EU Commission plans new Regulation for risk assessment of genetically engineered plants - Testbiotech: proposed amendments are not sufficient

Munich/ Brussels. 25 January 2012. The European Commission has presented a new draft Regulation for the risk assessment of food and feed. For the first time, it would mean that the European Food Safety Authority EFSA would have to work to legally binding standards. However, as a first Testbiotech analysis shows, the proposed standards are not sufficient to exclude risks for human health and the environment.

“The planned new EU regulation shows that current risk assessment as performed by EFSA is not sufficient. But there is still no concept for a comprehensive risk assessment. In result, this Regulation would allow fast track authorisation without delivering the high level of protection for consumers and the environment required by the EU legal framework,” says Christoph Then from Testbiotech.

Some deficiencies of the planned new regulation exposed by Testbiotech are:

- The concept of comparative risk assessment should be replaced by a more comprehensive risk assessment.
- A stress test should be requested to investigate the genetic stability of the plants.
- Testing for health risks should include a stepwise concept that takes into account mandatory in vitro investigations, targeted investigation of certain health risks and mandatory long term and multi generational feeding studies.
- Stacked events should not be assessed less rigorously than single events.
- There needs to be a strong interplay with pesticide regulation; residues that result from spraying with complementary herbicides should be taken into account.
- Combinatorial synergistic, additive and accumulated effects need to be fully assessed
- The applicant must present fully evaluated methods to measure gene expression in the plants.
- Cut off criteria that allow rejection of an application should be defined.
- Post- marketing monitoring allowing identification of negative health effects has to be established in each case.
- An overall integrated concept should be developed which takes risks as well as ethical and socio economic issues into account.
- Industry should be required to bear the costs of the authorisation procedure and to contribute to public funds for independent risk research.

Further information: EU Commission’s draft for implementing regulation on applications for the authorisation of genetically modified food and feed [1]
Testbiotech Background 25-1-2012 [2]

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