Annual Report 05

fefana
EU Feed Additives & Premixtures Association

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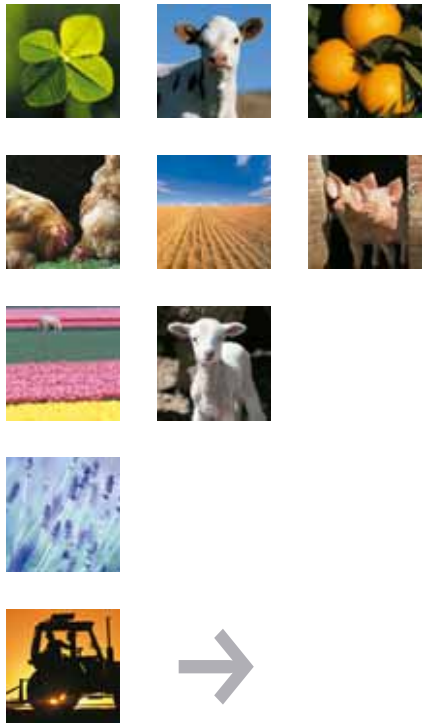


From the President

There is an increasing understanding of the fact that animal feed is an integral part of the food chain. This means that the feed market needs careful regulation. At the same time, the industry must ensure that the regulations designed to create safe food do not compromise the industry's ability to offer significant product innovation and international competitiveness.

Regulations require not only formulation, but also validation and, where necessary, adaptation. Lobbying for such new perspectives is a key element of FEFANA's role within the Feed Additives and Premixture industries. Lobbying means assuming ownership of a position vis-à-vis the regulators so as to ensure that the regulatory environment is appropriate for industry, customer such as farmers and also consumers. This calls for significant networking as well as the development and dissemination of position papers articulating the industry's viewpoint on key issues at many different interfaces throughout the entire food chain.

This is one reason why FEFANA has been restructured over the past two years into a fully integrated pan-European trade association. The transformation started originally from 10 national associations and 16 direct company members, and now aims to cover national representation in all 25 member states after the expansion of the European Union. The majority of the association's permanent staff is headquartered in Brussels, but also now includes remote staff complemented by representatives from over seventy member companies throughout Europe. These companies include both additives and premixtures operators, directly affiliated to FEFANA and its national network.

Additives and premixtures are now surrounded by a consistent regulatory system, including the Feed Additives, Feed Hygiene and Feed and Food Control Regulations. This is one of the most complete and demanding systems of the entire food chain. The membership of FEFANA supports this move but is at the same time concerned about the global competitiveness of the EU industry. The viability of the system is directly dependent on the proportionality and predictability of the authorisation system.

FEFANA strongly supports the Feed Hygiene Regulation, which is in the industry's view complementary to the Feed Additive Regulation and should considerably contribute to enhanced food safety. The industry has met its responsibility in this respect by developing and implementing a safety assurance system, FAMI-QS (Feed Additives and Premixtures Quality System), that fosters and supports the implementation of the Feed Hygiene Regulation for European and non-European operators. FEFANA understands that the European and national authorities, as well as FEFANA's food chain partners, welcome and appreciate this responsible move. FEFANA now expects that they rapidly grant FAMI-QS the official recognition it deserves.

The Board is convinced that the improved communication and lobbying at all levels of European and national authorities by the restructured FEFANA will lead to more reliable production from food producing animals. This will be an important factor in maintaining the confidence of the end consumer.

Dr. Georg Kau

From the Secretary General

Like the many companies they represent, EU associations constantly need to adapt their activities in order to meet their member's contingencies and expectations. When such a requirement is further stressed by major changes in the legislative framework, it is obviously time for the association to undergo a radical renovation. That is what FEFANA started in 2004 and implemented in 2005, building an updated and more efficient organisation on a strong base at both national and European level.

Being fully committed to its role as the voice of the European feed additives and premixture industry, a large emphasis was put on the relationship with the authorities and stakeholders; big steps were made in this area.

FEFANA profiled itself as a working partner with the European Food Safety Authority (EFSA), through its involvement in the EFSA stakeholders consultative platform, of which it is a permanent member, and through regular contacts with the co-ordinating staff and the scientific panels. As expected, one of the main challenges for EFSA is to maintain its much appreciated transparency policy, while safeguarding the independency of its scientific judgements. We respect this and want to help to find a mutually acceptable balance. Through the year, we organised several meetings and with inputs from the FEFANA experts notably to the Feedap panel (Panel on additives & products on substances used in animal feed-EFSA), we hopefully contributed to progressing in that direction.

The Directorate General of Health and Consumer Protection (DG SANCO) remained one of our main interlocutors. The integration of the major feed legislations, including the Feed Additives Regulation, Feed Hygiene, compound feed, undesirable substances and food and feed control, in one single unit certainly contributed to making the EU feed additives and premixture legislation what it is today: in our view one of the most coherent and consistent areas of legislation in the entire food chain. The recent reorganisation of the Commission's services will now put the emphasis on the transverse link between food and feed. This has of course merits but should be underlined by very strong co-ordination in order not to jeopardise what has been established in the feed chain. The bi-dimensional aspect of the food chain has been on FEFANA's agenda, notably through the various industry co-ordination platforms in which we participate (feed or feed/food oriented) in order to exchange and align as much as possible with our food equivalents. We however know that there are still enormous differences between the legislation in place in these two fields, and that a real integration would require major changes in the EU legislation.

The past year has also seen a major drift in the Commission's policies, following the problematic adoption of the EU constitution. The sustainability of EU legislation and competitiveness of the EU industry have definitely gained in importance. FEFANA warmly welcomes this move towards more pragmatism but would also warn against a complete standstill of the legislative process : our industry can neither afford an open free-for-all legal situation nor over-regulation, as sometimes experienced in the past. We call for progress in the direction of openness, constructive dialog, and shared responsibilities.

At Member States level, the past year was characterised by the progressive disappearance of the Rapporteur system which was familiar to our industry, and by the increasingly active participation of the new Member States in the decision-making process. Times are changing, but the pivotal role of the national administrations in the Regulatory process remains, with probably an increased emphasis on harmonised implementation and control aspects. Based on its long-standing relationships at national level, FEFANA wants to contribute to this most important step in European integration.

The new Feed additives Regulation has also triggered the setting up of the CRL (Community Reference Laboratory) and its network of NRL (National Reference Laboratories). The analytical aspects are a new, strong aspect of the EU feed additives regime. FEFANA members took stock of the challenge, developed scientific activities, and became one of the privileged industry partners of the CRL. We also actively supported method standardization at CEN (European Committee for Standardization). A compilation of methods of analysis of vitamins is just freshly printed, and the standardization of a method for analysing phytases and for the enumeration of authorised probiotics is entering the final adoption phase at CEN.

