



Annual Report

07-08



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President's report

The work of FEFANA, and many of our members, has been dominated in recent years by Feed Additive Regulation 1831/2003. The publication of the Guidelines for the application, assessment and authorisation of feed additives earlier this year shows the benefits of positive engagement between the Authorities and FEFANA. We very much believe that we now have a regulatory environment where both our members and the authorities can work to ensure the unequalled safety of our part of the food chain while also encouraging innovation in our sector. Our members now face the enormous task of submitting dossiers for the authorisation or re-authorisation of all existing feed additives prior to November 2010. FEFANA has taken two major steps to support our members in this onerous task. Firstly, we have produced Guidance documents that provide our members with a tool to facilitate the production of dossiers. Secondly, FEFANA has supported and facilitated the establishment of a series of Consortia that will help co-ordinate the efforts of operators, whether or not they are members of FEFANA, to succeed in the authorisation of existing feed additives and to ensure a common approach to dossier construction.

We have also contributed to the continued growth and success of FAMI-QS, the feed additives and premixtures safety and quality system set up in response to Feed Hygiene Regulation 183/2005. The formal approval of this system in January 2007 by the EU Standing Committee on Food Chain and Animal Health was a tribute to all the members that contributed. We are pleased to see that over 300 sites have been certified, including an increasing number of non-EU sites.

The Association has continued to be active in a number of other areas, including Analysis, Labelling, Definitions, Feed Supplements and the Environmental Impact and Sustainability of our industry. We have also been at the forefront of discussions regarding the proposal for a regulation on Marketing and Use of Feed in areas that could affect our members (e.g. labelling, claims and feed supplements).

FEFANA has continued to go from strength to strength, and has broken through the 100-member barrier ! We have also strengthened our Brussels-based staff team, with 8 permanent employees at the end of 2008, to cope with the extra workload. We have active FEFANA Platforms of interested members representing our Association in many of the major EU countries, although we hope to extend our activities in the new EU Member States, particularly Poland and Hungary, in the near future. FEFANA has also become an active associate member of the International Feed Industry Federation (IFIF), representing the interests of our members in this worldwide forum. At the end of 2008 I am pleased to say that FEFANA is a growing and successful Association, built on a strong financial foundation and actively representing the interests of our members within the EU and elsewhere.

I would like to thank the Board for their work in setting the Association strategy and in particular the other office-holders for their support. On behalf of the Board, I would also like to express our deepest gratitude to the members of the Operating Team, who have continued to produce outstanding work for FEFANA, often against very tight deadlines. Thanks also to all those members who participated in FEFANA National Platforms, Working Groups and Task Forces - your involvement has contributed strongly to the continued success of the Association. Finally, I would like to thank the Secretary General, Didier Jans, and his Brussels-based staff for the excellent support they have given to me and Association members.

Dr. Hadden Graham, President.





Secretary General's Report

Over the past few years, FEFANA has been more engaged in implementing the regulatory framework for feed additives than in participating in the development of new legislation. The regulatory framework has been the main focus of our Association since last year, although activities involving "new" regulations are steadily returning to our agenda. These generally consist of revisions to existing regulations.

We have also been focusing increasing attention on control aspects - an important part of implementation - generally at the Member State level, and very often using the FAMI-QS added value. FAMI-QS is the EU Feed Additives and Premixtures Quality System, a set of guidelines for good practice that received the official approval of the European authorities on 29 January 2007. It is supported by FEFANA. Operators have confirmed the value of the initiative, so FAMI-QS is establishing itself as a major reference at global level.

Within the general framework of the Food Law, feed additives are now governed by one of the most comprehensive and consistent legislative systems of the entire food chain, including the Feed Additive, Feed Hygiene and Food and Feed Control Regulations. FEFANA is highly committed to contributing to the effective implementation of these regulations and has been extremely active in this respect.

Our implementation efforts in support of our members are not restricted to the Feed Additive Regulation but have touched on other areas as well, such as imports, worker protection and transport, to name but a few. As we have come to recognise, implementation is much more than simply applying what has been established. Very often, it is the phase where a large part of the harmonisation work is carried out.

FEFANA's activities are intense, as are our communication efforts. These involve regular internal workshops with members, events that have evolved into an increasingly used internal communication tool. Our communication efforts also involve member participation in the 100 or more working groups and task force meetings we organised in 2007, which resulted in the positions, guidances and codes that were produced by members.

This annual report provides an opportunity to give our members and stakeholders an overview of our efforts and the links between our specific activities, which conform to a handful of essential criteria :

- ▶ A clear regulatory framework that is well articulated and well organised, and that everyone can reasonably understand.
- ▶ Transparency of rules. We need to understand rules and avoid surprises or differences of interpretation. We are truly an EU industry, operating in a very competitive environment at a global level, and cannot afford uncertainty.
- ▶ Fair implementation of rules. This naturally applies not only to EU-based operators, but also to imports. Now that the EU has considerably increased its food chain legislation pressure, there is much that needs to be done in this area to avoid jeopardising our industry, both in the global markets and in our own playing field.
- ▶ Eliminating and preventing barriers to trade. This stance influences our attitude towards establishing Regulations - an area in which the European Commission is generally very attentive - and towards implementation. Our actions are driven by the general strategy defined by the Board and its implementation driven by the Operating Team and permanent staff.



Dr. Didier Jans, Secretary General.



2007-08 at a Glance : High-Priority Activities

FEFANA was very active in the area of the feed additive regulations.

EC Regulation 1831/2003

- ▶ Guidelines in April 2008 : FEFANA started working towards proportionate and adapted guidelines in early 2002, even before Regulation 1831/2003 was published. FEFANA also produced a complete series of aids (guidance documents) for each of the categories and cases identified in Annex III, along with practical toolboxes.
- ▶ Re-authorisation organisation : FEFANA has opted to play an active part in supporting its members in the authorisation and re-authorisation process, by actively supporting the creation of Consortia.
- ▶ Premixtures/orphans : The re-authorisation of additives is a topic of particular concern to the premixtures industry, which FEFANA regards as an important segment of its membership. One of the main challenges is to ensure open access to ALL feed additives, particularly those that are marginal niches for operators commercialising them.

Analysis

Analysis has become an increasingly important aspect of the authorisation process. FEFANA is working in close cooperation with the Community Reference Laboratory (CRL) and is actively involved in CEN standardisation.

Labelling

FEFANA proposes an interpretation of labelling regulation requirements - the "labelling concept" - that covers the package label and all accompanying documents up to and including general information. A practical Code of Practice for additives and premixtures was produced. FEFANA supports a revision of Article 16 of Regulation 1831/2003, which has proven to be impractical.

