



FEFANA Questions and Answers Sheet

**Regarding the establishment of consortia
for the re-evaluation of feed additives in
accordance with Regulation (EC)
No 1831/2003
on additives in animal nutrition.**

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About FEFANA

FEFANA is the EU Feed Additives and Premixtures Association. It was established on October 13th, 2004 and is the new juridical form of the feed additives producers association that was founded in 1963. With over 82 members (including producers, traders and importers) from 28 countries, the association is the interface between the feed additives and premixtures industry and the European Union authorities, including Member States authorities, in order to promote, safeguard and defend common and general interests of the industry (in several topics like guidelines, register, labelling and definitions, analysis, feed hygiene and food chain safety or non-feed use of additives).

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This 'Questions and Answers' document is aimed to explain to all feed business operators how to participate to consortia for the registration of feed additives in accordance with Article 10 of Regulation (EC) No 1831/2003.

1. Background

1.1. What is a consortium for the re-evaluation of feed additives?

A consortium is a group of companies under an appropriate legal framework aimed at to co-ordinating, preparing, submitting and following up registration dossiers for feed additives, already placed on the market and registered without a link to a specific holder of the authorisation. FEFANA has made the choice of establishing consortia that are distinct legal entities from FEFANA Asbl, mainly to allow the participation of non-member companies in the consortia. The FEFANA consortia are established as European Economic Interest Grouping (EEIG), which is the legal instrument established by the EU legislation to foster cooperation between companies within the respect of the EU competition rules. Though there are strong links between the consortia and FEFANA, they are legally and operationally separated from FEFANA Asbl.

1.2. Why do we need consortia for the re-evaluation of feed additives?

Regulation No 1831/2003 requires the re-evaluation of additives already placed on the market before the date of entry into force of the Regulation No 1831/2003. In particular, Article 10 of that Regulation states that any applicant shall provide an application to the European Commission before the 07th of November 2010 to maintain its feed additive on the European market.

Some feed additive categories do not benefit from a holder specific authorisation and therefore, any feed business operator may provide an application. However, it is necessary for a specific feed additive to remain legally on the market, that an application is submitted to the authorities in due time. Furthermore, each business operator will have to ensure that its product will be compliant with the specific requirements (e.g. purity criteria) set in the Register on the basis of the application. Hence the benefit of providing a dossier that covers different potential suppliers.

The authorisation through a consortium is a shared responsibility of all the operators that produce, use or place a certain additive on the market. All operators aware of these developments realised that it would be very inappropriate to wait for somebody else to care alone about the authorisation, not only because it would be unfair to their competitors, but also because the specifications, purity criteria and manufacturing processes are to be part of the evaluation and final authorisation of each additive. Waiting for somebody else to take care of the authorization would obviously be a very risky and irresponsible approach.

For diverse legal reasons, it is easier to build a specific organisation (such as a consortium) to prepare such common applications.

1.3. What is FEFANA's role in the consortium?

Due to its high visibility in the feed additive arena and to its contacts with the authorities, FEFANA is probably the organisation best suited to support the feed business operators in the establishment and coordination of consortia. The role of FEFANA is limited to the administration of and advice to the consortium. Furthermore, FEFANA will act as the interface with the authorities. However, FEFANA is also helpful in the process of selecting specific consultants for each consortium, thereby ensuring alignment between the consortia.

1.4. Which are the consortia already created by FEFANA?

As of today, FEFANA helped to create five consortia:

- Feed Flavouring Authorisation Consortium (FFAC) is dealing with re-evaluation dossiers for chemically defined and botanical extracted flavouring compounds used as feed additives
- Amino Acids Authorisation Consortium (AMAC) is dealing with re-evaluation dossier for amino acids, their salts and analogues
- Vitamins Authorisation Consortium (VITAC) is dealing with re-evaluation dossiers for vitamins, provitamins and chemically well defined substances having a similar effect, used as feed additives
- Carotenoids Authorisation Consortium (CARAC) is dealing with re-evaluation dossiers for colorants aimed to add colour to food of animal origin (the former carotenoid group).
- Trace Elements Authorisation Consortium (TREAC) is dealing with re-evaluation dossiers for trace elements used as feed additives

Further consortia are in the process of being established, according to the interest showed by the FEFANA members.

2. Rules of consortia

2.1. Can I participate in a consortium when I produce in a non-EU country?

Yes.

However, due to the legal framework regulating the consortia in the European Union, it is not possible for a company located outside the European Union to participate as such in consortia. In order to participate in a consortium, the company located in a non-EU country shall have a representative in one of the EU Member States. This representative will have the duty to represent the company in the consortium. This is consistent with the EU Feed additive Regulation that provides that only applicants established within the Community can seek authorisation.

2.2. What are the additives represented by the consortia?

The additives to be supported in the consortia are in principle additives which are listed in the Register (e.g. copper sulphate monohydrate or vitamin E – DL alpha-tocopherol acetate). Any supplier of these additives or its representatives for non-European Union producers (see question 2.1) can provide information and support the dossier for its additive.

