Activity Report 2011-2013

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In 2013 FEFANA celebrated its 50th Anniversary, a unique opportunity with a number of networking initiatives to highlight the role of our industry in the feed and food chain. At the occasion there were wider discussions of trends and issues of relevance not only for the FEFANA membership but also with regards to the EU and national authorities and other relevant stakeholders. One key concept was the central role that FEFANA has to play not only at European level, but also internationally: our association has to be not only a player but also the leader of the European industry of Specialty Feed Ingredients and their mixtures, being the global reference for quality and continuing working to create value for innovation.

Many of the activities of the past three years are linked - but not exclusively - to the implementation of Regulation (EC) No. 1831/2003 on feed additives, from the follow-up on the re-authorisation process to the establishment of the new category of mycotoxin binders, on which FEFANA and member companies had worked relentlessly. With the re-authorisation process we have identified a number of issues some of which we have to focus on in the future as you can read in dedicated sections in this report.

“FEFANA aims at a strong and balanced EFSA. Direct experience with the re-authorisation of feed additives has put us in a privileged position to work on areas that need improvements, especially in terms of refining risk management and risk assessment options. We urge to bridge the real assessment with the regulatory aspects of products, and the risk management to lead towards pragmatic decisions to aid up EU industry competitiveness and innovation.” (Didier Jans – FEFANA Secretary General)

Innovation being a core value of FEFANA members, our industry has been involved in a number of European and International activities such as Organic Farming and Sustainability. For example the association helped rationalise the life cycle organic production legislation in line with parallel EU legislation in this area and it has been called for greater involvement on projects on Sustainability and on Convergence of Regulatory Principles in different regions of the world.

“While our industry acknowledges the necessity to adapt our products to local markets and to specific needs in the EU and in different regions of the world, FEFANA membership strongly believes that it is vital to look for common requirements to ensure products are safe, effective and of quality, without adding unnecessary burdens bringing no further safety.” (Marco Bruni – FEFANA President)

On this international landscape the increasing role of FAMI-QS – as facilitator of global trade of Specialty Feed Ingredients and premixtures - is growing. FAMI-QS has positioned the European industry on the global market creating a benchmark for others to follow, which was not possible building up on industry self-reliability. It has made remarkable progress in the recent years. All significant developments were possible because of the efforts of all members of the FEFANA membership and staff, as well as the fruitful collaboration with other stakeholders and the EU Member State authorities. We are particularly thankful to our National Platforms through which FEFANA made her voice heard across Europe, reinforcing the coordination and cooperation with the Brussels-based activities.

We thank you all and we hope you will enjoy reading this report.

Didier Jans Marco Bruni
FEFANA Secretary General FEFANA President
The year 2010 ended on a high note with the submission through the Consortia that FEFANA promoted of dossiers covering over 1000 feed additives (see Table 1 for more details). These are now progressively being evaluated by European Food Safety Authority (EFSA) for re-authorisation, a key step in the roadmap outlined by Regulation (EC) No 1831/2003 on additives for use in animal nutrition. FEFANA activities have since shifted towards actions dictated by the re-authorisation process. The evaluation phase of the dossiers submitted by our members through the Consortia is still ongoing and its completion might take a few more years. The various dossiers are at different stages in the re-authorisation process: some feed additives have already been re-authorised with new conditions; for some others, opinions are just being published; whilst many more are still under evaluation (see Table 2 for a complete overview).