FEFANA work is underlined by a solid working organisation fully integrated at EU level. Beside the Operating Team (OT) this includes the Working Groups (WG, product categories oriented) and the Task Forces (TF, issue driven). The system favours a high degree of integration between members and gives more opportunities to all members, from international companies to SMEs (Small & Medium Size Enterprises), to contribute to our industry's positioning on subjects that are crucial to their future.

The new FEFANA organisation is also putting increased emphasis on external and internal communication. The FEFANA website was recently launched, and notably includes an information service for those who want to be updated on FEFANA's views and positioning. Considerable communication efforts towards the members are also provided along four main lines : the holding of regular OT workshops, the Info Sheet (information sharing system) which is regularly distributed, specific Project Sheets (issues managed by TFs) and the Feature Information (topical and analytical information).

The main issues that have crystallised FEFANA's efforts over the last year are undoubtedly the new Feed Additives Regulation (including the Register), the guidelines for the assessment of additives, the implementation of the Feed Hygiene Regulation (FAMI-QS initiative), and the Genetically Modified Food and Feed (GMFF) debate. More information on these important topics, and many more, are provided in the following pages.

Dr. Didier Jans

2005 Activity Review

Major events in the work calendar of FEFANA in 2005 have included :

Structure

The integration of national platforms within FEFANA has resulted in an improved flow of information between Member States and FEFANA and vice versa. FEFANA membership has increased from 40 to over 70, as a result of its streamlined and fairer pan-European membership fee structure.

Guidelines

This year has seen a frenzy of activity from the commission and the European Food Safety Authority (EFSA) with regards to preparation of guidelines for implementation of Regulation 1831/2003. FEFANA produced its own version of guidelines in an attempt to prompt the European Commission (EC) and EFSA into a more sensible method of evaluation of additives with respect to efficacy and safety. The principal aim is to ensure that the data requirements for safety and efficacy are proportional to the hazards and the claims being made. This activity has been ongoing throughout 2005 and has, after some initial disappointments, met with some success, with both the EC and the EFSA viewing the FEFANA proposal quite favourably. Work will continue through 2006.

REACH

The chemicals regulation which was designed to demand safety information on all chemicals used in the EU at first looked like it would capture feed additives in its scope. This would duplicate the information required for 1831/2003 registration. Successful lobbying of Member States, relevant committees and Members of the European Parliament (MEPs) has succeeded in the removal of the overlap between this general legislation and that specific feed regulation to additives.

Feed Hygiene

This Regulation (183/2005), which came into force in January 2006, is affecting all involved in the chain of supply of feed additives. FEFANA has been playing and will continue to play a leading role in describing methods of compliance, principally through adherence to its own FAMI-QS Safety Assurance scheme, which was specifically devised for this regulation.

Questions & Answers (Q&A)

In order to support member companies regarding questions they have relating to the practical aspects of legislative implementation, several Q&A documents were produced and regularly updated. It includes a Q&A on the Feed Additives Regulation 1831/2003, and one on the Feed Hygiene Regulation 183/2005. Other documents are in preparation regarding interpretation of feed-related definitions and labelling of additives and premixtures. It is an excellent first step for those who have run into problems interpreting Regulations, and contributes to harmonised implementation.

Notification/Register

FEFANA has been in the vanguard of this activity, initially providing a web-based community from which like-minded companies could notify their feed additive products effectively and efficiently. FEFANA also picked up orphan additives and notified those that appeared to have value in animal nutrition, and continues to lobby the EC to ensure the register is fair in terms of its content and structure. FEFANA sees the register as being extremely important to the industry and will continue to work in this area until satisfied with the outcome.

Future events

In addition to maintaining activities in the above and many other topic areas, FEFANA will continue to update its members through its Workshops, which have proven to be popular and successful. The next Workshops are scheduled to take place in March, June and October 2006, most probably in Brussels. Details of the contents of these meetings will be circulated closer to the events.

FEFANA new structure

Since its creation in 1963 by EU National Associations, FEFANA evolved progressively to a mixed membership (National Associations and company membership), and decided upon a major change in October 2004, improving both the organisation itself and its modus operandi. FEFANA did not only re-establish itself as an independent entity, but also switched to direct affiliation at European level of all member companies.

This decision was triggered by the fundamental changes that occurred in the feed additive and premixture legislation, EU enlargement, and the continued concentration of the feed additives industry.

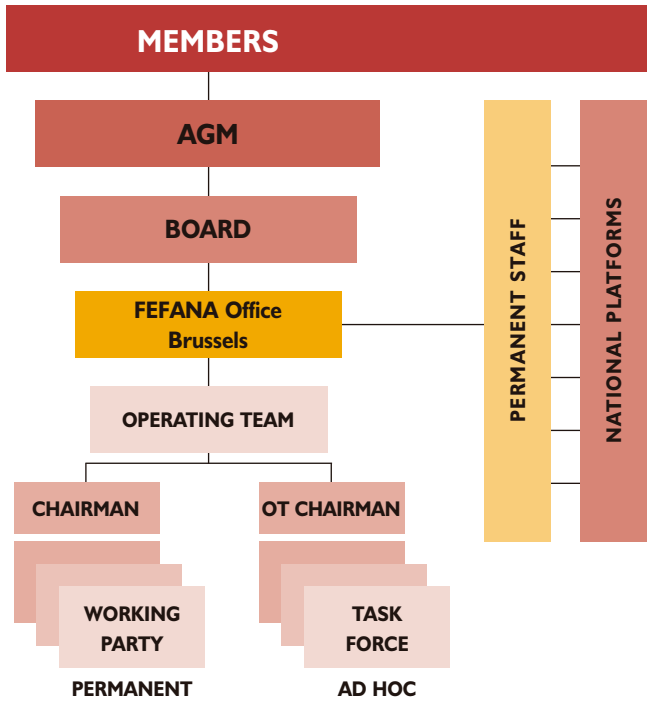
Through this new organisation, FEFANA confirmed and re-enforced a national and regional presence on the basis of existing National Associations, the well established partners with the national authorities and stakeholders. This was accompanied by a complete integration of resources and decision-making. This reorganisation allows FEFANA to be fully effective across the EU-25, with regional representation possible through an up-to-date highly flexible network organisation. Platforms and network nodes are now available throughout the EU-25, allowing FEFANA member companies to optimise participation in representative structures throughout Europe while minimising resource investments.

One of the key principles of the new FEFANA is to avoid work duplication, thus improving efficiency across the European network. Working Groups and Task Forces are now organised at FEFANA level in an integrated structure with support from the staff at FEFANA office in Brussels or the national offices.

Priority setting and the allocation of resources are decided by all members at the annual FEFANA General Assembly, where all members have an equal say. Besides the obvious savings in resources, this new structure also offers medium and small size companies better opportunities to monitor and actively participate in the EU regulatory process.

