## Table of Contents

### FEFANA’s mission

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Foreword by the FEFANA President and Secretary General</td>
<td>03</td>
</tr>
<tr>
<td>2. Authorisation of feed additives</td>
<td>04</td>
</tr>
<tr>
<td>2.1. Re-authorisation and FEFANA Consortia</td>
<td>06</td>
</tr>
<tr>
<td>2.2. New functional groups</td>
<td>09</td>
</tr>
<tr>
<td>2.3. Regulation on preparations</td>
<td>11</td>
</tr>
<tr>
<td>2.4. Withdrawal regulations</td>
<td>12</td>
</tr>
<tr>
<td>2.5. Revision of feed additive application guidelines</td>
<td>12</td>
</tr>
<tr>
<td>2.6. Use in water</td>
<td>14</td>
</tr>
<tr>
<td>2.7. Bacillus safety</td>
<td>14</td>
</tr>
<tr>
<td>3. Labelling of feed additives</td>
<td>17</td>
</tr>
<tr>
<td>3.1. Optimised labelling of feed additives along the chain</td>
<td>17</td>
</tr>
<tr>
<td>3.2. CLP/GHS feed additives and their mixtures</td>
<td>18</td>
</tr>
<tr>
<td>4. Engagement with decision-makers and feed &amp; food chain partners</td>
<td>21</td>
</tr>
<tr>
<td>4.1. REFIT</td>
<td>21</td>
</tr>
<tr>
<td>4.2. Industry partnership on EFSA work</td>
<td>21</td>
</tr>
<tr>
<td>5. International undertakings</td>
<td>23</td>
</tr>
<tr>
<td>5.1. Global Regulatory Convergence Project</td>
<td>23</td>
</tr>
<tr>
<td>5.2. Sustainability</td>
<td>23</td>
</tr>
<tr>
<td>6. A responsible industry ...</td>
<td>27</td>
</tr>
<tr>
<td>6.1. Choline chloride</td>
<td>27</td>
</tr>
<tr>
<td>6.2. Dioxin monitoring</td>
<td>27</td>
</tr>
<tr>
<td>7. Publications</td>
<td>28</td>
</tr>
<tr>
<td>8. About</td>
<td>29</td>
</tr>
<tr>
<td>8.1. Place in the feed &amp; food chain</td>
<td>29</td>
</tr>
<tr>
<td>8.2. Scope</td>
<td>30</td>
</tr>
<tr>
<td>8.3. Secretariat</td>
<td>32</td>
</tr>
<tr>
<td>8.4. Board of Directors</td>
<td>32</td>
</tr>
</tbody>
</table>
FEFANA Mission

FEFANA – the European Union (EU) Association of Specialty Feed Ingredients and their Mixtures - is the united voice of the specialty feed ingredients business in Europe. Our membership comprises manufacturers and traders of feed additives, functional feed ingredients, premixes and other mixtures of specialty feed ingredients that enter the food chain via feed. FEFANA facilitates the dialogue between EU institutions and feed business operators, whilst promoting feed and food safety, a fair and competitive market, and a favourable environment for innovation and growth.

OUR GOALS

FEFANA aims to:

- Promote, defend and represent the common- and general interests of the specialty feed ingredients business in Europe.
- Promote and support understanding of the benefits of specialty feed ingredients and mixtures made from them.
- Promote the transparent and scientifically-based evaluation of the safety of specialty feed ingredients.
- Maintain cooperative contact with EU- and Member States’ authorities and other stakeholders in the feed and food chain to ensure the right flows of information.
- Participate in the decision-making process with regard to new-, amended- or revoked legislation.
- Support harmonised implementation of existing legislation.
- Develop professional voluntary tools that ensure the transparent, effective and safe use of specialty feed ingredients and mixtures made from them within the European market.
- Support our members’ efforts to produce safe, cost effective products for the food chain.
- Support innovation and development of specialty feed ingredients and mixtures made from them.
- Promote the sustainable development of livestock production by using specialty feed ingredients and mixtures made from them.

1. Foreword

by the FEFANA President and Secretary General

We are delighted to introduce to you the latest version of the FEFANA biennial report. This is an evolution of our regular activity report that not only reviews accomplishments and activities of the last couple of years but also provides a forward-looking perspective.

Thanks to the active engagement of our members, we have come a long way and have achieved important results for our industry over the last couple of years.

Earlier in 2015, FEFANA received the opportunity to present the sector’s priorities to the European Commissioner for Health & Food Safety, Vytenis Andriukaitis. It stressed the need to reinforce the European Commission’s leadership on risk management, vis-à-vis the European Food Safety Authority (EFSA)’s risk assessment role, and to ensure consistency and proportionality of the feed legislation. Together with other European stakeholders, FEFANA emphasized the key importance of securing the management of the Animal Nutrition Unit in the European Commission’s Directorate General for Health and Food Safety (DG SANTE), as a prerequisite for appropriate management of feed and food safety.