FEFANA acknowledges the huge task undertaken by EFSA with the re-evaluation of feed additives. However, we believe that the system needs improvements to be more efficient and smooth going. We can certainly identify a number of issues from the re-authorisation process which has led to higher workload without bringing any concomitant food safety measures. Rules have been sometimes modified during the process and applied either retroactively or inconsistently, thus not allowing adequate transparency and predictability of the process. Guidance has been interpreted in sene stricto instead of being considered as what it should be - an orientation. Questions have been posed without the necessary clear background, thereby leading to poor responses. Also it would appear that the Authority has encountered quite a number of difficulties in addressing the aspect of the legislative requirements for the specific applications and products, however within the current system, we were not offered real and concrete opportunities. Furthermore, it remains unhelpful that the boundaries between risk management and risk assessment are not as clear, leading to poor predictability. The launch in 2013 of EFSA guidance document regarding the preparation of dossiers for the 10-year renewal of authorisations could be seen as an example: whilst we understood that with this self-task EFSA FEEDAP Panel aimed at providing further support to the applicants in the preparation of their dossiers for renewal, to our understanding Regulation (EC) No 1831/2003 does not require complete re-evaluation of additives every 10 years. Article 14 instead requires for a renewal process that would verify that the additive on the market had not been modified to the extent to pose a feed safety concern and that no new information may lead to the need of a re-evaluation. We believe that in this circumstance EFSA has misunderstood the intention of the legislator but we believe that there is still room for the risk managers and risks assessors to coordinate and clarify the issue. Full cooperation amongst the EU bodies and relevant stakeholders will be vital in the coming years to ensure a more successful risk analysis and to allow safe products on the EU market.

### Table 1

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>N° OF ADDITIVES</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TECHNOLOGICAL ADDITIVES</td>
<td>113</td>
<td>11%</td>
</tr>
<tr>
<td>SENSORY ADDITIVES</td>
<td>862</td>
<td>85%</td>
</tr>
<tr>
<td>NUTRITIONAL ADDITIVES</td>
<td>39</td>
<td>4%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1014</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>CONSORTIUM</th>
<th>N° APPLICATIONS</th>
<th>N° OPINIONS</th>
<th>N° REGULATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACIAC (organic acids)</td>
<td>10</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>AMAC (amino acids)</td>
<td>4</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>FFAC (flavourings)</td>
<td>58</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>HYFAC (hygiene of the feed chain)</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SILAC (silage additives)</td>
<td>7</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>TREAC (trace elements)</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>VITAC (vitamins)</td>
<td>14</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

Note: figures updated at 31-12-2013
Approval of the first Mycotoxin Inactivator

This success story was backed by the view of member companies who, with FEFANA support, developed a strategy to bring mycotoxin inactivators to the market and led to this despite a number of difficulties encountered since early 2005. Close cooperation between the companies and FEFANA was fundamental to this success but it also depended on discussions over a number of years with the European Commission and the Member States. This goes to show that FEFANA members are keen to take on the EU institutions’ call for more research and innovation. However, inefficiencies in the registration process seem to be a drawback as there appears to be quite often unnecessarily complicated pathways to bringing innovative products to the market. Following the opening of the category of mycotoxins’ inactivators in May 2009, an authorisation was first granted in 2013 to “Bentonite” as mycotoxin inactivator for poultry, pig and ruminants.

This was the first ever additive authorised under this functionality and draws attention to these products demanding an appropriate legal positioning.

The use of Article 13 of Regulation (EC) No. 767/2009 - “claims on feed materials” - was for a while a pragmatic means to cope with the uncertainty in the decision-making process, but one can now expect that the situation will evolve, both from a market and also legislative control points of view.

New consortium on Hygiene of the Feed Chain

Controlling contaminations by micro-organisms in feed might be challenging and our industry felt the need to offer innovative solutions to the feed chain. In July 2011 FEFANA launched a new consortium - HYFAC EEIG - focusing on a new range of feed additives which favourably affect the hygiene of the feed chain. The aim of the new consortium is to secure, through coordinated applications dossiers, the authorisation on the EU market of an important range of new products able to contribute to the reduction of the impact of microbiological contamination in the feed chain.

Withdrawal Regulations

Between 2012 and 2013, the Commission published two implementing Regulations on the withdrawal of certain feed additives. These Regulations were the consequence of the fact that no applications for their continued authorisation were submitted before the deadline of 8 November 2010. Obviously, if applications for these products are submitted, the fact that they were Regulations withdrawing the products from the market is inconsequential especially if they are assessed to be safe and meet the functional group’s activities for which the application was intended.

FEFANA welcomed these Withdrawal Regulations as a significant step forward for the credibility of the whole re-authorisation process.

