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Science based criteria for a simplified risk assessment of genetic engineered crops developed using identical or similar constructs

ILSI Argentina Working Group on Biotechnology

Boari, P., Burachik, M., Cuadrado, V., Herrmann C., Junco, M., Lede, S., Lema, M. A., Lewi, D., Maggi, A., Meoniz, I., Noe´, G., Roca, C., Robredo, C., Rubinstein, C., Vicien, C., and Whelan, A.

Background

Experience with Agricultural Biotechnology and the widespread adoption of different genetically engineered (GE) crops around the world has enabled breeders to develop different crops with similar phenotypic characteristics using the same or related genetic constructs. Identical constructs would be used mostly on vegetatively propagated crops, which need to be transformed *de novo* to produce new varieties with the same phenotypic characteristic(s), while similar constructs would also be used to develop different GE crops.

The history of safe use of different methodologies by breeders to generate diversity in crops, current knowledge about plant genome dynamics, and experience with transgenesis provide a reasonable basis to focus on the introduced traits and phenotypes. Additionally, when assessing risks, the domestication, conventional breeding, and the intrinsic plasticity of plant genomes are recognized as greater sources of genetic changes than methodologies based on genetic engineering[1].

All of the above, in addition to the available risk assessment (RA) of GE crops and experience with constructs, the traits, crops, and crops–traits combinations support a simplified evaluation process for new events transformed with constructs that are identical or similar to those used in previously evaluated GE crops.

Data requirements consistent with a science based analysis and focused on identifying any new potential risks would help bring new developments to the agricultural landscape in an efficient way, without compromising the robustness of the RA. For the same reasons, numerous regulatory agencies worldwide have proposed simplified treatments for these particular cases, although with different degrees of scope and application.

In Argentina, the International Life Sciences Institute (ILSI Argentina) convened a tripartite working group, which brings together experts from Academia, Government, and Industry (www.ilsi.org), to develop a construct-based RA framework for GE crops[2,3] and to formulate a tool that both risk assessors and developers could use for a simplified RA. A general process based on a problem formulation[4] methodology was defined, supported by a list of guiding questions that builds on available information from prior safety assessments and on familiarity. This framework would provide guidance for identifying new risk hypotheses and define additional data that might be required.

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Definitions

For the purpose of these discussions, a **construct** is defined as a set of nucleotide sequences designed to express certain phenotypic characteristics when introduced into a recipient organism. **Construct similarity** is defined based on functional similarity of constructs designed to obtain the same phenotypic characteristic(s) through the same biological mechanism(s).

Risk assessments considerations

A list of guiding questions was formulated by the working group to assist in developing a construct-based, simplified RA process. In this process, the analysis of new transformation events with identical or similar constructs within the same or different crops would be carried out in a scientifically sound manner based on prior environmental and food/feed safety assessments done for precedent GE crops.

Conducting a problem formulation exercise as the first step in the risk assessment process contextualizes the case and makes use of available data and familiarity to identify any new or different risk hypothesis for the new crop. The main aspects to be considered for this simplified RA process are: 1) eligibility of the construct; 2) familiarity with the crop and the trait; and 3) potential environmental and dietary exposures.

Eligibility for a simplified treatment

New cases under assessment would be eligible if developed using a construct that falls under the definition of construct similarity, provided that the precedent case had a favorable review or if it was previously approved by a regulatory authority. Under this framework, knowledge of the functionality of the introduced genes is key, as two constructs can be deemed as similar if designed to confer the same characteristics through the same biological mechanisms. In the case of similar protein expression products, these requirements would commonly apply to the protein family, derived from a common gene, and not need to be necessarily reflected in high sequence homologies. However, any similarity claim (other than identity) should be supported by bioinformatics and other relevant evidence.

Familiarity and exposure assessments

Problem formulation, exercised on eligible cases, will help identify the relevant questions that need to be addressed for the new crop/trait combination, in addition to the available information to be considered. In this regard, it is relevant to consider the level of familiarity of the new crop in the receiving environment, as well as with the trait in the same or other crop(s). Familiarity has been defined as "the knowledge gained through experience over time, that considers the nature of the crop that was modified, the characteristics of the trait that was introduced, the likely receiving environment for the GM crop, and the likely interactions between these."[5]

As mentioned, potential exposure is a relevant factor to consider. For this, it is essential to have a thorough knowledge of the biology of the host crop, the extent of cultivation and consumption expected, as well as to consider the agronomic practices and intended uses, in order to assess if these would be different from precedent cases. In particular, the biology of the crop would be a key aspect for new transformation events in different species, if the new crop lacks a history of cultivation in the receiving environment or if it is new to the diet of the local population.

Basic information

A basic set of data typically would be required to confirm that previously available information on the construct or crop/construct combination can be reliably and appropriately applied to the new transformation event. The scope and level of detail of the information needed will depend on the case under study. Molecular characterization provides identity to the GE event and confirms that the desired trait derives from the introduced construct.

Protein expression levels might be relevant in specific cases, e.g., in terms of environmental or dietary exposure, depending on the trait. Compositional data may also be needed (on a crop-specific basis), depending on the presence of specific components such as known toxicants, anti-nutrients, or key nutrients in the new crop.

