OECD Workshop: ***Environmental release of engineered pests: Building an international governance framework***

GM insect regulation in Europe

John Mumford
Centre for Environmental Policy
Imperial College London
Silwood Park Campus
Ascot, Berkshire SL5 7PY, United Kingdom

Abstract

Within the European Union, Directive 2001/18/EC covers the deliberate release of all genetically modified organisms (GMOs) into the environment. The Directive requires a rigorous environmental risk assessment (ERA) before market approval. Application of the GMO Directive to insects is more recent than plants. European Food Safety Authority (EFSA) guidance on ERA for GM insects was provided in 2013. No GM insects have yet been approved in Europe, but development for GM forms of sterile insect technique is occurring. Evaluation of a specific GM insect application by EFSA would be shared publicly with Member States and the European Commission. The ERA is highly structured in the 2001 Directive. The EFSA GM Insect Working Group found much of the ERA structure originally aimed at plants was applicable, but some aspects needed further interpretation for novel applications with insect pests. This is particularly true of population replacement strategies, such as insect gene drive systems. Persistence is a key positive property in replacement. Pests are undesirable as target organisms, and are often themselves introduced in the environment, making it difficult to separate considerations of harm and benefit. Relevant comparators may be at population and management system level, rather than organism level. The guidance for GM insect ERA provides explanation, elaboration and examples to support applicants in the purpose and type of information they should provide. The guidance benefited from public consultation by EFSA, highlighting areas needing more detail. Complexity of potential GM insect applications is a significant constraint in effective public consultation and demonstrates the need for public awareness and understanding to ensure full participation. GM insects received most public comments among the GM animals covered by the guidance, revealing high public interest. Control of insect vectors raised particular public concerns related to effects on human health due to accidental intake or biting/stinging.