Surrogate Species Selection for Assessing Potential Adverse Environmental Impacts of Genetically Engineered Plants on Non-Target Organisms

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on the flora, fauna and microbial population of the rhizosphere present in the agro ecosystem is split into sub-items. The sub-item D.11.1 looks into the effects of the GM plant on non-target organisms (or substitute species) that directly or indirectly interact with the crop by assessing the product expressed in the GM plant, the plant material and/or by planting the GM plant. The sub item D.11.2 looks into the effect of the GM plant on species and ecologic interactions relevant for the local agro ecosystem. The first assessment refers to different approaches (laboratory bioassays, semi field trials, or field trials) to assess the risk hypothesis for pest resistant traits and their effect on non-target organisms. The second sub-item comprises all other information specifically related to species and ecological interactions that could be relevant for the local agro ecosystem for a particular trait that have not been addressed in the first item and must be addressed case-by-case. In relation to these points of the application form, last year we conducted a two-day meeting with experts on four relevant crops (soybean, maize, cotton and sugarcane) to analyze which are the valued entities (particular valued species, gilds of species or ecological interactions) in the Argentina's agro ecosystem for each of these crops.

Another new issue in the amended regulations is the introduction of the Previous Consultation Instance (ICP in Spanish). This is an evaluator-applicant exchange mechanism that aims to clarify some of the information to be included in the form and provide details of the criteria to be used in the application. This instance is optional and designed for the benefit of the applicant rather than an instance of debate of regulatory criteria.

The evidence to be provided by the applicant for the non-target organisms risk assessment must entail: the setting of testable risk hypotheses, the definition of the criteria for appropriate selection of test species and ecological functional group, the laboratory and field studies results with an appropriate experimental design and the estimation of risk/safety based on conclusions of these studies. Some specific issues are taken into account for the information submitted and those must be consistent with the hypothesis to be tested. These issues include: the mode and spectrum of action of the expressed proteins and biochemical interactions, the exposure pathway and the level of exposure. In all cases, the evidence provided must be relevant, accurate, complete and reliable. Regarding reliability, those studies that use validated or standardized methods and/or are conducted under good laboratory practices (GLP) as well as peer-reviewed literature and also those studies based on consensus documents of international organizations are considered among reliable sources of information to pursue a risk analysis.

3.3.2 Brazil

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In Brazil, Law Nº 11.105, of 24 March 2005 regulates items II, IV and V of Paragraph 1 of Article 225 of the Federal Constitution, provides for safety norms and inspection mechanisms for activities that involve genetically modified organisms (GMOs) and their by-products, implements the National Biosafety Council (CNBS), restructures the National Biosafety Technical Commission (CTNBio), provides for the National Biosafety Policy (PNB), revokes Law Nº 8.974, of 5 January 1995, Provisional Measure Nº 2.191-9, of 23 August 2001, and Arts. 5, 6, 7, 8, 9, 10 and 16 of Law Nº 10.814, of 15 December 2003, and provides for other measures. The Brazilian legislation includes one law, two decrees, seven communications, CNBS resolutions, and nine normative resolutions. Normative Resolution No 05, of March 12, 2008, gives provisions on rules for commercial release of Genetically Modified Organisms and their derivatives, and includes the norms on non-target organisms.

General and Preliminary Provisions

In Article Nº 1, the law provides for safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of GMOs and their by-products, guided by the drive for attaining scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and the compliance with the principal of environmental precaution. The Annex IV governs the Environment Risk Assessment and gives provisions on rules for commercial release of GMOs and their derivatives. These rules include plants, organisms used for biological control, and invertebrate animals.

The first part of these rules includes the plants.

A) PLANTS: Negative and positive effects to target and non-target organisms, that may take place with the released GMO, listing the species assessed, reason of the selection and techniques used to explain the impacts;

The second part of these rules includes all the organisms used for biological control including information about the non-target organisms.

