Review of the requirement to perform 90-day feeding studies in rodents

Commission Implementing Regulation (EU) 503/2013 on applications for authorisation of genetically modified (GM) food and feed contains a clause for the Commission to review the requirement for applicants to perform a 90-day oral toxicity study in rodents with each single GM event on the basis of new scientific information and to publish the results of the review by 30 June 2016 at the latest.

In its review, the Commission has concluded that, it is extremely difficult to define with the necessary precision a set of specific criteria and the level of uncertainties which would require the submission of 90-day oral toxicity study in rodents on a case-by-case basis.

In addition, conducting a 90-day oral toxicity study in rodents on each single GM event adds an additional safety layer to ensure high level of health protection for GM food and feed and strengthens consumer confidence.

On that basis, the Commission considers it is appropriate to maintain the requirement for the submission of a 90-day oral toxicity study in rodents for each single GM event as part of the application data package needed to support the authorisation of GM food and feed in the European Union.

The requirement for the 90-day oral toxicity study will be reviewed in the future in light of progress made in the development of validated in vitro methods. The review of the 90-day study requirement and the Commission's views on it, were discussed with Member States at the Standing Committee meeting on Genetically Modified Food and Feed and Environmental Risk on **27 January 2017**.