Classification of substances and products

FEFANA has pursued its work on a tool to properly classify (from a regulatory point of view) substances and products used in animal nutrition with a third version of its operational classification tool for use by both the industry and the authorities. It has also released a public user-friendly version of this tool, ID-Feed, via its website.

Feed Supplements

FEFANA worked on a comprehensive concept for all these types of additive concentrates (short- and longer-term use) in a co-ordinated fashion with feed chain partners. FEFANA has especially developed a Code of Practice for the manufacturing, distribution and use of feed supplements.

Proposal for a regulation on Marketing and Use of Feed

This proposal, which is centred on feed, has many implications for additives and premixtures. It must be made coherent with the Feed Additive Regulation in order to avoid creating unfair regulatory-based competition. FEFANA is requesting the creation of a legal framework for feed supplements that would allow for recognition of its code of practice.






2007-08 at a Glance : Press Releases

FEFANA communicates on a regular basis, notably via press releases intended to provide members, their customers and the authorities with accurate and timely information concerning its actions and proposals.

29 January 2007 - FAMI-QS is recognised as a Community Guide to Good Practice. The Standing Committee on the food chain and animal health has formally adopted the Community Guide to Good Practice for feed additive and premixture operators, thus recognising FAMI-QS as a suitable system for implementing the ambitious requirements stipulated in feed hygiene regulations.

6 June 2007 - FEFANA anticipates feed additive registration success through consortia and foresees close partnership with EFSA : FEFANA's 4th General Assembly focused on assessment guidelines and the establishment of consortia for the registration of feed additives. EFSA Executive Director Catherine Geslain-Lanéelle was the keynote speaker at the Assembly, at which nine new members were elected to the Board.

25 July 2007 - FEFANA establishes three Consortia (flavouring additives, vitamins, amino acids) in support of feed additive industry efforts to obtain EU authorisation for existing additives under Feed Additive Regulation 1831/2003.



25 September 2007 - FEFANA's Board unanimously elects Dr Hadden Graham (AB Agri) as its new President. He succeeds Dr Georg Kau (DSM). Dr Diedrich Kahrs (Lohmann Animal Health) has been elected Vice-President, while Dr Franz-Josef Schöner (BASF) continues as Treasurer. The new President will focus on expanding FEFANA's activities and ensuring continued growth, innovation and safety in feed additives and premixtures.

15 November 2007 - FEFANA promotes its Code of Practice for feed additives and premixtures classification. It has developed a user-friendly tool, based on a simple questionnaire and a decision tree, to help feed business operators and the authorities classify feed products and mixtures according to the EU regulatory framework.

15 January 2008 - FEFANA announces the launch of its new web pages on feed additive authorisation consortia, containing information on consortia membership, purpose, scope, the list of additives concerned, and a helpful Q&A section.

13 February 2008 - Feed phosphate crisis : Phytases are a readily available part of the solution. FEFANA is offering support to address the current feed phosphate shortage in a sustainable manner without undermining EU feed chain safety.

7 April 2008 - FEFANA launches three new Consortia, for acids, silage additives and trace elements. The threat of losing market authorisation is real. Co-ordinated efforts by producers and users of these products are urgently needed to secure their authorisation on the EU market and maintain an appropriate diversity of sources.

23 April 2008 - FEFANA announces the release of a set of regulatory tools. The FEFANA guidance documents provide an operational interpretation of the new feed additive guidelines and help applicants building regulatory dossiers for new and existing additives.

22 May 2008 - FEFANA welcomes the publication of eagerly awaited guidelines for preparing and assessing feed additive dossiers in the Official Journal of the European Union. This document is seen as a pivotal tool for the transparency of the assessment process that leads to the authorisation of feed additives, including the re-authorisation of existing products.

12 June 2008 - General Assembly : FEFANA organised an informative open morning session for members and guests, including representatives of fellow associations. Attendees included former EU Commissioner Dr David Byrne. Two new Board members were elected during the afternoon session.

21 October 2008 - FEFANA launches a new Consortium on antioxidants. This Consortium is focusing on antioxidants classified in the technological additives category determined in Annex I of the 1831/2003 legislation and has been named ANTOXIAC. Losing market authorisation remains a risk for any feed antioxidant operator. Therefore, coordinated efforts of those producing or using antioxidants are urgently needed in order to secure their authorisation on the EU market and also maintain an appropriate diversity of sources.

27 October 2008 - FEFANA breaks through the 100th member barrier. FEFANA has continued to go from strength to strength and has just broken through the 100th member barrier. This is another important milestone for the Association after a reorganisation which took place four years ago.



FEFANA's Organisation and Membership



FEFANA, the EU feed additives and premixtures association, was established on 13 October 2004. In its new legal form, it succeeds the Feed Additive Producers' Association founded in 1963. With 100 members from 28 countries, the Association serves as the interface between the feed additive and premixture industry and the EU authorities, including Member State authorities. FEFANA also interacts with the other sectors of the feed chain. Its mission is to promote, safeguard and defend the common and general interests of the industry in areas including guidelines, registration, labelling and definitions, analysis, feed hygiene and food chain safety, and non-feed use of additives.

FEFANA operates as a European network. Member companies (EU producers, traders, importers, premixers) are direct affiliates. Within the individual Member States, Platforms represent FEFANA towards national authorities and industry partners. They inform and co-ordinate national feed additive and premixture operators. The Platforms operate through various channels, such as informal groups of companies, a FEFANA office in a given country, or representation by an existing FEFANA member association, as required by the level of activities and the industry structure in the country. FEFANA member companies are automatically entitled to join Platforms in countries where they have legal entities. Some existing member associations maintain a formal structure, but operations and financing are largely driven by the FEFANA General Assembly, at which all members vote on the main activity programmes and resource allocations.

Work is conducted by Working Groups (WG) and Task Forces (TF) at the FEFANA level in order to avoid duplication of efforts.

The Working Groups essentially deal with product-type specific issues, and also allow bottom-up identification of the topics about which members are concerned. They are permanent bodies whose pace of activity varies according to the surrounding context and developments.

The Task Forces are issue-driven bodies, organised on an ad hoc basis to deal with clearly identified issues. Their scope and duration is extremely variable depending on topic : from a one-meeting project to others extending over several years. This approach offers members the opportunity to be involved in the topics of concern to them in a more focused way. While this is important even for the large companies, it is often crucial for the smaller companies that cannot afford a permanent presence in a wide range of bodies.

The current Working Groups are as follows: WG Amino acids, WG Aromatic and Flavouring Substances, WG Carotenoids, WG Enzymes, WG Micro-organisms, WG Premixtures, WG Probiotics, WG Silage Agents, WG Vitamins. A further Working Group is dedicated to analytical aspects.