B) ORGANISMS USED FOR BIOLOGICAL CONTROL: Seven basic pieces of information must be given by the applicant:

1. Target species of biological control and direct effects of GMO on such species compared with the effects on the parental organism;
2. Spectrum of organisms susceptible to the GMO and susceptibility of non-target organisms to the GMO, describing the criteria employed in the choice of organisms assessed;
3. Ways of GMO dispersion from one individual to another and factors that affect such dispersion;
4. Secondary effects that may happen to predators, preys, competitors, and parasites of the target species;
5. Metabolites produced by the GMO that may cause direct or indirect harmful effects on other species through concentration along the food chain;
6. Effects resulting from horizontal transfer to another organism, as the case may be;
7. Possible genetic modifications that may happen in populations of the target organism as a result of the GMO use.

The third part of these rules includes all the invertebrate animals, including information about non-target organisms.

C) INVERTEBRATE ANIMALS: Eight basic pieces if information must be provided by the applicant:

1. GMO effects in the invertebrate's food chain;
2. Possible production of new metabolites or toxins by the GMO that are able to cause harmful effects on the invertebrate's parasites or predators;
3. Possible adverse effects of such GMO releasing in the local ecosystem;
4. Records of likely natural populations of the parental organism within Brazil and, in the affirmative, discuss their effects, either beneficial or harmful, to agriculture, environment, and public health;
5. Likelihood of the transgene to be transmitted to other species through non-conventional reproduction mechanisms and, in the affirmative, specify the transfer mechanism, listing the species;
6. Possible existence of experimental work on the phenotypic expression of the transgene in breeds of specific lineages modified with wild organisms. In the affirmative, describe what these results were;
7. Change in distribution and abundance of natural populations by the possible integration of the transgene to the genic set of such populations, reporting on the possible effect of such change;
8. Mechanisms to be used to check dispersion of the GMO to other environments.

Normative resolution Nº 5 also rules the Post-Commercial Release Monitoring that is required in Brazil. Some basic information is also required regarding the non-target organisms.

1. The monitoring shall be conducted by the applicant with the purpose of oversee the effects resulting from commercial release of a GMO and its derivatives to the environment and human and animal health.

2. The monitoring shall be conducted under strict observance of the principles of precaution, transparency, and scientific independence.
3. The monitoring shall be guided by internationally recognized scientific methodology and experimental designs adequate to the inferences to be made.

Considerations

The expression in plants of foreign genes of agronomic interest using modern transgenic technologies has provided different options to produce important genetically modified (GM) crops. Despite the high rate of adoption of GM crops, there are many concerns about the possible impact of these crops on the environment. The primary ecological concerns to the release of transgenic plants include those related to their possible invasiveness in ecosystems, out-crossing, horizontal gene transfer, development of pest resistance and effects on non-target organisms (Conner *et al.*, 2003). One of the primary concerns related to the adoption of insect resistant transgenic plants in the environment is the detrimental effect that these may pose on non-target organisms, including entomophagous arthropods (parasitoids and predators), which have an important function in regulating pests (Dutton *et al.*, 2003). Effects of GM plants on non-target entomophagous arthropods (predators and parasitoids) have been a major concern, as these organisms often play an important role in natural pest regulation and are considered to be of economic value. Moreover, this group of organisms may be a good indicator of potential ecological impacts of transgenic plants as they belong to the third trophic level in the food chain (Groot and Dicke, 2002).

In Brazil, CTNBio members (regulators) are identified with their area of expertise. These areas include: Crop Science and Environment, Human, and Animal Science. At least two regulators, depending on the dossier, are chosen to evaluate each GMO to be commercially released. Each dossier is evaluated case by case, and step by step. So, the possible effects of GM crops on non-target organisms follow the same rules and regulations.

