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Spanish Commission on Biosafety: Strategy and challenges in assessing a trial with a GM olive fly

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ABSTRACT

In December 2012 Oxitec Ltd. applied to Catalonian regulatory authorities for a permission to carry out a netted field evaluation of a genetically modified (GM) olive fly strain as a novel approach to controlling one of Europe's most damaging agricultural pests. If approved, the study would be the first outdoor trial of a genetically modified insect in the EU.

The olive fly (*Bactrocera oleae*) is the single major pest for olives, causing widespread crop damage and significant financial losses to Europe's olive farmers. This olive fly strain carries a genetic modification which consists in GM males which are released to mate with wild females, resulting in the death of all the female offspring. These GM flies also contain a fluorescent marker to use in the monitoring of the trial.

The Catalonian Competent Authority asked for the ERA report to the Spanish Commission on Biosafety. During the assessment process, the CNB requested the applicant to supply with additional information regarding control and contained trial conditions and relating to other environmental safety issues. The CNB was mainly concerned about some aspects linked to the control and contained conditions of cages, the effectiveness of the lethality trait, the potential for horizontal gene transfer and the unexpected adverse effects on non-target organisms.

Throughout risk analysis, as a whole, other ethics, political and socioeconomic issues were considered. A broad discussion in the media was generated as well at the possibility of conducting this test. Finally, in 2015 Oxitec Ltd. withdrawn the application.