With this in mind, we urge the EU institutions to publish as soon as possible the withdrawal regulations for the orphan feed additives still remaining on the market.
The distinction between feed additives and feed materials has critical implications for the placing of these products in the European market. Making the wrong choice can have severe legal and practical consequences for both the producer and user of a product. For this reason FEFANA felt the need for a Classification Tool aimed at differentiating feed additives from feed materials.

In fact the legal status of any type of feed in the EU is mainly determined by the definitions contained in Regulations (EC) No. 1831/2003 on feed additives and (EC) No. 767/2009 on the marketing of feed. However operators and control authorities have faced difficulties to apply a consistent interpretation of these definitions in a somehow complex legal environment.

Launched in December 2011, the classification tool aspired to support the feed business operators and the competent authorities to have a common understanding of a given substance and to help document their assessment.

The tool on the basis of answers to a number of straight and precise questions categorizes the product in question as either feed additive, feed material or a ‘functional feed ingredient’. In addition to its use as a macronutrient or as a carrier, a feed material may also be used in order to perform one of the additive functions as defined in Article 5 of the Regulation No. 1831/2003.

While this distinction does not exist in the EU feed legislative framework, it corresponds to a practical reality: these products are close to the additive concept, while being legally defined as feed materials. Hence the need of a classification tool. Furthermore, it still remains their sole responsibility to classify products that they place on the European market as the legal obliges.

The tool is available in several languages and further details on the tool can be found at the FEFANA website with the Classification Tool itself.
In addition to a number of measures to rationalise and bring into line relevant parallel legislation on animal nutrition, Commission Implementing Reg. (EU) No 505/2012 amending the Organic Farming legislation also extended the list of ingredients that may be used in organic feed production.

For feed additives to be introduced in the annex of this Regulation, a request must first be submitted to a national Competent Authority, who would act as a ‘rapporteur’ – forwarding such a request to the European Commission and Member States’ experts for assessment.

FEFANA has worked closely with the European Commission to develop an application form to submit applications to the authorities for substances to be considered for use in organic production. The application package is completed by a FEFANA Guidance to help companies fill in the form and a List of contacts of Competent Authorities in the Member States.

Principles for Labelling of Feed Additives

Regulation (EC) No 1831/2003 provides some general and specific requirements for the labelling of feed additives and premixes.

While the nature of the information required might have been clear in the legislation, practically some of them are subject to misinterpretation as noочка nothing nor laws were defined in that legislation.

This has left a certain degree of uncertainty for the operators and control authorities. Labelling rules for feed additives in feed are covered by Regulation (EC) No 767/2009 whilst labelling of feed additives is set out in Regulation 1831/2003. With some inconsistencies and other provisions it then becomes impractical to address some of the common issues in both legislations. In addition, within the framework of the re-authorisation of feed additives, additional labelling requirements adopted by the DG SANCO Standing Committee on Animal Nutrition - as “other provisions” in the annex entries of Official Journals authorising feed additives are a source of increasing concerns for feed business operators.

For this reason therefore the industry associations such as FEFANA, FEFAC, EMFEMA and COPA-COGECA joined forces to establish the key principles for labelling feed additives through the supply chain.

The common grounds were established during a seminar on 31st January 2013 gathering representatives of the four aforementioned organisations, focusing on the labelling objectives as stated in Regulation (EC) No 767/2009. The result of this exercise is reflected in a joint document. This aims at describing the flow of relevant information as far as labelling is concerned on the feed supply chain as envisaged by the EU feed chain operators and takes into account the needs of different operators:

• Business to Business;
• Business to Professional operator;
• Business to Consumers; and
• Information flow for Control Authorities.

The next step would be to set a roadmap to assess the performance of the current labelling rules on case-study basis and to identify practical solutions for improving these requirements.

The new labelling rules for feed additives will be covered in a separate report.

Harmonised Classification and Labelling of Substances

With the help of FEFANA membership, classification of certain categories of substances and mixtures on the Global Harmonised System (GHS) has been aligned with the EU legislation on Classification, Labelling and Packaging.

