Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
Canberra ACT 2601 Australia

Telephone: 1800 181 030
Email: ogtr@health.gov.au

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Amfep comments on the review of Gene Technology Regulations Consultation

Amfep – the European Association of Manufacturers and Formulators of Enzyme Products – submits this document as a response to the Office of the Gene Technology Regulator discussion paper on options for regulating new technologies under the Gene Technology Regulations 2001 published in October 2016.

Amfep appreciates the opportunity to comment on this discussion paper and would like to express our support for the proposed options 3 and 4, based on the reasoning below.

Traditionally, classical mutagenesis (CM) has been used to provide advantageous changes in the genome of microorganisms used as production strains for enzymes. This method has been used for many years for product improvement (e.g., for removal or reduction of undesired enzymatic side activities, like amylases or proteases, etc). CM is based on random changes of the genome and therefore it requires the identification of the appropriate strain by screening a very large number of strains that contain non-relevant mutations.

With the emergence of genome editing, the precise modification of target genes has become a state-of-the-art methodology for analysis and studying of gene functions. Genome editing encompasses a number of technologies with high specificity for the target gene that allows the screening of a reduced number of strains and prevents the accumulation of off-site changes in the selected strain. When using such technologies without donor DNA, no exogenous DNA remains in the final strain and therefore the changes introduced are equivalent, yet more precise, than using CM.

Amfep therefore agrees with the considerations in the discussion paper that organisms produced using genome editing technologies (SDN-1 or SDN-2) are genetically indistinguishable from organisms which occur naturally and do not differ from organisms produced by CM techniques which are already excluded from regulation on the basis of a long history of safe use.

Based on the above, Amfep supports options 3 and 4 in the discussion paper.

Kind regards,

Patrick Fox
Secretary General
Amfep