FEFANA is widely-recognized for playing a crucial role in ensuring a harmonised EU market place and fair competition, especially when it comes to the (re-)authorisation of feed additives. The publication of the Regulation on Preparations in March 2015 is a development of the Consortia activities. This was the result of long, but productive discussions with the EU and national Competent Authorities that enabled examination and incorporation of the practical aspects of industrial manufacturing practices. The respective measures will be fully implemented by 23rd March 2017, and FEFANA is actively working on formulating guidance to help its Members with its implementation. On other aspects of feed additive legislation, we welcome the final realisation of the withdrawal of the feed additives listed in Annex II of the EU Register, as a significant step forward on the credibility of the whole re-authorisation process.

Over the last couple of years, FEFANA has been intensively engaged with other European associations to call for a stronger and more credible EFSA. Progress has been achieved in terms of communication, for example, with the introduction of electronic support for the application for and setting up of annual open sector meetings for regulated products. Steps are being proposed to implement a more efficient risk assessment process in the future. This is of vital importance in the authorisation process.

FEFANA has a key role to play, not only at European level but also internationally. We continue to work on creating a level platform for innovation and growth of our industry. FEFANA strongly supports the development of global feed safety standards and supports an overseas group aimed at integrating a higher level of legal convergence, without compromising the high EU feed and food safety standards. As highlighted on other occasions, specialty feed ingredients will also have a role in a sustainable future. FEFANA will continue to demonstrate and communicate the benefits of specialty feed ingredients in livestock production in a world, in which the demand for animal-produced food is increasing rapidly.

Whilst our structure and mode of action continues to evolve, together with the political landscape, economic dimensions and legislative developments within the EU and across the world, FEFANA will continue to remain true to itself in promoting, supporting and defending the industry of specialty feed ingredients and mixtures made from them.
2. Authorisation of feed additives

Flow-chart of the authorisation process

Applicant: company/ies applying for an authorisation of feed additive(s)
Example: FEFANA Consortia are applicants.

EC: European Commission
The Directorate General on Health and Food Safety (DG SANTE) is in charge for this matter.

SC PAFF: Standing Committee on Plants, Animals, Food and Feed
Made-up of representatives of Member States. The section Animal Nutrition liaises with the applications of feed additives.

EFSA: European Food Safety Authority
The FEEDAP Panel, made up of external scientific experts, is responsible for the risk assessment of feed additives.

EURL: European Union Reference Laboratory
It operates within the remit of the European Commission Joint Research Center (JRC).

Samples + Fee

Application

Dossier

Supplementary information from Applicant

Scientific Risk Assessment

Adoption and publication of EFSA Scientific Opinion

EC / SC PAFF discussion on EFSA opinion and proposal for authorisation

EC / SC PAFF adoption of authorisation

Publication of authorisation in EU Official Journal

Q & A

EURL

Assessment of analytical methods

Summary

Publication of EURL Report

Applicant: company/ies applying for an authorisation of feed additive(s)
Example: FEFANA Consortia are applicants.
2.1. Re-authorisation and FEFANA Consortia

Background

The Consortia for (re-)authorisation of feed additives - as per Article 10(2) of Regulation (EC) No 1831/2003 - is a success story, in which FEFANA has facilitated the uniting of resources within our industry. Through an efficient cooperation system, manufacturers and importers of feed additives were offered the opportunity to participate in FEFANA Consortia and jointly-prepare applications for re-authorisation of additives of their interest. Via the Consortia, the operators shared data and costs for preparing their applications for re-authorisation of additives (e.g. reference samples, technical dossier) to fulfill the legislative requirements for the marketing and safe use of feed additives. Consortia have also been formed for authorisation – as per Article 4 of the feed additive regulation – for instance for the establishment of a new functional group of technological feed additives, the ‘Hygiene Condition Enhancers’. Overall, FEFANA was responsible for the submission.

Number and percentage of feed additives by category, as submitted by the FEFANA Consortia

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>N° OF ADDITIVES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technological additives</td>
<td>113</td>
</tr>
<tr>
<td>Sensory additives</td>
<td>860</td>
</tr>
<tr>
<td>Nutritional additives</td>
<td>39</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1 012</td>
</tr>
</tbody>
</table>

Differences between re-authorisation and authorisation at a glance ...

- **Product already exists in the EU market?**
  - Re-authorisation: Yes
  - Authorisation: No

- **Article in Reg. (EC) No 1831/2003**
  - Re-authorisation: Art. 10.2
  - Authorisation: Art. 4

- **Deadline for application**
  - Re-authorisation: November 2010
  - Authorisation: At any time

- **Still possible to apply through this route?**
  - Re-authorisation: No
  - Authorisation: Yes (always possible)

- **Can be marketed during the procedure?**
  - Re-authorisation: Yes
  - Authorisation: No

List of FEFANA Consortia and their status

(last update as of 30/10/2015)

<table>
<thead>
<tr>
<th>Consortium</th>
<th>Application route</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIAC (Organic Acids)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>AMAC (Amino Acids)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>ANTOXIAC (Antioxidants)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>CARAC (Carotenoids)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>EMULAC (Emulsifiers)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>FFAC (Flavourings)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>HYFAC (Hygiene of the feed chain)</td>
<td>Authorisation – Art. 4</td>
<td>Open</td>
</tr>
<tr>
<td>SILAC (Silage additives)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>TREC (Trace elements)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
<tr>
<td>UREAC (Urea)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Closed</td>
</tr>
<tr>
<td>VITAC (Vitamins)</td>
<td>Re-authorisation - Art. 10.2</td>
<td>Open</td>
</tr>
</tbody>
</table>