Both the new Feed Additives and the Feed Hygiene Regulations required a re-consideration of the traditional membership scope of FEFANA. The Feed Additive Regulation now includes premixtures within its scope; their legislative fate is now closely determined by the additives authorisations. The Feed Hygiene Regulation considerably broadens the range of responsibilities and obligations on all feed business operators (i.e. not only the producers). As a result, FEFANA broadened its membership eligibility to all legal entities with corporate responsibility for a registered and continuous business activity in the manufacture, import or distribution of feed additives or premixtures in the European Union (including Norway, Switzerland and Iceland). Associate membership is also open to legal entities that are producers of feed additives outside the European Union without registered or approved EU-representatives.

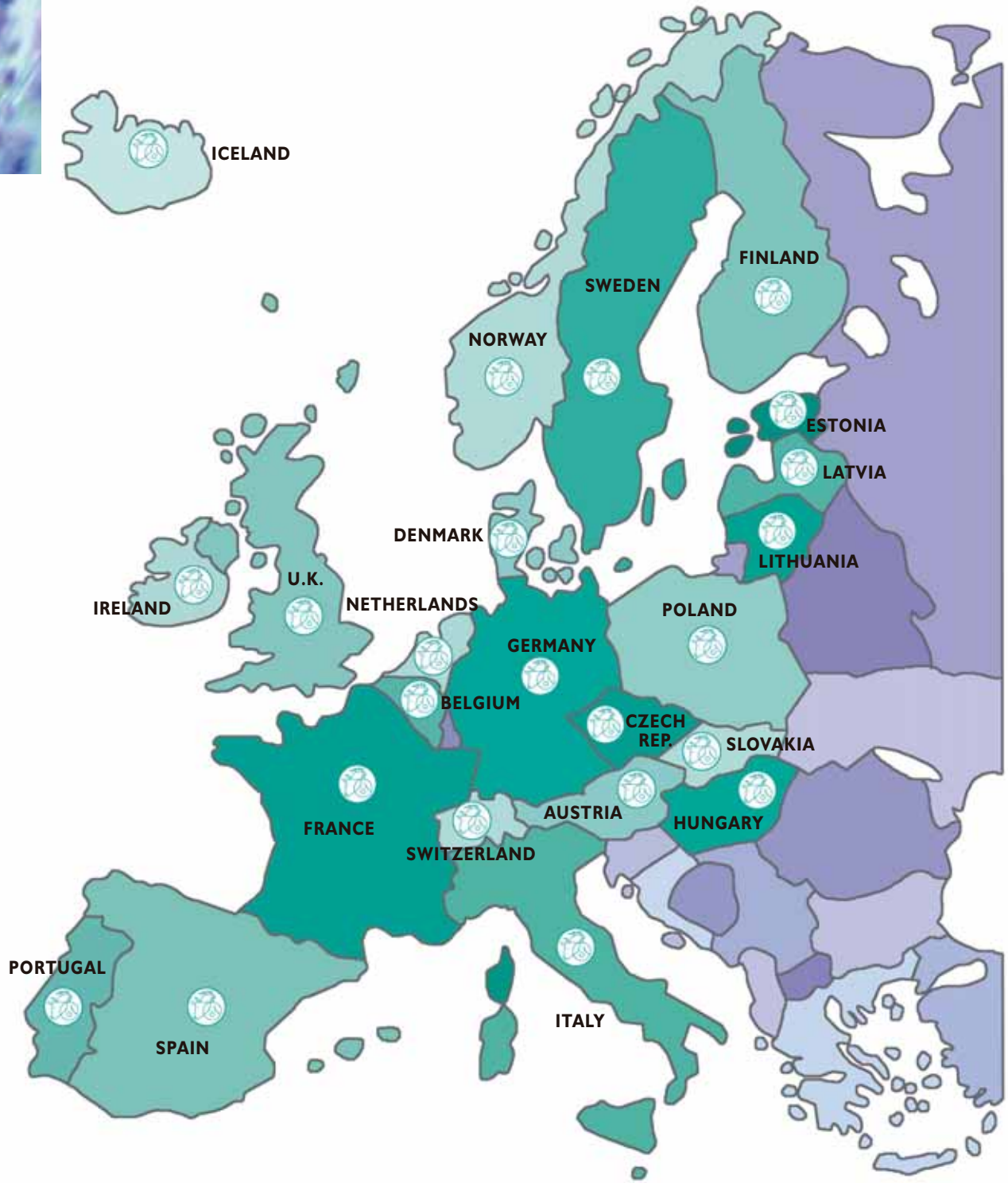
As is obvious from the latest membership list, the feed additive business is massively supporting this evolution of FEFANA. With now more than 70 member companies, FEFANA will continue to play a key role in the feed chain legislation.



New FEFANA Stucture

FEFANA Member Companies

ABNA	Delacon	Olmix
Addcon	Denkavit	Optivite
Adisseo	Deutsche Vilomix	Orffa
ADM	DSM	Pancosma
Agravis	Extra-Vit	Perstorp
Agrimin	Genencor	Phodé
Agroferm	Jadis additiva	Phytobiotics
Ajinomoto	Kemin	Phytosynthèse
Akzo Nobel	Kemira Oyj	Pre-Mervo
Alltech	Kemira GrowHow	Probiotics Intl.
Alpharma	Lactosan	Purac
Andres Pintaluba	Lallemand	Quaron
BASF	Lesaffre	Retorte
Béghin Meiji	Lohmann	Ropafarm
BFI	Lonza	Roquette
Biomin	Lucta	Sunvit
Bonapp	Luzenac	Sinta
Borregaard Lignotech	Manghebati	Symrise
Buteressence	Miavit	Syngenta
Ceva Nutrition Animale	Micro +	Syngenta Animal Nutrition
Chr. Hansen	Mitsui	Tessenderlo
CJ-Europe	Near	Trouw Nutrition
Crina	Novozymes	Volac
Danisco	Novus	
Degussa	Nutrinova	



FEFANA National Platforms

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

From the Operating Team

The Operating Team (OT) has become the nerve centre of the FEFANA organisation. The OT is at the forefront of FEFANA advocacy and communication with all the stakeholders, including of course the Authorities. Since the reorganisation of FEFANA, it reinforced links with the remote permanent staff. One of its fundamental roles is to make sure that the actions and positions developed throughout the FEFANA network are compatible each with the others, and in line with the strategic objectives defined by the Board and the General Assembly. It notably triggers the establishment of Task Forces whenever it is useful and ensures that, by this means and further consultation, all FEFANA members contribute to positions and actions. This is based on a very strong commitment of the high level regulatory experts who are appointed in the OT by the Board, including those who have been active on the OT for several years and those who have recently joined.