Working Groups

WG Premixtures is an active forum where players in the EU premix industry can join forces and discuss the practical consequences and implementation of current and further legislation. Input from many different companies across the EU is helpful for defining possible directions and solutions.

Peter Fidler - Trouw Nutrition
Chair WG Premixtures

Thanks to the joined efforts of WG Aromatic and Flavouring Substances (WP ARAP) and the Aromatic Notification Consortium established by FEFANA, a total of 1520 chemically-defined flavourings, 606 botanicals and 5 flavourings of animal source have been notified. We are confident that the next phase of re-authorisation of several hundred notified flavourings can be successfully achieved through the work carried out by WG ARAP in relation with the EEIG Feed Flavouring Authorisation Consortium (FFAC) supported by FEFANA.

Maria Seemann - Lohmann Animal Health
Chair WG ARAP

WG Micro-organisms acts as a steering group that crystallises and coordinates the FEFANA actions on all technical and political issues affecting the micro-organisms used in feed.

Gerard Bertin - Alltech
Chair WG Micro-organisms

The use of probiotics as gut flora stabilisers has found its way into contemporary animal nutrition and is now a well established practice. The scientific body of knowledge is continuously increasing and it is important that users are kept abreast of these developments through the efforts of WG Probiotics.

Eric Auclair - Lesaffre
Chair WG Probiotics



Thanks to a large extent to the activities of the WG Amino Acids, the environmental benefit of amino acids in feed is gaining increasing recognition. Controlled protein content in diets is not only recognised as a Best Available Technique (BAT) under EU legislation, but is also bringing solutions to the need for more responsible and efficient use of scarce resources in the feed chain, including implications up to global warming issue.

Marc Redshaw - Evonik
Chair WG Amino acids

Analytical aspects have become one of the important pillars of the feed additive authorisation process, closely associated with the controls carried out by the responsible authorities. WG Analytical coordinates the activities of the various analytical task forces working in FEFANA, in order to ensure the coherence of FEFANA activities with the CRL (Community Reference Laboratory) and with the EU and international standardisation bodies.

Gerard Bertin - Alltech
Chair WG Analytical





Task Forces

In addition to the various analytical Task Forces, the main task forces active over the period include : TF Feed Supplements, TF Mycotoxins, TF Validation and Verification, TF Labelling, TF Process Change, TF Environment and Sustainable Agriculture.

Several types of feed additives have the potential to make a positive contribution to the environment and sustainable agriculture, which is high on the feed chain agenda. In recognition of this fact, the newly created TF Environment and Sustainable Agriculture is now conducting FEFANA activities in this area.

Michael Binder - Evonik
Chair TF Environment and Sustainable Agriculture



EU Regulation 1831/2003 has foreseen the possibility to authorise feed additives in further categories and functional groups than those initially included in the Regulation. TF Mycotoxins was established in order to promote the creation of such a new category for additives capable of adsorbing and/or degrading mycotoxins at concentrations below the legal levels for mycotoxins in EU legislation. This is expected to result in the authorisation of a new range of feed additives in Europe to the benefit of animal productivity and feed chain safety.

Dian Schatzmayr - Biomin
Chair TF Mycotoxins

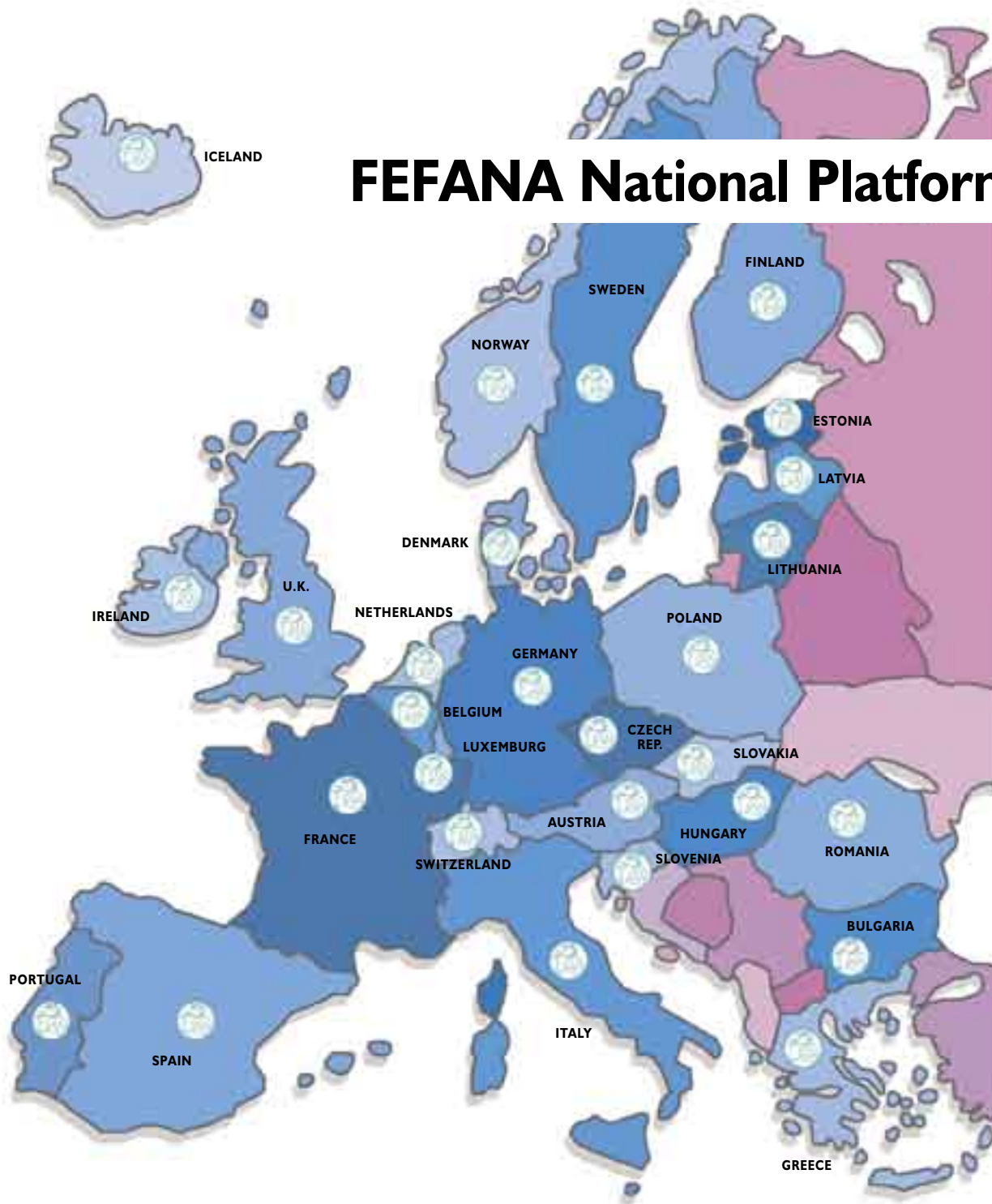
Feed additives are surrounded by a harmonised and comprehensive regulatory framework. Probably the only remaining gap in this system relates to additive concentrates used directly at farm level for direct delivery to animals. Such products have become an important element of current feeding practices, bringing much-needed flexibility to professional animal producers. The present legislative vacuum has created uncertainties and a lack of harmonisation for producers and users of these important products. In coordination with the segments of the feed chain concerned, TF Feed Supplements has been working towards establishment of a harmonised framework for the production, distribution and use of these products, under an equilibrated balance between regulatory constraints and self-management by the industry.