Progress and state-of-play

Whereas the re-authorisation process was expected to be a quite straightforward exercise at the time of publication of Regulation (EC) No 1831/2003, applicants and the authorities soon realised that the assessment of the additive dossiers would take much longer than anticipated. Over the past five years, the risk assessments of more than 60% of the applications for re-authorisation submitted by FEFANA through the Consortia were finalised, resulting in the publication of corresponding EFSA opinions. From these published opinions, approximately 30 regulations for implementation were published, establishing the rules (e.g. identity, conditions of use) for the authorisation of the feed additives in the EU (see figure below).

Following the assessment of the additives and publication of the EFSA opinions, the FEFANA Secretariat and participating companies have been engaged in ensuring that the result of the risk management linked to the EFSA opinions are practically implementable.

Major developments have been observed in the last months for Vitamins and for some Carotenoids. FEFANA will, of course, remain active until all remaining EFSA opinions are published and will liaise appropriately with the authorities.

However, there is still the specific case of the flavouring compounds, for which it is foreseen that the current, post-opinion work on chemically-defined flavourings and the assessment of botanical-flavourings will require additional years to enable finalisation of the re-authorisation of these additives.
Status of applications for authorisation of feed additives submitted by FEFANA re-authorisation Consortia
(last update as of 30/10/2015)

<table>
<thead>
<tr>
<th>EFSA opinions</th>
<th>N° regulations</th>
<th>pending opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>35</td>
<td>25</td>
</tr>
<tr>
<td>30</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>15</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Some major changes

Through the re-authorisation process, changes have been introduced in the description of the additives and conditions of use. Several authorisations now determine the identity of the additives through a very detailed description, including purity- and impurity criteria. A new, interesting element is that for substances produced by fermentation, such as some Organic Acids, Amino-Acids and Vitamins, the specific strain of production organisms is assessed by the EFSA. As a consequence, only the additives produced with the evaluated production strains, which are shown to be safe by the applicant under the proposed conditions of use, will be authorised. This will be further reflected in the authorising regulation(s) for these additives, with the production strains indicated.

Regarding conditions of use, some feed additives are no longer allowed for use in all animal species, due to limited data available either for safety or efficacy (e.g. Cobalt, Inositol, Taurine); others have had their permitted maximum use levels decreased (e.g. Vitamin A) or limits have been introduced (e.g. Fumaric Acid); and some other additives may now only be incorporated into compound feed via premixtures. As a result of the re-authorisation, and considering that only products compliant with the criteria set in the authorising regulation are allowed on the EU market, the market place has evolved during the last years, towards a safer and more transparent situation.

What’s next for the FEFANA Consortia?

With good progress made during 2014-2015, several FEFANA Consortia are now seeing their list of feed additives almost fully (re-)authorised. The work of these Consortia is, therefore, slowly, but surely, coming to an end. However, FEFANA will remain as a reference point for any eventual questions related to these additives and for providing reference samples to the European Reference Laboratory (EURL), as required by the legislation.

In addition, in the near future, the first feed additives authorisations obtained via the Consortia will expire and an application for renewal of authorisation will be required for certain additives, as from 2020, according to Article 14 of Regulation (EC) No 1831/2003. FEFANA will remain at the disposal of the business operators to support them in efforts to keep their additives authorised for an additional ten years.

2.2. New functional groups

The participation of FEFANA in the authorisation of feed additives has not been limited to the creation of re-authorisation Consortia. After serving at the origin of the creation of a new functional group of technological additives in 2009 – Category 1m: ‘Substances for reduction of the contamination of feed by mycotoxins’, as set in Regulation (EC) No 386/2009 - FEFANA launched a Consortium focusing on feed additives that favourably affect the hygiene of the feed chain (HYFAC - Hygiene of the Feed Chain Authorisation Consortium) in July 2011. Two applications have already been submitted by FEFANA: One on formaldehyde and one on formic acid and its salts, and the relevant EFSA opinions have been issued. As an initial result, a new functional group of technological additives was adopted by the European Commission’s Standing Committee on Plants, Animals, Food and Feed on Animal Nutrition in July 2015 – Category 1n: ‘Hygiene Condition Enhancers’, defined as: ‘substances or, when applicable, microorganisms that favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination’. The relevant regulations for the above mentioned feed additives are expected to be published in the near future.
2.3. Regulation on preparations

The definition of feed additives encompasses the use of preparations. However, feed additive preparations were not specifically defined in the legislation, and, thus, clarity was required when the European Commission’s Standing Committee on Plants, Animals, Food and Feed on Animal Nutrition started discussing feed additives marketed as preparations. FEFANA was a key stakeholder in the discussions with the EU and Members States’ Authorities, and finally, it became necessary to amend the feed additives legislation to provide detail on: what a preparation is; which ingredients can be used; and how preparations and their ingredients should be labelled (as additives and in the premixtures containing them).