Guideline

Regulation 1831/2003 foresees the establishment of new guidelines for feed additives, to take into account the requirements laid out by this Regulation, notably the strong request for proportionality and predictability of the authorisation process. As a result of wide-scale preparatory work, FEFANA tabled a comprehensive guideline proposal well ahead the start of the decision-making process. The Commission released a draft guideline Regulation at the end of April 2005. This draft was commented upon by many stakeholders, including the European Food Safety Authority (EFSA) and FEFANA.

In order to secure the predictability of the assessment, FEFANA strongly supports the Commission view regarding the necessary sharing of responsibilities between the Risk Management and Risk Assessment : the guidelines must clearly be decided by the Commission and the Standing Committee. Practical details of implementation should then be contained in guidance produced by EFSA. Furthermore, the rules defined by guidelines should be organised in such a way that there is no room for misinterpretation by the applicants, the risk assessors or the risk managers.

FEFANA has established and presently maintains an intensive dialogue with the Commission and EFSA, aimed at establishing the following principles into the feed additives guidelines :

- the guidelines shall be proportionate and allow for a predictable review and approval process;
- the identity section of the guidelines shall be adapted to the type of authorisation (generic vs. holder-specific);
- the safety section of the guidelines shall be adapted to the nature and history of use of the substance;
- the efficacy section of the guidelines shall be adapted to the intended use of the additive (related to the category and functional group);
- existing uses and safety evaluations shall be taken into account;
- flexible rules for extrapolating safety and efficacy studies between related animal species / categories shall be established;

- the decision criteria allowing the applicant to determine which studies should be run shall be described in the guideline Regulation, while the technical and scientific details on how to conduct such studies shall be described in EFSA guidance documents;
- the list of animal categories shall be related to actual husbandry practises rather than to physiological considerations.

FEFANA is calling for the guidelines to be produced as soon as possible, without endangering their quality. They are urgently needed by the additives and premixture industry, not only to prepare for the registration of existing products by 2010, but also to enable new product developments (new authorisations and extensions), which currently are largely frozen due to the lack of clear guidance on dossier requirements from the Authorities.

M. Leclerc

Register 1831

Following the notification process, the European Commission published, on the 7th of November 2005, the first register of feed additives. FEFANA was involved in discussions preceding the publication of the register. The main topic under discussion during this preparatory work was related to the listing of products which were until now covered by "generic" entry (e.g. flavourings, vitamins, pro-vitamins and chemically well defined substances having similar effect) or which were newly covered by the Regulation (e.g. silage additives). Thanks to its commitment and the support of members, FEFANA's main arguments were taken into account, with special emphasis on listing of individual substances in the register for the additives in the technological, nutritional and sensory additives categories.

However, the Register as first published was not satisfactory, as there were some omissions, mistakes and even misspelling in this register. Therefore, the Operating Team has proposed to the FEFANA members to support their products and help the EC to come up with a reviewed and first complete register, which should then be regarded as a positive list of feed additives. Furthermore, although FEFANA understands that the current register is a starting point of the process, it is important to ensure that newly approved products and already existing products are handled in the same way in the register, in compliance with Article 9 (8). Keeping this perspective in mind, the FEFANA OT is currently working on a proposal to the Commission, which should be issued by mid - 2006.

P. Becquet

Feed Hygiene

On the first of January 2006, the Feed Hygiene Regulation entered into application, repealing Directives 95/69/EC and 98/51/EC. To help FEFANA members to implement this new regulation, a complete set of actions was undertaken :

- part of the OT workshop of the 20th of October was dedicated to explaining the regulation;
- a "Question and Answer" document was distributed;
- a Feature Info briefed members very concretely on transitional measures (notification and application) under Feed Hygiene Regulation. FEFANA has established three standard forms (notification, application, declaration) and recommends members to use them in order to keep a coherent approach to the application of Regulation (EC) 183/2005 transitional measures across the EU. These standard forms were also sent for information to Member States;
- a standard letter of information on the Feed Hygiene Regulation was sent to members and their operators for transport and storage of feed additives and premixtures. A standard form for application of these operators was also proposed;
- a list of contact points at national or regional authorities based in most European countries, useful for FEFANA members and operators in transport and storage.

A harmonized implementation of the Hygiene Regulation is the key to our industry. Amongst the two options available, our industry clearly prefers the pan-European over national implementation tools.

Our high level of commitment towards the implementation of this Regulation is evident through the Safety Assurance scheme that we developed in response to this Regulation : FAMI-QS (Feed Additives and preMIxtures - Quality System). This system is made up of two separate elements : a code and a certification system. These two parts are distinct and complementary: the code was designed as a supporting tool to the implementation of the Feed Hygiene provisions; the certification system is a means to obtain necessary recognition in the market place and to support national control authorities. Both modules are of course voluntary. Since the earliest stages, our industry made considerable efforts to co-ordinate these developments with downstream user safety schemes and stakeholder expectations. We have also actively contributed to the setting up of a co-ordination platform with the other feed "ingredients" supply industries, the European Feed Ingredients Platform (EFIP), to review wider quality assurance within the food chain.

H. Lionet

Working Groups (WG)

Amino Acids

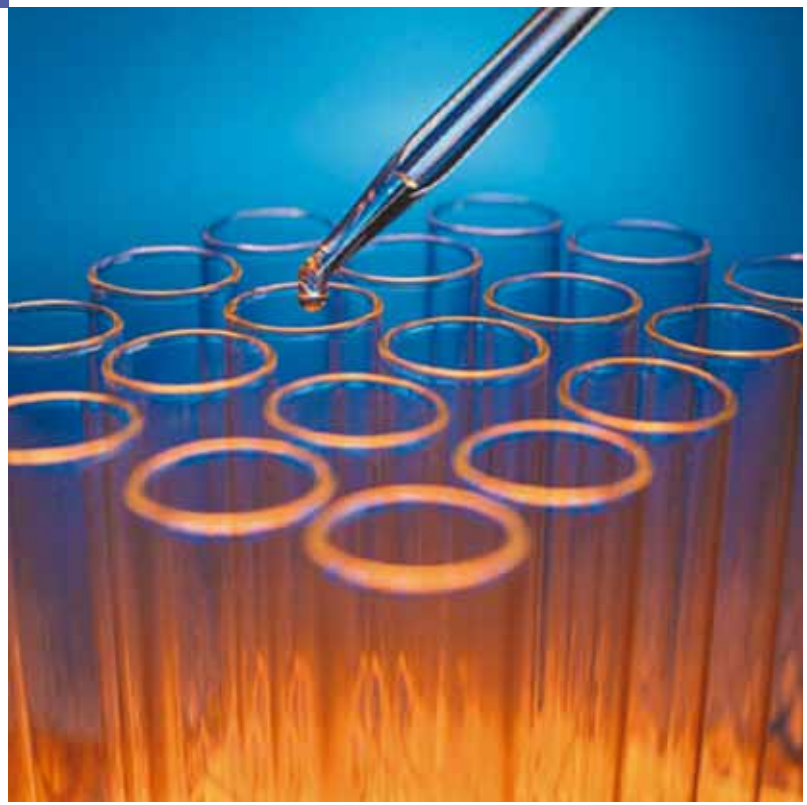
In the framework of the Regulation (EC) 1831/2003, much attention was given to the additional requirements of the amino acid registration process. So far, our efforts to get our products notified have been successful: all commercially important amino acids, their salts and analogues have been transferred into the new register. To date it is not clear what the guidelines and the guidance for the preparation of the registration dossiers will look like. Therefore, the uncertainty whether or not FEFANA members should go for co-ordinated registration is not yet decided. One of the main issues for the Working Group Amino Acids (WG AA) in 2006 will be to serve as a platform and a catalyst regarding the possible role of consortia in the amino acid registration process. Regarding the current and ongoing discussion about the scope of the GM Food and Feed Regulation (EC) 1829/2003, the WG AA believes that amino acids, including those produced by fermentation, are extensively regulated by Regulation (EC) 1831/2003, which will provide the necessary risk assessment linked to the use of modern biotechnology tools for their production. At the same time, the deliberate release of new feed additives would fall under the scope of Regulation 2001/18. This would be in line with the Council's recognition of White Biotechnology and the Union's Strategy for Europe on Life Science and Biotechnology. An evaluation of amino acids from hydrolysis has been and will be on the agenda. None of these products is on the notification list and it therefore needs to be checked how the respective producers are going to market their products.