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (the so-called ‘CLP Regulation’) which entered into force on 20 January 2009 - implements the general principles of the GHS. The GHS has been adopted at international level by the United Nations and provides a system to harmonise the criteria for classification of substances and mixtures relating to physical and health hazards during handling (e.g. worker safety), environmental hazards, as well as the rules of labelling and packaging for hazardous substances and mixtures.

While Annex VI of the CLP Regulation lists the existing harmonised classification and labelling of substances according to the GHS, it does not cover every substance currently defined as a feed additive. Furthermore, the EU legislator mandates manufacturers and importers of the same substance to make every effort to agree on a single classification for that substance.

FEFANA has therefore helped consolidate the classification for certain categories of substances like Vitamins and Carotenoids, whilst leaving room for other substances to be added at a future date. More details on this initiative may be found on FEFANA website.
Since its creation FEFANA has continuously built upon and gained a positive reputation across Europe towards the EU and Member States authorities, in particular in contributing to the reform of EU animal feed legislation. In this light, FEFANA contributed to discussions of EU platforms, such as the EFSA Stakeholders Consultative Platforms and the DG SANCO Advisory Groups on the Feed Chain and Animal and Plant Health, and we will continue to do so in the future.

FEFANA also dialogues with other industry stakeholders with the aim to bring about sound and pragmatic changes that were welcomed by food safety. In this perspective, in July 2012 FEFANA and EFSA established a cooperation agreement to facilitate the promotion of probiotics in animal nutrition. The two associations have joined forces with the aim to generate, develop and share their know-how and information on probiotics with feed chain stakeholders and partners.

Moreover FEFANA has placed itself as a reliable interlocutor not only within the EU but also in the international landscape to represent the unitary voice of the European industry of Specialty Feed Ingredients and their Mixtures. FEFANA has achieved a high level of engagement in many fora, such as IFIF (International Feed Industry Federation).

Global Regulatory Convergence Project

With the Global Regulatory Convergence Project FEFANA membership, in collaboration with IFIF, is aiming at facilitating access to regulation and enforcement practices in different regions of the world, fostering mutual understanding of the regulatory framework applicable to SFIs and their Mixtures, to provide a basis for convergence and bridging of the authorisation, operators’ certification, and control practices in the regions. A report comparing the regulatory systems in the US, Canada and the EU has recently been published while further work on the extension to cover regulatory systems elsewhere continues.

Sustainability

In 2012 the FEFANA Task Force on Sustainable Agriculture tabled a Review on the specific role of feed additives in agricultural food production, in respect to the environmental benefits of their application in animal nutrition. Efficient feed consumption and feed conversion has a key role to play to ensure a successful balance between the nutritional demand of the animals and the quality of the locally available feed raw materials. Feed additives have a specific role to support or improve feed intake, to increase feed digestibility or balance gaps in the nutritional demands of the animals. Moreover in the recent years FEFANA members have a specific role to support or improve feed intake, to increase feed digestibility or balance gaps in the nutritional demands of the animals.

FEFANA and EPA established a cooperation agreement in 2012 as a holistic approach for maintaining food safety management systems in the regions. A report comparing the regulatory systems in the US, Canada and the EU has recently been published while further work on the extension to cover regulatory systems elsewhere continues.

The results of the study were validated by an independent Scientific Committee made up of global experts in the fields of life cycle assessment methodology and animal production, this approach ensured scientifically robust inputs in the analysis and prepared the ground for a future peer reviewed publication of the study. The final findings of the SFIS study will be published in scientific literature at later stage.

The use of SFIs in animal diets reduces the consumption and environmental impact during livestock production, resulting in a clear reduction of Global Warming Potential, Eutrophication and Acidification Potential.

The overall results of the study were announced early in 2014, including the high value of the FAMI-QS certificate and to ensure harmonization in the auditing process.

The framework applicable to SFIs and their Mixtures, fostering mutual understanding of the regulatory aiming at facilitating access to regulation and enforcement practices in different regions of the world, fostering mutual understanding of the regulatory framework applicable to SFIs and their Mixtures, to provide a basis for convergence and bridging of the authorisation, operators’ certification, and control practices in the regions. A report comparing the regulatory systems in the US, Canada and the EU has recently been published while further work on the extension to cover regulatory systems elsewhere continues.