In March 2015, the ‘Regulation (EU) No 2015/327 detailing the requirements for the placing on the market and conditions of use of additives consisting of preparations’ was published in the Official Journal of the European Union, which clarifies the status of the products: “In some preparations, authorised as additives in accordance with Regulation (EC) No 1831/2003, technological additives and other substances or products are incorporated to exert a function on the active substance contained in the preparation, such as stabilising or standardising it, facilitating its handling or its incorporation into feed. […] The technological additives or other substances or products added to maintain the integrity of an active substance are however not intended to perform a function in the feed, in which the preparation is to be incorporated.”

This Regulation also mandates that operators provide information about the composition of the preparations placed on the market, since such information enables the end-user or the purchaser to make an informed choice, allows appropriate risk assessment and contributes to fairness of transactions. Annex III to Regulation (EC) No 1831/2003, on specific labelling requirements for certain additives and for premixtures, and Annex IV, thereto, on general conditions of use, were, therefore, amended to incorporate this update.

The approach taken by the authorities provides practical solutions for the feed business operators and ensures transparent and effective flow of information along the chain, whilst maintaining a high level of feed safety.

The Regulation on preparations allowed the European Commission’s Standing Committee on Plants, Animals, Food and Feed on Animal Nutrition to restart the discussions for adoption of authorising regulations and several Consortia authorisation procedures could be finalised during 2015, accordingly.

EFENAA classification tool for mixtures

To support effective implementation of the Regulation on Preparation, FEFANA is developing a Classification Tool for Mixtures aimed at promoting a common understanding of the status of products that comprise of mixtures of ingredients within the industry. The tool is being developed, because the definitions of the Regulation are not sufficiently self-explanatory, but need to be implemented in a harmonised-, transparent- and practical way. The tool should help operators and authorities agree on classification of the different types of feed mixtures marketed in the EU (feed additive preparations, premixtures, compound feed).

Development is based on common understanding between the industry and authorities, dialogue and shared experience amongst FEFANA members, as well as expertise gained during the registration process. It is anticipated that the tool will be implemented as an online, user-friendly feature, similar to the FEFANA Classification Tool for substances. Additionally, a ‘Questions & Answers’ document has been produced, which mostly deals with aspects related to labelling. These initiatives will be available on the FEFANA website.

1 Art. 2(a) of Regulation (EC) No 1831/2003: ‘feed additives’ means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water.
2.4. Withdrawal regulations

According to Regulation (EC) No 1831/2003, feed additives, for which no application for re-evaluation was submitted before the deadline of 8th November 2010, should have been withdrawn from the market. In recent years, three withdrawal regulations have been published:

- 2012: Regulation (EU) No 451/2012 for certain feed additives belonging to the functional group of silage additives;
- 2013: Regulation (EU) No 230/2013 for certain feed additives belonging to the group of flavouring and appetising substances; and

Now the European Commission intends to publish a single regulation to withdraw all remaining additives so far included in the Annex II of the EU Register of feed additives from the EU market. FEFANA welcomes and supports this, as a significant step forward in the credibility of the whole re-authorisation process. This would help create a more transparent and fairer platform in feed additives.

Substances listed in the withdrawal regulations will then be non-authorised feed additives and therefore cannot be placed on the market. If business operators see finally the need for those products to be marketed in EU, they must submit a new application for authorisation.

2.5. Revision of feed additive application guidelines

In the frame of the authorisation of feed additives, European Commission Regulation (EC) No 429/2008 regarding the preparation and the presentation of applications and the assessment and the authorisation of feed additives – herewith referred to as ‘the guidelines’ – represents the core document to be consulted by applicants when preparing their technical dossier for application for authorisation of a feed additive in the EU. It should be a key document for reference to ensure transparent and predictable authorisation of feed additives.

Through the work in the Consortia, a lot has been learned during the preparation and the assessment of re-authorisation dossiers and the need to update the guidelines was identified early in the process by FEFANA and its Members. In fact, since 2014, a group of FEFANA experts has been working on the main issues arising from implementation of the guidelines. The main objective for our industry is to ensure improved transparency and ensure a level platform across feed businesses. Risk assessment should be as predictable as possible and innovation should also be included as part of the guidelines. This requires a guideline that clearly defines the content of the dossiers, the information needed for the assessment and the data that can be waived upon sound justification by the applicant. This formed the basis of the FEFANA guideline principles shared with the European Commission during 2015.

The European Commission has confirmed its intention to revise this Regulation during 2015-2016. FEFANA will continue to provide its contribution to the authorities to achieve the above mentioned objective for a fair, transparent, science-based assessment of feed additives.
2.6. Use in water