Philippe Becquet - DSM Nutritional Products
Chair TF Feed Supplements

When standard methods are not available, operators seeking authorisation for an additive under Regulation 1831/2003 can provide an in-house analytical method. However, such methods need to be properly validated and verified. Working in close cooperation with the CRL, the purpose of TF Validation and Verification is to draw up guidance adapted to the different categories of methods and additives in order to carry out these important duties regarding analytical requirements. TF Validation and Verification is also busy with other guidance and standardisation activities related to the preparation of application dossiers.

Gerard Bertin - Alltech
Chair TF Validation and Verification

The Operating Team is at the centre of the process, implementing the strategy defined by the Board, co-ordinating the work of the WG and the TF, initiating the creation of new TFs as needed and supporting the work of the permanent staff.



FEFANA National Platforms

As of 1st January 2008, Adiprem (Federación Española de Aditivos y Premezclas para la Salud y la Nutrición Animal) is responsible for representing FEFANA in Spain. The Adiprem-platform now provides FEFANA's Spanish members with strong representation in Spain and across the EU-wide FEFANA organisation.

The FEFANA Italian Platform is made of major companies in the feed additive sector in Italy. As part of the FEFANA integrated European network, this entity is the interface with the Italian authorities in order to promote and defend common general interests of the industry in this country.

FEFANA National Platforms

Belgium	Nordic Countries (Norway, Sweden, Finland, Iceland)
Bulgaria	& Baltic Countries (Estonia, Latvia, Lithuania)
Czech Republic	Poland
Denmark	Romania
France	Slovakia
Germany + Austria	Slovenia
Greece	Spain + Portugal
Hungary	Switzerland
Italy	U.K. + Ireland
Luxemburg	
The Netherlands	

List of 100 FEFANA Members

1	AB-Agri	26	Borregaard Lignotech	51	Lactosan	76	Probiotics Intl.
2	Addcon	27	Buteressence	52	Lallemand	77	Provimi
3	Adisseo	28	Chemoforma	53	Lesaffre	78	Purac
4	ADM	29	Chr. Hansen	54	Lohmann	79	Quaron
5	Agolin	30	Chr. Olesen	55	Lonza	80	Quimidroga
6	Agravis	31	Citrex Special Nutrients	56	Lucta	81	Realdyme
7	Agrimin	32	CJ-Europe	57	Manghebati	82	Retorte
8	Agroferm	33	Danisco (UJ) Ltd	58	Miavit	83	Rio Tinto
9	Ajinomoto Eurolysine	34	Delacon	59	Micro plus	84	Roquette
10	Akzo Nobel Surface Chemistry	35	Deutsche Vilomix	60	Mitsui	85	Rubinum
11	Albion	36	Dostofarm	61	Near	86	Silvateam
12	Alltech	37	Dr. W. Kolb	62	Nekk	87	Sinta
13	Almapharm	38	Dr. Schaette	63	Neofarma	88	Süd-Chemie
14	Alpharma	39	DSM	64	Norel	89	Sunvit
15	Atilis (ex-Ceva)	40	Europe Asia	65	Novozymes	90	Syngenta
16	Andres Pinaluba	41	Evonik	66	Novus	91	Taminco
17	Anitox	42	Exquim	67	Olmix	92	Tanin
18	Azelis	43	Extra-Vit	68	Optivite	93	Technovit
19	Balchem	44	Huvepharma	69	Orffa	94	Tessengerlo
20	BASF	45	Indukern	70	Pancosma	95	Todini
21	Béghin Meiji	46	ITPSA	71	Perstorp	96	Trouw Nutrition
22	BFI	47	Jadis additiva	72	Phodé	97	Vertellus
23	Biomin	48	Kemin	73	Phytobiotics	98	Volac
24	Boehringer Ingelheim	49	Kemira Oyj	74	Phytosynthèse	99	Yara
25	Bonapp	50	Kerry Bio-Science	75	Pre-Mervo	100	Zinpro



Feed Additive Regulation 1831

FEFANA has long been active in preparations for, and especially the application of, EC Regulation 1831/2003 on feed additives. As early as 2002, even before the discussions preparing the Regulation were finalised, FEFANA was holding discussions on proportionate and adapted guidelines. In 2003, it submitted a complete set of guidelines based on decision trees to the European Commission European Food Safety Authority (EFSA) and the EU member states.

Since late 2003, FEFANA has been working closely with these bodies to ensure that the principles established in the Food Law (separation of functions between risk manager and risk assessor, governance of assessment work by FEEDAP, the EFSA panel on additives and products or substances used in animal feed) and in EC Regulation 1831/2003 (adapted and proportionate requirements) are implemented in feed additive guidelines.

These guidelines were published five years after the regulation itself. The European Commission formulated a regulation establishing the basic principles for preparing and evaluating feed additive dossiers, for use by both applicants and risk assessors. The FEFANA proposal has been one of the important bases for establishing these guidelines. The annexes are the guidelines themselves. Annex III is particularly innovative, meeting FEFANA's goal of achieving transparency and proportionality (described in the proposed decision trees), and replacing the unfair and inefficient "shopping list" approach (Directives 87/153, 2001/79, 94/40) that was previously in use.

FEFANA translates guidance requirements into usable information

Although refinable in some respects, this key document is a valid starting point for preparing the 2010 additive re-authorisation process, considering the practical work that lies ahead. For example, refinements or interpretations will be needed in the sections on target animal safety and the identity of non-holder-specific authorisations.

Interpretation of guidelines and a coordinated approach by the feed additive Industry are the key to ensure proper understanding with the authorities. During the discussion with the European Commission and the EFSA, the members of the Operating Team have developed a set of guidances implementing the proposed guidelines. The documents were finalised just after the vote in the Standing Committee on the Food Chain and Animal Health and were made available to FEFANA members on the day of publication of the regulation providing guidelines. The FEFANA guidance documents cover all categories and cases identified in Annex III. These guidances are also an important tool for the Consortia and the consultants working for them.



