

FOOD AND FEED TESTING

Current situation

Food and feed risk assessment covers hugely diverse areas, including additives, colours, flavours and sweeteners for use in foodstuffs; food supplements; novel foods and novel food ingredients; plastic materials and articles intended to come into contact with foodstuffs; analysis of marine biotoxins; plant protection products; additives for use in animal nutrition and genetically modified organisms.

The European Food Safety Authority (EFSA), which was set up in January 2002 as an independent body, provides scientific advice and communication on risks associated with the food chain. Requests for scientific assessments of feed and food are received from the European Commission, the European Parliament and EU Member States. Accordingly, EFSA's advice frequently supports the risk management and policy-making processes covering feed and food.

The EFSA policy is to include in its Opinions statements on unjustified (animal) studies or animal use. Additionally they provide all panels with sufficient information on animal studies for which there are accepted alternative approaches and details of all regulations referring to animal welfare issues. Animal welfare issues related to food and feed producing animals are covered by the Panel on Animal Health and Animal Welfare (AHAW).

On 8 June 2009, EFSA published its opinion on 'Existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment'⁸⁶. The opinion focused on food and feed aspects which fall under the remit of EFSA.

Analysis of marine biotoxins is extremely important as these toxins from algae (phytoplankton) which are eaten by shellfish (bivalve molluscs) can cause diseases in humans that range from diarrhoea to possibly lethal paralytic diseases. The algal toxins are not destroyed by heating or any other means of food preparation. Therefore, in accordance with the EU food hygiene legislation, shellfish may only be put on the market for human consumption, when it has been established that they do not contain such biotoxins.

Legislation

Marine biotoxins

Under EU regulatory requirements, the standard safety test is the mouse bioassay (MBA) which is a very distressing animal test using death as an endpoint. During this test, mice are injected with extracts from the shellfish and the time until death is recorded. The mouse bioassay is poorly reproducible, not very sensitive and not reliable. According to EU legislation, shellfish are withdrawn if two out of three mice die, i.e.: if only one mouse dies, the shellfish are put on the market for human consumption.

⁸⁶/Available at: <http://www.efsa.europa.eu/en/scdocs/doc/1052.pdf>

Alternatives to the MBA exist including chemical assays and biological test methods which are much more reliable, highly sensitive and highly reproducible.

The European Commission requested 9 EFSA Opinions on marine biotoxins, their detection methods and regulatory limits. EFSA tasked its scientists to address the question to “*assess the current EU limits with regard to human health, as well as new emerging toxins*”. The opinions were adopted between January 2008 and July 2010 as well as a summary on regulated marine biotoxins, which advised the Commission to use alternative methods to the mouse bioassay.

GMO – Food and feed testing

Regulation (EC) No 1829/2003 on genetically modified food and feed lays down the general framework for regulating genetically modified (GM) food and feed in the Community. The Regulation is complemented by *Regulation (EC) No 1830/2003 that ensures traceability and labelling of GMOs at all stages of placing on the market*. Previously GM foods were regulated under the Novel Food Regulation 258/97, whilst GM feeds were partially regulated under Directive 2001/18 on the deliberate release of GMOs into the environment.

The new regulatory framework was adopted at a time where the authorisation process of GMOs and GM food and feed had come to a halt. In fact, between 1998 and 2004, no new authorisations had been granted. With the entry into force of the new legislative framework, the regulatory approval process for GM food and feed has been re-launched. Nevertheless the authorisation of GM food and feed remains a very sensitive issue.

Novel foods

Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree before 15 May 1997. Regulation EC 258/97 lays out detailed rules for the authorisation of novel foods and novel food ingredients. In January 2008, the European Commission adopted a proposal to revise this Regulation with a view to improving the access of new and innovative foods to the EU market, while maintaining a high level of consumer protection and ensuring food safety (COM(2007)872). The proposal foresees covering food from cloned animals. It is presently going through the co-decision process in the European Parliament and the Council.

In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. This safety assessment includes testing on animals. Only those products considered to be safe for human consumption are authorised for marketing.

Future action

- Presently, there are a number of visible discrepancies in data requirements which need to be resolved, these include: level of detail for active ingredient testing (food, feed, pesticides, enzymes, flavourings); extensive testing of preparations (feed) versus limited (food supplements); efficacy testing required (feed) or not (food); mandatory data requirements mentioned (chemicals) or not (food, feed additives); Assessment of individual substances (additives) or groups of related substances (flavours); and data requirements based on exposure assessments (chemicals) or unrelated to exposure (additives).
- The Commission must start procedures to work towards replacing EU regulation which obliges the use of outdated animal tests as is the case in the safety testing of shellfish biotoxins. The use of the MBA should be stopped immediately. Instead, the development of alternative methods should be promoted and those alternatives which are more reliable and sensitive should replace the MBA immediately.
- Good stakeholder interaction is necessary on all levels to ensure adequate exchange of information and transparency.