Regulation (EC) No 1831/2003 acknowledges that feed additives can be intentionally added to feed or water. Within the frame of the applications for authorisation of feed additives, several applicants, therefore, included ‘use in water’ as a new use for the additives. It must be noted that ‘use in water’ is not a new practice. Our industry has been innovative in this field for several decades with different specialties formulated for use in water. Specific equipment to supply nutrients via water is also available for on-farm use, as well as in pastures. However, the definitions of two categories of feed additives - i.e. technological additives and sensory additives - restrict their use to feed only. FEFANA is working closely with the European Commission to clarify the conflicting issues that have arisen with the feed additives regulation, allow their use in animal drinking water and reflect current practice. This would require an eventual amendment of the feed additive regulation. Once clarification of the situation regarding these additives has been achieved, it will be possible to finalise the authorisation procedure of the additives for which a decision is pending, due to a legal gap on ‘use in water’. In other cases, where the EFSA does not recommend the approval of two routes of administration for the same product, the additive has not been authorised to be used, as such, in water (e.g. Vitamin A - Regulation (EU) No 2015/724). However, the European Commission and the EU’s Member States recognise that such prohibition does not apply to those additives incorporated in compound feed subsequently administered via water (see Recital 6 of Regulation (EU) No 2015/724). This means that it is possible to supply Vitamin A to animals via their drinking water, as long as this is done through a complementary feed specifically formulated for that purpose. Such feed specialties often contain also other vitamins and compounds of trace elements, for example.

2.7. Bacillus safety

The revision of EFSA Guidance (2014) on the assessment of the toxigenic potential of Bacillus species used in animal nutrition was well received by FEFANA. In fact, the Bacillus species have been widely used for decades in microbial feed additives (probiotics and silage inoculants) and as production organisms for enzymes and other fermentation products for feed and food use. In the revised Guidance, EFSA acknowledged that the link between food-poisoning/toxicity and lipopeptides has not yet been established. During the EFSA consultation, FEFANA joined forces with AMFEP – The Association of Manufacturers and Formulators of Food Enzyme Products – to provide appropriate and highly scientific arguments on the safety of Bacillus. This approach demonstrates that the only way to meet the highest scientific standards is through open dialogue and consultation with all parties and available technical experts and to provide appropriate, high quality and reliable scientific evidence on the safety of Bacillus.
3. Labelling of feed additives

3.1. Optimised labelling of feed additives along the chain

An initiative of the feed chain with the objective to facilitate the labelling regime for feed additives without compromising safety.

Have the current rules on labelling of feed additives met the objective to ensure that information presented is consistent, coherent, transparent and understandable? Does the information required on labels enables purchasers to make the optimal choice for their needs, especially considering that purchasers have not access to the package label when deciding on the feed they will purchase? Why should the information be provided on the label instead of other means of communication between the vendor and the purchaser? Does label information significantly contributing to traceability and control?

These and other questions were the subject of a workshop with the European Commission and national Competent Authorities in November 2014. The workshop was the result of a joint initiative of FEFANA, with the European Farmers and Agri-Cooperatives (COPA-COGECA), European Manufacturers of Feed Minerals Association (EMFEMA) and European Feed Manufacturers Association (FEFAC). Its aim was to define the key principles for optimised information flow regarding (labelling of) feed additives along the feed chain.

The objectives of the workshop were to outline the principles for efficiently improving transparency, as identified by the four associations:

- Information provided should fit the need of the user.
- Information should be readable and understandable.
- Information should be available via different means.

These principles aim to capture both regulatory requirements and the needs of regulatory/legislative authorities and consumers. The final goal is to guarantee an informed use of feed additives at all stages in a harmonised European Market.

To ensure consistency, FEFANA works continuously towards harmonisation of rules within the feed legislation framework and interpretation across the EU Member States. This work takes account of the complete feed chain and considers the information needs of regulators and operators at different stages of the value chain, from feed additive producers to compound feeders and farmers. In practice, different product information is needed and is provided according to the stage of the feed chain. The most typical scenarios are considered as: business to business; business to final users (e.g. farmers, pet owners); and business to regulatory/legislative authorities, with each requiring specific, but different information according to their activity.

So what are the next steps?

A FEFANA Expert Group on Labelling along the Feed Chain has recently been established to work on practical aspects for implementation of the principles for improved labelling. In addition, the joint association initiative will follow-up on a second workshop with the European Commission and national Competent Authorities for presenting concrete details of industry’s proposal. Hopefully, this will provide a fruitful discussion and a pragmatic solution that serves the need of users and regulatory/legislative authorities.
3.2. CLP/GHS of feed additives and their mixtures

Feed additives

Industry considers its responsibility towards society and its customers to be that products are handled properly and safely. Therefore, FEFANA’s Members successfully developed a CLP-GHS (a Globally Harmonised System of Classification, Labelling and Packaging of Chemicals) listing of a number of categories of feed additives over the years, for instance, for Organic Acids and their salts, Vitamins and Carotenoids.

The GHS was adopted at international level by the United Nations (UN) and provides a system to harmonise 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 labelling- and packaging rules. Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (the so-called ‘CLP Regulation’) implements the general principles of the GHS within the EU.

Back in 2012, FEFANA already started working on the harmonisation of the classification for certain categories of substances based on the GHS and in alignment with the EU legislation on CLP.

Whilst Annex VI of the CLP Regulation lists the existing harmonised classification and labelling of substances according to the GHS, it does not cover every substance currently defined as a feed additive. In addition, the EU legislator mandates manufacturers and importers of the same substance to make every effort to agree on a single classification for that substance. To achieve this objective and fulfil its commitment to promote worker safety, FEFANA has made great efforts to consolidate the classification of several substances.

