

Submission



Office of the Gene Technology Regulator
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Office of the Gene Technology Regulator 2016-17 Technical Review of the Gene Technology Regulations 2001

Submission made by;
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AMFEP – the European Association of Manufacturers and Formulators of Enzyme Products – submits this document as a response to the call from the Office of the Gene Technology Regulator for comments on the proposed amendments to the Australian Gene Technology Regulations 2001.

AMFEP appreciates the clarification brought forward and supports the proposed amendments.

At the same time, AMFEP would like to re-iterate our comments submitted for the 2016 discussion paper, that organisms modified using the technologies mentioned as SDN-1 or SDN-2 may be genetically indistinguishable from organisms which occur naturally and do not differ from organisms produced by classical mutagenesis which are already excluded from regulation based on a long history of safe use.

AMFEP recognizes the difficulty in precisely distinguishing between the techniques mentioned as SDN-2 and SDN-3, and acknowledges the decision to limit the organisms not being regulated as GMOs to those modified using site-directed nucleases without templates to guide genome repair (i.e. SDN-1).

In order to avoid above-mentioned difficulties for current and future techniques, AMFEP suggests that a future amendments shall aim at moving the Australian Gene Technology Regulations away from the current process-centric regulation in the direction of a product-centric regulation

Many thanks in advance for your consideration of these comments,

Kind regards,

Patrick
AMFEP Secretary General.