Annual Report
Contents

2 President’s report
4 Secretary General’s report
6 2006 activities short overview
8 The FEFANA organisation and membership
10 THE MAIN ISSUES
10 - The Feed Additive Regulation 1831
11 - Guidelines
12 - Register
13 - Labelling
14 - Consortia/Registration 2010
14 - Analysis
17 - Food Chain Safety and Feed Hygiene
20 - Non-feed use of additives
21 - Additives in water
22 - Other legislations
23 THE WORKING GROUPS
23 - Amino acids
23 - Aromatic and flavouring additives
24 - Carotenoids
24 - Enzymes
25 - Micro-organisms
25 - Probiotics
26 - Silage additives
26 - Vitamins
27 - Premixtures
28 FEFANA Teams
President’s report

During 2006, FEFANA passed two important milestones within the change strategy for more efficient representation of its membership: implementation of the modus operandi of the new structure and finalization of the strategic direction for the association.

Implementing the new modus operandi throughout Europe included the challenge to adequately manage the balance of industry representation between national and European authorities as the two important pillars of European legislation. It remains demanding to ensure at the same time that all new EU-27 member states are integrated right from the first moment of their participation considering that association structures in most cases were not existing. The new way of working enabled FEFANA bodies and its members to keep pace with the fast development of markets (e.g. industry consolidation, exposure to disease breakouts, etc.) on one hand and the challenging requirement of the legislation for registration of products and operations as well as feed hygiene on the other.

In its new organisational structure, FEFANA increasingly experienced much stronger links with the network of stakeholders in the food chain. Representing the feed additive and premixture industry as a key group on the supply side of the value chain, FEFANA is aware of its role and contribution for the safety of food products of animal origin.

After finalization of the Association’s organizational structure, FEFANA Board worked out a vision and mission which was presented and approved by all members at last year’s General Assembly in Brussels.
Vision

“FEFANA contributes to establish and maintain an appropriate regulatory, political and scientific environment for the Feed Additive and Premixture Industry to operate and develop in Europe.”

Mission

1. Regulatory

FEFANA maintains a cooperative contact with the European and Member States authorities and keeps our members involved and informed on regulatory issues.

2. Scientific

FEFANA promotes benefits and safety of feed additives and premixtures to support our members to be more successful and to provide safe and cost effective products to the food chain.

3. Political

FEFANA strives for an adequate recognition of FEFANA in the food chain, enables our industry to participate in the decision-making processes and supports an efficient flow of information.

To have a pronounced and documented strategic direction was for the FEFANA Board the last important step to complete the transition into the New FEFANA. Both elements will support FEFANA’s intent to more efficiently align the representation of its members on all levels and ensure full transparency of FEFANA position on the wide scope of feed additives and premixtures industries on a day-to-day basis. It also helps the regulators to stay close to the industry stakeholders and ensure the adequate rollout to the European Bodies such as the European Commission and the European Parliament but also European Food Safety Authority (EFSA).

For FEFANA, it is essential to stay close to the authorities, as our members need reliability and confidence that investments into innovation will pay-off. Processes have become increasingly complex and costly so that innovation can be easily blocked if the framework tends to overregulate. That is one of the reasons why FEFANA has a vast interest to support the shaping of the regulatory framework in a proactive way. If the industry wants to sustain growth through the expected changes ahead, the system has to provide adequate flexibility to ensure competitiveness and innovation on a global scale.

FEFANA increasingly reaches a global dimension as its membership includes companies operating worldwide. At the same time, trade in meat and other products of animal origin is focusing on Europe as an important consumer market. FEFANA is aware that Europe is more and more watched by supply and regulatory operators outside the EU, who are starting to implement the high standards developed by Europe. FEFANA is striving to accept this challenge and will integrate this global dimension into its activities to contribute constructively to the protection of the consumer in Europe.

Dr. Georg Kau
Secretary General’s report

FEFANA’s most recent activities focused on the implementation of the legislation established over the last years, rather than engaging in entirely new regulatory initiatives. Under the general framework of the food law, feed additives are now surrounded by one of the most comprehensive and consistent legislative system of the entire food chain, including the Feed Additive, the Feed Hygiene, and the Food and Feed Control Regulations. FEFANA is highly committed to contributing to the effective implementation of these Regulations and has intense activities in this respect.

This is carried out under a set of leading working principles: we want to contribute to a straightforward regulative framework while increasing predictability and product safety, while striving for free and fair competition on the European market (same rules for all). We also seek consistent and equal enforcement of rules in order to pull down remaining barriers to trade in the EU.

The implementation of the Regulation 1831/2003 on Additives in Animal Nutrition is one of the priorities for our industry. The publication of the Feed Additives Register represented a first critical implementation step; it is the most transparent tool our industry and the users ever got from the EU. We now see the establishment of implementation rules and guidelines for the authorization process of feed additives as the next most critical step; the old rules and approaches being obsolete in the new regulatory context. The guidelines are to provide the transparency and proportionality warranted by Regulation 1831/2003. Over the last months, there has been a close co-operation between the European Commission and Member States (The Risk Manager), the EFSA (The Risk Assessor) and our industry on the establishment of these guidelines, sometimes under the cloudy sky of discussions on limits of responsibilities between Risk Assessor and Risk Manager. This eagerly awaited text shall have a determining impact on the competitiveness and innovation capacity of our industry; all three parties are bound to find out the right balance between the necessity of assessment on one hand and affordability of generating data on the other.

The appointment of the new Executive Director of EFSA came as a very positive element in this context. While EFSA has put openness high in its working principles since its creation, it is now acquiring with its new Director the necessary maturity to engage in a more active, two ways co-operation. Both EFSA and FEFANA share the objective to make the registration of existing additives - currently more than 2000 substances - a success story. While the Commission guidelines will be a determining element in this process, we already engaged with EFSA and FEEDAP in the practical preparation of the work. Based on the positive experience we acquired during the notification phase in 2004, FEFANA is currently establishing registration consortia, to streamline and help with the process.

