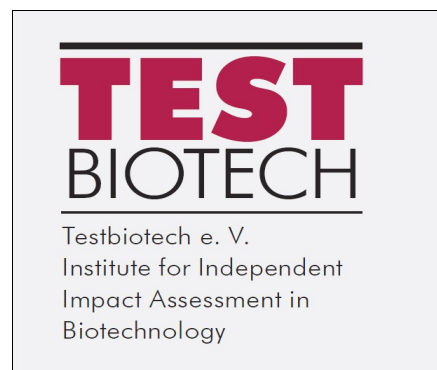


Testbiotech comment on EFSA's draft Guidance for risk assessment of GMMO



EFSA's Guidance needs clarification and cut off criteria

Christoph Then

Testbiotech comments on: *EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance on the risk assessment of genetically modified microorganisms and their derived food and feed products. EFSA Journal 20YY;volume(issue):NNNN. doi:10.2903/j.efsa.20YY.NNNN. Available online: www.efsa.europa.eu/efsajournal.htm*

Line 174

We agree with the statement of EFSA that "Guidance on the risk assessment of microorganisms generated by Synthetic Biology requires a separate document which takes into account the unique features of such organisms." However, in Line 574 the Guidance refers to synthetic DNA that might be used in Genetically Modified Organisms. What is missing is a clear distinction between Synthetic Biology and those organisms that are assessed under the planned Guidance.

Line 1136 ff and line 1180 ff

The Guidance lacks clear cut off criteria for organisms that contain genes from pathogenic organisms and/or synthetic genes and/or genetic information that has not previously existed in the receiving environment.

These organisms and their genetic information should not be released into the environment because there is no sufficiently reliable way of predicting their future impact on ecological systems or human health. Their release should be perceived as a hazard per se, especially, if these organisms are able to survive (persist) and proliferate in the receiving environments. Therefore, these organisms should be excluded from any release into the environment.