The independence of the EFSA is enshrined in its scientific assessment of the data provided within the framework set by the guidelines. Proactive interpretation of the guidelines by EFSA could be viewed as an encroachment upon the risk managers' prerogatives. FEFANA is of course perfectly willing to pursue open discussions with EFSA in order to fine-tune the industry's interpretation of the guidelines. The separation of risk assessment from risk management is crucial.

FEFANA has developed practical toolboxes for problematic sections of the dossiers. It has also designed an 1831/2003-compliant annex entry format that is similar to, but more precise and transparent than, the current format. FEFANA expects this to be adopted in future authorisations and reflected in the structure of the Additives Register.

FEFANA supports QPS

FEFANA supports Qualified Presumption of Safety (QPS) for evaluating micro-organisms to be used in fermentation or as feed additives, as a replacement for individual case-by-case evaluations. The Association feels that QPS should be applied on a consistent basis and that the model should find its place in the legislative, risk-management framework. In 2007 FEFANA called upon EFSA to immediately begin using QPS as one of its risk-assessment tools, a call that seems to have been heard.



aciac

amac

antoxiac

carac

emulac

ffac

silac

treac

vitac

Re-authorisation : Consortia and Organisation

EC Regulation 1831/2003 governs access to the EU market for feed additives. The pre-market approval system applies to all additives. It includes provisions allowing for previously authorised feed additives to remain on the market provided that a series of conditions and applications are successfully met (article 10). Only additives actively supported by producers or importers through an authorisation dossier will continue to be authorised after the transition period, which ends in November 2010. The authorisation of feed additives under EC Regulation 1831/2003 is far more precise than in the past - including relevant specifications, purity and manufacturing process details - and therefore the diversity of possible sources of a given additive is at stake. The challenge is not only to develop dossiers for as many additives as possible, but also to ensure that application dossiers include the information required to cover the diversity of sources. As individual companies cannot be expected to work on securing market access for their competitors, it is crucial that as many operators as possible become involved in the dossier preparation process. FEFANA has counted no fewer than 600 non-holder-specific additives and more than 2,000 flavourings, illustrating the scope of the task at hand.

As early as June 2007, at its 4th General Assembly, FEFANA made it clear that the establishment of feed additive consortia was one of its key priorities in the light of the November 2010 deadline for full authorisation of all existing feed additives. These consortia were given the form of European Economic Interest Groupings (EEIG), which are legally independent but are actively supported by FEFANA.

Co-ordinated efforts and limited number of dossiers

The first three consortia - Feed flavouring additives (FFAC EEIG), Vitamins (VITAC EEIG) and Amino acids (AMAC EEIG) - were launched in mid-2007, followed by Carotenoids (CARAC EEIG). In 2008 FEFANA established three new Consortia in one nutritional and two technological categories : Trace elements (TREAC EEIG), Acids and their salts (ACIAC EEIG), and Silage additives (SILAC EEIG). Acids and their salts cover both preservative and silage functions; silage additives are enzymes and micro-organisms. Two further Consortia were established in the second half of 2008 : EMULAC (emulsifier, thickeners, gelling agents), and ANTOXIAC (antioxidants).

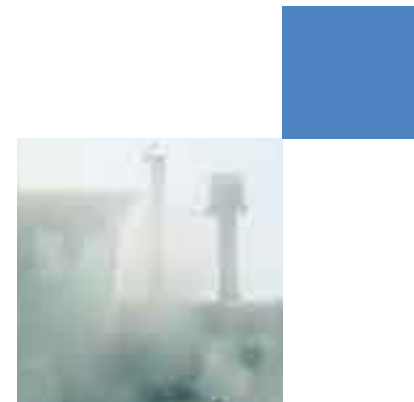
A given consortium will not necessarily cover all the additives pertaining to it. Each grouping has its own objective criteria for choosing the specific additives it wishes to deal with, based upon the interest and commitment of its members. All consortia are open to all feed additive business operators, yet due to the pace of ongoing efforts, it is becoming increasingly difficult for newcomers to join established groups. Companies working within these consortia are positioning themselves as responsible and reliable partners for the future.

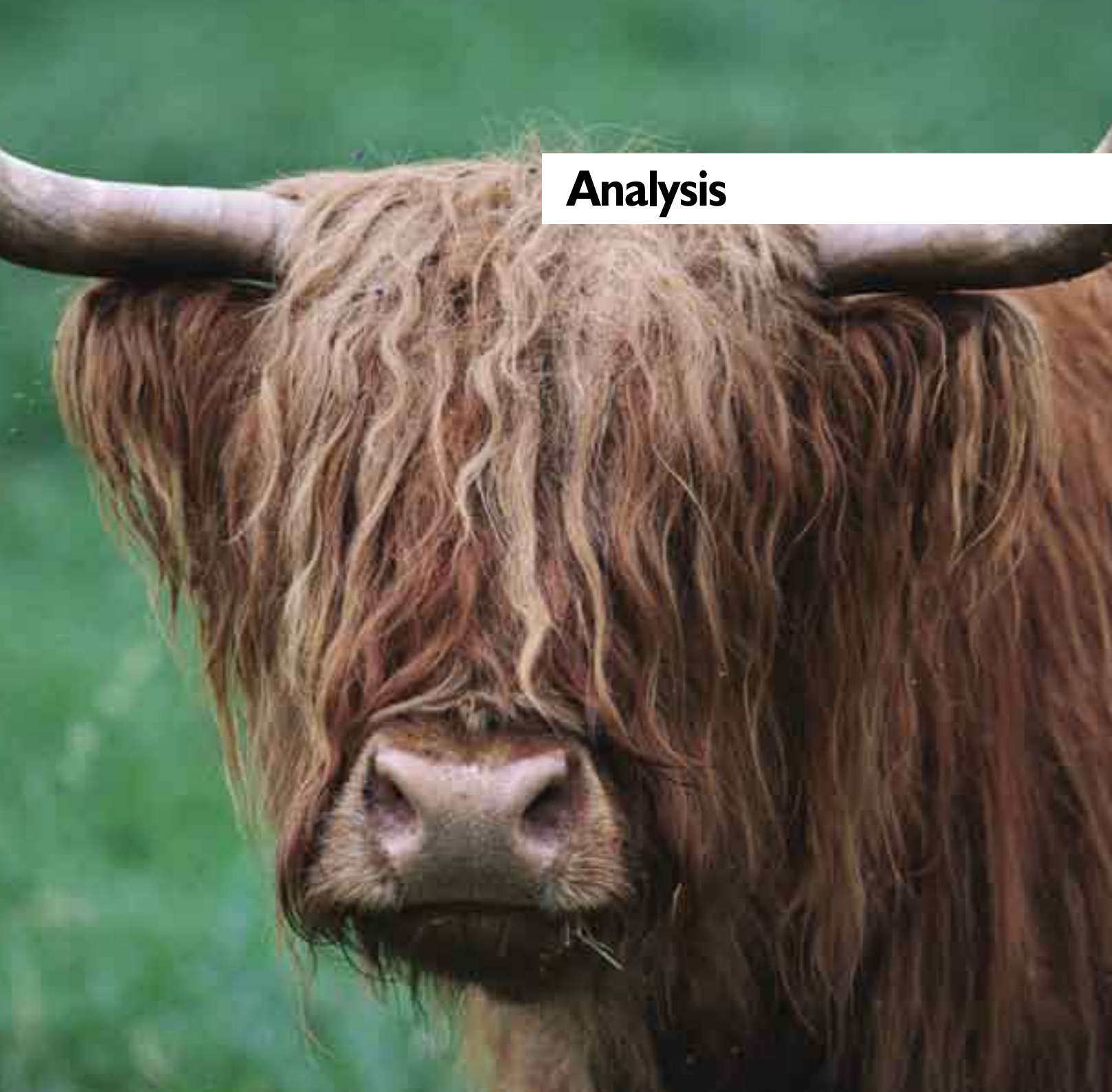
The FEFANA website (<http://www.FEFANA.org>) now contains informative pages about the authorisation Consortia, describing their scope, purpose and membership.