Dialog with stakeholders also took a new dimension on DG Health and Consumers’ side, through the Healthy Democracy initiative. Under the chair of DG SANCO Director General, FEFANA was able to contribute to this very courageous review of the relationship between DG SANCO and its stakeholders. It explored openly the most relevant aspects of this relationship, including the comitology procedure that is so important in our regulatory environment. The first outcomes from these reflections are already being enacted by DG SANCO and FEFANA is committed to help sustaining this open dialog in the future.

CRL (Community Reference Laboratory) and its NRLs are close to the implementation of the additive Regulation, but also to the analytical aspects of control since they have received new responsibilities. The analytical challenge is huge and probably calls for some further thought on prioritization, particularly as far as control is concerned. We are proud of the trusty relationship and open dialog we established with CRL, thanks to the reliable scientific level of the various analytical groups and projects established.
Trust and reliability are the red lines of our long standing relationship with the representatives of the National Administrations that care for feed additives. The implementation of the new Additive Regulation fundamentally modified National Administrations’ role in the authorization process, with the disappearance of the rapporteur function. Though individual company contacts with these administrations will likely be less frequent, FEFANA is deeply convinced about the need to maintain regular contacts and dialog, particularly in view of harmonised implementation of the feed chain legislation. The FEFANA national and regional platforms are becoming the nodes of this intense dialog network while the establishment of further platforms in the new EU countries is being pursued.

Besides the Additive Regulation, the Feed Hygiene Regulation one is the other keystone of the “additive system”. This Regulation is highly ambitious and its implementation will not go without the active involvement of the economic operators, a fact recognised by the legislator that entrusted us with a part of the implementing responsibilities. As far as feed additives are concerned, the new rules made some steps back compared to the previous provisions, in particular regarding the identification of registered establishments, but on the other hand they greatly streamlined other aspects. Imports from third countries are amongst the very delicate aspects of the Hygiene legislation where we think authorities might benefit from industry’s support and initiatives. The feed additives and premixture industry set up FAMI-QS in order to help EU and third country operators to fulfil their Feed Hygiene requirements. The recognition of the large efforts we made came in early 2007, with the formal approval by the Standing Committee on the Food Chain and Animal Health of the document submitted by FAMI-QS, as a valid community guide for good practices for additives and premixtures. Our sector was amongst the first three ones to obtain this recognition. The reference to FAMI-QS has been published in the Official Journal. This process was underlined by a strong and efficient co-operative spirit with the European Commission and Member States representatives. Our industry is very satisfied with such an approach to the implementation of the EU legislation. The outstanding development of the FAMI-QS system and the increasing trust it is gaining towards national control authorities and feed operators confirms that it came up to real expectations at EU and third country level. FEFANA also embarked actively in transversal reflection and activities about hygiene rules with EFIP (European Feed Ingredients Platform), which brings together representatives of the vast majority of the ingredients that enter the feed chain.

Important new changes are emerging at EU and global level. To mention just a few: the new orientations of the Common Agricultural Policy and the increasing demand for biofuels. In both cases, feed additives have important contributions to make, either to support the shift in agriculture objectives - from quantity to quality or other aspects like the environmental dimension - or to help adapting to new feed sources. This is of course subordinated to the possibility to bring innovative additives on the market under economically viable conditions; which is directly influenced by the regulatory context and the guidelines.

The following pages will give the reader an insight into the main issues we are dealing with.

I would like to take this opportunity to thank all members, the Operating Team and partners for their commitment to building the future of the feed additives and premixtures in Europe.

Dr. Didier Jans
**2006 activities short overview**

**Guidelines**

The most burning file for the feed additive industry at the present time. This long-awaited document will drive the requirements and obligations for getting an EU authorisation. It is not only the sustainability and innovation potential of the feed additives and premixture industry that is at stake, but the document will indirectly have a major impact on the entire food chain in the EU. As foreseen by the Food Law, it is intended to govern the way the Risk Assessor will carry out its work, in order for the Risk Manager to take sound decisions. FEFANA developed a comprehensive proposal and participated actively, sometimes inviting itself, in the discussions between the Risk Assessor (EFSA) and the Risk Manager (EU Commission and Member States). FEFANA strives to keep the result close to the spirit of the Feed Additive Regulation, i.e. transparency and proportionality of the assessment procedure, without compromising safety.

**Definitions**

Fair and smooth implementation of the EU legislation is one of the FEFANA priorities. While the feed legislation now includes proper definitions for the vast majority of the concepts used, we recognised that there were remaining gaps in the practical interpretation of these definitions, both within the industry and at authority level. Since this has direct regulatory consequences, FEFANA developed a simple and efficient interpretation tool that alleviates a very large part of the subjectivity and uncertainty that used to prevail. Through two decision trees, this tool allows the consistent classification of all single component and mixtures types used in feed business.
Labelling

The new Feed Additive Regulation introduced new labelling rules for feed additives and premixtures. It however proved very difficult to implement the requirements of this Regulation, either because the necessary information is not yet available for many additives, or because the text leaves room for interpretation. FEFANA, in cooperation with the compound feed industry, developed a code of practice that not only help operators to behave according to the law, but also paves the way for an innovative and more efficient way to conceive labelling.

Q&A and Guidance

In order to support its membership to understand and properly apply the EU legislative requirements, FEFANA developed and maintains a number of Questions & Answers and Guidance documents. Important ones include a Q&A on the Feed Additive Regulation 1831 and on the Feed Hygiene Regulation 183. Guidance documents are constantly developed in order to bring practical support to members, for instance in order to help members with the practical aspects of authorisation dossier preparation. This brings permanent information, additional to that presented at the regular workshops organised for the members.
The FEFANA organisation

FEFANA Asbl is the Association of European feed additives and premixtures operators. It was established on 13 October 2004. It is the new legal form of the Feed Additives Producers’ Association, which was founded in 1963. The association is the interface between the feed additives and premixture industry and the European Union authorities, including Member States authorities, in order to promote, safeguard and defend common and general interests of the industry.

