

EU Additives Regulation – Where do we stand?

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At the end of the 1990's, food policy in the European Community was reorganised. Feed regulations becoming essentially equated with food. The framework for restructuring the laws governing food and feed was the "White Paper on Food Safety" from the year 2000. For feed additives, Directive 70/524/EEC, valid since 1970, has now been superseded by Regulation (EC) No. 1831/2003. This has applied in every Member State of the European Community since 18 October 2004.

During the preparatory phase of this Regulation, there were tough discussions concerning its structure. It was planned to create the foundations for ensuring a high level of protection for human health, animal health and welfare, and the environment in connection with feed additives, as well as to bring the interests of manufacturers, users and consumers largely into line. It was also planned that at the end of this process the common market in this sector should continue operating without any disturbance.

In the meantime we have entered into the transitional phase from the old to the new law. The existing additives are those that were already authorised under the old Additives Directive, as well as certain substances from the Bioprotein Directive (amino acids, their salts and analogues, urea and its derivatives), as well as the silage additives, for which authorisations were not harmonised across the European Union (EU). These must all be transferred into the scope of the new Additives Regulation on the grounds of transitional provisions.

The existing additives may still be kept in circulation if the person

and/or interested parties first placing them on the market have "notified" them to the European Commission (EC) and the European Food Safety Authority (EFSA). The notification procedure covered a period of one year and had to be completed by 7 November 2004. This was a major challenge for all parties introducing products onto the market, as well as for the EC and EFSA.

FEFANA and its national associations contributed by coordinating assistance for its members in this process. In order to pool efforts, consortia were formed under the umbrella of FEFANA in which the documents for notifications were prepared jointly,

for example for flavouring compounds.

Altogether about 9000 products were notified to the EC, representing about 2500 different additives. Of these, approximately 2000 substances were accounted for by flavouring compounds and the other 500 were divided among other additive categories and functional groups.

Based on the products notified, the EC, with support from EFSA, had a period of one year to draw up a common register for feed additives and make this accessible to the public. This register was published by the European Commission on 7 November 2005. However, it was not and is not the register as laid down in the Regulation and which the feed business operators had expected. For instance, it does not contain all the information that it ought to according to the Regulation. In an explanation on the register, it is stated that the register only has an informative character (i.e. has no legal status) and cannot replace legally valid regulations on



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authorising individual substances. The EC states that although the register largely contains most of the authorised additives, it does not include them all. Hopes for a better overview of authorisations were only partly fulfilled by the original register. The second version that appeared on 19 December 2005 has done nothing to improve this.

What is the position regarding the status of existing additives that were previously authorised as a group? This accounts for the group of vitamins (except for vitamins A and D) and the flavouring compounds.

FEFANA is most definitely of the opinion that there must be a legally binding list of all additives, even during the transitional phase, in the form of a positive list. This means that – as before – no additive may be brought into circulation and used that is not authorised in a legally binding fashion. It is absolutely vital that the EC creates legal certainty here! Otherwise this could lead to unfair competition in the Common Market and vis-à-vis additives from third countries. It is also possible that dangerous situations can arise as a result of the use of additives not authorised in the EU.

At present the additives in the categories with authorisation not issued to a specific holder (technological, sensory and nutritional additives) are listed in the community register as active substances, and those with a holder-specific authorisation (zoo-technical additives, coccidiostats and histomonostats) are listed as preparations. Regrettably, some additives are still incompletely or incorrectly listed in the register. In particular, there are missing products and unclear information for silage additives, flavouring compounds, vitamins and provitamins, as well as amino acids. FEFANA is currently working together with the EC on improving the register in this respect and making the necessary extensions and corrections. The aim is to draw up a first, complete and correct register of the additives authorised in the European Union in the form of a "closed positive list". This would make a major contribution to clarity and to im-

proving safety of use of additives, and be an important step in the right direction.

This list can also serve as a basis for the EC to keep the community register up to date as a "living tool" that correctly and consistently reflects the current status in additive authorisation.

