets);

- The **particular required functions** mainly provided by the inclusion of zootechnical additives or coccidiostats. The levels (minimum and maximum dosages) and conditions of use of zootechnical additives or coccidiostats are usually defined by the authorisation and by scientific tests on animals to define the most efficient and safe doses to be used;
- The **carrier** used for complex premixtures depends on the concentration of the premixtures in the final feed (inclusion rate, usually from 0.2 to 2.5 % but varying from 0.05-5% depending on markets), on the composition of the premixture and also the possible interactions between the ingredients. The number of carriers may vary from 1 to 3 different carriers, mainly from plant and mineral origin.

2. Nutritional aspects

The amount of nutritional additives (vitamins, trace elements, amino acids) and feed materials (usually minerals) in premixtures depends on the requirements of the target animal and the intended use and dilution (complete/complementary feed, nature of other components of the daily ration, etc). The needs for each animal mainly depend on the species, age category, physiological condition (gestation, lactation, etc). Allowances for each nutrient further take into account a safety factor for individual differences. These basic animal requirements and allowances are published by different scientific bodies, but not regularly updated.

With constant improvement of growth capacities and production yields of modern livestock, the intake of essential nutrients needs to be adapted regularly in order to best utilise the genetic potential of these animals.

This is why industry recommendations also take into account the need to maintain the perfor-

mance and welfare of animals. Industry recommendations may also consider the potential losses of feed additives during manufacturing, storage and further processing into feeds (steam/heat treatment).

Once the desired concentrations of each component are defined, formulators should also take into account the bio-availability of the ingredients, the potency (e.g. biological activity of vitamin E) and purity of the different forms of additives (e.g. concentration of active substance in the preparation or from different salts/esters of the additive, etc) to define the right amount of each additive or mineral in the premixture.

3. Characteristics of the ingredients

Each ingredient of a premixture has particular physical (particle size, shape, density, flowability, compressibility) and chemical (potency, purity, pH, reactivity, stability) characteristics that influence the overall recipe.

Physical characteristics usually play a role on handling and mixing properties, while chemical characteristics may particularly influence the stability of the mixtures.

Particles of uniform size and density tend to form homogeneous mixtures, while particles with different sizes and coarse shapes will have greater tendency to segregate or not to mix properly (see Chapter VIII).

Interactions between ingredients when mixed are also an important aspect of the formulation and depend on different factors (nature of the blend, concentrations, nature of carrier, moisture content and water activity, etc).

Although these handling/mixing properties and interactions can

be predicted to a certain extent, only a solid experience helps to anticipate and prevent the above-mentioned issues and adjust the formulations accordingly.

4. Choice of carrier(s)

These ingredients should be chemically inert to avoid any interaction with the additives, and have a particle size, shape and density compatible with the other components in order to allow proper mixing. Particle size and shape of carriers are important aspects. Two kinds of carriers are commonly used:

- Inorganic carriers of mineral origin, such as limestone (calcium carbonate), dicalcium phosphate, etc
- Organic carriers of vegetable (wheat middlings, etc) or sometimes animal origin (e.g. lactose, whey, etc)

Although carriers are inert and present little or no nutritional value, they have a crucial role in the premixture. The selection and incorporation rate of the carrier(s) is therefore an important aspect of the formulation. Carriers can perform different roles:

- Adjusting the formulation to the desired incorporation rate
- Diluting the ingredients to avoid interactions and improve stability

- Neutralising water activity to protect water-sensitive ingredients
- Increasing the density of the premixture to reach the desired level
- Increasing the minimum ignition energy of the blend and therefore reduce the risk of dust explosion
- Increasing flowability and improving handling properties of the product (can also be achieved by the use of specific additives)



Picture 3:
Organic carrier

Water can also be used as carrier for premixtures (liquid blends). Other formulation aids/technological additives (emulsifiers, acidity regulators, preservatives, etc) are usually necessary to reach homogeneous emulsion/ suspension, limit contamination and stabilise the pH of the premixture. Naturally the behaviour of feed additives in a liquid environment is very different from the behaviour in a solid blend and predicting interactions and stability requires specific experience and know-how.

5. Handling properties

Handling properties of powders are important throughout the production process, from the starting materials up to the final product:

- Products having poor flowability may result in bridging, caking and product losses in the production process. This conditions the throughput and good functioning of the production lines
- Dustiness of the additives and carriers is also an important aspect in the choice of the ingredients, as dusty products will result in product losses, risk of explosions and higher worker exposure (skin/eye irritation, inhalation exposure)

Improved handling properties can be achieved by the selection of the right ingredients and carrier(s).

6. Safety and quality aspects

As concentrated blends of different substances, premixtures can present specific hazards and it is important for formulators (and users) to be aware:

- Physical hazards: the main physical hazard for premixtures is dust explosion, related to electrostatic properties of the components. Although the risk is less with premixtures compared to pure substances, because of the dilution with inert carriers, some concentrated blends of specific ingredients may have an important explosive potential. It may therefore be useful to use mineral carriers to dilute these blends if possible. Specific packaging types are also selected according to the level of risk
- Health hazards: some feed additives can present risks for the professional users/workers, especially when exposed daily to concentrated blends and pure ingredients. The choice of non dusty ingredients (e.g. preparation of additives) and formulation

can help reducing dusting potential of premixtures and thus exposure of workers

Some ingredients may also present risks for the target animal if not dosed in the right amount. Feed additives may have maximum limits that need to be complied with. For other critical ingredients such as “functional feed ingredients” or new feed materials, a safety evaluation also needs to be performed to ensure that the product can be used safely at the desired dose in feed.

The quality management system of the operator should therefore include a check of each formulation before production.

Quality and safety aspects are expanded further in the relevant chapters.

7. Regulatory requirements

Premixture manufacturers need to comply with all legislations in force in the European Union.

Of particular importance for formulation is the need to take into account all the specific restrictions of use for each feed additive, such as maximum (or minimum) limits, incompatibilities, contraindications, target species, etc...

In addition, specific requirements also apply for organic production (positive list of additives, origin of carriers) or genetically modified substances (e.g. carriers of vegetal origin).

As premixture manufacturers also sell across European borders, they need to comply with the requirements from third countries. This may have an impact on the choice of certain ingredients and potentially imply the use of feed additives not authorised within the European Union, which is done under very tightly controlled conditions.

8. Specific customer requirements

As most premixture formulations are tailor-made, the formulator has to meet particular specifications of customers:

- On the ingredients: absence of genetically modified organisms (eg for organic feed), specific origin for products, preferred additives, etc
- On the final product's characteristics: inclusion rate, handling properties, particle size or bulk density, resistance to feed processing, shelf life, etc

9. Logistic aspects

The premixture industry is global and purchases ingredients all over the world. Availability of quality ingredients is therefore an important parameter that affect the formulation. The substitution of an ingredient/additive by another in a formulation should always be evaluated carefully with regards to each of the aspects developed in this chapter and in line with quality management system.

10. Conclusions

In conclusion, the formulation of premixtures is not simply an arithmetic exercise to calculate the right concentration of each ingredient in the target feed. It requires not only expertise in animal nutrition but also fundamental know-how, borne by experience, for the selection of the right ingredients, in close relationship with all departments (sourcing/purchasing, sales / commercials, quality, regulatory affairs, production and occupational safety).

IV. MANUFACTURING

1. Intake and storage

Facilities used to store ingredients, packaging and products shall provide protection against contamination from e.g. dust, condensation, drains, waste and pests. Storage areas for dry ingredients and premixtures shall be kept dry and well ventilated.

All packaged materials shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.

The storage area shall be managed to allow maintenance and cleaning, prevent contamination and minimize deterioration. Chemicals not intended for product inclusion (e.g. cleaning materials, pesticides) shall be stored in a separate and secure (locked or otherwise access controlled) storage area when not in use. Monitoring and control of temperature can be applied where specified for stored ingredients.