Another important issue in 2005 has been the discussion of Net Energy (NE) systems in pig and broiler nutrition. Although there is no big impact of the NE system on broiler diet formulation, the impact in diets for growing pigs is enormous. Pig diets formulated to NE are more accurate in meeting the animal's energy requirement and at the same time tend to be lower in crude protein and higher in amino acid inclusion rates.

In consequence, NE systems drive up cereals content in pig diets and have a huge potential for reducing environmental pollution. Our efforts in promoting NE as the optimum energy system in pig nutrition will therefore be continued.

In the field of Organic Farming, to date all activities to get an opening for amino acids into this sector have failed. At present, the subject is no longer a priority objective for the WG AA, but some contacts to the stakeholders in this sector are kept open.

A. Petri



Analytical

The Working Group Analytical had a very active year with three meetings, a FEFANA Workshop on "Methods of analysis" (March), attendance to the two CRL workshops, and two CEN meetings in response to develop contacts and represent FEFANA at CRL (Community Reference Laboratory) and CEN (European Committee for Standardization) levels :

- CRL collaboration :
  FEFANA made a presentation at the 3rd Workshop (14-15 April 2005) on Feed additives and analytical methods - Flavourings, industry's approach to analytical challenges.

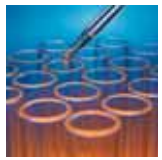
  We also presented the update on phytase project and the measurement uncertainty in the field of microbiology, industry's perspective at the 4th Workshop (5-6 October 2005).
  FEFANA also participated in the elaboration of the CRL guidance, to build up the Commission Regulation (EC) n° 378/2005, avoided the need for having a culture collection at the CRL but gave CRL access to existing producer collection. We had a meeting for method of analysis on vitamin additive per se.

- CEN collaboration :
  FEFANA participated in the two meetings of CEN/TC 327 that had phytase and probiotics on the agenda 13 June and 18 November 2005.
  We are reaching the final stage of harmonization for enumeration methods for the authorised probiotic, identification method for yeast, and analysis of phytase.

  The probiotics methods package was initially included in a pan-European DG research project. Besides working towards the standardisation of the method finalised, our experts are pursuing efforts in order to complete the method that still required further work, in particular typing methods for Bacillus, Enterococcus, Lactobacillus, Pediococcus etc…

This Analytical WG is a steering group supervising different Task Forces : Phytase, Xylanase, Plant extracts, Carotenoids, Vitamins, Mycotoxins and Uncertainty. A very important topic on the Working Group's agenda will be the development of the concept of uncertainty for methods of control, what is expected to have broad consequences on the practicalities and harmonisation of control practices. Openness and close collaboration with the CRL will be pursued.

G. Bertin



ARAP

The Working Group Aromatic and Appetising Substances (WG ARAP) had an active year with four scheduled meetings dealing primarily with the proposed changes in feed additive legislation. A consortium set up in 2004 succeeded in notifying over 2000 flavour ingredients to the European Commission (EC) and to the European Food Safety Authority (EFSA).

The progress of the notifications has been carefully followed by the ARAP and many ingredients were successfully notified. However unfortunately late in 2005 it became apparent that a significant number of flavour ingredient notifications had been suspended by the EC and this now must be vigorously pursued in the future.

Notification of flavour ingredients is only the first step in the new feed additive legislation. Consequently a considerable amount of time has been devoted to developing procedures for the final registration of flavour ingredients. Initial information suggests that this could cost as much as €5,000 per dossier. For permanent registration of 2,000 ingredients this amounts to €10,000,000. This is an amount of money which could not be easily funded by the industry, even in a consortium.

A possible registration strategy would be to follow the European Flavour Association and register ingredients in groups. Therefore it was decided to seek a closer collaboration with the European Flavour and Fragrance Association (EFFA) to ensure that there are no great conflicts or variations in the respective registration approaches. A very constructive dialogue was opened with the Commission in this area and will be pursued.

A small sub-group of the ARAP will compile some model registration dossiers in order to see what information is readily available. A problem here however is the development of new guidelines, which is not yet completed. This is of great concern to the ARAP members and is being closely followed. Another sub-group of ARAP members have formed a TF for Flavour Analysis and their results will have a direct impact upon the registration procedures followed by the WG ARAP.

The future programme will require close monitoring of the notification of outstanding flavour ingredients and the development of registration procedures in line with the new guidelines.

Dr. C. Adams

Carotenoids

As a consequence of the SCAN opinion on canthaxanthin, which was based on the concept of MRL (Maximum Residue Limit), the Working Group developed an alternative assessment system based on intake. It was proposed by the FEFANA Board to use this new intake-based system for all feed additives. Modifications of the current MRL system were proposed based on the dietary habits of the population in the EU. A demonstration of the new system was provided using data from the UK. In order to enlarge the database and to implement the new system into all FEFANA feed additive groups, a TF Intake was established which took over this part of the work

Following the limitation of the maximum permitted level for canthaxanthin, the European Food Safety Authority (EFSA) was requested to re-evaluate the safety of carotenoids. The WG had provided EFSA/Feedap (Panel on additives & products on substances used in animal feed-EFSA) with dossiers dealing with canthaxanthin (establishing MRLs) and all other carotenoids. EFSA is expected to publish a safety assessment concerning astaxanthin.