FEFANA does not know how the dossiers will be handled when they reach the Commission and EFSA, but it has broached the issue with them. As many or most of the dossiers will come from the Consortia, they will naturally have some influence on the procedure. Our common goal is to prevent the re-authorisation process from disrupting the market, but also to prevent disruption of the authorisation process, the credibility of which is at stake in this ambitious exercise.

New functionalities

EC Regulation 1831/2003 imposes numerous constraints, but also provides opportunities. This is well understood by a number of the FEFANA members that are working on innovative products. As our President, Dr Graham (AB-Vista), pointed out when he was elected in 2007, FEFANA is close to its members in this area, helping them to develop a consistent and co-ordinated approach, create the necessary tools (for example guidance aids), and open regulatory doors.





Analysis

Analysis has become an increasingly important aspect of the authorisation process. FEFANA is working in close cooperation with the Community Reference Laboratory (CRL) and is actively involved in standardisation with the European Committee for Standardisation (CEN). In this respect, FEFANA is working intensely through several Task Forces that bring together the analytical experts of our companies.

The association has developed substantial expertise in enzymes. Methods used to analyse enzymes in feedingstuffs that are legally commercialised in the EU have not been harmonised yet. Analysis is generally conducted using in-house methods. For three years, FEFANA has worked with CRL and national reference laboratories (NRL) to devise a standardised method for phytase in accordance with ISO/CEN. FEFANA has evaluated the feasibility of developing a similarly harmonised method for analysing all xylanase products currently on the market and has been forced to conclude that this is not feasible.

FEFANA is also working on live strain identification methods to provide guidelines strictly limited to live micro-organisms for phenotypical (morphological and enumeration) and genotypical identification. This will result in standardisation of the methods at CEN level.

Efforts in other sectors are continuing apace. A comprehensive analysis programme is still underway on carotenoids. TF Vitamins is pursuing its work following the publication of a reference database for “tel quel” products. The programme for vitamins included in premixtures and feeds is close to completion. The Flavouring Consortium has launched a programme that is very important for its dossier preparation tasks. WG Amino acids has structured its activities in view of standardising methods.

There is no systematic need to achieve full CEN standardisation in all cases; FEFANA adapts its strategy to the cascade approach recommended by CRL (from EU official methods when they exist down to in-house methods) in order to focus efforts on the areas of common interest to industry and control authorities. In cases where no standard method exists, the methods proposed in dossiers must be validated and subsequently verified. FEFANA has been working in close cooperation with CRL to develop guidance tools for both the validation and verification of the methods. The close and cooperative working relationship established with CRL can be seen as a remarkable win-win achievement for the CRL, a division of the EU Commission, and for the industry.



A white duck with a brown patch on its neck and back, standing on a paved surface. The duck is facing left. The background is a blurred green lawn.

Labelling

Article 16 of EC Regulation 1831/2003 governs the labelling of feed additives and premixtures. FEFANA interprets the “labelling concept” as the set of requirements pertaining not only to the label on the package, but also to accompanying documents and general information. The feed industry supports our interpretation. We have no issue with the information to be provided, but rather with the way it is provided, which should be efficient for industry and users alike. It is important to bear in mind that the feed additive and premixture activities are business-to-business.

In November 2007 FEFAC, then followed by others, adopted FEFANA's proposal for a comprehensive, industry-wide Code of Practice for labelling feed additives and premixtures, which gives operators information and options for applying Article 16. The document is divided into four main parts : a code of practice for labelling feed additives, a code of practice for labelling premixtures, templates for product specification sheets for feed additives and premixtures, and label templates reflecting the various options. This Code was established as an implementation tool within the limits of Article 16, for use in discussions with supervisory authorities. The labelling concept that we developed has gone the right way, and has been taken up in the proposal for a regulation on marketing and use of feed (see page 30).

The benefit of using feed additives obviously extends beyond the direct users who include them in premixture or feed, as they bring a strong added value to compound feed containing them. This information must permeate through to the animal production level. The categorising of feed additives, introduced by Regulation 1831/2003, according to precise functional groups gives an increased opportunity to develop advertising on their use in compound feeds. A series of claims related to the various functions is now being developed to ensure consistent and topical information relating to the use of feed additives in complete feed.

Lastly, in line with the re-casting of feedingstuff marketing regulations, FEFANA is calling for an alignment of the labelling concept between the respective regulatory frameworks for feed and feed additives.



A white cow is lying down in a lush green field. In the background, there is a wooden fence and some trees under a cloudy sky. The cow is the central focus of the image, resting on the grass.

Classification of Substances and Products

In 2008 FEFANA pursued its work towards the classification of all products and substances used in animal nutrition in response to the constant flow of questions raised by the feed business operators. EC Regulation 1831/2003 defines not only products and substances themselves (feed additives, premixtures), but also feed materials, compound feedingstuffs, complete feedingstuffs, complementary feedingstuffs, mineral feedingstuffs, dietetic feedingstuffs, veterinary products and substances, and medicated feedingstuffs.

Products and substances are subject to different regulatory requirements depending on their classification. For example, a product classified as a feed additive requires authorisation following a pre-marketing evaluation, and therefore may not be commercialised for at least two years. If the same product is classified as a feed material, however, it may be commercialised without any prior authorisation and the labelling requirement is different.

