



## PRESS RELEASE

### **New Regulation 885/2009 modifies sampling rules and fee structure regarding analytical part of feed additive authorization process**

**Brussels, 6 October 2009 – In the frame of the feed additives applications under Regulation (EC) No 1831/2003, the European Commission published a new Regulation (EC) No 885/2009 amending Regulation (EC) No 378/2005 as regards reference samples, fees and the laboratories listed in Annex II in the Official Journal of the European Union issued on 26 September 2009. FEFANA welcomes this publication which, among others, will allow many applicants for authorizations of feed additives to put forward grouped applications and benefit from important economic advantages, as both the number of samples to submit and the fees to be paid to the Community Reference Laboratory (CRL) will be significantly reduced from now on.**

FEFANA has been actively working in the development of this Regulation and is deeply satisfied with the excellent results which are translated into pragmatism for the applications and direct economic savings for our industry. “Negotiations with the authorities started when some FEFANA Members raised concerns about the CRL fee structure in particular for grouped applications dossiers. The pragmatism and openness of the CRL allowed to bring these discussions to a good end in time for the wave of applications under Article 10 of Regulation (EC) No 1831/2003, what we all can be pleased with”, says Didier Jans, the Secretary General of FEFANA. Within the legal framework to date, it was not possible to solve all issues linked to non-holder-specific applications. The new text however meets expectations as much as it possibly can.

This amendment of Regulation (EC) No 378/2005 is an important step forward for our industry and it comes just in the nick of time; deadline November 2010 is approaching and the majority of the re-authorization dossiers will be presented during this one-year period. In many cases, grouped applications for more than one feed additive are submitted in the same dossier and this required some further appropriate rules regarding the analytical part of the application. The new provisions are especially advantageous for this kind of applications, as from now the fee to be paid at CRL will be proportional both to the number of products to be authorized and to the number of methods of analysis to be evaluated by the CRL. This will result in savings of thousands € for companies that are submitting grouped applications.

The procedure and fees have also been changed regarding applications for extending the terms of a previously existing authorization. In these cases, applicants will also be exempted of sending samples again, as they are already available at CRL.

Finally, applicants for authorization of additives consisting of or containing microorganisms will also benefit of a smoother application process as they are now relieved from sending samples of the pure active agent to the CRL; an authorization to access the deposited

microbial strain in the culture collection will be sufficient. This was another significant aspect that was put forward by FEFANA and is now included in the Regulation.

FEFANA is informing its Members about the technical details and examples of how this new Regulation can positively affect their application processes.

### **About FEFANA**

FEFANA is the EU Feed Additives and Premixtures Association. It was established on 13 October 2004 and is the new juridical form of the feed additives operators association which was originally founded in 1963. With more than 100 members from 28 countries, 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 (in several topics like guidelines, register, labelling and definitions, analysis, feed hygiene and food chain safety or non-feed use of additives). FEFANA's President is Dr. Frank Chmitelin of Adisseo.

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