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One of FEFANA's objectives is to raise awareness and improve knowledge on Specialty Feed Ingredients and their Mixtures. FEFANA aims to provide technical and scientifically sound information on the benefits and safety of the products of its industry. In this framework, in May 2013 FEFANA launched its Virtual Library. The FEFANA Booklet on Premixtures was the first to be published of a series of intended product categories' publications, and more are expected during the course of 2014!

Premixtures booklet

In this booklet, we provide detailed information about the role of the premixture industry in the feed to food chain. The feed premixture industry has developed greatly over the last decades and it is regarded as a key partner for the compound feed industry, farmers, and other feed business operators in handling complexity - just to mention a few: in global sourcing of specialty feed ingredients, in managing many formulations, of safe and smooth handling of ingredients with many different properties - as provider of tailor-made solutions and a partner to work on convenient and sustainable feed to food solutions.

The different chapters in this booklet aim to draw a picture of the European premixture industry and are based on EU legislation at the time of editing, which we aim at updating as appropriate. We hope this booklet helps to clarify the landscape in which the EU premixture industry is operating today.
FEFANA was founded on 22nd January 1963 by the then national industry association of Belgium, France, Germany, Italy, and the Netherlands, to which others joined over the years. The structure of the association has since changed and FEFANA established itself as a European association of companies while maintaining a strong national representation through its integrated National Platforms.

The 50 years has been the chance to stop and reflect on the path the association had taken since its creation. Some of the milestones includes the evolution of the then Directive 70/524/EEC to the Regulation (EC) No 1831/2003 and the associated re-authorisation process that included the establishment of the Consortia. It was also an opportunity to reflect on the establishment of FAMI-QS following yet another Regulation which came into force in 2005, the feed hygiene Regulation (Regulation (EC) No 183/2005).

FEFANA 50th anniversary has been a unique networking opportunity at different levels, consolidating the past and walking together towards the future.

A number of events took place in 2013 involving not only FEFANA members but also all relevant stakeholders, including representatives from national authorities, the European Commission, and fellow associations active in the food and feed chain. It came out that FEFANA should play as leader of the global network of European SFIs industry, be the global reference for quality, create value (innovation), and communicate appropriately about its tasks and products.

Some specialist press has since followed up on the outcome of the various discussions including how far FEFANA had come and where the membership is looking to go.

Further information on the FEFANA first 50 years can be found in the FEFANA Golden Book. Released earlier in 2013 this booklet, available on FEFANA Virtual Library, highlights in more details the evolution of our association and how it evolved as a result of European Union’s policy on food and feed safety. It also covers the association’s main achievements and its role in the food chain since its inception.
FEFANA currently counts over 100 members and is open to any company involved in the business of SFIs and their mixtures. Any legal entity with corporate responsibility in manufacture, import or distribution of SFIs and their mixtures in the EU and EFTA countries can apply for full membership, associate membership instead is open – since 2013 – to those companies with no legal entity in the EU and EFTA countries.

Through an integrated European network, FEFANA brings together business operators of the sector, to promote the benefits and safety of Specialty Feed Ingredients (SFIs) and their Mixtures, and to support Members’ effort for safe and cost effective products in the food chain. It represents the views of its Members to the EU and Member States authorities. FEFANA’s numerous working groups and task forces address issues of interest for the European market, for both companies inside and outside the EU.

FEFANA, together with FAMI-QS, continue dialogues with third country authorities and other organisations in supporting, coordinating and facilitating international trade.

FEFANA structure allows addressing specific topics in “à la carte” way so that not only issues of overall general interest are treated but also those that may have an impact for a few members.