More information and the relevant listings are available on the FEFANA CLP-GHS dedicated webpage at: http://fefana.org/clp-ghs.html

Mixtures

Whilst the position is clear for feed additives in that they fall under CLP Regulation, the situation for mixtures made from feed additives is more complex, and is interpreted differently in EU Member States. Further clarifications are anticipated from the EU authorities, as to whether CLP of chemical substances apply to mixtures of feed additives. FEFANA members are preparing actively for a practical-, harmonised- and organised implementation of the Regulation in all EU Member States.
4. Engagement with decision-makers and feed & food chain partners

FEFANA is strongly committed to making a contribution to the EU arena. For instance, we are present in a number of stakeholders groups – including: the EFSA Stakeholder Platform; the European Commission’s Directorate General for Health and Food Safety (DG SANTE)’s Advisory Group; the European Commission’s Directorate General for Agriculture & Rural Development (DG AGRI)’s Civil Dialogue Groups, the European Committee for Standardization (CEN)’s Working Group TC327; the European Commission’s Directorate General for Trade (DG TRADE)’s Directorate G – Market Access and Industry - on which our regular presence ensures feedback and flow of information from/to the membership to the relevant authorities and other actors. Our industry is also engaged in co-ordination efforts at different levels with relevant stakeholders in the EU feed chain, namely: the European Feed Manufacturers’ Federation (FEFAC); the European Manufacturers of Feed Minerals Association (EMFEMA); the EU Vegetable Oil and Protein meal Industry (FEDIOL); and the European Pet Food Industry Federation (FEDIAF).

We appreciate a holistic approach and the leverage of joint views with partners in the feed chain for certain issues as appropriate, for instance, as done through the industry partnership on EFSA work (see further down).

4.1. REFIT

The evaluation of Regulation (EC) No 178/2002 - the ‘General Food Law’ (GFL) - forms part of the European Commission’s Regulatory Fitness and Performance Programme (REFIT). The purpose of the evaluation was to assess if the regulatory framework established by the GFL is effective and efficient and if it provides added value to stakeholders. We believe this ‘fitness check’ to be of paramount importance to ensure a high level of public health on one hand and a competitive EU industry on the other. It has also provided opportunities for FEFANA to raise issues and call for improvement, in particular, in the field of fair competition and proper risk assessment and risk management separation. Over the past two years, FEFANA has contributed actively to this exercise through the Working Group of the European Commission’s Directorate General for Health and Food Safety (DG SANTE) Advisory Group, by providing position papers and comments, as appropriate. FEFANA has also taken part in dedicated surveys that have contributed to the development of the REFIT Programme of the GFL per se on one side, and Rapid Alert System for Food and Feed (RASFF) and crisis management procedures on the other side - targeted at key stakeholders involved in the GFL.

We have pointed out that one of the objectives of the REFIT Programme is to improve the regulatory framework and reduce ‘red-tape’ for businesses, as well as to reduce costs and time for EU- and Member States’ officials and operators. We also aim at a harmonised risk analysis approach, in which the same principles apply to all EU Member States to ensure comparable results and a level platform for all stakeholders.

4.2. Industry partnership on EFSA work

Back in 2014, a joint letter from several European associations, who collaborated in a partnership of associations representing industry within the remit of EFSA, was addressed to EFSA calling for a stronger and more credible EFSA and providing several proposals on communication, quality and transparency of mandates. FEFANA held a leading position in this group, particularly as the key contact point on different occasions. This has resulted in a number of exchanges and reactions from EFSA and other EU authorities. Although there is still a way to go in setting a level platform, it is worth mentioning that certain steps have been made in the right direction, for instance, more systematic organisation of sector events, the introduction of teleconferences with applicants, new possibilities to submit data through electronic means, and a new catalogue of services.
5. International undertakings

FEFANA is a well-recognized, full member of the International Feed Industry Federation (IFIF) and the only one representing feed additives and functional feed ingredients, so far. These products play a significant role in the feed and food chain, and share a common responsibility base with the compound feed industry. We see IFIF as our interface to certain key international organisations, such as: the Codex Alimentarius (International Food Code); the World Organisation for Animal Health (OIE); and the Food and Agriculture Organization of the United Nations (FAO); and the ideal platform to meet with other actors in the feed chain. In addition, FEFANA has led some important international projects, such as: the Speciality Feed Ingredients Sustainability (SFIS) Project, which focuses on sustainability; and the Global Regulatory Convergence Project, which promotes harmonised risk assessment approaches.

5.1. Global Regulatory Convergence Project

This initiative has been launched with the aim of ensuring understanding of regulatory framework for feed ingredients around the globe. Two documents have been published comparing the regulatory approaches in seven jurisdictions in total, starting with Canada, the United States of America (USA) and the European Union (EU), followed by Brazil, South Africa, China and Japan. From an initial approach that recognised the different regulatory approaches, it was agreed to progress with a potential harmonisation of risk assessment methodologies. This approach, inspired from the veterinary field, aims at aligning the risk assessment methodologies between the jurisdictions, hence reducing overall costs of product entry on the markets, for the authorities and industry. It could also support product registration recognition and further facilitate global trade of feed ingredients. The next step of the project is expected to lead to the creation of a platform for dialogue, upon which industry and authorities will develop guidance for risk assessment.

