PRESS RELEASE
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Update on the EU Regulatory Framework

Authorisations

AMINO ACIDS, THEIR SALTS AND ANALOGUES

The evaluation of safety regarding the production strain is an integral part of the EFSA assessment on the safety of feed additives produced by fermentation. Conclusions in EFSA opinions are restricted to the strains described in the applications and there is a clear link between the active substance and the producing strain for additives produced by fermentation. This is a fundamental change since all sources of a given fermentation additive not fulfilling the authorisation, i.e. that are produced with a strain not referenced in the authorisation, will be illegal on the EU market.

Some amino acids, like L-threonine, have been re-authorised. In the particular regulation are stated the Transitional measures that all Operators need to follow.

Here is the link pointing to the latest version of the Community Register of Feed Additives pursuant to Reg. (EC) 1831/2003 – Click here. All re-authorisations are clearly mentioned in the Register.

IMPLICATIONS FOR FAMI-QS CERTIFICATION

As previously mentioned, in order to place a fermentation additive in the European market, produced with a specific strain, Operators need to make sure that the strain used is the one referenced in the authorisation of said fermentation additive.

The FAMI-QS authorised Certification Bodies shall confirm and communicate through the audit report that the strain used by the Operator to produce a fermentation additive matches the one of the authorisation of said additive.
In the event that the additive is to be placed in other market than the European one, this shall be clearly mentioned in the audit report. During the audit, it shall be confirmed that there are measures in place to avoid cross contamination issues between the authorised and non-authorised (in EU) additives produced by fermentation.

Withdrawal regulations

According to Regulation (EC) No 1831/2003, feed additives for which no application for re-evaluation was submitted before the deadline of 8th November 2010, should be withdrawn from the market via the adoption of a regulation.
In recent years, four withdrawal regulations have been published:

- **2012**: Regulation (EU) No 451/2012 for certain feed additives belonging to the functional group of silage additives
- **2013**: Regulation (EU) No 230/2013 for certain feed additives belonging to the group of flavoring and appetizing substances
- **2014**: Regulation (EU) No 107/2014 for certain sources of cobalt
- **2017**: Regulation (EU) No 2017/1145 for certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives

Substances listed in the withdrawal regulations are no longer authorised feed additives and therefore cannot be placed on the market. If business operators see finally the need for those products to be marketed in EU, they must submit a new application for authorisation.

IMPLICATIONS FOR FAMI-QS CERTIFICATION

Certification Bodies shall confirm that Operators take the required steps to adapt their scope and make the necessary exclusions for placing their products in the EU market.
Due to the fact that some withdrawn additives can still be legally placed in other markets besides the European one, Certification Bodies shall ensure that the Operators take actions not to mislead their customers and take into account the GMP procedures and HACCP plans in all processes covered by FAMI-QS.