Authorization of Feed Additives

Lawsuit of Rubinum SA against the European Commission failed

In its ruling of 21 May 2015, the European Court of Justice dismissed the complaint of the Spanish feed additive producer Rubinum SA against the European Commission. The Commission had suspended the European feed additive authorizations for Rubinum SA products containing *Bacillus cereus* var. *toyoi* by Regulation No. 288/2013. Rubinum SA filed a lawsuit against this procedure.

In the course of re-evaluation according to § 10 of Regulation (EC) 1831/2003, EFSA had requested from the company data on the complete sequence of the *Bacillus cereus* var. *toyoi* genome – which was handed in by the company. This led to the publication of the Scientific Opinion No. 2924 in which EFSA states that the strain "shows resistance to two antibiotics – one of which at least can be ascribed to an acquired resistance" and that "the strain harbours all of the genes coding for non-haemolytic and haemolytic enterotoxins". As a consequence, the EU Commission decided to suspend all feed additive authorizations with this active substance and to withdraw all products from the market – by Regulation No. 288/2013.

Rubinum SA had filed a lawsuit against this procedure, but its claim was rejected - both for procedural reasons, but also for other reasons which might be very informative to anyone dealing feed additive authorizations:

- A current feed additive authorization can be suspended as soon as it is evident that "feed..is likely to constitute a serious risk to human health, animal health or the environment.." (Article 53 of Regulation (EC) No 178/2002). This might happen as new scientific evidence and correlations evolve.
  This is applied in the Europe on the basis of the precautionary principle, which is implemented for food and feed in Art. 7 of Regulation (EC) No 178/2002: "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required…."

- The European Court of justice also stated that organs of the European Union which have to deal with complex assessments enjoy a wide discretion. Judicial review of these assessments is limited to the question whether an obvious error or misuse of power has occurred or whether the organ has obviously exceeded the limits of its discretion. Thus - apart from performing a plausibility check - the court is not allowed to replace an EFSA scientific assessment with its own assessment.

- Even if the European Commission had not made its decision within the legal deadline, the Regulation is still valid.

This decision of the European Court of justice is a strong message to feed additive industry: EFSA scientific opinions are not to be questioned and legal deadlines do not have to be met by the authorities. We will have to deal with that.

http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d0f130de5940d8e8e68046e9bc4797412e5cc553.e34KaxiLc3eQc40LaxqMbN4ObxuQe0?text=&docid=164363&pageIndex=0&doclang=DE&mode=lst&dir=&occ=first&part=1&cid=497252