5.2. Sustainability

Since 2008, FEFANA has been committed to activities that establish the role of specialty feed ingredients in sustainable production and consumption. In fact, since specialty feed ingredients play a key role in animal nutrition and welfare, they also represent efficient tools for environmental mitigation options. Improving sustainability performance along the feed to food value chain is only achievable by using specialty feed ingredients and understanding their benefits. Thus, the recently-finalised Life Cycle Assessment (LCA) study on the contribution of Specialty Feed Ingredients to Sustainability in Livestock Production (SFIS) represents a milestone in our cooperation with IFIF. The overall results of the study show that the use of specialty feed ingredients in animals’ diets modifies the use of basic feed ingredients. In addition, the study demonstrates that the use of specialty feed ingredients results in clear reductions of the Global Warming Potential, as well as the Eutrophication Potential and Acidification Potential during livestock production, due to reduced Nitrogen (N) and Phosphorus (P) in manure. The rigorous SFIS analysis employed LCA to examine the use of low protein diets (Nitrogen) and Phytase (P) in pigs and poultry. In addition to the positive results, the study also points towards future developments, such as improved feed conversion driven by advancing technologies in animal feeding through use of specialty feed ingredients. This independent study, in line with the international

---

standard DIN EN ISO14044:2006, is well recognised by other members of the value chain both downstream and upstream. The FAO Guidelines published in 2015 clearly address the evidence on ecological data for feed additives when assessing sustainability of feed. Based on this study, the project group tabled the so-called ‘Product Category Rules’ (PCRs), as easy-to-use guidelines for sustainability assessments of specialty feed ingredients in the future. Protein reduction and efficiency improvement are other important key elements of modern livestock production, and have significant impact on improved sustainability performance. New Best Available Techniques (BAT) phase feeding and protein reduction will be introduced in the Best Available Techniques Refer- ences Document (BREF Documents) of the Intensive Rearing of Poultry and Pigs (IRPP) initiative of the Eu- ropean Commission, to which the FEFANA Task Force on Sustainable Agriculture significantly contributed. The final document will be published in 2016. 

With these experiences and outcome in hand, FEFANA, as well as some member companies as individual partners, are taking part in the initiative of the European Commission on the establishment of Product Ecological Footprint Category Rules (PEFCR), which started in 2014 and is expected to be finalised after 2017. This initiative aims to establish harmonised rules for the assessment of the sustainability performance for all consumer goods in the European Union. It was initially set up to work on common voluntary methodologies that could facilitate the future establishment of carbon audits for organisations and the calculation of the carbon footprint of products. The initiative has evolved in role and now establishes mandatory rules for assessment, benchmarking and labelling.

As next steps towards further improved sustainability of livestock production by using Specialty Feed Ingredients, FEFANA plans to start a new project to check established PCRs for applicability in other Specialty Feed Ingredients that improve animal performance and welfare. This will be another important milestone for independent guidance on the assessment of the mitigation option of the functionality of that very specific product group within the feed to food value chain.

Asia is another important global region of livestock production, not only in terms of growing emergence, but also with regards to increasing environmental problems related to livestock production. Therefore, it will be important to extend implementation of relevant knowledge and experience gathered from the SFIS study performed in Europe, North America and South America, to that part of the world also. Due to the recent developments of water shortage in some regions of the world (i.e. Africa, Southern Europe, California), the severe impact of livestock production on water consumption, and yet the dependence of agricultural production efficiency on water, becomes dramatically obvious. Since the use of specialty feed ingredients also positively influences the water consumption of livestock production, this specific topic should be considered in some water footprint projects in the future.
6. A responsible industry …

6.1. Choline chloride

Back in January 2014, a first notification on the presence of unauthorised, genetically-modified (‘Bt 63’) rice in Choline Chloride 60% corn cob from China, was published on the RASFF Portal. This was the result of a company’s own check in France. Other rapid alerts were then published from several EU Member States. Since the beginning of this, FEFANA - in a synergistic approach together with FAMI-QS and FEFAC - investigated the best way to address this specific issue in good cooperation with EU- and Member States’ Authorities, as well as with Chinese operators and authorities, and in a proportionate and responsible way. We have certainly succeeded in implementing proportionate measures within the EU. In particular, we recommended that testing was focused mainly on feed additive and premixtures with the highest inclusion rates of Choline Chloride. Later that year, the EU Food and Veterinary Office carried out an audit in China on feed additives and premixtures in China, with the above-mentioned incident in mind. The overall conclusion of the report was that: “the system for official controls in China provides satisfactory guarantees that feed additives and premixtures exported to the EU comply with requirements at least equivalent to those set out in the relevant EU legislation on feed. […] Most establishments exporting feed additives and premixtures to the EU adhere to FAMI-QS, an industry-based safety assurance scheme. This adherence provides additional guarantees that these establishments meet the relevant standards set out in EU law.” It was also mentioned that the proactive approach taken by FAMI-QS on this has been the main driver on the preventive measures adopted by the Chinese manufacturers to prevent this kind of contamination from happening again.