Over the last few years new WGs and TFs have been created according to the needs of our industry. Below the list of groups active over the period 2011-2013:

Working Groups
- Amino-acids
- Analytical
- Carotenoids
- Enzymes
- Micro-organisms
- Monosodium inosinates
- Organic acids
- Premixtures
- Probiotics
- Trace elements
- Vitamins
- Assessments
- Claims
- Certificate
- Dairy feed
- Fermentation
- Hygiene of food
- Quality assurance
- Organic farming
- Selenium yeast
- Sustainable agriculture
- Tolerable limits / Rapid Alert
- Vitamin A

Memberships
- AGM
- Board
- Management Team
- Lobbying Team
- Regulatory Affairs Team
- Communication Team
- Working Groups
- Task Forces
- Consortia Working Group

Structure

Working Groups and Task Forces

Working Groups (WGs) and Task Forces (TFs) are the core of specific technical discussions. They are the place where issues of interest are discussed in details and a FEFANA opinion or position is built. WGs and TFs usually address longer term issues within general and wider subject areas, Task Forces

es are created to tackle specific issues within an established shorter timeframe. The membership of WGs and TFs comprise members that are committed in carrying out this everyday work – ticking over the functioning of the association especially with regards to make contributions to fine-tune legislation and or making recommendations on their im-

plementation.

FEFANA currently counts over 100 members and it is open to any company involved in the business of SFIs and their Mixtures. Any legal entity with corporate responsibility in manufacture, import or distribution of SFIs and their Mixtures in the EU and EFTA countries can apply for full membership, associate membership instead is open – since 2013 – to those companies with no legal entity in the EU and EFTA countries.

The European Food and Feed Law framework is becoming a benchmark worldwide and, with FEFANA proving to help meeting the demands of EU rules, it is not surprising that non-EU countries are becoming more and more interested in FEFANA.

Over the last few years new WGs and TFs have been created according to the needs of our industry. Below the list of groups active over the period 2011-2013:

Working Groups
- Amino-acids
- Analytical
- Carotenoids
- Enzymes
- Micro-organisms
- Monosodium inosinates
- Organic acids
- Premixtures
- Probiotics
- Trace elements
- Vitamins
- Assessments
- Claims
- Certificate
- Dairy feed
- Fermentation
- Hygiene of food
- Quality assurance
- Organic farming
- Selenium yeast
- Sustainable agriculture
- Tolerable limits / Rapid Alert
- Vitamin A

Memberships
- AGM
- Board
- Management Team
- Lobbying Team
- Regulatory Affairs Team
- Communication Team
- Working Groups
- Task Forces
- Consortia Working Group

Structure

Working Groups and Task Forces

Working Groups (WGs) and Task Forces (TFs) are the core of specific technical discussions. They are the place where issues of interest are discussed in details and a FEFANA opinion or position is built. WGs and TFs usually address longer term issues within general and wider subject areas, Task Forces

es are created to tackle specific issues within an established shorter timeframe. The membership of WGs and TFs comprise members that are committed in carrying out this everyday work – ticking over the functioning of the association especially with regards to make contributions to fine-tune legislation and or making recommendations on their im-

plementation.
National Platforms

The work carried out by the FEFANA National Platforms are vital to the functioning of the association. Through contact with the relevant stakeholders acting at local level, the National Platforms are able to deal with issues that are more pertinent or significant in a specific territory, some being even involved in educational trainings at University level. The exchange of information flow between Brussels and the Platforms is essential for a “one industry” concept but taking into considerations the national differences. Platforms' Presidents meet regularly in Brussels thus bringing them together to coordinate common issues that could be tackled at community level.

Austria www.platform-fefana.org/Austria
Belgium - FRANA www.frana.be
Denmark - DAFAPA* www.platform-fefana.org/Denmark
France - SYNPA www.synpa.org
Germany - AWT www.awt-feedadditives.org
Italy www.platform-fefana.org/Italy
Nordic and Baltic Countries (Iceland, Norway, Sweden, Finland, Estonia, Latvia, Lithuania) - NoFAA* www.platform-fefana.org/NoFAA
Poland www.platform-fefana.org/Poland
Spain and Portugal - Adiprem www.adiprem.org
Switzerland - SGCI www.platform-fefana.org/Switzerland
The Netherlands - NEFATO www.nefato.nl
United Kingdom and Ireland - BAFSAM www.bafsam.org.uk

* Note: as from 1st January 2014 DAFAPA and NoFAA merged into one platform.
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Note: FEFANA Secretariat members in charge at the time of publication.