The Food Standards Agency (UK) is working on harmonized analytical methods for astaxanthin and canthaxanthin in feed. The WG established a TF Analysis Carotenoids, whose mandate is to develop when possible a unique analytical method for each carotenoid (pure product and in feedstuffs). When available, these methods will be published on the FEFANA website. Furthermore the TF was asked to evaluate the FSA (or EFSA) methods as soon as they are published.

Finally the WG participated to the establishment of the register for feed additive, with regards to carotenoid products.

C. Günther

Enzymes

The Working Group Enzyme pursued its activities regarding the switch from temporary to permanent authorisations under Directive 70/724. The difficulties encountered highlighted the need for clear procedures, both from applicants and authorities' side. Hopefully, good sense has prevailed from all sides on this delicate question. The transition from Chapter IV (provisional approvals) to Chapter III (approval without a time limit) is now considered as solved - especially since the publication of the Register.

However, enzymes are not assigned to the 'zootechnical' category in the Register created according to Article 17 of Regulation 1831/2003. This is likely to create problems as soon as new authorisations are granted under the 1831/2003 system. This issue is being addressed through an overall dialogue with DG SANCO on the structure and contents of the Register.
Overall, it is felt that the WG has an opportunity to re-define its goals and activities, due to the change from product-oriented to horizontal management of feed additive regulatory issues and in the context of the new FEFANA organisation. This will be done at the beginning of 2006.

M. Leclerc

Micro-Organisms

The Working Group Micro-Organisms had an active year with two meetings. It finalized the probiotics booklet "Probiotics in animal nutrition" built up in close collaboration with AWT Germany, Alltech, Chr-Hansen, DSM Nutritional Products, Kemin, Lallemand, Lesaffre and Volac. This booklet, available from Fefana, provides a good insight into the rationale of using probiotics in animal nutrition.

The WG has developed a close collaboration with CRL (Community Reference Laboratory), to establish a procedure to give access to the international culture collection and to develop the concept of "Uncertainty of Measurement" applied to micro-organisms (particularly for yeast).

We also developed close collaboration with CEN (European Committee for Standardization), to finalize the validation under the CEN/ISO standard of methods for enumeration for 6 probiotics and to finalize the validation for PCR yeast evaluation as a technical standard.

The WG Micro-organisms has issued 2 position papers : one concerning QPS (Qualified Presumption of Safety) and the other concerning micro-organisms antimicrobial resistance and its transferability.

This WG has already worked on the additive guidelines, and continues to review it.

Next year the WG Micro-Organisms will react to any European Food Safety Authority (EFSA) position on QPS and antimicrobial resistance, continue to push the Uncertainty of Measurement concept as applied to all micro-organisms methods, and finalize the harmonization of typing methods for the 6 micro-organisms using PFGE.

G Bertin

Premixtures

The various new Regulations in the feed area (additives for use in animal nutrition, feed hygiene regulation, etc.) have a very significant impact on the placing on the market of premixtures. Premixtures have regularly been at the centre of FEFANA reflections while taking position on these various Regulations. The scope of the new Feed additives Regulation clearly covers premixtures; the regulatory fate of this category of products being now closely related to that of additives. Recognising that many of its members were involved in the production of premixtures, FEFANA ascertained that this product group should be within its organisational and membership structure. This year, two meetings were organized to re-activate the premixture WG, to raise member's awareness on upcoming challenges and to identify its priority activities.

The members of the WG Premixtures are coming from different countries and companies, and as such the group is able to see things from different perspective. The main task is to steer and influence regulators in such a way that legislation becomes very clear, specific, realistic and applicable. We all have a common interest in bringing safe products to the market. There is a clear role for the FEFANA WG Premixtures on how we as manufacturers and users of feed additives would prefer to put our products on the market with clear and relevant information for our customers. That it is a very interesting period for us, with agenda items like the definition of a premixture versus complementary feed, the publication of the feed additive register according to Regulation (EC) 1831/2003, the label requirements for feed additives and premixtures, hazard labelling of premixtures, and new amendments on Directive 2002/32 regarding undesired substances.

P. Fidder

Silage Agents

The inclusion of silage agents in the new additive regulation (EC) n° 1831/2003 had a considerable effect on the regulatory status of this category of products. This resulted in intense activity amongst the companies concerned.
The organisation of the notification procedure was one of the priority areas. The operators decided to join efforts in a specific notification consortium, which grouped ten companies and successfully notified more than 80 additives.

Important options retained by the WG and the Commissions were that :

- the micro-organisms used for silage agents should be listed in the Register with their own international standard collection number while for enzymes, only the activity should be mentioned, with no reference made to the strain;
- formulated silage products were not to be listed in the Register, since according the Additive Regulation, they are "a premixture of additives", which can be freely put on the market as long as each of their ingredient is authorised;
- registration of formulated silage agents will be possible, as zootechnical additives, provided the product demonstrates a relevant effect.

The silage additive list has been reviewed in close collaboration with the Commission before the publication in the Register; FEFANA insists on having only one silage agents list and not having some products listed in the preservative category with no reference to silage agent functionality (9 products).

Some MS have previously had National registration systems for silage additives. In view of the fact that these additives are now covered by Regulation 1831/2003, these systems would appear to be inappropriate, creating artificial trade barriers and discrepancies between countries. The WG is evaluating the situation across the EU with the aim to see these systems leaving the floor to the new EU regulatory regime established by Regulation 1831/2003.

The group also objected that the silage agents would be evaluated under a specific set of guidance, that EFSA started to prepare. As any other type of additives, they should be covered by one single set of -new- guidelines.

Early next year the WG Silage will be involved in the implementation of silage agents under additive regulation 1831/2003 within all member states.

G. Bertin

Vitamins

During the last two years the WG has been engaged in several major FEFANA issues :

Transition from EU Directive 70/524 into EU Regulation 1831/2003, and the subsequent establishment of a complete positive list of all commercially traded substances, has led to coordinated WG approach concerning the notification of vitamins in 2004. Nearly all industrial vitamin products were thus covered, as far as they were known and that a Fefana member took responsibility for them. Nevertheless, recently published versions of the official EU Register are still lacking some well-established substances. The industry is currently in the process of notifying the EU Commission of these findings. In view of these facts, it has been decided to continue the FEFANA Vitamin listing with an updated 2006 edition in order to maintain an industry point of reference.
Focus will soon be shifting to the expected new guidelines, which will be instrumental for dossier preparation during the next phase of the EU re-authorisation process. It is hoped that the extensive FEFANA contribution will bear fruit and allow for a pragmatic registration of the Vitamins that are on the EU market.