FEFANA operates as an integrated European network. The member companies (producers and non-producers) affiliate directly to FEFANA. FEFANA assures its representation in the EU Member States via platforms; this includes representation vis-à-vis national authorities and industry partners, and information to and co-ordination of national feed additives and premixture operators. These platforms can be an informal group of companies, a FEFANA office in the country, or a representation assured by one of the existing FEFANA member associations. All FEFANA member companies are automatically entitled to be member of the platforms of the countries in which they have legal entities. The formal structure of the existing member associations is maintained in some cases, but operational and financial functioning is largely driven by the FEFANA AGM. Main activity programmes and allocations of resources are decided by all the members at the FEFANA AGM.

The work is organised through Working Groups (WG) and Task Forces (TF) at FEFANA level in order to avoid duplication of efforts. The Working Groups are permanent product-oriented bodies. The Task Forces are issue driven bodies, created on an ad hoc basis to deal with subjects of identified interest. The Operating Team is at the centre of the process, coordinating the work of the Working Groups and Task Forces and triggers the setting up of new Task Forces as necessary.
FEFANA National Platforms

<table>
<thead>
<tr>
<th>Belgium</th>
<th>The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>Nordic Countries (Norway, Sweden, Finland, Iceland) &amp; Baltic Countries (Estonia, Latvia, Lithuania)</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Poland</td>
</tr>
<tr>
<td>Denmark</td>
<td>Romania</td>
</tr>
<tr>
<td>France</td>
<td>Slovakia</td>
</tr>
<tr>
<td>Germany + Austria</td>
<td>Slovenia</td>
</tr>
<tr>
<td>Greece</td>
<td>Spain + Portugal</td>
</tr>
<tr>
<td>Hungary</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Italy</td>
<td>U.K. + Ireland</td>
</tr>
<tr>
<td>Luxemburg</td>
<td></td>
</tr>
</tbody>
</table>
The main issues

The Feed Additive Regulation 1831

“The raison d’être of FEFANA is very much entwined with the implementation of this regulation and the difficulties it presents to the industry. Whilst the industry welcomed the much greater degree of harmonisation for methods of regulation on feed additives, there are still many areas covered by 1831 which either need to be developed, implemented, or correctly interpreted for the industry, either through dialog with the implementing authorities or through production of industry code of practices.”

Marc Leclerc and Philippe Becquet, Members of the Operating Team

Guidelines

Regulation 1831/2003 foresees that the assessment and authorisation process of feed additives have to be adapted to the different categories of additives and, very importantly, to be proportionate. The guidelines are the tool intended to make the rules concerning the preparation and the treatment of the applications transparent. Furthermore, the Food Law provides that these guidelines will govern the evaluation of feed additives by EFSA and will define the binding requirements for each type of assessment and additive; this is a clear expression of the separation between risk assessment and management responsibilities decided by the legislator, and his recognition of the need for a high level of transparency. It is under these strong facts that our industry supported this new Regulation.

After three years of intense work with the Commission and EFSA, this goal is not yet reached, and the authorisation process is still quite uncertain while the deadline for the authorisation of the 2000+ existing additives is approaching quickly. Innovation is also being hindered by this lack of legislative perspective.

Finding the right balance between a possible tendency to over-evaluate applications on some aspects and the need for pragmatism has proven to be a delicate exercise. The main stumbling blocks in the final phase of the preparation are the assessment of efficacy, of target animal safety, and endorsement by the risk manager of the QPS system established by EFSA.

As far as efficacy is concerned there is a growing recognition that it has very little to do with the primary goal of the legislation: assuring safety of the feed chain. While a reasonable degree of efficacy demonstration should be part of the authorisation process, both the additives producers and users made it clear that they are in a business-to-business relationship and that the assessing body should not overestimate the relevance of their assessment in this area. With the implementation of the Hygiene legislation there is hardly any operator left who is not a professional of the feed chain, taking informed decisions. In order to assure coherence with the requirements of the legislation, regulatory demonstration of efficacy is to be strictly focussed on the functionality of the additives, according to the category and functional group for which the authorisation is sought. The purpose of using feed additives is evolving toward much more diversified effects than simple animal performance, as was clearly endorsed by Regulation 1831/2003.
The assessment of the target animal safety has grown up from the old “tolerance test” approach, a unique case in the EU legislation where possible accidental use of additives is part of the decision-making for granting the authorisation. While the industry fully supports the aim of guaranteeing the safety of the animals receiving additives, one should not lose sight of consequences on animal testing and welfare in general; the use of the existing body of knowledge and extrapolations should be maximised. Comprehensive target animal testing should be restricted to the cases where quite obviously a potential risk is identified. Just like the efficacy assessment, generalised target animal testing has a direct influence on the feasibility of the application, and hence on the availability of feed additives, by number and for different animal categories.

The QPS (Qualified Presumption of Safety) is one of the first risk assessment method developed by EFSA that applies horizontally to live micro-organisms and derived products, across different sectors and regulatory areas (food, feed, biocides, etc.). It is understood to be both state-of-the-art in the area and a means to safeguard applicant and authorities resources from unnecessary assessment. The guidelines for the assessment of feed additives are the first opportunity for the Risk Manager to endorse this risk assessment approach. It would greatly affect the credibility and transparency of the authorisation process if the Assessor was to use a methodology that is not recognised by the Manager.

These discussions on the assessment process have also resulted in important steps forward, for instance in the area of consumer safety. When deemed necessary in the risk assessment of an additive, the applicant must determine the level of exposure the consumer of animal products subjects himself/herself to when consuming meat, milk or eggs from animals offered the additive in question. FEFANA has developed a methodology for the assessment of consumer exposure to any compound through review of eating habits. Based on realistic consumption data and conservative attitude, it uses a tiered approach which models animal product consumption in a scientific manner. FEFANA produced a Guidance document and method, following several years of consultation with experts in this field.

Our work in this area is converging with the assessments made by FEEDAP, which realised that previous approaches were outdated. Example assessments for several types of additives using the FEFANA methodology were compared with the results from FEEDAP risk assessments. The outcome provided consistently comparable results and as a result lent credibility to the FEFANA method, though on the basis of a much more transparent approach.