The adaptation of the labelling of additives and premixes is a further problematic step in the transition of the requirements. We are currently in the midst of this process. Since the community register does not contain all the data necessary for labelling, it is not easy to apply the new labelling rules. For example, the register has not stipulated the functional group of existing enzymes and micro organisms. As a consequence, the Member States have widely diverging opinions regarding the time and nature of the labelling adaptation – ranging from "immediate" to "wait and see". In order to create clarity in this question, FEFANA believes it is necessary for the EC to discuss and quickly reach an agreement with the Member States in the "Standing Committee for the Food Chain and Animal Health, Animal Nutrition Section". We as an Industry cannot implement labelling rules differently for individual Member States. On the contrary, the same requirements must apply throughout the EU! However, the transitional measures are not completed with the notification, listing in the community register and adaptation of labelling. The "biggest job" is still in front of all those first placing existing products on the market – the re-evaluation process.

An application for authorisation accompanied by a complete dossier in accordance with Article 7 of the new Additives Regulation shall be submitted for all existing additives by 7 November 2010. This may appear a long way off for some, but regrettably this is not the case! There are only just over four years left for preparing and filing such applications for all existing additives. If this is not done, the additive in question will be withdrawn from the register and can then no longer be marketed! Under certain circumstances this could lead to supply

gaps, even for essential additives. An application for authorisation with a period of validity of ten years must be submitted in accordance with the Guidelines for Assessing Additives in accordance with Regulation (EC) No. 1831/2003. These guidelines are so far only available as a Commission draft and are currently being deliberated on between the EC and the Member States!

FEFANA is greatly interested in active and constructive discussions on the development of the Guidelines and the "Guidance documents". After all, the requirements for registration of an additive do not only concern its safety and effectiveness for humans, animals and the environment, but also the outlay and associated costs for the applicant. Accordingly, FEFANA busied itself intensively with this area very early in the whole process and drafted its own proposal for guidelines as early as 2004, forwarding this to the EC and the relevant authorities in the Member States. What we now need is some urgency and a high degree of willingness on the part of the EC and the Member States to cooperate with the Industry associations. In FEFANA's view, the guidelines ought to be published at the latest by the end of 2006 to allow sufficient time for the applicants to prepare their dossiers!

This matter concerns the provision of a reliable framework to work under and predictability for our Industry. Accordingly, the guidelines should enable the ap-

plicant to determine relatively easily what input in terms of research work, time and, not least, costs have to be invested to file an application for authorisation of a certain additive in a certain category and functional group and for a specific target animal species/category. This is an essential point for FEFANA Members and the whole Industry, and is in line with the principles of the Regulation. It is stated in the Regulation that the requirements for registration should be stipulated in the guidelines, and adapted to the additive category and functional group.

In this connection, FEFANA also believes that the spheres of responsibility of the EC and EFSA should be clearly demarcated and practiced in accordance with the rules laid down in the Additives Regulation. For instance, the EC is responsible in its role as "Risk Manager" for elaborating the Guidelines, and EFSA as "Risk Assessor" for elaborating the Guidance Documents. The Guidelines should indicate what information should be provided to obtain an authorisation. The Guidance Documents on the other hand should describe precisely how these requirements are to be satisfied, with detailed scientific backing. As an example, we could say that the Guidelines lay down for which additive category or functional group and for which target animal species an efficacy test has to be carried out. The corresponding guidance document would then describe in detail how the efficacy test is to be carried out for a certain target animal species/category.

So that all applicants can master the forthcoming challenge of re-evaluation in time, structuring of these Guidelines and Guidance Documents enjoys absolute priority for FEFANA. Since this is so important for the authorization of existing and new additives, FEFANA shall continue to collaborate actively and constructively in designing these documents. We expect continued involvement and constructive cooperation with the European Commission, the Member States in the Standing Committee and the European Food Safety Authority in this matter.

FEFANA Asbl is the EU Association of feed additives and premixtures operators. It was established on October 13th, 2004 and is the new juridical form of the feed additives producers association that was founded in 1963. The association is the interface between the feed additives industry and the European Union authorities, including Member States authorities, in order to promote, safeguard and defend common and general interests of the industry. www.fefana.org
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