In order to achieve greater clarity in the marketplace, FEFANA has conducted an extensive review of the situation and the different types of currently available products. Judging by input from members and close scrutiny of actual market conditions, FEFANA has determined that it is possible to classify all individual products and mixtures used by the feed industry, and even draw unclear distinctions between premixtures and complementary feed, on the basis of answers to a small number of straightforward questions. The questions are simply worded and formulated, with the aim of ensuring predictability (the same answer from different operators concerning the same product) and enabling operators to justify their choices to the supervisory authorities.

The decision tree approach that FEFANA has developed defined criteria for evaluating products and substances used in animal nutrition. These criteria will allow operators and the supervisory authorities to classify products in a consistent and transparent manner, thus minimising confusion in the marketplace. For the sake of clarity and simplification, FEFANA has devised a single decision tree divided into five parts.

The EU Authorities and Member States recognise the need for transparency. For this reason, FEFANA has brought hands-on experience and observations to produce a third operational version, which has been available since January 2008. An on-line publicly available version is being made available via the FEFANA website. This tool has important implications for the fair implementation of feed legislation in general and has proven its practical usefulness within the FAMI-QS certification system, where auditors are using it on a daily basis.



<http://www.fefana.org/ID-feed/Start.htm>



Feed Supplements



EC Regulation 1831/2003 takes into account the use of additives by routes other than compound feed.

Additives used in water

The use of additives via animal water supply has given rise to wide-ranging discussions. Additives in water must be viewed as a part of the farm management system. Administering liquid feedingstuffs on a farm, for instance, can be likened to serving soup to humans. They generally contain nutrients other than feed additives, and can be produced by adding water to solid feed or by using liquid feed material such as whey. Feed additives used with liquid feed should be handled in the same way as those used with solid feed. However, an increasing number of additives are not being delivered to the animal via the traditional feed route, but through their water supply. This mode of use has proven to provide the flexibility needed under current practices in animal husbandry.

Feed Supplements

In addition to the additives delivered via water, a number of other types of additive concentrates are used at farm level. These additive concentrates are used on either a short- or long-term basis. A comprehensive concept has to be developed for them, recognising that farmers need them for reasons of flexibility, but that they are falling out of the regulatory framework for feed.

Feed supplements are given directly or mixed with daily rations or water in various forms, including pellets, crumbs, capsules, pastilles, tablets and pastes. They may be stored in dropper containers, sachets, ampoules and other containers.



FEFANA is putting the finishing touches to a Code of Practice for the production, distribution and use of feed supplements, prepared in co-operation with feed chain partners concerned, particularly FEFAC (European Feed Manufacturers' Federation) and the farmers' organisation COPA-COGECA (Comité des Organisations Professionnelles Agricoles - Confédération Générale de la Coopération Agricole). FEFANA is also working on a programme to advise farmers on conditions for use, since it is important for distributors and farmers to have access to a consistent and coherent information base in order to ensure proper use of these particular products.



A photograph of a laboratory flask containing a blue liquid. The flask has handwritten text in green marker, including 'Blu' and '99L'. In the background, there are other laboratory flasks, one containing a yellow liquid, and a grid paper with some handwritten numbers and text.

Proposal for a Regulation on Marketing and Use of Feed

The European Commission's proposal for a regulation on marketing and use of feed focuses on feed but has numerous implications for additive operators in such areas as labelling concept, functional claims, dietetic feed and revisions to Article 16 of EC Regulation 1831/2003. FEFANA is taking great care to ensure coherence between this proposal and the feed additive regulation in order to prevent problems that might affect both the legislation and the companies bound by it.

The proposal contains some very positive points. It includes the labelling concept and recognises the value of industry codes based on experience of the feed hygiene regulation. Unfortunately, however, it was initially intended to restrict industry's role to voluntary aspects and it takes a prescriptive stance on those that are mandatory.

The thrust of FEFANA's actions in respect of this proposal has been to create a legal framework for feed supplements that would allow for recognition of its code of practice, co-ordinate the rules governing additive-based or related claims, and obtain a revision of Article 16 of Regulation 1831/2003 in order to ensure consistency between the respective frameworks for feed and feed additives and thus secure recognition of FEFANA's feed additives and premixture code of practice.



FEFANA's Proposal on Claims Linked to Function

The objective of this proposal is to develop a future code of practice for the advertisement of feedingstuffs containing additives. Advertisements should be informative, without misleading users or consumers.

FEFANA feels that advertisements on an additive's function in a feedingstuff should be linked to the presence of the specific additives ensuring this function at an appropriate concentration. Claims made in an advertisement should be clearly linked to functions as defined in Annex I of EC Regulation 1831/2003 authorising the use of the additive in the feed. With the exception of coccidiostats/histomonostats, additives have no medicinal functions, and therefore the use of terms employed to define veterinary products (such as prevention and cure) must be prohibited. Similarly, FEFANA believes that it is unlawful to use an existing functionality for which authorisation has not been granted. In the case of nutritional additives, for example, the known nutritional aim of the compound may be used (e.g. vitamin D and mineral metabolism) but an enzyme classified as a digestibility enhancer may not be claimed to have an impact on the environment (if not authorised in this field).





The Environment and Sustainable Agriculture

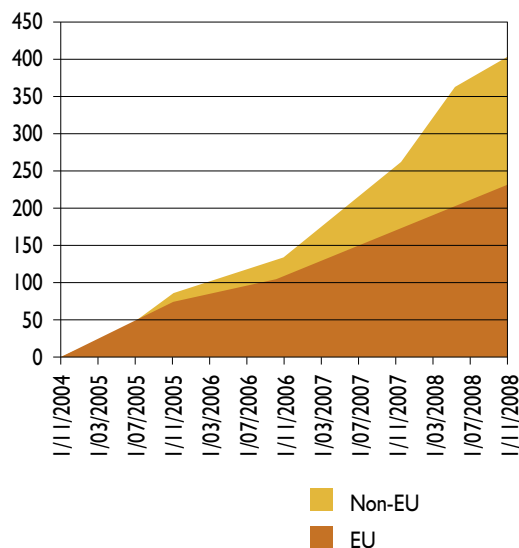
The European Commission DG Environment invited FEFANA to participate in the stakeholder consultation procedure on environmental impact as part of the European Agri-Food Network (EAFN). Two exhaustive studies by the Institute for Prospective Technological Studies (IPTS) on the Environmental Impact of Products (EIPRO) and Environmental Improvements of Products (IMPRO) have identified intensive farming as a sector with significant environmental impact. Meat and milk are daily consumption products with a high potential for reductions in environmental impact. At the same time, the IPPC (Integrated Pollution Prevention and Control) dossier has been reopened. For all these reasons, FEFANA has established a new Task Force on Environment and sustainable agriculture.