Picture 4:
Example of storage of premixtures

2. Suitable Equipment

Since production of premixtures is generally regarded as a batch operation, only equipment for batch mixing will be considered in this chapter. As a rule, premixtures are produced in specialized and well equipped plants with trained personnel.

The production of premixtures, although diversified, is not in itself a very complex process. Nevertheless the whole process of premixture production must be able to handle complexity.

Basically a standard premixture plant could consist of the following:

- An area for the storage and preservation of micro ingredients, concentrates and various preparations. The department has to be equipped with suitable storage facilities and equipment. Extreme temperatures and high relative humidity must be avoided
- An analytical laboratory able to run diverse routine analyses, including control of the additives in respect of uniformity, appearance, color, moisture and temperature where applicable. Various equipment and standards for comparison are needed.
- Silos are commonly used for the storage of carriers and macro ingredients like minerals.
- Where supply of carriers with a certain particle size distribution is not possible, a suitable mill for finer grinding of the carrier or mineral substances could be installed
- Screens for the separation of lumps from some ingredients
- A number of accurate scales of various sizes, suitable for rapid and precise weighing and/or an installation based on loss in weight principles
- A small "laboratory" mixer, capacity 20kg
- A mixer for the final premixtures, capacity 500- 2000kg. Opinions differ as to the best type of mixer, but horizontal mixers are (still) the most common. The mixing capability is of vital importance and is typically 1: 100 000
- Equipment for bagging or packing premixtures, as well as a suitable way to transfer premixtures to bulk trucks, when delivered in bulk
- The above machinery and equipment for conveying, trans-

port and storage should be so installed and arranged as to minimize labour requirements.

When considering installation and the choice of equipment, the plant designer should bear the following features in mind:

- Safe and convenient access to the mixer for sampling and inspection, as well as the possibility for cleaning must be provided.
- Possibility of supervising the cleaning and inspection of the system, emptying the mixer, transporting, sacking and storing premixtures.
- Design of the production process to provide the shortest and most direct route of conveyance, especially in case of final premixtures.



Picture 5:
Silos

In addition it is very important to control all risks of dust explosion. In order to do this, the equipment and layout of the plant must be designed to take into account the European Directives concerning equipment and avoidance of dust explosion at the workplace, known as ATEX Directives (“ATmospheres EXplosives” - Directives 94/9/EC and 1999/92/EC).

3. Conveying

There are many different types of equipment for conveying ingredients from one part of a premix plant to another, or from one piece of equipment to another. Some are designed to operate horizontally, some on a slope, others elevate the material vertically to a different level of the building. The requirement for elevators and conveyors will depend on how automated the design and the plant layout are.

The utmost use of such equipment is made in the modern animal feed mill (often using pneumatic systems) to minimize labour needs and to maximise the use of available space by building multi-storey, rather than horizontally arranged plants.

For premixture ingredients and premixtures as such, a lot of specialized equipment is available. However, in general premix manufacturers seek to avoid conveying as much as possible.



Picture 6:
Bulk delivery with a truck

4. Weighing and dosing

This is probably the most critical part of the process of making pre-mixtures. If the required raw materials are not weighed correctly, then the resulting premixes may not be within the specified tolerances required.

The design of a weighing system is very complex and many factors need to be taken into account such as:

- Number of products in a premix to be dosed
- Quantities of each products be dosed
- Accuracy of each product to be dosed
- Throughput of the plant
- Batch sizes to be produced

Due to the above factors the weighing system is usually automated and controlled by a computered Process Control System (PCS) in order to control the complexity. Dependent on these factors, the design of the premix plant may incorporate a combination of the following weighing methods:

- “Gain in Weight” system – where the automated control system measures the in-

crease in weight into a weigher mounted on loadcells.

- “Loss in Weight” system – where the automated control system measures the decrease in weight from the weigher, where the weigher is the storage silo and dosing screw mounted on loadcells.
- Hand dispensing weigher on a high accuracy platform scale

Within most premix plants and animal feed plants, the normal method of weighing is “gain in weight” and ‘hand weighing’ in a dispensary.

Loss in weight requires an increased cost of equipment, as each silo/dosing screw combination requires its own set of loadcells, amplifier and software. In addition, at the moment a bin/silo is being refilled, the use of such system is impossible.

Loss in weight systems are however faster for production as multiple feeds can take place simultaneously, unlike a ‘Gain in weight’ system, where each feed has to be done individually. Therefore, such system is often used in some specific applications.

A well designed dosing system will have multiple weighers, which will vary in capacity to allow for accurate weighing, for increased dosing speeds and a shorter batching time, as weighments can take place over each scale if required simultaneously. Each weigher will then have multiple silos above it which will contain products that are required in similar quantities.

The accuracy of the weighing system also depends upon many factors, for example:

- The type of loadcell being used
- The number of loadcells being used on each weigher
- The location of the weigher
- The design of the weigher
- The design of the equipment around the weigher

Most weighing systems are accurate to within 0.1% of the scale capacity. Therefore a 1000kg scale will be able to dose to within 1kg of the required product target, a 50kg weigher should be within 0.05kg or 50g.

A high accuracy hand dispensary scale will be able to be within 1g to 5g on a 60kg scale. These are typical tolerances, but a good weigh-

ing system may be more accurate than this.



Picture 7:
Weigher in a weigher. The combination of two weighing hoppers of different sizes allows for accurate dosing over a wide range of weights.
Source: ALFRA

5. Premixture Mixing (types of mixers)

A mixer intended for preparation of premixtures must be able to provide homogeneous mixtures of physically diverse particles incorporated at various inclusion levels in the mix.

Specification for a premixture mixer:

- Affords good homogeneity with the component included at the lowest possible content
- Affords good homogeneity with components of different particle size
- Short mixing duration
- Variable degree of filling, with no loss of mixing efficiency
- Complete emptying
- Easy cleaning
- Possibility to add liquids
- Ability to disintegrate clumps
- Absence of heating during mixing
- Low consumption of energy when starting and during mixing
- Low maintenance costs

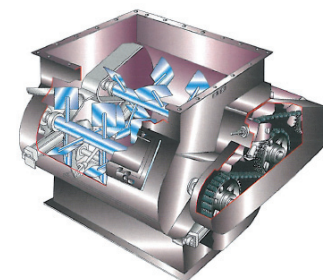
The following types of mixers are the most commonly used within the premix production industry:

- Rotating mixers: V-blender or Y-blender and cubic containers turning on an axle
- Ribbon mixers, with a double spiral on the same axle, or with a single spiral in two separate screws within an omega shaped mixer
- Turning –screw vertical cone mixer



Picture 8:
Vertical cone mixer.
Source: Hosokawa –Nauta

- Twin-axle paddle mixers. These machines perform well for preparing vitamin premixtures



Picture 9:
Twin-axle paddle mixer. Source:
Forberg

- Pneumatic mixers with air-flow mixing are conventionally included in this category. This equipment is mainly used by the animal feed industry for mixing very fragile re-fatted powders which require working with cold air.

All these mixers are available in various sizes, typically ranging from the liter size to 10,000 liters according to the required application. Mixers are generally available in mild steel or stainless-steel. There is no one-fit-all type of mixer; the actual choice of the type of mixer is dependent on many factors including plant design, capacity required, types of raw materials and final type of premix etc.

6. Mixing Procedures

The following steps should be followed:

- Ensure that the equipment is well suited to the type of product(s) to be mixed
- Make sure that static parts and mobile parts of the mixer are fully grounded with the rest of the equipment
- Verify that the amount to be mixed is in accordance with the mixer specification and the sufficient mixing time (insufficient or excess filling will make it impossible to perform correct mixing and reach suitable homogeneity)

7. Production / dosing sequence

Production and dosing sequence can be relevant to reduce or eliminate unwanted contamination or carry over. Generally speaking, any variation in the quantities or properties of each ingredient, not foreseen in the composition of the premix, can be regarded as a form of contamination.

Contamination may be due firstly to the nature of the ingredients which are mixed; secondly to the production procedures and thirdly to subsequent processing by the compound feed manufacturers. Special attention is needed for correct packing of ingredients and premixtures to protect them against any contamination.