The EU Feed Additives Register

The Register is a living tool established through the Feed Additive Regulation (Regulation (EC) 1831/2003) and is published and maintained by the European Commission on the SANCO website. Its purpose is to allow industry to identify the legality of additives of interest placed on the market, including their conditions of use. The Register is needed to meet the requirements in Article 17 of Regulation (EC) 1831/2003 concerning its update and publication. It is of great help to facilitate access to consolidated information on feed additives authorisation in general, and has even the value of a proof of regulatory compliance for the existing additives, being in this case a de facto positive list.

The Register, which the Commission updates on a very regular basis, is installing itself as a major information source for the placing of feed additives on the EU market, both for the operators and control authorities.

The current content of the Register is however subject to some concern. According to article 9 of Regulation (EC) 1831/2003, the Register should indeed contain far more elements of the genuine authorisation than it is the case, such as the category, functional group and name of the holder (if applicable), specifications and purity criteria, method of analysis, etc. Since the vast majority of products on the Register have not been through the process of authorisation under 1831, such information has not been presented to the authorities in an unambiguous form. Nevertheless, as newly authorised products appear, there is an urgent need to shape the Register as foreseen in Regulation 1831/2003. FEFANA will seek to find solutions to this problem in the coming year.
Labelling

There have been two main areas of activity for labelling in 2006, namely: the implementation of current labelling requirement as well as a reflection on labelling of additives and feed in general in the context of the proposal for a new regulation on the marketing of compound feedingstuffs.

The purpose of the Code of Practice for the labelling of feed additives and premixtures is to aid understanding and therefore application of Article 16 of Regulation 1831/2003 on additives in animal nutrition. The Code of Practice is being used to improve the quality of information available for users and purchasers of the products alike by providing the relevant information in the right place. FEFAC (the EU federation of compound feed producers) has subsequently supported FEFANA views, which resulted in the FEFANA Code of Practice being co-endorsed as a joint FEFANA/FEFAC initiative. Both organisations intend to further promote this Code within their memberships and with the Authorities both at European and local levels throughout the upcoming year.

Following the announced re-cast of the marketing of compound feedingstuff Regulation, and particularly the labelling aspect it will cover, FEFANA identified an opportunity to address in a holistic way several aspects of feed labelling, including the link with feed additives and the functionalities they bring to the compound feed. We see this as a unique opportunity to re-build the labelling obligations on the basis of identified and sound grounds, like the purpose of the labelling, the targets, the means, etc.
Consortia/Registration 2010

Regulation 1831/2003 provided for a transition period for the feed additives previously authorised, including harmonisation efforts on certain groups of additives that were not clearly covered under the former regime. The notification exercise that ended in 2004 can be seen as merely a minor formality compared to the full registration obligation, due by November 2010: besides the hundred of “holder-specific” additives, the Register includes about 600 additives subject to non-holder-specific authorisation and more than 2000 flavouring additives, all of which need to be assessed and approved. These impressive figures can be further increased by multiplying factors such as manufacturing processes and identity, animal categories or functionalities. The risk of losing authorisation for many products or animal categories is far from being trivial, with clear consequences on market disruption and an increase of the burden on control authorities. The guidelines are of paramount importance to keep the process at an affordable but appropriate scale. In view of co-ordinating the efforts of the operators, but also to help limit the number of dossiers, FEFANA is establishing Registration Consortia. These are progressively developed in order to meet the needs of the FEFANA members, including premixture manufacturers, regarding the groups of additives on which the members identified interest. Once established, the Consortia are open to non FEFANA members. Though not obligatory as in other regulatory areas, participation in these Consortia offers many advantages to the operators, including cost reduction, coherence of dossiers and sharing of expertise.
Analysis

“The analytical aspects are growing in importance in the EU feed additives regulatory framework. They are fully integrated in the authorisation process, but are also increasingly addressed from the control point of view. FEFANA took an active stance in this field, both with the EU authorities and CEN, from in-house validation to international standardisation.”

Gérard Bertin, Member of the Operating team

Currently, FEFANA is running five separate WGs or TFs busy on specific analytical projects, under the coordination of a dedicated steering group. This work is carried out in close coordination with the CRL (Community Reference Laboratory) and CEN (European Committee for Standardization), which enhances communication between industry and the authorities.

The steering group has been very active throughout 2006, making great strides to further develop the already close relationship with CRL and CEN and to increase the consciousness of analytical aspects amongst the additive industry. FEFANA representatives have been regularly and actively contributing to CRL Workshops, making industry contributions to reflection on methods of analysis.

Two very important aspects are under our current limelight: the establishment of agreed standard for method validation according to the specificities of the additives to analyse (carotenoids, vitamins, flavourings), and the generalisation of the concept of “measurement of uncertainty” in all analytical aspects relating to feed additives.
FEFANA is also participating in CEN/TC 327 meetings with a view towards finalizing the harmonisation of methods for enumeration of probiotics and activity of phytases, both of which have now been included in the Commission mandate M382. A joint CRL/FEFANA publication of the phytase method in the Journal of AOAC International is planned for 2007, with a further publication planned by FEFANA participants later in 2007.

For probiotics (6 enumeration methods), the financial and political mandates were approved in December 2006 and these methods will now be pushed through the standardisation procedure. Further work will be pursued on typing method for some micro-organisms.