6.2. Dioxin monitoring

Regulation (EU) No 225/2012 - amending Annex II to Regulation (EC) No 183/2005 on Feed Hygiene with regards to the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof - was adopted in a context of crisis. It was apparently deemed, at that time, to be the best option to deal with the perceived need to reinforce the implementation of feed legislation in the oil- and fat sector. It basically required the Feed Business Operators (FBO) to be subjected to an approval, rather than registration under the Feed Hygiene Regulation, and to compulsory monitoring and reporting requirements for these products. The emergency context might certainly explain that these measures, which were required by the legislator to be reviewed after two years. Based on the experience gained with the application of this Regulation in the last two to three years, FEFANA recognises that this piece of legislation unbalances the Feed Hygiene Regulation, which has served the development of good practices approaches and HACCP implementation within the approved establishments. Finally, it has had disproportionate impact on the feed additive sector that was not targeted by these measures. FEFANA considers that the Feed Hygiene Regulation creates an over-arching, feed safety system approach, and that the creation of sector-specific rules within its Annex II creates confusion and challenges the fundamental principle of co-responsibility that underpins this Regulation.
As the expert on Specialty Feed Ingredients and their Mixtures, FEFANA aims to provide technically- and scientifically-sound information on the benefits and safe use of the products of its industry. After the publication of our first booklet on Premixtures in 2013, four more booklets have been published in the past two years: Organic Acids; Carotenoids; Amino Acids and Vitamins. These publications are the result of remarkable efforts of our Membership, who have joined forces to share their state-of-the-art knowledge. All our booklets, and other publications, are available on FEFANA’s Virtual Library. In the words of FEFANA President, Marco Bruni: “FEFANA has always been committed to the promotion of the benefits of safe use of its industry’s products, but has certainly gone a step further with the publication of a series of booklets that are now shared throughout the supply chain, within EU- and Member State authorities and also with the general public.”

8. About

8.1. Place in the feed & food chain
8.2. Scope

The scope of FEFANA covers specialty feed ingredients and their mixtures. Specialty feed ingredients comprise feed additives and functional feed ingredients. Mixtures of specialty feed ingredients comprise premixtures and specialty complementary feed, including dietetic complementary feed (or feed for particular nutritional purposes), which contain specialty feed ingredients. FEFANA has developed a user-friendly Classification Tool – available on FEFANA website at http://www.fefana.org/ClassTool/ - to help the feed business operators and the competent regulatory/legislative authorities in EU Member States achieve a consistent approach in the classification of substances, with regard to the differentiation between feed additives (as defined in the Regulation (EC) No 1831/2003 and its amendments) and feed materials (as defined in Regulation (EC) No 767/2009 and its amendments).

Specialty Feed Ingredients and Mixtures

- Speciality Feed Ingredients
- Mixtures
  - Feed Additives
  - Functional Feed Ingredients
  - Premixtures
  - Speciality Complementary Feed
  - Speciality Complementary Dietetic Feed

Feed additives

Feed additives are substances, micro-organisms or preparations that are intentionally added to feed or water to perform one or more of the functions described in Article 5 of Regulation (EC) No 1831/2003, on additives for use in animal nutrition.

Functional feed ingredients

Functional feed ingredients are feed materials as defined in Regulation (EC) No 767/2009 that in addition to their nutritional function, are used in feed or animal drinking water to perform one of the following functions: micro-nutrition; technological; sensory; and zoo-technical.

Premixtures

Premixtures – defined in Regulation (EC) No 1831/2003 - are blends of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers that are not intended as direct feeds for animals.

Specialty complementary feed

Specialty complementary feeds are compound feeds containing specialty feed ingredients from all categories, except additives listed in Annex IV, Chapter 3 of Regulation (EC) No 183/2005 on Feed Hygiene, but which, by reason of its composition are insufficient for a daily ration. Production and use of specialty complementary feed is ruled by Regulation (EC) No 767/2009.

Specialty complementary dietetic feed

Specialty complementary dietetic feed are specialty complementary feed intended to fulfil a specific nutritional purpose as defined in Regulation (EC) No 767/2009. These are feed aimed at fulfilling a temporary, increased and/or specific nutritional needs of animals. They are given separately from, or together with, the daily ration or via water. Production and use of specialty complementary feed is ruled by Regulation (EC) No 767/2009.
8.3. Secretariat

Joerg Seifert
Secretary General

Elena Miod
Communication and Regulatory Manager

Ludovic Arnaud
Consortia and Regulatory Manager

Yara Antonissen
Regulatory Affairs Officer

Tomasz Grudnik
Technical and Regulatory Officer

Pascale Furnelle
Executive Assistant, Event Organizer and Office Manager

Bertrand Larsimont
Assistant

8.4. Board of Directors

Marco BRUNI
DSM
President

Gerritjan VAN DER VEN
Balchem
Vice-President

Peter FIDDER
Trouw Nutreco

Dieter GREISSINGER
Evonik

Thomas HOOPS
Sunvit

Hans MÜSCHEN
BASF

Sigrid PASTEINER
Biomin

Claire RELANDEAU
Adisseo

Jan Poul TEN HOVE
ADM

Dirk THEISSEN
Chr. Olesen

NOTES

- Secretariat Staff and Board Members are those at the time of publication.