The original IPPC Directive (1996), the aim of which is to minimise pollution from a variety of industrial sources around the European Union, has been amended four times since it took effect. Operators of some 52,000 industrial installations in the EU countries covered by Annex I of the IPPC Directive are required to obtain authorisation in the form of an environmental permit. On 21 December 2007, the Commission adopted a proposal for a directive on industrial emissions, which recasts seven existing directives (particularly IPPC) into a single legislative instrument. The IPPC Directive has recently been codified (Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control). The exchange of information on Best Available Techniques (BAT) being organised by the Commission is a legal obligation of Council Directive 96/61/EC on integrated pollution prevention and control. Its main objective is to provide guidance for authorities within the EU when determining BAT as required by the Directive.

In 2003, environmental protection assessment procedures focused on livestock production, mainly intensive pig and poultry farming. The use of amino acids and of phytase were granted formal BAT status. In 2008 the process continued, with new definitions introduced for BAT applicable to sustainable agriculture. FEFANA is pleased to report that it has obtained very positive results from the IPPC/BAT process. The feed industry is devoting increasing attention to sustainability aspects, particularly to those linked to the source of feed material at the global level.

Feed additives have a larger contribution to make in this area. For this reason, FEFANA has created this new Task Force with the strategic role of promoting FEFANA activities in this area.





FAMI-QS is being promoted to national and local supervisory authorities as a formal or informal factor of supervisory prioritisation. Active cooperation with the EC Food and Veterinary Office has been established, supporting for instance FVO on their most recent assignment in China. These developments all point to an increase in the supervisory value of FAMI-QS certification.

FEFANA (in coordination with FAMI-QS) is also active outside the additives field. For instance, we are working together with the European Feed Ingredient Platform (EFIP) on implementation of the Feed Hygiene Regulation for all feed ingredients (raw materials).

FAMI-QS has naturally thrust FEFANA into the area of international feed hygiene at a time when similar requirements for feed safety arise in various parts of the world.

Feed Hygiene Regulation and Supervision

Certified 403

China	125	India	8	Slovakia	3	Mexico	1
Germany	44	Belgium	8	Japan	3	Republic of Korea	1
France	40	Finland	7	Russia	3	South Africa	1
Spain	24	Turkey	7	Ireland	2	Taiwan	1
Denmark	23	Austria	6	Israel	2	Hong Kong	1
USA	20	Brazil	5	Czech Republic	2	Uruguay	1
Italy	18	Hungary	4	Greece	1	Serbia	1
UK	9	Canada	4	Norway	1		
The Netherlands	9	Poland	4	Indonesia	1		
Switzerland	9	Sweden	3	Malaysia	1		

In progress 59

China	20	Denmark	4	Germany	2	Russia	1
Spain	7	USA	3	The Netherlands	2	Republic of Korea	1
India	6	Brazil	3	Poland	1	Switzerland	1
France	4	Italy	2	Belgium	1	Uzbekistan	1

Applicants 9

China	5	Spain	2	India	1	Belgium	1
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Total 471

China	150	Belgium	10	Sweden	3	Malaysia	1
Germany	46	UK	9	Japan	3	South Africa	1
France	44	Brazil	8	Slovakia	3	Uruguay	1
Spain	33	Finland	7	Ireland	2	Norway	1
Denmark	27	Turkey	7	Czech Republic	2	Greece	1
USA	23	Austria	6	Israel	2	Uzbekistan	1
Italy	20	Poland	5	Republic of Korea	2	Taiwan	1
India	15	Hungary	4	Mexico	1	Serbia	1
The Netherlands	11	Canada	4	Hong Kong	1		
Switzerland	10	Russia	4	Indonesia	1		

A helping hand for supervisory authorities

In January 2007 the EU Standing Committee on the food chain and animal health formally adopted FAMI-QS. The authorities thus recognise this “Community Guide to Good Practice for Feed Additives and Premixture Operators” as a suitable system for implementing the ambitious requirements of Feed Hygiene Regulation 1831/2003, which encourages the development of European guides to good practice (Articles 20 to 22). FEFANA took an active interest from the earliest stages of the process.

FAMI-QS
European Feed Additives and PreMixtures Quality System

Position paper on financial guarantees

The Feed Hygiene Regulation has requested the Commission to analyse and make legislative proposals as appropriate in order to implement a system of financial guarantees for feed business operators. Those guarantees should provide cover for the total costs for which operators could be liable as a consequence of the withdrawal and/or destruction of any feed, animal or food produced thereof. FEFANA opposes the introduction of such a system. The feed business operators are responsible for evaluating the hazard of their products and take all appropriate measures to cover their liability. A liability regime covering feed, food and animal products would go beyond any current practice and would be prohibitively expensive, presenting the operators with the choice of ceasing activities or operating under illegal conditions. Besides inconsistencies and conflicts with the general liability regime in EU law, such a system would implicitly recognise the fact that the feed chain legislation is not appropriate or fully implemented. FEFANA prescribes focusing effort and resources on upstream implementation and control, rather than preparing for failure of the system with unbearable financial constraints.



Discussion on position of third country list

In 2004, prior to adoption of the text, the additives industry established an integrated safety and quality system - FAMI-QS - open to all feed additives and premixture operators. It included all the requirements contained in the Regulation, clearly demonstrating the industry's commitment to effective, concerted implementation. Official adoption of FAMI-QS established a formal link with the Feed Hygiene Regulation. In other words, a feed additives or premixtures operator that applies FAMI-QS principles is complying with the Regulation. In addition to promoting fully harmonised implementation throughout the market, this system is expected to facilitate the work of the supervisory authorities. FAMI-QS has been given a positive appraisal by the panel of experts from the EU Member States. For the sake of transparency, the approval process was completed by public consultation on the English version of the DG Sanco website.

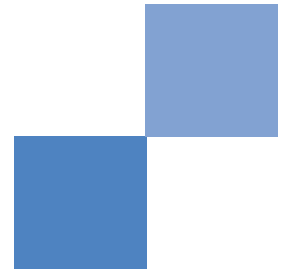


FAMI-QS serves two purposes. It is a feed hygiene regulation document designed to help operators. It is also an independent certification system, supporting implementation of the Feed Hygiene and Food and Feed Control Regulations. Translations in German, Spanish, French, Italian and Dutch are available on the FAMI-QS website (www.fami-qs.org).

As the additives market becomes more global in scope, cooperation with China, the United States, Brazil and other countries is being sought. Recognition for this Guide is increasing around the world. In November 2008, certification had been granted or was in progress for 471 sites : 403 fully certified (232 in the EU, 171 non-EU), 59 in progress (24 EU, 35 non-EU) and 9 applicants.

FEFANA Board

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FEFANA Team

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