The Task Force “Analysis Carotenoids” has also focused on harmonisation of the analytical methods used for the determination of various carotenoids in commercial feed additive products and in premix/feed. The current versions of the various carotenoid methods were presented to the CRL who was supportive and provided valuable feedback on many topics, e.g. validation requirements. The methods for Beta-carotene and Astaxanthin are well advanced and submission is planned in the near future. Lutein, perhaps in combination with Zeaxanthin and Capsanthin, will follow later in 2007. The TF “Analysis Carotenoids” is approximately half way through its work to harmonise carotenoids methods, and is expected to complete this task in 2008.
The Task Force “Method of Analysis Vitamins” has completed its first task, namely analysis of vitamin content in commercial feed additive products, and disseminated the results in a brochure in the first quarter of 2006. Since then the TF pursued its work in order to establish methods for vitamin determination in feed and premixtures. Emphasis will be placed on tried and tested methods which are practised in the industry and are clearly documented and characterised. Special attention will be paid to the validation of the methods. CRL and CEN have been informed of the fact that the TF has started this premix/feed project. The goal is to produce harmonised methods that all companies involved can accept. The project is divided into three phases: collection of available methods, comparison and assessment of the methods and collection of arguments to decide which methods can be proposed and used. It is planned to involve CRL for critical review and acceptance of the final methods. The target is to publish a reference brochure. Both for the operators and the authorities, developing methods of analysis for the 2000 flavouring additives included in the Register is a potentially impossible target to manage. FEFANA embarked on a reflection on the purpose of this requirement and the pragmatic way to satisfy it. Obviously, the aim of the legislator is to ensure that control authorities have the necessary tools to analyse the substances that raise potential safety concerns. On this basis and parallel with the food legislation, FEFANA TF “Analysis of Flavourings” developed a method which can be used to analyse 10 such priority additives (so called “active principles” according to the food flavour legislation) from various substance classes for identity and purity. The first results confirmed that the method is suitable for the qualitative and quantitative determination of chemically-defined flavourings as such. Analysis of chemically-defined flavourings in a matrix (premixture and compound feed) is planned.
Food Chain Safety and Feed Hygiene

“The integrity of a safe food chain is assured where the hygiene of its production facilities are maintained, in addition to the quality, wholesomeness and safety of its various supplies. This requires clear rules, active endorsement by operators, and strict and harmonised controls by the authorities. FEFANA took broad initiatives to support implementations of these principles on its own and at the level of the chain.”

Bernadette Okeke, Member of the Operating Team

In the wave of the White Paper on Food Safety, a number of strategies to tighten the legislation in place were taken, such as:

- a holistic approach to traceability and assurance including hygienic assurance (Food Law, Food and Feed Hygiene, Official Feed and Food Controls Regulations);

- introduction of extensive controls on premises where food and feed are produced, including in third country establishments, placing for the first time greater responsibility on food/feed operators with regards to food safety. This making it mandatory for certain feed establishments to adopt the principles of hazard analysis and associated controls, in particular the ‘Hazard Analysis and Critical Control Points (HACCP)’ (Feed and Food Hygiene, Official Feed and Food Controls Regulations).

- the creation of a European Food Safety Authority to be responsible for risk assessment on EU wide issues.

FEFANA welcomed the proposed changes, and have worked tirelessly to maintain similar goals through a number of initiatives including the introduction of industry self-regulated food quality and safety management systems. Working with the European Commission, European Food Safety Authority, and Member States, FEFANA was instrumental in implementing the required guarantees of feed safety to ensure a higher level of human health and consumer protection.

To enable a clear and pragmatic interpretation of the Feed Hygiene and, to a lesser extent, the Official Feed and Food Controls Regulations, FEFANA has provided its members with a regularly updated guidance document in a question and answer format in the course of the last year. This provides a much needed interpretation of the requirements of these EU laws, and most importantly practical guidance on their implementation. By integrating the various safety requirements of the Feed Hygiene Regulation in its voluntary Code of Practice for feed additive and premixture operators (see sub-section on European Feed Additive and Premixtures Quality System, FAMI-QS), FEFANA has provided the feed additive and premixture industry with the perfect tool to assure safety.

In recognition of this fact, the document developed by FAMI-QS was amongst the first to be recognised by Member States and the European Commission as Community Guide to show compliance with the Feed Hygiene Regulation. FEFANA continues to work, often with or alongside its other industry counterparts, in pursuing its efforts (see sub-section on European Feed Ingredients Platform, EFIP) to ensure harmonised implementation of EU law across the 27 Member States.
A significant part of the additives, and to a lesser extent premixtures, placed on the EU market comes from third countries. With about 30% of the affiliates being established outside the EU, the system is becoming a key reference in order to meet legal requirements for placing feed additives and premixtures on the EU market. In this respect and in the context of the demanding legal requirements in the EU, FAMI-QS strongly contributes to the always difficult establishment of a level playing field at global level; this has an important impact on the safety of the feed chain. With the support of its partner network of certification bodies, the system not only helps to inform third country operators but also implements in practice the EU requirements directly at operators’ level. In this area, FAMI-QS is assuring close co-ordination of the certification bodies and, besides several events in EU, organised a first training session in China that gathered more than 20 auditors this year. The development of FAMI-QS in China is very pleasing, and other exporting countries do not lag far behind.

Another great achievement of FAMI-QS during 2006 was the recognition gained from the established and leading feed schemes, which greatly contributed to the operability of the system on the market place, in a context of mutual trust.

www.fami-qs.org

FAMI-QS, the EU Feed Additives and Premixture Quality System

Although being still a very young organisation, FAMI-QS is establishing itself as a significant element within the animal feed landscape. This success finds its roots in two main aspects: the sustained dynamic that its members have put into the project and the strong support that the additive and premixture industry gave to it.

Throughout the process of recognition under the Feed Hygiene, FAMI-QS was enriched with a number of additional elements and guidance documents, intended to support practical implementation by the operators. This process was underlined by a strong and efficient co-operation spirit with the European Commission and Member State representatives. The value of the FAMI-QS system is increasingly obvious to the operators who see it as a convenient and coherent way to satisfy both legal and market requirements. The market is now recognising and increasingly requesting FAMI-QS certification, and as a result, the association has more than 200 affiliated members today.
Chain approach EFIP

FEFANA and FAMI-QS invested significant efforts in co-ordination with other food chain partners, having particularly taken an active role in the establishment of EFIP (European Feed Ingredient Platform) since its foundation.

This spontaneous and voluntary initiative brought together the vast majority of EU associations or federations representing the sectors that supply feed ingredients (processed, non processed, co-products and additives) to our market. Together, the EFIP members represent the vast majority of all “ingredients” that enter the food chain via compound feed (cereals, processed vegetables or animal products, additives, and co-products from the food processing industry).