It should be noted that premixtures contain concentrations hundreds of times higher than those in the final feed. Any dust, residues in the equipment, or wastage during premix production can be the cause of contamination. For this reason too, it is very important to carry out the production of premixtures at producers with dedicated equipment that is carefully cleaned from time to time.

The points in a plant where con-

tamination is most liable to occur are elevator heads, worm conveyors, dust collectors and pneumatic elevators. These parts of the equipment should be permanently controlled and kept clean.

Nowadays a lot of equipment is designed in such a way, that it is free or at least almost free of any contamination, as well as easy to inspect and clean. In any case where no possibility to change the production sequence and where the system is not cross-contamination free (between product types), a cleaning/flushing batch should always be run in between. Dust is an important source of contamination in premixture plants. It can however be controlled and eliminated with the choice of suitable ingredients and carriers, as well as anti-dust agents.

8. Hygiene and Cleaning

Cleaning programs should be established and documented to maintain hygienic conditions. Programs should be monitored for continuing suitability and effectiveness.

Where identified in the hazard assessment, sanitizing programs should be established and documented for wet cleaning and for wet-process areas.

Cleaning and sanitizing agents should be fit for purpose, clearly identified, stored separately and applied properly to avoid contamination of raw materials or finished products. Cleaning and sanitizing tools should be designed and maintained in a condition that does not present a potential source of extraneous matter.

Cleaning and sanitizing programs should specify, as a minimum:

- Areas, items of equipment and utensils to be cleaned and/or sanitized
- Responsibility for the tasks specified
- Cleaning/sanitizing method and frequency
- Monitoring and verification (e.g. post-cleaning and/or pre-start-up inspections)

Care should be taken to prevent product contamination when cleaning is being carried out. For example, mixer openings should be covered to prevent entry of debris.

Periodic cleaning and sanitizing activities should be recorded. Routine housekeeping activities are not considered periodic and do not need to be recorded.

Cleaning and sanitizing programs should be verified for their continuing suitability and effectiveness.

9. Maintenance and inspection

Equipment for manufacturing of premixtures should be fit for purpose and designed and constructed to facilitate cleaning and maintenance. Surfaces in contact with product shall be constructed from materials suitable for animal feed and able to resist repeated cleaning. Equipment in contact with product should be smooth, accessible, cleanable and constructed of materials compatible with the intended use.

A preventive maintenance program should be in place and include all devices used to monitor and/or control feed safety hazards. Examples of such devices include screens and filters (including air filters), magnets and metal detectors.

Corrective maintenance should be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination. Maintenance requests that affect product safety should be given priority. Temporary fixes should not put product safety at risk. A request for replacement by a permanent repair should be included in the maintenance schedule.

Lubricants and heat transfer fluids should be fit for purpose where

there is a risk of direct or indirect contact with the product. The procedure for releasing maintained equipment back to production should specify sanitation and pre-use inspection measures.

Site-specific prerequisite program requirements should apply to maintenance areas and maintenance activities in process areas. Maintenance personnel should be trained in the product hazards associated with their activities.

All scales and metering devices used in the manufacture of premixtures should be fit for purpose for the range of weight or volume to be measured and tested for accuracy regularly according to the risks.

Where necessary to verify results, measuring equipment should be:

- Calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards. Where no standards exist, the basis for calibration or verification shall be recorded
- Adjusted or readjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments

that would invalidate the measurement result

- Protected from damage and deterioration during handling, maintenance and storage



Picture 10:
Routine equipment inspection

V. PACKAGING AND TRANSPORT

1. Packaging types

In most cases, premixtures are being packed and transported in small units, such as bags or containers of 25 kg each. In some instances, however, bulk shipments are the norm. How do we know which packing is the most suitable one for feed premixtures? As straightforward as this question may seem, choosing the “right” packaging is actually a highly specialized area of the premix business that needs to take into account both the special requirements of the goods as well as customers’ wishes.

Table on the next page provides an overview of possible characteristics of premixes. Each of these brings with it certain requirements as to suitable packaging types. In this context it is also important to remember that the premix market is an international one, and that climatic conditions, processing equipment as well as human preferences vary from country to country. The packaging solution of choice in one location will not necessarily work in another.

Additive Characteristics:	Specific Challenge for Packaging
Powder, granulated and liquid forms	Different characteristics = not all packaging types are appropriate
Voluminous or very dense products	Packaging must be sturdy enough for the product it contains
High content of feed additives that are sensitive to direct light and air	Packaging must be airtight and provide a barrier against light and / or UV rays
Hygroscopic products or product components	Packaging must protect the additives against humidity. Since air carries moisture, packaging must be air-tight
Aggressive products (e.g. acids)	Packaging must securely contain the contents in order to protect the environment from an aggressive medium
Products with a high content of aroma or flavour additives	Flavours and aromas are volatile. A suitable packaging must protect the aroma until it reaches its intended target, i.e. the feed
Premixes which contain concentrations of ingredients that may be harmful upon direct contact	Packaging must be strong and safe enough to protect people handling the product

In order to comply with the different requirements of their products, premix businesses work with a host of packaging types. The following are some of the most common packaging systems.



Picture 11:
Process control screen packaging line

2. Packaging in bags

Bags made of paper or other materials, of various constructions, in capacities from 1 to 30 kg. Characteristics may include:

- Reinforced paper bags
- Sometimes laminated with plastics, to provide moisture barriers, or to prevent direct contact of product with paper / outer wall
- Valve bags with outside- / inside- / thermo valve
- Sewn round bottom bags
- Flat hexagonal bottom bags
- Bags for dangerous goods (UN-approved)
- For special requirements it is sometimes necessary to use bags made of materials other than paper, e.g. aluminium or plastic
- Sometimes it may be important to ensure complete impermeability to air and liquids



Pictures 12:
Bag filling process



Filling of bags with premix is typically done on automatic or semi-automatic bag filling lines (stations). In fully automatic lines, and for filling weights from 1 to 30 kg, empty bags are typically picked

up by suction cups, positioned under the filling station and then filled (see Pictures). Weighing can either be done on a net basis (weighing of content only) or on a gross basis, which takes into account the weight of the bag.

Modern filling lines will often be equipped with aspiration systems for dust control, a vibration system for efficient filling and finally a filling control system. Bags are closed either by sewing or by welding.

Before or after the filling process, bags are labelled to clearly identify their content. Label systems can be automatic or semi-automatic. In an automatic system, the label information is generated by a formulation and label software system. The system prints the information directly into a label area on the bag. In a semi-automatic system, labels are first batch-printed and then stuck onto the bags either by hand or machine. In all cases, labelling systems must be able to handle a large variety of different formulations and translate it into compliant labels. The system must also be flexible enough to cope with any change in formulations and legal requirements.

3. Packaging in IBC

IBCs, or Intermediate Bulk Containers, are a group of packaging that can be used for the packing, transport, and storage of liquid, granulated and powder premix products. In particular, if a feed miller handles larger quantities of premixes IBCs can be very useful. The normal gross weight of an IBC ranges from 90 to 1300 kg. The biggest benefit of IBCs is that their footprint is similar to a EURO pallet – a quadratic format containing a large amount of premix. IBCs can be handled by hand lift or a forklift truck. In the premix business two types of IBC types are in practical use:

Type 1: FIBC - Flexible Intermediate Bulk Container (also known as Big Bags)

Big Bags are made of synthetic fibre and carry loops on which they can easily be picked up by a forklift truck. Typical specifications in the premix business include the following:

- Recyclable, hygienic material
- Material is UV stable
- Large Containers with predominantly four carrying handles
- With or without inlay to minimise product exposure to air and moisture

- Can be used as a disposable or reusable packaging
- Big Bags for dangerous goods (UN-approved)
- Classified as without static protection or with full static protection
- Closed top with filler plug
- Closed bottom with drain outlet



Picture 13:
Flexible Intermediate Bulk Container

The Big Bags here depicted have an approximate capacity of 1000 to 1300 litres. The filling process of Big Bags is similar to that of paper bags, but due to their larger size filling usually is semi- rather than fully-automatic.

