Feed Additives: Renewals of Current EU Authorisations Explained

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14 April 2014 - Under Regulation (EC) 1831/2003, all feed additive authorisations are granted for 10 years (according to the procedure outlined in Article 14 of the Regulation) and permanent authorisations for feed additives in Europe no longer exist. Therefore, at the end of the 10-year period, authorisations need to be renewed.

The first feed additive re-authorisation under Regulation (EC) No 1831/2003 was granted at the end of 2005. And the European Commission's Directorate for Animal Health and Welfare (DG SANCO) informed Feedinfo News Service that the first applications under Article 14 are expected in the second half of this year, given that applications for authorisation renewal must be sent at the latest one year before the expiry of the 10-year period.

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- DG SANCO

According to DG SANCO, the procedure for the 10-year authorisation renewal for feed additives has been simplified and a "full Article 4 dossier" must not be submitted. The guidelines (outlined in Regulation (EC) 429/2008) provide feed additive producers with some information about the necessary data to be submitted.

"The requirement to apply for the renewal one year before expiry date should ensure a continuation of the authorisation in case the conditions are met", said a DG SANCO spokesperson.

Feedinfo News Service spoke to FEFANA's Secretary General, Didier Jans, to get a better understanding of the European feed additive re-authorisation situation today.

"The first point to clarify is that, in Europe, there is no permanent authorisation for feed additives. Regulation (EC) 1831/2003 has indeed foreseen that all authorisations are granted for 10 years. At the end of this period, the authorisation needs to be renewed", said Jans. "This Regulation has also provided that the additives that were on the market before entry into force of the Regulation – those authorised without a time limit - can remain on the market provided that they successfully undergo a re-authorisation process (Article 10 of the Regulation; these additives are commonly referred as "Article 10 additives" by the operators)".

Jans highlighted the fact that this re-authorisation process included several phases: a notification, the establishment of the EU register of feed additives, the tabling of an application dossier, assessment of this dossier, and finally re-authorisation of the additive by the European Commission and Member States.

"The application dossiers were required by November 2010 and we are currently still in the assessment and authorisation phase", he said. "If one considers only the applications carried out through the consortia that FEFANA has supported, it counts more than 100 applications dossiers, covering more than 1000 additives, and many more were submitted independently. The work is massive".

Regulation (EC) 1831/2003 also provides that until assessment/authorisation is concluded, the additives that have properly fulfilled the re-authorisations steps can remain on the market.

"Some of them have completed the process and so are now authorised according to the criteria of Regulation 1831 (for 10 years from the time of their authorisation, and so including an ending-date in their authorisation), while others are still under their former authorisation (which indeed were granted without time-limitation under the previous legislative regime)", commented Jans.

"There is no fixed timeframe for the re-authorisation to be completed, but one can expect that this will take approximately one or two more years. But as far as access to the EU market is concerned, this makes no difference. Both types of additives: those that have finished their journey and those that are still under the Article 10 re-assessment can be placed on the market (according to the criteria of their authorisation)", he added.

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Furthermore, according to Jans, there is no fundamental difference between domestically-produced feed additives and imported ones, given that the same rules apply for all. The third country operators must, however, act through a representative established in Europe.

Jans went on to explain that the additives for which no application for re-authorisation was submitted are to be withdrawn from the market.

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"This is formally set up through a series of withdrawal regulations (meaning: withdrawal of the existing authorisation) and the Commission has already published two such regulations (for silage and for flavourings), and others will follow. The additives that are in this withdrawal process can easily be identified since they are grouped in a special section of the EU Register of feed additives", said FEFANA's Secretary General. These additives are also known as "orphan additives".

In the case that a decision on the renewal of the authorisation would not be taken before the expiry date, for reasons beyond the control of the applicant, Jans stated that the authorisation will be automatically prolonged until a decision is taken.

While the situation is rather straightforward for the holder-specific authorisations that can be expected to take initiative on their products (authorisation belongs to a specific operator

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-case of the zootechnical additives- and it is their responsibility to carry-out the application), Jans argued that for "non-holder specific" additives a repeat of the same issue FEFANA experienced for the "Article 10 additives" can be expected.

By that he means in the latter case some operators might have been tempted to wait for others to do the job and so to piggy-back on others' efforts. "Experience with Article 10 has shown that this might be detrimental to those who are not taking their share of the process", Jans commented.

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"One should probably not expect that the renewal principle will be questioned, but hopefully that this will not be a full-fledge re-assessment process. The recent guidance produced by EFSA on its own initiative might in this context appear as largely overdoing the legislator's intention and should not be taken as read for the time being", he added.

Finally, Jans stressed that FEFANA places important hopes in the ability of the European Commission to keep control on the feed additive renewal process and has opened dialogue with the Commission on this matter. FEFANA is offering information and support to its members about these developments, he said.