With the aim to provide harmonisation and consistency between the sectors in the way they implement the Feed Hygiene Regulation, EFIP activities are, among others - development of benchmark tools, evaluation of sector guides, sharing of experiences, cooperation and offer of concerted guidance to all of their members on the implementation of the Feed Hygiene Regulation and relating safety schemes.

www.efip-ingredients.org

E. Vecino, FAMI-QS, Quality Manager
Non-feed use of additives

“Feed additives can only be used in animal nutrition if they are authorised and meet the appropriate specific conditions laid out in Regulation 1831/2003. However under certain circumstances, feed additives and raw materials are used to meet particular nutritional objective(s) - satisfying temporary increased or specific nutritional needs of pets or productive livestock in some physiological situations or when the process of digestion, absorption or metabolism could be impaired, enabling animals to benefit from an adjustment of their nutrition more appropriate to their condition - and/or to achieve/maintain a desired nutritional status - including e.g. the use of technological additives such as organic acids, colourants, etc. to maintain the quality and integrity of feeds. A certain degree of confusion prevailed, which FEFANA started to unlock.”

Juliette Mélédié, Member of the Operating Team

Several types of additive concentrates are present on the market. The Feed Additive Regulation provides a good basis of harmonisation of practices, but has not entirely streamlined the practices. While looking for a proper regulatory management of these products, one has to pay attention not only to the nature of the products, but also to the way they are used.

A range of products is known as “nutritional supplements” : they are satisfying the temporary or specific nutritional needs of particular pets or productive livestock in certain physiological situations or where the process of digestion, absorption or the metabolism could be impaired or there are special need. Others additive concentrates are used by breeders and farmers on a more regular basis. They have been on the market for many years, covering different forms (powder, paste, liquid, capsules, etc.) and different means of distribution (directly in the mouth, mixing in water, free access, etc.), and fulfil important needs in livestock production in the EU.

The uses of these feed additive concentrates are not covered under a specific harmonised framework, and are more or less regulated at individual Member State level. It is imperative that their use be subject to some harmonised approach and controls in order to continue to ensure feed/food safety. Attempts to agree a common Community law by the Commission and Member States continues, albeit very slowly; current discussions at Standing Committee level focus on the use of additives in water (see below), but FEFANA believes that one should adopt a wider perspective and look at the use of additive concentrates in general. This should not only be done on the basis of the Feed Additives Regulation, but also at the light of the Feed Hygiene Regulation and with greater emphasis on industry ownership of traceability. It is pertinent that the industry and users assumes some responsibility in progressing and addressing this issue.

In this light, FEFANA has worked over the last year in identifying the practices that fall within this bracket across the Community. FEFANA’s goal is to put in place pragmatic measures which will afford controls in the use and marketing of nutritional supplements and concentrates in general across the community but also assure consumer safety and protection. FEFANA considers that this could be achieved through a Community industry guide of good practice on the marketing and use of nutritional supplements and concentrates.
Additives in water

In some cases, additives, not necessarily fulfilling a particular nutritional purpose, are delivered to livestock via water supplies.

The use of additives in water has also been a reality on the market place for decades. While the Regulation 1831/2003 on additives in animal nutrition creates the possibility for feed additives to be used in water if it is authorised, it does not currently foresee any arrangements such as a transition period for this use. FEFANA considers that, as for the use of additives in feedingstuffs, a transition period until 2010 should be created for the use of additives in water at the European level; this would provide the basis for a harmonised approach, and avoid serious market and animal production consequences.
Other legislations

REACH (Registration, Evaluation and Authorisation of Chemicals)

In 2006 the European Union adopted a fundamental revision of its chemical legislation, with a new regulatory framework for the Registration, Evaluation and Authorisation of Chemicals and a recasting of the Dangerous Substances Regulation. Its declared prime function is to improve the protection of human health and the environment. To help in achieving this, it will set up a system for the Registration, Evaluation and Authorisation of Chemicals (hence the acronym REACH) and will largely amend or supersede Directive 67/548.

REACH places a duty on industry to manage the risks from chemicals and to provide safety information on the substances it uses. Manufacturers and importers will be required to assemble data on the properties of their substances, in order that they can be managed safely. This information will also be held on a central database run by a central Chemicals Agency, which will be based in Helsinki.

FEFANA actively worked on this proposal in order that the specific and comprehensive regulatory framework put in place for feed additives be taken into account and overlaps avoided. The result of these activities is that feed additives are exempt from the provisions laid down in Titles II, IV, V, VI and VII of the Regulation. In essence, this means that although feed additives fall under the general scope of the regulation, they are exempt from the Registration, Evaluation, and Authorisation requirements of the Regulation and there is no overlap between REACH and the Feed Additive Regulation (1831/2003). That does not mean that feed additives are entirely exempt from any chemical-legislation related duties, which is an area where FEFANA has taken several initiatives to support members’ information and harmonised implementation of the EU law.
The Working Groups

In the FEFANA organisation, Working Groups are permanent product-oriented bodies, watching for the impact of regulatory developments on a specific group of additives, taking initiatives according to these developments, and caring for the general image and recognition of this specific group of additives. The establishment of these groups and activities are driven by members' interests.

Amino acids

In 2006, the Working Group Amino Acids participated in preparation of the AWT brochure which was published this year (in German). Regulatory affairs, however, were the major focus of most Working Group activities and discussions. Of particular interest to the group was the issue of labelling of amino acids. Amino-acids, which previously were regulated under the Directive “on certain products used in animal nutrition”, are “newcomers” in the Additives Regulation 1831. The transition phase established by this Regulation left some questions open, for instance regarding labelling obligations. The view of the WG/FEFANA is that the labelling obligations as detailed in our code of practice apply to this category of additives as to all others. The preparation of dossiers for the individual amino acids for submission to the Commission/EFSA has also started to keep the WG busy. The principal point at stake with regard to dossier preparation was the difficulty to satisfy the degree of precision expected on identity description in a context of non-holder-specific registration, as opposed to holder-specific authorisation.

M. Redshaw, Degussa, Chairman

Aromatic and flavouring additives (ARAP)

The year’s work commenced with consolidation of the notification of feed flavour ingredients under new EU legislation, with over 2000 ingredients being successfully notified. This large number of substances, however, raises a serious challenge for the process of full registration in the future. To address this challenge, ingredients will be divided into two major groups: chemically defined substances and botanicals. Furthermore, various groups of flavour ingredients could be grouped within a single dossier to reduce the regulatory burden. Even with the concept of groups, registration will be a lengthy, difficult and expensive process since there may be as many as 30 groups, plus botanicals and sweeteners. Wherever possible, information for registration will be taken from the food industry so as to avoid unnecessary repetition of work.