While the filling process itself can be handled by an automatic control unit, Big Bags first need to be hooked up to the filling station by hand.

A fully-automatic filling system would be fitted with a floor scale or an overhead scale. When the designated net weight is reached the filling system will automatically stop the filling process. To optimise the filling process a vibration system is frequently employed, especially for more voluminous premixes. An effective aspiration is imperative for proper dust control.

Static electricity and the possibility of dust explosions pose the greatest risks in the filling and emptying of Big Bags. It is therefore important to choose a suitable kind of Big Bag, depending on the operational conditions in the plant:

▪ Type A FIBC

Big Bag with no measures against build up of static electricity. Only to be used for ingredients that are not sensitive to dust ex-

plosion (like minerals) and that are used in areas in which an explosive atmosphere in the form of a cloud of combustible dust in air is not likely to occur in normal operation but, if it does occur, will persist for a short period only.

It is essential that they are not used to store or transport combustible materials or used in flammable or combustible environments. Many organic materials such as sugar, flour, corn starch, milk powder, wood pulp, etc, can form combustible dust clouds or layers that can be ignited by electrostatic discharges from Type A FIBC.

▪ Type B FIBC

Type B FIBC is similar to Type A FIBC. The difference is that Type B bulk bags are made from materials that have a low breakdown voltage to prevent the occurrence of highly energetic, and dangerous propagating brush discharges designed to prevent occurrence of sparks and propagating brush discharges and should be used as a standard FIBC for all non-mineral type of products.

▪ Type C FIBC

Type C Big Bags, conceived with conductive elements interwoven in the packing material (carbon threads) are designed to prevent incendiary sparks, brush discharges and propagating brush discharges. They must be earthed during filling and emptying! To be used for product with a low so called minimum ignition energy.

▪ Type D FIBC

Dissipative, made from static protective fabric to prevent incendiary sparks, brush discharges and propagating brush discharges. No earthing needed. The use of Type D FIBC in antistatic bulk bags eliminates the risk of human error associated with the manufacturing and use of groundable Type C FIBC.

It is the responsibility of the premix producer to use a suitable Big Bag type.

A filled standard Big Bag will have a footprint similar to a Euro pallet and will be 1,5 metres high. To clearly identify their contents, Big Bags must be labelled. Labels will usually be put into the information pockets provided on the bags, but when large amounts of recurrent

products are manufactured it may be more economical to print the relevant information directly onto the Big Bags. A purpose-built emptying station greatly facilitates the discharge of product from Big Bags.



Picture 14:
FIBC for dangerous goods

Type 2: Composite IBC

Due to its cubic shape, this type of IBC is widely used for storage and transportation of liquid premixes. Typical specifications of this IBC for use in the premix industry include the following:

→ Impermeable to odours and

flavours

- Highly effective barrier against gases (e.g. oxygen), dioxin and other undesirable substances
- Transportable with all commercial industrial trucks
- Stackable
- Can be used as a disposable or reusable packaging
- Can be used for storage and transportation of dangerous goods (UN-approved)
- Can be reconditioned
- Closed top with filler plug
- Closed bottom with drainage outlet



Picture 15:
Composite IBC

The IBC depicted above is a combination of a cubic synthetic tank boxed inside a caged frame. The inner container has a standard volume of 1060 litres and dimensions of 1200 x 1000 x 1160 mm. Fill-

ing is done by either of two methods, depending on the structure of the liquid premix to be filled. For products which are prone to foam easily or that are susceptible to static charges during filling, the below-level filling method preferably should be used. For products that are easier to fill, however, it is common to use the above-level filling method. Both systems can be employed either fully- or semi-automatically, either with or without filling and weight control. To clearly identify IBC's content, a label must be added directly onto the IBC.

4. Packaging in Drums

Since ancient times, drums have been used for packaging of powder, granular and liquid products. Drums come in many, often standardized shapes and sizes, and therefore have many applications in the feed industry as well. On the negative side must be noted their relative bulkiness which can make storage and transportation difficult or expensive.

Following are some typical specification for drums:

- Wide range of capacities, from 6 litre to > 200 litre
- Different materials, such as plastic, metal or fibre
- High barrier against gases, such as oxygen
- Can be used both as a disposable or reusable packaging
- Drums for dangerous goods (UN-approved)
- Can be reconditioned



Picture 16:
Plastic and metal drums

In the premix industry, drums could be of particular importance whenever a premix contains a high content of hazardous material or in case of liquid premixtures. In order to protect workers and the environment during transport and storage, drums may be the packaging of choice for these premixtures.

Drums can be filled in an automated process, even when a plastic bag as inner packaging is called for. In this scenario the bag first is inserted into the drum, either semi- or fully automatically, and then filled. Filling typically is optimized by a vibrating system, weight control and aspiration. In the final step, which again can be automated, the drum will be closed by a lid.

5. Packaging should protect the premixes during transport and storage

All packaging has one thing in common: it should protect the workers, the general environment as well as the product contained in the packaging, throughout storage, transport and handling of the goods. To fulfil this, the packaging must be appropriate for the intended use, and should be sturdy and strong enough to withstand even a certain amount of abuse.

Unfortunately, packaging material that has withstood some standardized tests and conforms to certain safety norms is difficult to come by. The notable exception is packaging that has been approved for use with dangerous goods and carries a UN number.

When choosing a packaging material, there often is a trade-off between practical aspects and safety provisions, especially during transport. Bags and Big Bags have no hard sidewalls and so are prone to shift; drums can easily tip over when not properly secured. Apart from the obvious fact that packaging itself must be strong enough to prevent leakages, there are a variety of measures that can be

taken to prevent this and to ensure a safe transport: palletized bags can be wrapped in stretch foil; filler material and braces can be used to prevent individual packaging units from shifting against each other; ratchet tie-downs and supporting edges keep cargo in place when transported on flat-beds, etc. A multitude of securing aids are commercially available but, as with the choice of packaging material, it is the responsibility of the shipper to determine which measure will ensure a safe transport.



Picture 17:
Example from European Best Practice Guidelines on Cargo Securing for Road Transport

6. Waste management

Much emphasis is today placed on the re-usability of packaging material, or whether it can be properly recycled. Apart from its primary function of protecting the contents, packaging material today needs to fulfil the additional function of helping to save scarce resources and protecting our common environment. As such, packaging material has become an important step in the industry's sustainability efforts.

While the different EU Member States operate different re-use and recycling systems, they all are based on the premise that re-use is preferable to recycling. This, however, needs to take into account that not all packaging material can be re-used (depending on the material itself, or what it previously contained), that some packaging is more environmentally friendly to produce than others, and that the cost of cleaning or re-conditioning a container, including water consumption thereof, must be balanced against the cost of recycling it.

If a packaging is to be re-used it must first be completely emptied, meaning that it must be free of any

remnants of its previous content. In determining whether a packaging can be re-used or must be recycled, the label of its last content is a good indicator and helps in the efficient sorting of previously used packaging material. Special care to protect both humans and the environment must be taken with packaging that previously contained hazardous substances. If in any doubt, it is wise to have a specialized recycling company taking care of the sorting.

As a conclusion it can be said that awareness of the locally applicable laws and the available options is the key to an effective waste management in the premix industry.

7. Premixtures in Bulk

It is common practice in many countries to deliver premixtures in bulk transport; in this case, the Premix producer pays strict attention to the loading procedure, in order to avoid contaminations with previous loads. Before loading, the transport certifies which previous loads have been carried by the applicable truck, what cleaning regime has been applied and finally, the truck is inspected prior to loading. In this way, it is guaranteed that premixtures are transported and delivered in clean and non-contaminated bulk trucks.

There are defined specific requirements for cleaning and disinfection for the cases where the prior loads can be regarded as high risk materials, potentially microbiologically contaminated material or materials constituting a physical and/or chemical risk.

