

# Agricultural BioTech Regulatory Network

August 31, 2011

## The Agricultural BioTech Regulatory Network urges the European Food Safety Authority to retain the internationally agreed OECD study design for the 90-day study

The Agricultural BioTech Regulatory Network (ABTR Network) recently urged Europe's Food Safety Authority (EFSA) to retain the OECD internationally accepted and approved design for the 90-day study used as the pivotal study for substances from all sectors including food and GMO safety.

International harmonization of toxicity studies for the purposes of standardization and addressing the 3Rs (Reduction, Refinement and Replacement) to minimise the use of animals continues to be at the top of the safety testing agenda. In order to prevent trade disruption by asynchronous approvals, guidance documents by regulatory bodies should promote international harmonization and should provide clarity to developers on how to address data requirements proportionate to the substance(s) under evaluation.

Recently, EFSA concluded its public consultation on proposed guidance for repeated-dose 90-day oral toxicity study on whole food/feed in rodents. ABTR Network submitted detailed technical comments that highlight how EFSA's proposal deviates from internationally agreed approaches, is confusing as to its purpose and will inevitably trigger unnecessary duplication of animal studies required solely to respond to new data requirements in Europe.

ABTR Network's concerns centre on:

- the justification for a specific guideline for a 90-day rodent feeding study for novel food/GMO when the OECD 408 Guideline has proved reliable over years and OECD has considered the need and does not consider this to be necessary,
- the unclear and contradictory positioning of the study as a confirmatory test (i.e., used to test specified hypotheses) vs. as an exploratory test (i.e., used to generate hypotheses),
- those study design elements that will confound interpretation of important endpoints,
- the emphasis on new statistical analyses while understating the importance of scientific interpretation, and
- the use of more research animals due to study duplication.

The 90-day rodent studies with whole food are not routinely needed, but may be required for specific cases. We believe that this important premise must be stressed rather than embarking on a new design, which has nothing to offer compared with the time-served OECD international standard (OECD 408) which can be readily adapted case-by-case.

ABTR Network's full comments can be found at [www.abtrnetwork.com/news](http://www.abtrnetwork.com/news).

---

Established in 2006, the ABTR Network is a unique global network of independent regulatory affairs managers/services serving the agricultural biotechnology industry from product conception through commercialization. Services cover the entire range of regulatory support required for AgBiotech projects, including project management, project evaluation, risk assessments, contained/confined use permits; field trial permits / notifications; regulatory files; commercial permits; movement of biological materials; compliance audits; compliance systems; training; quality control; study design; documentation systems; regulatory strategies; regulatory management; issue management; communication; emergency response & public advocacy.

Visit [www.abtrnetwork.com](http://www.abtrnetwork.com) or e-mail [info@abtrnetwork.com](mailto:info@abtrnetwork.com) to learn more about the services we offer and how regulatory professional can join.