GMO/Biotechnology Issues continued to require careful monitoring and follow-up. The general interpretation of the current GMFF Regulation (1829/2003) by FEFANA and the Standing Committee does not see vitamin products derived from "contained" industrial fermentation as being "in the scope" of this legislation, and these products are thus excluded from mandatory GMO labelling. However, this view is by no means shared by all Member States; more wide-spread science-based lobby work will therefore be required in order to advance understanding of "White Biotechnology" at all levels.

K. Collins

Task Forces (TF)

Analysis Carotenoids

A TF grouping the companies LOHMANN, DSM, ADM and BASF was set up in the context of the ongoing risk assessment of carotenoids. Risk-based limits are indeed of limited relevance if not supported by reliable analysis methods

The TF is open to further concerned companies.

Contact was made with the Food Standards Agency (UK) in November 2005, which sponsored a carotenoids analysis project. They sent back an outline of a method for the determination of Canthaxanthin, Astaxanthin and other carotenoids in fish feed and poultry feed. This method was used within a collaborative study starting in May 2005. Due to the fact that the evaluation is not completed yet, we aspire to renew contact in February or March 2006 and to ask for the final report.

A DSM-BASF harmonized spectrophotometrical method for the determination of Beta-carotene in product forms was submitted in July 2005 to the Working Group Analytical. In the next step, further discussions with CRL will take place. A BASF-DSM harmonized method for the photometrical determination of Astaxanthin in product forms was completed. This method was used within a ring-test during 2005. The evaluation will be finished in January 2006. Submission to WG Analytical and arrangements with CRL are planned within 2006.

Further objectives during 2006 : completion of a harmonized method for Lutein, Zeaxanthin and Capsanthin in product forms and completion of a collaborative trial. Preparation of harmonized methods for Lutein, Zeaxanthin and for Capsanthin in premixtures and feeds. Submission of a harmonized method for the determination of Astaxanthin in premixtures and feeds to WG Analytical. Development of harmonized methods for Canthaxanthin, Citranaxanthin and Apo-8-Ester in product forms.

D. Weller

Analysis Flavourings

Originally the Task Force Flavour Analysis was established in order to evaluate the feasibility of harmonised methods for the analytical control of approved botanicals. During the first meeting of the TF in March 2005 it was decided to extend the mandate and to include also the chemically defined flavourings. The first task of the group was to prepare a presentation intended to be shown at a CRL meeting in April. In this presentation, the particular problems of flavour analysis, especially with regard to the analysis in final feed and to traceability of plant derived flavour "compounds" (e.g. plant extracts), was pointed out in order to alert the authorities to the issues of uncertainty of flavour analysis in general. As a conclusion, the development and application of harmonised methods for volatile chemically defined flavourings seem possible for the feed additive as such and with some limitations also for the analysis of the additive in premixtures; for non-volatile chemically defined flavourings greater difficulties have to be expected and the way forward is still unclear at this stage.

In view of the huge number of individual materials in the functional group "flavouring compounds", the TF members decided to start with the development of a general method which allows the analysis of a great number of substances at the same time. Meanwhile such a general method for the determination of all volatile chemically-defined flavourings has been worked out. The feasibility is being checked by the majority of the TF member companies, using 13 different flavourings that are typical of different substance classes, polarities and retention times. In parallel, the group is collecting analytical methods for non-volatile flavourings and for botanicals.

The objectives for the next year are to present a general method for the determination of volatile chemically-defined flavourings to the CRL, and to develop methods for the analysis of non-volatile flavourings and botanicals products.

M. Seemann

Method of Analysis - Vitamins

The Task Force Method of Analysis Vitamins finalized the first part of the collection of analytical methods for the determination of vitamins in commercial feed additives products. The brochure is available from January 2006 and disseminated to the industry, governmental bodies in administration and analysis as well as to private laboratories. CRL (EU Joint Research Centre) was contacted in September 2005. The aim and the work of the TF were presented and well accepted. In 2006 we will continue collecting methods for vitamin determination in feed and premixtures, with a view towards publishing a second brochure.

R. Blum

Intake

The Task Force Intake has been re-launched in 2005, following significant support from members in the General Assembly of FEFANA in June 2005. The mission of this TF is to promote and develop a new approach for exposure assessment for feed additives, in the context of the new feed additives guidelines. This also is in relation with the need for the European Food Safety Authority (EFSA) to align the exposure assessment methods used in different assessment contexts.

In 2005, the TF members confirmed the validity of the exposure method developed by FEFANA over the last two years through review by an external expert. The method is based on consumption data originated from the United Kingdom. FEFANA has also triggered reflection and co-ordination with food chain partners, notably on the food side.

The objectives for next year are mainly related to the promotion of the new exposure assessment methods to the EFSA Scientific Committees, as well as with Member States. When possible, and in co-operation with other organizations working on the same subject, the TF Intake will try to improve its method, notably by ascertaining the European value of the consumption data base that underlies it. However, despite room for progressive improvement as general know-how in this field increases, the FEFANA members are convinced that the method as it now stands could already serve as a valid tool and should be used by EFSA.

P. Becquet

Labelling

In line with the implementation of Regulation 1831/2003, the Task Force Labelling members have identified different points which are creating practical difficulties in the labelling of feed additives and premixtures, e.g. translation into 20 languages for companies active EU-wide and the amount of information to be placed on the label. On that basis, the TF considered that, although the information should reach the users, the label should and could not be the unique source of information. Therefore, the TF assessed whether the information proposed to be on the label acts on traceability, use of the product by workers (premixture manufactures or feed mills) or farmers, or is of use (valid for any batch) for more technical people such as nutritionists. The main objective of such a split is to ensure that valuable information is delivered to the correct target person in an appropriate format. This pragmatic approach combines a realistic management of the flow of critical information to the user, the need for transparency, and the critical need for keeping labels focused and efficient.

The TF Labelling finalized its documents and strategy for labelling of feed additives and premixtures in 2005. In 2006, the TF will develop activities to promote this new concept to the European Commission and the Member States, with a view to implement different possibilities of informing the user of the products. Furthermore, the TF will follow up the procedure for the new regulation on marketing of compound feedingstuffs and will provide comment on the Questionnaire launched by the EC on this topic.

P. Becquet

Mycotoxin Inactivators

The introduction of limits for the main groups of mycotoxins in Europe may help to protect farmers against obtaining grains and feeds of very poor quality. However, they will not protect against the continuously observed health problems of animals in the field caused by moderate levels of fungal toxins, nor against problems caused by masked (i.e. non-detectable) mycotoxins and their synergistic effects.

The overall objective of the recently founded Task Force Mycotoxin Inactivators is to overcome the predominant political resistance against mycotoxin deactivating products by highlighting their need in the fight against mycotoxin-related problems caused by technically unavoidable contaminations, masked mycotoxins and synergistic effects.

Planned activities in 2006 aim at the agreement of the Commission and the European Food Safety Authority (EFSA) to open a new functional group in 1831/2003. A report will be prepared by the TF members in order to supply the decision makers with a scientific justification for this functional group. The outcome of already planned individual meetings and a workshop with decision makers will be crucial for reaching the overall goal.