VI. QUALITY MANAGEMENT

HACCP (Hazard Analysis and Critical Control Points) is a risk analysis tool that helps an operator identify feed safety hazards and evaluate the risk associated with their product(s) and processes with the view of controlling their occurrence. The system enables the operator to document, control and verify the effectiveness of these control measures.

It puts in place an effective Prerequisite program (PRP) to manage the daily tasks of good hygienic practice, good manufacturing practice (GMP) or other equivalent prerequisite program. The PRP is the backbone of any quality or safety system and without it no management program is likely to be successful.

The PRP defines the basic conditions and activities which are necessary to maintain a hygienic environment throughout the feed/food chain suitable for the production, handling and provision of safe premixtures.

These procedures give a solid operating foundation allowing the

HACCP team to focus on the few critical issues that may not be addressed as part of the daily program but still require special care.

Common topics in a PRP are:

- Buildings & environment
- Processes and workspaces
- Utilities
- Waste disposal
- Equipment, suitability and maintenance
- Selection and Management of suppliers
- Incoming material requirements
- Management of medications
- Prevention of contamination
- Cleaning and sanitation
- Pest control
- Personnel hygiene and employee facilities
- Rework
- Product withdrawal
- Warehouse and transportation
- Formulation
- Specifications for services
- Training and supervision of personnel
- Product information
- Traceability

For all applicable prerequisites, a written procedure on how to carry

it out, how its efficacy is to be verified and how it should be audited, it should be in place.

▪ HACCP purpose

The purpose of a HACCP program is to ensure product (feed) safety in a controlled manner based on systematic procedures. The program comprises any activities and process steps ranging from purchase of raw materials to transport of the finished products. In the hazard analysis a survey should be conducted to identify all potential hazards.

Based on this analysis, hazards should be classified according to risk, possible Critical Control Points (CCP's) identified and control procedures established. Special attention should be paid to hazards requiring specific control measures.

It is mandatory that operators follow the guidance for application of HACCP provided in the Codex Alimentarius Guidelines, and also taken up by European Union legislation, which is based on the following 7 principles:

- Conduct a hazard analysis
- Determine the critical control points (CCPs)
- Establish critical limits
- Establish a system to monitor the

control of each CCP

- Establish the corrective action to be taken if controls should fail
- Establish a procedure to verify that all the aspects of the HACCP system are working effectively
- Document all procedure and records to demonstrate the HACCP system is working effectively

For more detailed information on how HACCP principles can be applied and specific definitions on HACCP, see the annexes in the guidance to the FAMI-QS Code of Practice (www.fami-qs.org).

1. Finished product specifications

Full and detailed information regarding each premixture or group of premixtures is required in order to assess hazards presented by the process or delivery to the end user. Main issues to be considered are:

- Composition (e.g. raw materials, ingredients, additives etc.)
- Physical and chemical characteristics
- Processing
- Packaging / labelling
- Storage and distribution conditions
- Required shelf life
- Instructions for intended use / known unintended use
- Any microbiological or chemical criteria applicable
- Quality control program

2. Quality standards

Premixture manufacturers have in general set up a feed safety system that complies with the requirements of EU standards like FAMI-QS, GMP+ International, OVOCOM or UFAS.

They must document the system, implement it and maintain it as well as continuously improve its effectiveness.

It is important to establish and record the scope of the feed safety system. The scope must at least include the activities related to feed for which the operator is responsible.

The responsibility of the premixture manufacturer begins where the responsibility of the previous link (the supplier) ends, and ends where the responsibility of the following link (the customer) in the feed chain begins.

The premixture manufacturer must specify every premixture which he puts on the market, processes, treats or trades.

All business locations and pro-

cesses / process lines where production, treatment, processing, trade, storage, trans-shipment and transport of premixtures are carried out, must be brought under the scope of the feed safety system.

3. Quality Manual

A quality manual describes the scope of a feed safety system for premixtures manufacturers or traders, including the details of and clear justification for any exclusion. There are documented procedures required, like for example for document management, registrations, internal auditing, purchase, recall, complaint handling, yearly review, maintenance and hygiene, corrective and preventive actions as a minimum under the different Quality and Feed safety standards, which have been established for the feed safety system or a reference to them.

A description of the interactions between the processes of the feed safety system as well as the structure of the documentation is required.

4. Communication to customers: code of practice for labelling

Key European associations (FEFANA representing specialty feed ingredients manufacturers, FEFAC representing compound feed manufacturers, and EMFEMA representing mineral and trace element producers) have drafted an agreed Code of Practice for the labelling of feed additives and premixtures.

Drawing on regulatory principles introduced by regulation 767/2009 which distinguishes a feed 'label' (the document attached to each pack) from 'labelling' (general documentation using any medium), the proposal is for premixture labels (fixed to each pack) to focus on:

- Identification (for example product identification number, net weight)
- Traceability (for example manufacturers identification, batch number)
- Safety (for example details of target species, use rate, contra-indications & warnings, withdrawal periods, expiry dates and hazard warnings)

In the application of this code of practice, FEFANA endorses the issue of separate product specification sheets (including full additive listings, carrier lists, general directions for use etc.) when a product is first purchased and subsequently when a specification changes.

As a minimum, such a specification sheet will provide all of the mandatory information required on a premixture labelling.

The advantage of this approach is that:

- Premixture labels will be clearer and more relevant to users of the product, enhancing safety
- Full product specifications will remain confidential, but available for inspection by the control authorities at the site of use

5. Quality Control program for incoming ingredients

Each batch entering a site is normally uniquely registered by means of a batch number, full name of product, date of receipt and quantity received. Any damage is reported to an appropriate responsible unit, e.g. the quality control (QC) unit.

If the incoming material is delivered in bulk, a receipt and storage procedure is in place. If silos are emptied, this will be recorded and cleaning is evaluated.

Incoming materials are checked and formally approved prior to use according to written procedures. Samples of these materials are retained. Where appropriate, a retained sample should be available for at least the shelf life of the material, either at the suppliers or the operators.

The different applicable codes for premixture producers have guidance on sampling.

Handling of incoming product should be in accordance with its status, for example, a received product which is deemed unfit for use must be identified as such and segregated from those products released for use. In the same

light, perishable materials should be treated as appropriate to ensure their wholesomeness before use.

If incoming materials are rejected and thus not incorporated for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.



Picture 18:
QC laboratory

6. Quality Control program for finished products

- Each product shall have a written specification, which is amended when any change takes place
- All finished products should be inspected prior to dispatch, in accordance with written procedures, to ensure they meet specification. A retention sample of adequate size shall be taken of each product and held, as a minimum, for a time equivalent to the defined shelf life of the product. The samples must be sealed and labelled, stored in a manner that should prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use

7. Analytical / Technical tolerances

Tolerances include technical and analytical deviations, although it is apparent that the calculation of the total tolerance differs between control authorities in different Member States in the absence of harmonized legislation and harmonized analytical methods for all feed additives.

Analytical tolerances covering measurement of uncertainties and procedural variations are not fixed at EU level for feed additives. The analytical tolerance of the individual laboratory is used in the calculation that may vary from a laboratory to another.

Technical tolerance, covering natural variation in feed materials, weighing and mixing errors (premixtures and feeds) and losses during processing and shelf-life are fixed at EU level only for compound feed and not for premixtures.

Nevertheless, it should be logical to harmonize this approach for premixtures as well.

8. Sampling

When executing an analysis on premixtures or incoming ingredients, one of the most important things is to do that in a representative sample. Written sampling procedure should be available and adapted to the intended purpose (batch release, acceptance of consignments, special controls, etc.), to the type of controls (identity, composition, monitoring of contaminant, etc.), and to the material to be sampled (liquid/solid, bulk/packages, etc.). Operators taking samples should be trained and have sufficient knowledge of the practical aspects and materials or products in order to work effectively and safely.

Type of samples:

- **Sampled portion:** A quantity of product constituting a unit, and having characteristics presumed to be uniform
- **Incremental sample:** A quantity taken from one point in the sampled portion
- **Aggregate sample:** An aggregate of incremental samples taken from the same sampled portion

The sampling apparatus must be made of materials which cannot contaminate the products to be sampled.

