Ecological Indicators 36 (2014) 367–381

Contents lists available at ScienceDirect

Ecological Indicators

journal homepage: www.elsevier.com/locate/ecolind

Ranking matrices as operational tools for the environmental risk assessment of genetically modified crops on non-target organisms

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ARTICLE INFO

Article history:
Received 20 July 2012
Received in revised form 25 January 2013
Accepted 15 July 2013

Keywords:
Bt toxin
TC 1507 maize
Bacillus thuringiensis
Genetically modified plant
Bt maize
Environmental risk assessment
Selection procedure
Non-target organisms
Ecotoxicological test species

ABSTRACT

For the operationalization of the structured, stepwise selection procedure for non-target testing organisms integrated into the new EFSA guidelines for environmental risk assessment of GM plants practical tools – i.e. ranking matrices – were developed. These tools – some of them are new and some are refined from older ones – were tested using the GM case crop of TC 1507 maize. The selection procedure consists of six steps. The strategy builds on identifying the important ecological functions for the particular cropping system and compiling a species lists according to their ecological functions and presence in the specific receiving environments. Subsequently, the species numbers are reduced in a systematic, stepwise fashion to a relevant and practical number of testing organisms and/or processes.

Four ecological functional categories were selected: herbivory, pollination, natural enemies and soil organisms/processes. Based on these categories, the relevant species were chosen and subjected to the selection steps. Out of a total of 33 herbivores, 73 pollinators/pollen feeders, 48 natural enemies and 77 soil organisms/processes we started with in Step 1, 15 herbivores, 10 pollinators 17 natural enemy species and 9 soil organisms/processes were selected as relevant and suited for a testing program at the end of the selection procedure in Step 4.

Although the ranking tools will continue to need further refinement, we could demonstrate that this procedure allows to swiftly select the most important suite of species and processes from a large number of organisms. This expert-driven process increases ecological realism and transparency in risk assessment and tailors it to the particular receiving environment, thus, overcoming important deficiencies of the current approach that has attracted persistent criticism. We recommend balancing ecological requirements with practicability criteria and realism in the test strategy. At present, the ranking is abundance-oriented and, thus, excludes rare and/or endangered species that are sensitive to disturbances. We suggest additional selection criteria to strengthen nature conservation and off-field aspects.

1. Background and purpose

According to the regulation in the European Union (EU), an environmental risk assessment (ERA) for the approval of GM crop plants must be carried out on a case-by-case basis following the principles and recommendations given in Annex II of the Directive 2001/18/EC. In Annex II, a case is defined as a combination of the crop plant (its biology, ecology and agronomy), the novel trait relating to its intended effect and phenotypic characteristics of the GM plant, and the receiving environment related to the intended use of the GM plants. Currently, the identification and characterization of potential adverse effects for the ERA of GM crops on non-target organisms (NTOs) is mainly derived from tests with isolated novel

Abbreviations: EFSA, European Food Safety Authority; ERA, environmental risk assessment; EU, European Union; GM, genetically modified; GMO, genetically modified organism; HR, herbicide resistant; IOBC, International Organization for Biological Control; IR, insect resistance; PAT, phosphinothricin-*N*-acetyltransferase; NTO, non-target organism; EF, ecological function.

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http://dx.doi.org/10.1016/j.ecolind.2013.07.016

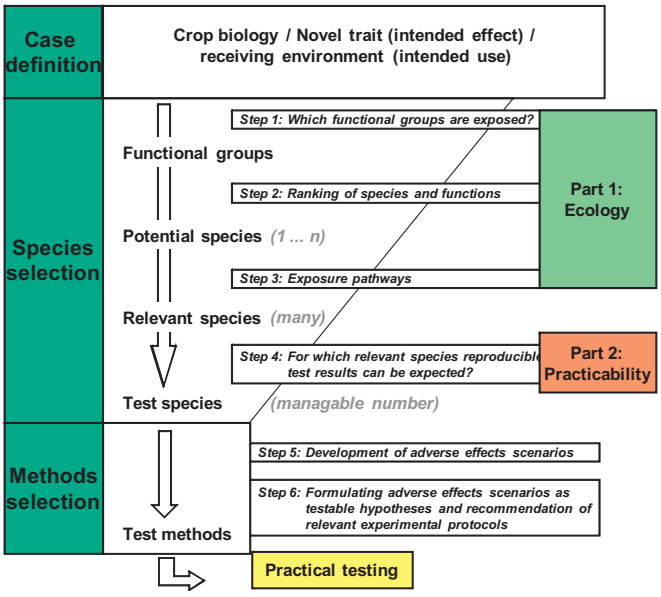

Fig. 1. Selection procedure scheme for non-target organisms as published by Hilbeck et al. (2008, 2011).

proteins and testing procedures that closely follow the testing strategy developed for pesticides. This approach has been criticized (Andow and Hilbeck, 2004; Hilbeck et al., 2011) because it presumes that most potential adverse effects of the GM plant on NTOs can be extrapolated from testing of an isolated bacteria-produced novel compound. This and other criticism (e.g. Spök et al., 2004; Dolezel et al., 2011) resulted in a request of the European Commission to the European Food Safety Authority (EFSA) to review its guidelines for ERA of GM organisms with special emphasis on the further development of the risk assessment for NTOs (see EFSA, 2010a, Background).