D. Schatzmayr

Nutritional Supplements

Created in June 2005, the FEFANA Task Force on Nutritional Supplements has met three times. The purpose of this TF is to elaborate a FEFANA proposal for a harmonised framework on nutritional supplements for animals.

The facts on nutritional supplements at the origin of the TF were as follows :

- various national situations in the EU countries,
- disagreement of the industry with a recent Belgian draft Royal Decree notified to the Commission end-January 2005 concerning the placing on the market and the use of nutritional supplements,
- an increased need for a specific harmonised framework.

The TF first defined the basic concepts by identifying examples of products forms, means of administration and nutritional objectives.

Considering existing formal and informal rules at national levels, the proposal submitted in 1997 by the European Commission (COM (97) 408 final and COM (98) 484 final), the existing EU legislation regarding additives for use in animal nutrition (Regulation (EC) No 1831/2003) and NRC maximum tolerable limits, the TF has begun preparing a FEFANA draft paper. This paper would cover the scope and definitions of Nutritional Supplements, requirements concerning composition and use, specific provisions on additives used, requirements concerning the placing on the market (including hygiene rules), labelling and packaging. The TF has now to complete, correct and finalise the content of this paper.

The TF is also considering how the fate of Nutritional supplements could be best harmonised at EU level, including regulatory and voluntary (e.g. a code of good practice) options. Once this has been established in draft form, the TF will also have discussions with other feed chain associations at national and EU levels.

J. Mélédié

Phytase

FEFANA decided to set up a Task Force in order to assess the feasibility of harmonizing Phytase determination in feed samples. This involved the five FEFANA members, Alltech, BASF, Danisco, DSM and Novozymes.

The underlying requirements of a harmonised method are to have identical assay conditions for all phytases on the market and the same unit definition.

The working program has been divided into two main phases :

- firstly, the internal FEFANA work;
- and secondly, the "Collaborative external work" and the ring test.

The internal phase (from September 2002 to September 2004) consisted of evaluating the AOAC (Association of Official Analytical Chemist) method as a standard method. The TF drew the conclusion that the published method is not applicable to all EU existing Phytases. According to the different laboratories' expertise, it was decided to improve the method and adapt it in order to have it harmonized.

As soon as the initial program was finished and a positive response was obtained, the main objective was to carry out a "Ring analysis" in order to test the method ("Collaborative external work" - from September 2004 to September 2005).

FEFANA contacted the CRL (Community Reference Laboratory) and as both parties immediately saw a common interest, a close relationship developed. The CRL proposed to adapt the IUPAC (International Union of Pure & Applied Chemistry) standard procedure. CRL and FEFANA worked out together a validation procedure, inspired by IUPAC, but adapted to our specific field.

At the same time, FEFANA called for participating laboratories. We finally had a collection of 14 laboratories : 6 belonging to the NRL (National Reference Laboratory) (Austria, Denmark, France, Germany, Hungary and Switzerland); 1 outside of the EU (Canada Food Inspection Agency, Ottawa); 2 private laboratories (France and Germany) plus 5 company labs (Alltech, BASF, Danisco, DSM and Novozymes).

The two separate statistic evaluations on IUPAC and FEFANA resulted in the same conclusions regarding reproducibility, repeatability and precision of the method. After three years of work, the deserved result was attained: a harmonized phytase control method.

This harmonized method has been submitted to the CEN (European Committee for Standardization)/ISO (International Standardisation Organisation) to be entered into the official standardization procedure, what is now well in the pipe. A joint publication by FEFANA/CRL in an academic journal is also planned.

G. Bertin

Processing Aids

The Task Force was created as a response to the issue raised by the proposal of draft guidelines for feed processing aids by the French AFSSA (Agence Française de Sécurité Sanitaire des Aliments).
The TF met in September and November 2005, in order to make an inventory of feed processing aids, look at existing risk evaluations, and come up with regulatory recommendations. The work of the TF was finalised with the following conclusions :

- a very limited number of substances are currently used as processing aids in the manufacturing of feed additives or feedingstuffs;
- these substances are covered by safety evaluations;
- therefore processing aids do not presently need to be further regulated at EU level.

M. Leclerc

REACH

On 29 October 2003, the Commission presented its proposals for a complete review of the EU's chemical substances policy. The proposal sets up a system for the Registration, Evaluation and Authorization of CHemicals (REACH) and will largely amend Directive 67/548/EEC.

In this proposal, thanks to early dialog with FEFANA, feed additives were exempt from the scope of title II "Registration" and consequently from "Evaluation", and from Title VII "Authorization" of chemical substances.
Nevertheless, they are not exempt from the general scope of the regulation under Title I. The consequence of this partial exemption is difficult to evaluate. FEFANA decided to lobby during the first reading in the European Parliament in order to secure an appropriate treatment of feed additive in this much discussed regulation.

During the first reading at the European Parliament (17th of November 2005), no doubt in part due to lobbying by FEFANA, there was a positive vote on an amendment for the full exemption of feed additives from the general scope of REACH. This amendment was subjected to final negotiations just before voting and, in this extremely political and confused situation, FEFANA succeeded in securing the exemption of feed additives from provisions in Titles II, III, V and VI. The European Council finalise a political agreement on the 14th of December 2005. In this proposal, feed additives are exempted from Titles II, V, VI and VII. This in practice means that an overlap between the REACH and the Feed Additives Regulation, and resulting additional burden for the operators, was successfully avoided.

Monitoring and actions, if necessary, will be continued during the second reading in order to maintain this positive situation.

H. Lionet

Tolerance test

A Task Force was created in order to define the goals of the tolerance test required to demonstrate product safety under Regulation 1831/2003, its scope, and the conditions for performing the test.
The group met in September and November 2005, and finalised its work in January 2006.
The view of the task force is that the tolerance test addresses a concern linked to a possible accidental, temporary over-dosage of a feed additive at the premixture or feedingstuff manufacturing premises, mainly from a zootechnical point of view. The duration of the test, as well as the parameters to monitor during the test, shall take this purpose into consideration. Additionally, it was felt that flexible rules allowing the extrapolation between related species or target animal categories should be established.
FEFANA is in active dialogue with DG SANCO and the European Food Safety Authority (EFSA) with regards to a more global framework of the incoming new feed additive guidelines, and on the best way to look at target animal safety in general.

M. Leclerc

Undesirable Substances

Due to other priorities, the Task Force Undesirable Substances had no meeting this year.
Next year the TF Undesirable Substances will be reactivated.

G. Bertin

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Georg Kau (President)	DSM
Hadden Graham (Vice-President)	ABNA
Franz-Josef Schöner (Treasurer)	BASF
Joop van Schaik (Honorary President)	FEFANA
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