Apparatus recommended for sampling of **solid** premixtures:

Manual sampling

- Flat-bottomed shovel with vertical sides
- Sampling spear with a long split or compartments. The dimensions of the sampling spear must be appropriate to the characteristics of the sampled portion (depth of container, dimensions of sack, etc.) and to the particle size of the premixture

Mechanical sampling

- Approved mechanical apparatus may be used for the sampling of moving premixtures

Divider

- Apparatus designed to divide the sample into approximately equal parts may be used for taking incremental samples and for the preparation of reduced and final samples

Apparatus recommended for sampling of **liquid** premixtures:

- **Agitator, sampling bottle, zone sampler and dipper, of appropriate size**

a. *Quantitative requirements*

The size of the sampled portion must be such that each of its constituent parts can be sampled.

The quantity, frequency and location of sampling should be based on the criteria below and a statistical approach may be followed where deemed appropriate:

- expected uniformity of the material
- parameters to be tested
- packaging unit size or volume
- confidence in the product source
- manufacturing processes employed
- product risk analysis

For the purpose of official controls, specific quantities are set by Regulation (EC) No. 152/2009 for each types of samples, taking into account the product form (liquid/solid, bulk/packaged) and batch size (tonnage or number of packages and package size). Different values are also set depending whether or not the product or substance to be analyzed is expected to be homo-

geneously distributed in the feed or not. At the time of writing this booklet, Annexes of Regulation 152/2009 are under revision

b. *Instructions for taking, preparing and packaging the samples*

General

The samples must be taken and prepared as quickly as possible bearing in mind the precautions necessary to ensure that the product is neither changed nor contaminated. Instruments and also surfaces and containers intended to receive samples must be clean and dry.

Incremental samples

In relation to the control of substances or products uniformly distributed throughout the premixture, incremental samples must be taken at random throughout the whole sampled portion and they must be of approximately equal sizes.

Bulk premixtures

An imaginary division should be made of the sampled portion into a number of approximately equal parts. A number of parts corresponding to the number of incremental samples required should be selected at random and at least one sample taken from each of these parts. Where appropriate, sampling may be carried out when the sampled portion is being moved (loading or unloading).

Packaged premixtures

Having selected the required number of packages for sampling as indicated in the table above, part of the contents of each package should be removed using a spear or shovel. Where necessary, the samples should be taken after emptying the packages separately.

Liquid premixtures

Having selected the required number of containers for sampling, the contents shall be homogenised if necessary and an amount taken from each container.

The incremental samples may be taken when the contents are being discharged.

Preparation of aggregate samples

In relation to the control of substances or products distributed uniformly throughout the feed the incremental samples shall be mixed to form a single aggregate sample.

Preparation of final samples

The material in each aggregate sample should be carefully mixed to obtain a homogenised sample. If necessary the aggregate sample should first be reduced to at least 2 kg or two litres (reduced sample) either by using a mechanical or automatic divider or by the quartering method.

At least three final samples should then be prepared, of approximately the same amount and conforming to the quantitative requirements de-

scribed above. Each sample should be put into an appropriate container. All necessary precautions should be taken to avoid any change of composition of the sample, contamination or adulteration which might arise during transportation or storage.

9. Validation of the system

Manufacturers of premixtures will validate their HACCP system to ensure that the hazards which were originally established by the HACCP team are complete and correct.

Defined hazards will be effectively controlled using the developed general and specific control measures, as well as the monitoring plan and the corrective actions and measures.

In addition to the HACCP, one or more independent members are added for the validation process. Management is clearly involved in this process.

Implemented corrective measures must show that they are satisfactory and prevent an unsafe feed from being released and provide proof that the situation can be immediately corrected.

VII. SAFETY

Feed is considered unsafe for its intended use if it is likely to pose a risk to human or animal health, or if its use may lead to animal products unsafe for human consumption.

All premixtures produced inside the EU must follow the strict norms that the European Commission's food safety policy has placed and set out primarily in the White Paper on Food Safety.

During the production the worker safety is assured, as the premixture producers have the experience of handling all the individual ingredients, with their different characteristics, the necessary equipment complying with relevant standards (eg ATEX - protection against occupational explosions), and the intelligence for knowing the best way of application, mixing and production of the final premixture.

Furthermore, and in order to ensure the safety of the users, Regulation (EC) No 1272/2008 regulates the Classification, Labelling and Packaging of substances and mixtures, according to the Globally Harmonized System (GHS)

adopted at international level by the United Nations. The GHS provides a system to harmonize the criteria for classification of substances and mixtures relating to physical and health hazards during handling (e.g. worker safety), environmental hazards, as well as the rules of labelling and packaging for hazardous substances and mixtures. It introduces the use of pictograms as those provided as an example in the pictures overleaf.

The aim of the premixture producer is to ensure safety of premixtures by minimizing the risk of adulterated feed additives, functional feed ingredients, carriers and premixtures entering the feed/food chain by providing measures to ensure that other applicable regulatory feed safety requirements are met.

The use of premixtures is the best way to apply additives into a feed for several reasons:

- The level of inclusion of every component is more controlled, as the premixture facility is better prepared to work with low dosages. This process diminishes the possibilities

of using dosages higher than recommended or lower than necessary for the animals

- Some additives may be considered dangerous for the user or the environment when used in very high concentrated forms; the risk is reduced when these hazardous substances are included in a premixture, and the possibility of incident is much lower. Also, the transport of dangerous additives is safer inside a premixture, as the dilution reduces the contamination possibilities in case of accident
- All products included in the premixture are considered safe for the animals at the recommended dosages. The premixture offers all the ingredients already mixed at the correct dose in correct proportions

The safety in the premixtures is controlled from the reception of the ingredients to the delivery of the final product in the feed producer factory. All components are controlled upon arrival, and stored according to the individual specific requirements they may have until they are included in the final premixture. At the moment of application in the premixture, the opera-

tor is provided with the adequate instructions for handling every component of the premixture. The premixture operator is able to implement the objectives of the feed hygiene Regulation (Regulation (EC) No 1831/2003). Contamination and cross contamination during production are avoided by correct identification, labelling and coding. If for any reason, the final product is considered unsafe, it is discarded. Finally, the premixture is packaged and labelled with a batch number that ensures the traceability of all the components from the supplier to the final user of the feed.

Tracking and traceability: Every product has unique written specifications, as well as name and code. All the information related to the production and ingredients used in the manufacturing of the premixture is kept in files with the code number of the production. In this way, the final user of the premixture has, with one code, all the required information about the components of the premixture, to avoid mistakes.



Picture 19:
Examples of pictograms according to the Globally Harmonized System

The premixture producer must calculate the hazardous level of the product applying the legislation in force (hazards and concentration factors laid down in GHS), and label the product accordingly. Finally, at the end of the production process, a Material Safety Data Sheet that follows regulation 453/2010 is produced. In this MSDS, all the aspects related to the handling and safe uses of the product are described, and are provided to the industrial user of the premixture.

The MSDS covers the following chapters:

SAFETY DATA SHEET
ACCORDING TO REGULATION (EU) N°453/2010

Revision: __ (EN)

Print date: _____

Revision date: _____

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY
2. HAZARDS IDENTIFICATION
3. COMPOSITION / INFORMATION ON INGREDIENTS
4. FIRST AID MEASURES
5. FIREFIGHTING MEASURES
6. ACCIDENTAL RELEASE MEASURES
7. HANDLING AND STORAGE
8. EXPOSURE CONTROLS / PERSONAL PROTECTION
9. PHYSICAL AND CHEMICAL CHARACTERISTICS
10. STABILITY AND REACTIVITY
11. TOXICOLOGICAL INFORMATION
12. ECOLOGICAL INFORMATION
13. DISPOSAL CONSIDERATIONS
14. TRANSPORT INFORMATION
15. REGULATORY INFORMATION
16. FURTHER INFORMATION

VIII. PHYSICAL AND CHEMICAL CHARACTERISTICS

1. Homogeneity and segregation

A homogenous mix is attained when all of the ingredients in a product are present, in the same ratios they were added, throughout the product. This is an important concept as a processing run that is not homogeneous may result in an overdose of additives in some instances and an underdose in others, both of which can be dangerous to animals and the consumer.