In a preceding project, an improved ERA concept for testing non-target effects of GM plants was proposed (Hilbeck et al., 2011). This concept is based on a procedure for the selection of the most relevant testing organisms and the development of appropriate testing methods (Fig. 1). This procedure builds on the outcomes of an initiative of scientists engaged in the international 'GMO ERA Project' run by the global working group 'Transgenic Organisms in IPM (Integrated Pest Management) and Biocontrol' under the auspices of the IOBC (International Organization for Biological Control) (Hilbeck and Andow, 2004; Hilbeck et al., 2006; Andow et al., 2008). The ERA concept from this group focuses on the whole GM plant instead of the isolated toxin (i.e. transgene product) only and tailors the ERA to the case definition as laid out in Directive 2001/18/EC. By doing so, the selection procedure from Hilbeck et al. (2011) aims to identify and select testing species from the receiving environment. This selection procedure (Fig. 1) has been integrated at least in part into the revised guidelines for ERA of GMO by EFSA (EFSA, 2010a,b) and will become part of the EU regulation upon final adoption.

However, the implementation of the improved ERA concept still lacks operational tools regarding how, in practical terms, the selection of organisms and methods can be done in a systematic, uniform and transparent fashion. Here, we introduce such practical tools for the proposed selection procedure and test them with the herbicide resistant Bt-maize TC 1507. The main objectives of this project were: i) to develop a set of detailed guidance and selection matrices to facilitate the ranking of the species in Steps 1 through 4 (see Fig. 1) of the selection procedure, and ii) to test these matrices-based ranking tools in the case example of Bt/HR maize in a 3-day expert workshop. In this article, we report about the outcomes of these two objectives.

2. Methods

In the following, we briefly describe the conceptual steps of the improved ERA concept and the tools specifically developed for their operationalization. One guidance table and one matrix are new and applied first time to this case example, two matrices have been further refined that had been developed in earlier projects.

2.1. Selection procedure

An effective way to understand the role of biodiversity is through ecological functions (EFs) that the diversity of organisms execute. The use of EFs allows focussing on the identification of possible adverse effects and subsequently testing of the relevant species and critical ecological processes. Identifying important EFs, thus, helps to limit the number of organisms that must be tested to those that are ecologically relevant. Choosing a functional approach to the selection of relevant test organisms is warranted when knowledge about species is limited and incomplete, as e.g. for soil organisms. The strategy is to compile species lists according to their EFs and their presence in the specific cultivation region(s) (i.e. the receiving environments). Subsequently, the species number is reduced in a systematic, transparent, and stepwise fashion to a relevant and practical number of test organisms and/or processes (Hilbeck et al., 2008, 2011). This procedure consists of six steps (Fig. 1). The first four steps that were applied to our case examples are briefly described below.

2.1.1. Selection procedure part 1 – ecology

Step 1–Concept: Identify important ecological functions for GM cropping system. EFs are identified that may be impacted by the GM crop in the given cropping system and receiving environment. The identification is based on biodiversity services such as pollination or biological control delivered by NTOs or certain ecological processes. The importance of these functions and services may vary with different crop species, recombinant traits and regions. Pollination, for instance, is of critical importance for insect-pollinated plants like oilseed rape but to a lesser degree for wind-pollinated crops like maize. However, impacts on nearby habitats like field margins or hedgerows and the interaction/influence between in field and off field living species on EF should be taken into account too.

Tool for operationalization. A new guidance table was developed that allowed for the systematic selection of the most important EFs required for sustainable production in the given agricultural setting of the GM plant (Table 1). The table is structured on the basis of the elements describing the 'Case GMO':

(i) The biology of the crop and its agronomic requirements for production.
(ii) The novel trait relating to the intended effect.
(iii) The receiving environments relating to the intended use.

The developed guidance table is still work-in-progress and should be refined with each further round of application. If archived and used for later applications of the same crop, they can be complemented and lead to a detailed and widely re-usable tool for a specific crop species.

Step 2 – Matching the ecological functions (EFs) with non-target organisms or ecological processes. For the most important EFs identified in Step 1, the species known to execute that function are assigned to these functions. Some organisms may contribute to more than one function (e.g. ladybeetles may be natural enemies and pollen feeders/pollinators). However, for many Efs, we do not know all contributing species. For example, many important EFs in soils are carried out by an unknown number of unidentified