According to the *The Economist* (2010) in less than 30 years Brazil has turned itself from a food importer into one of the world's great breadbaskets. It is the first country to have caught up with the traditional "big five" grain exporters (America, Canada, Australia, Argentina and the European Union). It is also the first tropical food-giant; the big five are all temperate producers. Due to a favorable climate, crops are planted throughout the year, and the farmers plant a second crop of corn or cotton called the safrinha. This new scheme of crop rotation is to first plant a rain-fed crop, such as rice, soybean or maize, and then after these crops are harvested, plant a second crop of soybean, sorghum or even maize. Safrinha can also be defined as a farming strategy whereby the farmer takes advantage of a long tropical growing season to produce two crops in a single growing season, thereby maximizing revenue per acre. This new fact also causes concerns because (GM) crops are planted after (GM) crops, and insects are always exposed to crops even during the dry season. Usually insects may be exposed to the same *Bacillus thuringiensis* (Bt) genes, although different crops are planted. Farmers will have to plan a "gene rotation" instead of (GM) crop rotation.

It also should be considered that a GM crop is attacked by different insect pests; however, these insect pests may attack more than one crop and may be exposed to more than one toxin (in this specific case, Bt toxins), and these insect pests will be the target of parasitoids and predators. Other problem that may evolve is that the non-target organisms may be exposed to different toxins.

In Brazil post-commercial release monitoring is required by law, however, for some researchers it doesn't make any sense, because to be commercially released, a GM crop must be fully studied and a dossier must be fully completed. So, when a GM crop is commercially available it is considered to be safe. On the other side, some researchers state that this monitoring is extremely important because some problems may occur in the future and the studies showed in the dossier are not enough. Some researchers recommend following these GM crops in the field for many years. However, another issue that is not clear is how to address the post-commercial monitoring. Some important issues are still discussed such as:

- If a GM crop is commercially approved and available in the market, there´s no need to do all the research again. Monitoring is different from research.
- Research on non-target organisms only if some questions arises. This research step should be GM crop and non-target organism specific.
- Monitoring all possible effects in the environment, however it should be considered when evaluating and based on actual events. Scientific evidence should be considered.
- It should be considered that sampling and surveying large areas of commercially available GM crops is totally different from sampling field trials.
- Monitoring should also consider the presence of single genes and stacked genes for insect pests. Possible interactions should be considered.

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3.3.3 EFSA'S Specific Approach to Assess Adverse Environmental Impacts on Genetically Engineered Plants on Non-Target Organisms

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In the European Union (EU) a scientific opinion (SO) on the assessment of potential impacts of genetically modified (GM) plants on non-target organisms (NTOs), hereafter referred to as NTO SO, was issued in November 2010 (EFSA, 2010a). The drafting of this document was an initiative undertaken by the European Food Safety Authority's (EFSA) Panel on genetically modified organisms (GMOs), with the aim of providing guidance for risk assessors on assessing potential effects of GM plants on NTOs together with a rationale for data requirements. Issues to which special attention was paid were (i) criteria for non-target (NT) species selection and (ii) advice on testing approaches.

Criteria for non-target species selection

Because not all NTOs present in the environment where a GM plant is grown can be tested in an environmental risk assessment (ERA), a representative subset of species (named "focal species" by EFSA) is selected. For the selection of focal species, a 4-step approach combining the strengths of two existing species selection approaches - the ecological and ecotoxicological approach - is proposed.

Starting with problem formulation (step 1), functional groups (*e.g.*, herbivores, pollinators, natural enemies, decomposers) relevant to consider in the ERA are defined. Subsequently (step 2), NT species occurring in the GM plant's receiving environment are categorised within the identified relevant functional groups. The GM plant's receiving environment to be considered is the European agro-ecosystem (EFSA, 2010a). If relevant, endangered species also need to be listed. A first prioritisation of species (step 3) is based on ecological criteria (*e.g.*, species' exposure to the GM plant, abundance, feeding habits, sensitivity to trait) as done in the ecological approach. When selecting the most appropriate species for testing (step 4) - the focal species - practical criteria (*e.g.*, species' availability and testability) considered in the ecotoxicological approach are applied. In the end, this approach results in the selection of testable species belonging to relevant