To prevent ingredient segregation (loss of homogeneity), the premixtures industry takes into account some parameters related to physical properties and process areas:

- the particle size, shape and distribution of the ingredient
- the design of the process line including extraction points and aspiration
- mixing time, overfill or apparatus failing to move ingredients through the mixing area such as gaps between mixing paddles and the mixer wall

The above problems are all commonly found in most processes. Common areas where they occur are:

- equipment vibration
- electrostatic hang up
- changes in air pressure
- free fall through or from equipment
- angle of repose, funnelling
- dust collection points

No matter how carefully or how thoroughly a premixture is blended, it will not remain uniform if it can be physically segregated. Some of the factors influencing segregation include:

- Carrier components exhibiting marked differences in physical properties
- Single carrier particles covering too wide particle size range
- Smooth surfaces on carrier particles
- Zero or negative electrostatic attraction between carrier particles and active ingredients
- Lack of oil on surface of carrier
- Too high a proportion of powdered active ingredients
- Inappropriate sieve between mixer and packing unit

Each carrier or combination of carriers appears to have a specific tolerance for powders. Well known carriers of similar 30-80 mesh range (150 - 600 μm) show widely different powder holding capacities of between 15 -50%.

If the carrier itself contains a high proportion of fine particles, such as flour in wheat middlings, this will decrease its ability to hold active ingredients in powder form.

- How to test for segregation during production and storage?

This is an example of a procedure that can be used to determine the efficacy of blending to ensure all ingredients are uniformly distributed:

- Determine the product to be tested. Use a product that has an ingredient that can be tested with a high degree of accuracy. Tracers such as zinc or manganese can be used
- Take and test retention samples of each raw material before production commences
- Mix the raw materials in accordance with normal procedure

- When the mixing is completed and packaged (but not sealed) samples should be taken from throughout the batch to check for consistency
- A sample must be taken from the first bag of product made and regularly thereafter
- Each retention sample must be tested for the active ingredients and results recorded
- The efficacy of the mixing process should be determined by calculating the standard deviation and coefficient of variation of the results
- Records of testing should be maintained in accordance with documented procedures
- The coefficient of variation of samples are usually around 5 to 10%
- In case of doubt regarding sieve performance it is suggested to take samples from the mixer after mixing, from the sieve (if possible) and from the bags and compare

2. Stability in premix

To control stability of feed additives in premix it is essential to pay attention to the specification of the product on the market as well as to the formulation of the premixtures. Essential are the choice of carrier(s) and their properties (like moisture content, pH) and awareness of incompatibilities between the different feed additives.

The stability of micro ingredients depends on various factors. There are no clearly defined standards for all micro ingredients. All vary in their stability. The destructive action of the other ingredients of the mixture on micro ingredients varies according to its moisture and mineral content.

In the case of vitamins, as biologically active biochemicals, they are in general quite sensitive to their physical and chemical environment. Feed manufacturing processes tend to improve the distribution of nutrients (premixing) and the digestibility of carbohydrates (pelleting, extrusion). However, these processes can be harmful to labile nutrients, such as vitamins, that can be easily oxidized.

In vitamin/trace mineral premixes, the dominant effect exerted on vi-

amins is redox reactions by trace minerals. Trace minerals also vary in redox potential. The type of trace mineral molecular structure, with copper, zinc and iron being the most reactive and manganese and selenium the least reactive, has a significant impact on vitamin stability. Free metal ion is the most reactive (metal filings) followed by sulphate, carbonate, oxide and the least reactive form is chelated. Chelated forms become incapable of initiating formation of free radicals.

In fat-soluble vitamins, esters are significantly more stable than alcohols. The hydroxyl group of alcohols is extremely sensitive to oxidation. The five double bonds in retinyl acetate (vitamin A) still make the compound sensitive to oxidations. Vitamin A is significantly more stable in vitamin premixes than in vitamin-trace mineral premixes because trace minerals catalyze oxidation of the five double bonds. Specific protected forms are available to overcome this problem to a certain extent.

Friction is also an important factor because it erodes the coating that protects several vitamins, including vitamin A, and reduces vitamin crystals to a smaller particle size.

3. Dustiness

Premixtures are usually prepared by dry blending of active ingredients with carrier.

The active ingredients in the form of fine powders will adhere to the coarser particles up to a certain limit. This limit is called Powder Carrying Capacity (PCC). The PCC of a carrier is influenced by its particle size, particle shape and surface texture.

Hence, two carriers having identical particle sizes may show widely different PCC's.

This difference is largely a matter of the surface area of the particles, which in turn is a function of particle shape and surface texture. In general particles with smooth flat surfaces have low PCC whereas those with highly irregular surfaces will hold powder better.

In addition to the powder carrying effects caused by the particle size and shape, the oil content of the carrier has a pronounced effect on the ability of the carrier to hold powders. The oil content may be of natural origin, such as that found in grains, or it may be added. So it is possible to prepare an oiled rice hull carrier which will have a higher PCC than that of ground corn.

4. Flowability

Free flowing properties are particularly important in a premix to be mixed in a feed by a continuous process via automatic dosing systems.

Premixtures must pass through feed milling equipment freely, without bridging or clogging. Proper carriers can be most effective in improving to improve the free flowing properties of the premix.

Free flowing agents can be added up to 5% to improve the flowability of premixes.

Another way to define flowability is compressibility.

Compressibility (Cp) is calculated by the formula

$$C_p = \frac{(td-ad) 100}{td}$$

Apparent density (ad) or non tapped density is determined by the weight of product freely filling a standard volume

$$ad = \frac{\text{Weight}}{\text{Volume}}$$

The tapped density (td) is determined by the weight of the product filling this same standard volume after removal of the air between the particles

$$td = \frac{\text{Weight (tapped)}}{\text{Volume}}$$

For most powders, the compressibility makes it possible to evaluate the behaviour of a powder in a static state (i.e. in a silo).

If the compressibility is low (<20%), the product normally flows freely. If the compressibility is high (>40%), the product packs and has a higher tendency to bridge in silo.

5. Carryover

Carryover is the contamination of a product with another material or product that originates from previous use of the same equipment.

Carryover has to be controlled during the production process in order to minimize and avoid its occurrence, until an acceptable level is reached. The operator should follow documented procedures and actions that have been taken to prevent carryover.

In order to limit carryover, special attention should be paid to the following:

- Transport (contamination with previous cargoes)
- Dosage
- Transport through the circuits within the factory
- Mixing
- Delayed dust return
- Electrostatic hang up
- Residue in equipment lines, walls, moving parts
- Leaking valves/gates
- Poor cleaning/flushing
- Preparation and storage

Operators must ensure that formal systems are in place to minimize the risk of carryover of feed additives and premixtures between them and/or with other products. Operators are required to take measures to avoid this carryover by providing, among others:

- thorough and complete cleaning of all equipment used between batches
- use of suitable sequencing and flushing techniques to prevent traces of restricted material entering the production line
- use of separate dedicated storage bins to store stock feed additives and premixtures, and to label each bin

Any operator shall have written procedures specifying:

- Control of the carryover critical points
- Sampling and analytical results
- Cleaning of the equipment when changing to a product with different characteristics from the product previously manufactured
- Verification of the adequate

maintenance and cleaning of the equipment (verification of the mixer total opening, verification of the cleaning program, etc.)

- Record the corrective measures taken, including their efficiency, in order to prevent or eliminate carryover

Where process lines may sometimes carry non-EU authorised products, this process must be used to demonstrate that there is no carry-over of this unapproved material into EU destined products.