Continuing along the lines of registration, a new consortium will be established to deal with the registration of flavour ingredients. At an initial meeting, some 28 companies, FEFANA members and non-members, expressed an interest to partake in a new consortium. The new consortium would probably only deal with a core group of substances which would be of interest to the vast majority of consortium members. FEFANA might create a website where companies can express interest in the flavour consortium for registration. It is intended that the consortium should be open to all interested companies whether they are FEFANA members or not.

In order to cope with uncertainty over the new guidelines for registration of feed additives in general and in particular the requirements for flavour ingredients, which were difficult to develop, a small Task Force from within the WG ARAP has been formed to work specifically on the new guidelines document.

There are substantial problems still to be addressed concerning flavour dose rates and analytical methods to support the registration dossiers.

Clifford A. Adams, Kemin, Chairman
Carotenoids

The Working Group established interactions with EFSA/FEEDAP on the risk assessment of red carotenoids, after having already contributed to these opinions during their evolution during 2005. The main thrust of the comments related to the manner of evaluation of consumer exposure to these compounds and activities subsequently led to a joint FEFANA/EFSA (FEEDAP) meeting in October 2006. This meeting gave FEFANA the opportunity to highlight its proposed consumer exposure method (see FEFANA Task Force Intake) and in particular to compare results obtained by this method with the information provided by FEEDAP in their opinions. This gave much strength to the FEFANA proposed method, which proved to deliver comparable risk assessment result to that of FEEDAP, but under a much more transparent and reproducible approach. There was a general agreement that the FEFANA method should be viewed in greater detail and a working plan with FEEDAP was established.

The WG also started communicating to the industry on the legislation and notification processes of carotenoids by publishing an article in De Molenaar’s special edition on sensory feed additives.

C. Günther, BASF, Chairman

Enzymes

The Working Group Enzymes faced a challenge at the outset of 2006 as indicated in last years annual report – that of defining an identity and purpose. With many of the interests of the WG Enzymes being dealt with at horizontal issues and Task Force level, it was becoming difficult to justify the continuation of some of the activities of the WG. Three areas of interest were identified – assay, guidelines and process change. The former two were covered in other TF and WG but process change was identified as a major point of interest for the group.

With respect to process change, at issue was the lack of a clear and defined guidance on the subject of whether a change in the process of manufacture required notification, re-authorisation or no action at all. This critical requirement was clearly within the remit of the WG Enzymes and was not covered by any other TF or WG. Several meetings and two teleconferences ultimately produced an internal working document which was modified significantly over time with respect not only to its content, but also with respect to its proposed end use. The most recent document looks to be highly pragmatic and based on sound reasoning. In current discussion is the question of exactly how this proposed code of practice or memorandum of agreement should be implemented.

The activity described above has implications for all products produced by fermentation and as a result there is likely to be an offshoot fermentation process change TF which will take all such products, not just enzymes, into account, to determine if such a proposed memorandum of agreement has wider application.

M. Bedford, AB Agri, Chairman
Micro-organisms steering group

2006 has seen significant changes in the legislative status of micro-organisms. Previously, in Council Directive 70/524/EC, live micro-organisms were only covered by the probiotic category. This has been extended in Regulation 1831/2003, in which silage agents are identified as having two main categories of products:
- chemicals;
- combined products with enzymes and live micro-organisms.

As a result, live micro-organisms could now be covered in three categories:
- silage additives;
- probiotics;
- other additive categories as they become apparent.

Whatever the final destination of the micro-organism, there are several technical problems which are common to all live strains. Consequently a new Working Group has been established which should be considered principally as a steering group, dedicated to the general technical problems which exist in this field. This group will not replace the existing Task Forces on silage and probiotics, both of which remain in order to address their own respective specific technical issues. In 2006, the group reviewed the problem of antibioresistance and the FEFANA position for QPS.

In 2007, the WG Micro-organisms will further promote its views on the uncertainty of measurement and extend the harmonization of methods of analysis to all live micro-organisms. The group will also further discuss the following topics with the CRL:
- analytical methods and control: enumeration, typing methods, uncertainty of measurement;
- identity assessment: culture collection: strain numbering reference? Whether a strain should be deposited in an internationally recognised collection, change of production process (but still using the same strain);
- safety assessment: antibioresistance, QPS status.

G. Bertin, Alltech, Chairman

Probiotics

The Working Group Probiotics was set up in autumn 2006; it was outsourced from Steering WG Micro-organisms. Aim of the group is the general promotion of Probiotics within Europe, its task is therefore to develop generic information on the particular benefits of Probiotics. In order to achieve this, the Group is currently preparing the major messages promoting the use of Probiotics in animal production, identifying the main institutional targets of the messages as well as exploring the way these messages should be conveyed to the relevant parties. For this purpose, the alignment with the work done in Task Force Labelling will be sought.

With the creation of WG Probiotics, FEFANA has entered a very new activity field. While it is the traditional job of industry associations to deal mainly with regulatory issues, the aim of this Group is now the marketing-oriented promotion of a whole category of products which is designed to be used in animal nutrition.

By the end of the year, the Working Group has after two meetings already presented proposal lists of stakeholders and of ways to carry out the necessary actions as well as strategy items containing a definition of relevant points to be matched such as the perception of Probiotics and their producers in the public. In early 2007, the Group will prepare the relevant tools, establish a definitive action plan and define the budget to support the communication strategy.

Eric Audair, Lesaffre, Chairman
Silage additives

The Silage Working Group has been working on two main topics during 2006, these being recognition of active substances as the registered product and the preparation of comments on guidelines on efficacy. The first task was to convince the EU Commission and Member States that only active substances should be in the Community Register. Formulated silage products should not be listed in the Register, since according to the Additive Regulation, they are “a premixture of additives”, which can still be freely put on the market as long as each of their ingredients is already authorised. Registration of formulated silage agents will be possible, as zootechnical additives, provided the product demonstrates a relevant effect. The group prepared the FEFANA input on silage additives efficacy evaluation and produced guidelines for evaluation of silage agents which were very positively echoed at EU Commission and Member States levels. A misunderstanding occurred on the side of the Commission regarding the listing of some silage additives, as preservatives. These silage agents should be classified in both functionality groups (preservative and silage agents), in accordance with the notification process, and in order to allow compliance with the Feed Hygiene Regulation.