However, if the additive is different from the one already registered (e.g. a new salt of a vitamin not already mentioned in the Register), this shall be considered as a new additive. It cannot be handled by the consortium. In that case, the producer shall follow the procedure for evaluation of a new feed additive (Article 4) and submit a specific application.

2.3. How is the list of additives for each consortium set up?

The consortium is potentially working on any additive, included in the EU Register, relevant to the general scope of the grouping (e.g. any amino acid included in the Register, or any vitamin). The precise list of additives on which each consortium is working is defined by the members of the consortium, through a pre-established procedure for the establishment of the working list. Practically, each member of the consortium must confidentially inform the consortium manager about the additives that it wants to include in the work of the consortium, and the working list procedure is then applied. It is a quite automatic system for

establishing the scope of work of each consortium. This protects the members against the quite risky (from EU competition law point of view) companies' bilateral discussions to include or not certain substances under the scope of cooperation, which could be seen as excluding certain operators from the advantage of coordinated work. In order to avoid "free-riding", the working list is confidential to the consortium members who might however decide to disclose it when the free-riding risk is over.

2.4. Are there only consortia created by FEFANA?

There is obviously no exclusivity regarding consortia, and even no obligation for interested parties to cooperate as it exists in other regulatory areas. Any interested party is free to create and /or participate or not in any coordination initiative. However, due to its expertise in the feed additives area and its contacts with the European Commission and the European Food Safety Authority, FEFANA is probably the best suited body to support and advise the establishment of such consortia.

2.5. As a user of certain feed additives, is it possible to know whether a specific compound will be supported by a given consortium?

In order to ensure that most if not all feed business operators willing to supply a specific feed additive on the European Union market will actively support the re-evaluation process, the consortia advised by FEFANA do not provide the exact list of compounds, which are supported by the groups of companies. Therefore, this information is not available on the website of the consortium nor of FEFANA, at least for the time when the consortium is establishing its working list. The information is of course available to the members of each consortium after they confidentially but transparently committed to cooperative work on a list of additives while entering the consortium.

2.6. What are the advantages of being part of a consortium?

The advantages of being part of a consortium are numerous and will depend on the company policies. However, amongst the major advantages, we can list, the following seem of interest for most of the operators:

- reduction of time and individual costs for writing the dossier
- sharing of information and data
- alignment of the product's specifications
- benchmarking of dossier and alignment on requirements
- industry consistency of dossier content and structure.

2.7. What are the disadvantages of being part of a consortium?

The disadvantages of being part of a consortium are relatively limited but depends on the company policy. As it seems, the most significant disadvantages are:

- need for resources to participate to the consortium
- need for consensus between companies on some parts of the dossier
- longer preparation time

2.8. What are the constraints of being in a consortium?

To be in a consortium means to respect the legal requirements of the consortium as well as its internal rules. Contracts and codes of internal rules are available upon request to the consortium Manager. . These include in particular decision-making, financial and intellectual property aspects. All consortia established by FEFANA are run according to a common scheme.

Additionally, the consortium needs to be administered and this involves costs to be handled by its members.

3. Contents of the dossiers

3.1. How will the consortium be informed on potential changes in the guidelines, guidance documents?

If the consortium is built and/or operated with the support of FEFANA, FEFANA will inform the members of each consortium about the developments regarding the construction and contents of the dossier to be provided. FEFANA will also support the members in the consortium with practical information on how to create and build a feed additive dossier.

For a consortium not built with the FEFANA supports, this support will not be provided by FEFANA and the consortium will have to find another source of information.

3.2. What will the contents of the dossiers submitted by the consortia be?

In the case of consortia built with the support of FEFANA, FEFANA will ensure consistency of the implementation of the guidelines and guidance documents within and between the consortia. This will help to ensure consistency of the answers to the requirements set by the European Commission and European Food Safety Authority.

In some cases, FEFANA may propose a list of consultants who can be selected by the consortia. These consultants will be informed and will receive all necessary information for the consortia supported by FEFANA under strict confidentiality rules.

3.3. Is there an overlap of requirements between the feed additive Regulation and the new REACH¹ Regulation?

Yes, most of the safety studies necessary for the evaluation of a feed additive are based on protocols used for the evaluation under REACH. This was one of the bases for the exemption of feed additives from the scope of registration in REACH. There is however no formal relationship between the two legislations and no commonality in dossiers (e.g. no use of the electronic format used in the chemical legislation). The information should be taken over and structured in the format required by an additive dossier.

This questions and answers document will be updated on a regular basis, taking into account modifications in the regulation and/or its interpretation, comments and new questions from FEFANA members.

FEFANA members are invited to provide any comments or new questions they would have or be confronted with to FEFANA secretariat General.

¹ See Questions and Answers on REACH