Instructions for testing carry over:

1. Determine product to be tested. Use a product that has a low inclusion rate of an ingredient that can be tested with a high degree of accuracy. Tracers such as zinc or manganese can be used
2. Retain samples of all raw materials to be used in the test.
3. Batch A containing the selected active raw material/tracer, must be produced in accordance with normal production procedures

4. A sample of Batch A must be tested and retained
5. If a flush takes place between Batches A and B, samples of the flush material should be taken from the very beginning and end of the flush
6. When Batch B is completely mixed and packaged (but not sealed) representative samples should be removed from the batch
7. All samples (including samples of flush materials) must be tested in accordance with prescribed procedures
8. Batch B should not contain levels of the active ingredient contained in Batch A to an extent that it poses a risk to the end user (Apply HACCP principles)
9. Records of testing should be maintained in accordance with documented procedures

Glossary

Acidity regulators:

Substances which adjust the pH of feedingstuffs (Regulation EC No. 1831/2003). They are classified as technological feed additives.

Batch:

An identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together (Regulation EC No. 767/2009).

Biomass:

Biological material derived from living, or recently living organisms. In animal feed, biomasses usually consist in products which act as direct or indirect protein sources and are manufactured by certain technical processes, especially fermentation.

Buffering:

Action of adjusting and limiting the variations of the pH.

Bulk:

Unpackaged cargo or goods.

Caking:

Tendency of individual particles to adhere.

Carrier:

Substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself (Regulation EC No. 767/2009).

Coccidiostats:

Substances intended to kill or inhibit protozoa (coccidiosis parasites).

Complementary feed:

Compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed (Regulation EC No. 767/2009).

Compound feed:

A mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed (Regulation EC No. 767/2009).

Critical Control Points:

Steps at which control can be applied

and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (ISO 22000).

Emulsifiers:

Substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs (Regulation EC No. 1831/2003).

Enzymes:

Proteins that catalyze (i.e., increase the rates of) chemical reactions. They are classified as technological and zootechnical feed additives.

Expiry date:

Date after which the quality of the product cannot be guaranteed in relation to specification.

Extrusion:

A continuous process by which moistened, expansible, starchy, and/or proteinaceous materials are plasticized and cooked by a combination of moisture, pressure, temperature, and mechanical shear. Extruded feed are mainly used for pets and fish.

FAMI-QS:

The Quality and Safety System for Specialty Feed Ingredients and their Mixtures.

Feed additives:

Substances, micro-organisms or preparations, other than feed material

and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions:

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

(Regulation EC No. 1831/2003)

They can be classified in the following categories:

- (a) technological additives, (b) sensory additives, (c) nutritional additives, (d) zootechnical additives or (e) coccidiostats and histomonostats.

Feed business operators:

The natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control (Regulation EC No. 178/2002).

Feed hygiene:

The measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use (Regulation EC No. 183/2005).

Feed materials:

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 (Regulation EC No. 767/2009).

FEMAS:

Feed Materials Assurance Scheme.

Flowability:

Capability of a liquid or loose particulate solid (powder) to move by. Flowability depends on flow properties of the material and equipment used. Flow properties of a powder are linked to its physical characteristics (density, compressibility, cohesive strength, etc).

Functional feed ingredients:

Products which are not legally defined as feed additives and which

are used in feed in order to perform one of the following functions: micro-nutrition, technological, sensory, and zootechnical.

GMP+:

Scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

Good manufacturing practice:

Series of procedures in a branch or sector in which the standard of conduct is laid down (often with respect to hygiene and safety).

HACCP (Hazard Analysis and Critical Control Points):

A system which identifies, evaluates, and controls hazards related to feed safety. (Codex Alimentarius).

Hazard warnings:

Series of labelling measures in order to communicate on hazards (pictogram, words, statements ...), in line with the GHS (Global Harmonised System) for labelling of dangerous goods.

Label :

Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of feed (Regulation EC No. 767/2009).

Labelling :

Attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed, such as packaging, container, notice, label, document, ring, collar or the Internet, including for advertising purposes (Regulation EC No. 767/2009).

Material Safety Data Sheet (MSDS):

Document that contains information on the potential health effects of exposure to chemicals, or other potentially dangerous substances, and on safe working procedures when handling chemical products.

Mesh (scale):

Measure for particle sizes of powders and granular materials.

Micro-organisms:

Microscopic organism that comprises either a single cell (unicellular), cell clusters, or no cell at all (acellular). They are classified as zootechnical additives.

Mineral feed:

Complementary feed containing at least 40 % crude ash.

Minerals:

Chemical elements required by living organisms, other than the four elements carbon, hydrogen, nitrogen, and oxygen present in common or-

ganic molecules; in Europe, macro-elements (i.e. phosphorus, calcium, magnesium, potassium, sodium, sulphur,...) are feed materials whereas micro-elements are feed additives (see definition of trace elements).

Nutritional additives:

Additives that satisfy the nutritional needs of animals. They include the following functional groups:

- vitamins, pro-vitamins and chemically well-defined substances having similar effect;
 - compounds of trace elements;
 - amino acids, their salts and analogues;
 - urea and its derivatives
- (Regulation EC No. 1831/2003)

OVOCOM:

Consultation Platform for the animal feed chain. OVOCOM is the scheme owner for the Belgium GMP certification scheme.

Pelleting (feed pelleting):

Processes consisting in forcing a soft feed through holes in a metal die plate to form compacted pellets, which are then cut to a pre-determined size. Feed are usually grinded and conditioned with different liquids and/or steam to improve pelleting. Pelleted feed (granulates) are used for many different animal species.

Perishable materials:

Material subject to decay or spoilage.

Premixtures :

Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals (Regulation EC No. 1831/2003).

Preparation (of feed additive(s)):

Combination of one or more feed additives with technological feed additives, feed materials and/or water used as formulation aids, and intentionally formulated or processed in order to (i) improve handling properties, safety of use or stability of the additive or additives, or (ii) synergistically perform a feed additive function.

Preservatives:

Substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites (Regulation EC No. 1831/2003).

QS:

Qualität und Sicherheit GmbH, Germany quality scheme for food.

Reworking:

Any appropriate manipulation steps in order to ensure a feed additive or premixture will conform to specifications.

Sample:

Quantity of product constituting a unit, and having characteristics presumed to be uniform and representative of a whole.

Sensory additives:

Any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals (e.g. colorants or flavouring substances).

Shear effect:

Effect obtained by friction of materials.

Shelf life:

Defined time period for which a product fully complies with its specification if stored appropriately.

Silo:

Structure for storing bulk materials. Specialty feed ingredients: Feed additives and functional feed ingredients. Trace elements: Dietary mineral that is needed in very minute quantities for the proper growth, development, and physiology of the organism. They are classified as nutritional feed additives (iodine, iron, selenium, copper, zinc, manganese, cobalt and molybdenum).

Technological additives:

Any substance added to feed for a technological purpose (e.g. preservatives, antioxidants, emulsifiers, stabilisers, anti-caking agents, binders, acidity regulators ...).

UFAS:

Universal Feed Assurance Scheme.

Vitamins:

Organic substances indispensable to the normal metabolic processes of animal organisms.

Withdrawal period :

Period necessary between the last administration of the feed additive to animals under normal conditions of use and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits set for the feed additive.

Xanthophylls (or phylloxanthins):

Yellow pigments that form one of two major divisions of the carotenoids group (the other one being carotenes).

Zotechnical additives:

Any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment.

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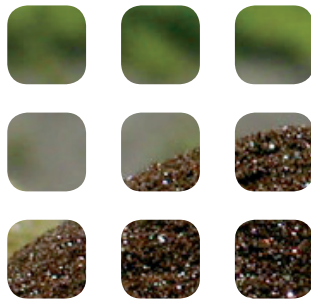
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Disclaimer

This booklet is intended to provide the best-of-our-knowledge information to anyone interested to get a better understanding about Premixtures.

However, FEFANA does not take any responsibility for whatever use of the information provided herewith, by either the general public or any actor in the food and feed chain.



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