G. Bertin, Alltech, Chairman

Vitamins

For the Working Group Vitamins, 2006 was a year of changes, which reflected the situation within the industry. Company representatives changed and companies withdrew membership. Chairman Kevin Collins went into early retirement and therefore retired as Chairman of the WG Vitamins in mid-2006 after having acted in this position for 15 years. Fortunately, new member companies have joined the WG Vitamins, maintaining its broad industry representation.

The various revisions of the Community Register of Feed Additives have been the main issue in 2006. The first revisions were incomplete, with major parts missing. In response, the WG members were encouraged to interact with DG SANCO, advising on the omissions and pointing out that these substances were still on the EU market and that they had been correctly notified and would continue to be marketed. In the 5th revision, vitamins A and E were listed only under a generic heading, not as individual molecules having vitamin activity. Though not entirely exhaustive, this version of the Register was seen as acceptable until the Registration process in 2010. Some B-vitamins were listed as individual molecules. Discussion followed with regards to Registration principles. Shall active substances or preparations be notified? Shall all active substances be notified within one generic dossier? Alignment with proposals from other Working Groups seems appropriate. Members showed tentative interest for submission of vitamin dossiers by consortia. This topic will be a key issue in 2007.

In December 2006, the 7th Register revision was released by DG SANCO, and the FEFANA vitamin listing has been updated at the end of 2006 in order to maintain an industry point of reference with the register.

For 2007, two topics of interest will be the initial focus of the WG.

Two reports have recommended possible limitations on the use of vitamin A in animal feeds. The reports have been discussed by the SCFCAH, and EFSA has been asked to undertake a risk assessment. The Working Group has set up a Task Force in December with the aim to provide information to the EFSA FEEDAP panel and assist with this assessment.

René Blum, LONZA, Chairman
Premixtures

The WG has been very active in 2006, with 18 participants taking part in four fully attended meetings throughout the year. The group is confronted with a broad spectrum of issues because most feed additives and all possible applications of these additives are relevant to the participants of this Working Group. The main topics of interest included:

- arriving at an agreement that “Premixtures not intended for direct feeding to animals” are not exempt from dangerous good labelling according to 1999/45/EC, concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; the WG also agreed to create a common view and a time frame for implementation;

- FEFANA’s WG Premixtures also made a statement regarding the dioxin regulation 2006/13/EC: the position made was that official methods of analysis of dioxins in various matrices such as minerals, trace elements, binders, vitamins and premixtures must in general be implemented and validated, before official limits on dioxin and dioxin like PCBs can be accepted;

- mutual recognition of FAMI-QS with PDV and OVOCOM has been realised last year which was in line with the position of the WG; the WG also lobbied for a gatekeeper solution within the FAMI-QS code, which is close to finalization;

- the WG participants contributed to a list of feed additives in use and their origin as a helpful tool to build consortia for registration of feed additives;

- the possible imposition of obligatory monitoring protocols, as proposed by GMP-system holders such as PDV, has been discussed along with the possible implications for our members;

- the use of feed additives and mixtures of additives in drinking water has been under discussion in 2006, with the WG providing considerable input into the final FEFANA statement on this topic.

For 2007, one topic which will be discussed is the concept of sharing information for the risk assessment of feed additives.

P. Fidder, Trouw Nutrition, Chairman
# FEFANA Teams

## FEFANA Board

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georg Kau (President)</td>
<td>DSM</td>
</tr>
<tr>
<td>Hadden Graham (Vice-President)</td>
<td>AB-Agri</td>
</tr>
<tr>
<td>Franz-Josef Schön (Treasurer)</td>
<td>BASF</td>
</tr>
<tr>
<td>Eckhard Baus</td>
<td>Sunvit</td>
</tr>
<tr>
<td>Frank Chmitelin</td>
<td>Adisseo</td>
</tr>
<tr>
<td>Aidan Connolly</td>
<td>Altech</td>
</tr>
<tr>
<td>Jean Falgoux</td>
<td>Ajinomoto Eurolysine</td>
</tr>
<tr>
<td>Dieter Greissinger</td>
<td>Degussa</td>
</tr>
<tr>
<td>Diedrich Kahrs</td>
<td>Lohmann</td>
</tr>
<tr>
<td>Jan Poul ten Hove</td>
<td>ADM</td>
</tr>
<tr>
<td>Joop van Schaik (Honorary President)</td>
<td>FEFANA</td>
</tr>
</tbody>
</table>

## FEFANA Operating Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Didier Jans (Secretary General)</td>
<td>FEFANA</td>
</tr>
<tr>
<td>Philippe Becquet</td>
<td>DSM</td>
</tr>
<tr>
<td>Gérard Bertin</td>
<td>Altech</td>
</tr>
<tr>
<td>Marc Lederc</td>
<td>Novozymes</td>
</tr>
<tr>
<td>Juliette Méleodé</td>
<td>Adisseo</td>
</tr>
<tr>
<td>Bernadette Okike</td>
<td>Lallemand</td>
</tr>
</tbody>
</table>

## FEFANA Staff in Brussels

<table>
<thead>
<tr>
<th>Name</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Didier Jans</td>
<td>Secretary General</td>
</tr>
<tr>
<td>Thorsten Guthke</td>
<td>Regulatory Manager</td>
</tr>
<tr>
<td>Pascale Furnelle</td>
<td>Executive Assistant</td>
</tr>
<tr>
<td>Bertrand Larsimont</td>
<td>Assistant</td>
</tr>
</tbody>
</table>
Contact Information

You can find FEFANA at the following address:

120, Avenue Louise (5th Floor B)
1050 Brussels - Belgium
Phone: +32 (0)2 639 66 60
Fax: +32 (0)2 640 41 11
E-mail: info@fefana.org
Web: www.fefana.org