To study environmental exposure, additional data would be needed, for example, for different species expressing the same insect-protection trait. Information about relevant non-target organism species known to interact specifically with the new crop but not with the one previously evaluated might be required, to determine if they could be affected. The available knowledge acquired through the evaluation of the precedent GE crop, together with the guiding questions, will help define the basic set of data needed to validate the use of prior assessments in the simplified RA.

Finally, as it is recognized that the selection process routinely applied during the development of new GE varieties effectively eliminates materials with unwanted characteristics, a comprehensive description of the breeding and selection process would add to the weight of evidence to support a simplified construct-based RA[1].

Risk hypotheses

The problem formulation methodology ultimately helps to identify new plausible risk hypotheses[6] that would need additional data for the RA. Some situations, like the use of identical constructs, may not identify any new risk hypothesis; while others, like the use of similar constructs in different species, may require specific additional data.

Applicability and conclusions

This framework was developed as a construct-based approach that would be applicable to many eligible situations. Based on the construct similarity definition, different situations may be identified which might use information of the precedent cases or eventually require different amounts and types of additional evidence to assist the RA.

It is expected that this kind of approach would be mostly helpful for developers in the public sector and small enterprises which typically would have limited resources to duplicate studies or to get information that could be already known from precedent cases for the purpose of the RA. In addition to major crops, this approach could also aid in the RA of other crops (i.e., food crops, medicinal, ornamental, forestry), including the so called ‘‘orphan crops’’ that can be of interest to many regions or countries[7,8].

Building on previous knowledge and familiarity, science-based decisions about the safety of new GE crop(s) can be made without compromising the robustness of the RA, while minimizing the development and review of redundant information and the use of limited resources. Finally, many of these considerations can also be extended to the RA of other situations (like molecular stacks and breeding stacks) to enable the availability of new combinations, like the ones that can help manage insect or weed resistance in a timely manner, without biosafety concerns.

Guiding questions

Is this case eligible for a simplified analysis ?
Is the construct identical to a previously evaluated/approved one? If not identical, does the construct fall within the definition of similarity?

What is the level of familiarity in this case?
Is there familiarity of the host crop in the receiving environment? Is there familiarity with the trait in the same and/or other species (GE or not)?

Which are the exposure scenarios involved?
Are the agronomic practices, geographic cultivation areas , consumption patterns or intended uses different from conventional or approved GE counterparts ?

Does this crop/construct combination raise new/different concerns over similar approved events? ***(new risk hypothesis)***

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First Doomsday Vault Withdrawal, NAS on GE Crops, and the Glyphosate Debate

Phill Jones

For 12 years, the Global Crop Diversity Trust (Bonn, Germany) has funded, equipped, and coordinated 11 global gene banks to preserve seeds, including thousands of varieties of seeds used to grow 17 essential world crops. In April, Crop Trust announced that the group had accumulated pledges totaling US$300 million from 14 nations, non-profit organizations, and the private sector. The figure doubles the amount of funds collected during the past two years. But the pledged amount is less than half the endowment goal required to protect 1.5 million critical seed populations.

Copies of the seeds are stored in the Svalbard Global Seed Vault, located inside a mountain on an island in the Svalbard archipelago, halfway between the northern tip of mainland Norway and the North Pole. This "doomsday vault" stores more than 860,000 varieties of seeds collected by more than 60 institutions from nearly every country in the world. The Crop Trust maintains the vault in partnership with the Norwegian government and the Nordic Genetic Resources Center.

During September 2015, the Svalbard Global Seed Vault allowed the first withdrawal of seeds. A gene bank called the International Center for Agricultural Research in the Dry Areas (ICARDA) had deposited backup seeds in the Svalbard Vault while it had been based in Aleppo, Syria. Due to the Syrian civil war, the group relocated to Beirut, Lebanon, and needed some of its deposited genetic material to reconstitute its collection to meet requests for germplasm from farmers and agricultural organizations. After reproducing the withdrawn varieties, ICARDA will return part to the Svalbard Vault. ICARDA's withdrawal of genetic material exemplifies one substantial value of seed vaults.

In an interview with Chris Mooney of *The Washington Post*, Marie Haga, the Crop Trust's executive director, explained another value of the stored seeds. "The trouble these days is that the plants that are the basis of our food are not able to adapt as fast as the climate is changing," Haga said. "And that is why we need to breed new varieties of our major crops that can stand high temperature, a more unpredictable weather, that give high in nutritional value, and this gives better meals." To achieve this, she said, researchers must use "building blocks of agriculture, this diversity of seeds."

Lee Hickey, Adnan Riaz, and their colleagues at Australia's University of Queensland are taking this approach to find genes in ancient varieties of wheat. They analyzed a panel of 295 accessions of wheat using 34,000 DNA markers. They obtained the genetic material from the N. I. Vavilov Institute of Plant Genetic Resources in St Petersburg, Russia. "The genomic analysis revealed a massive array of genes that are absent in modern Australian wheat cultivars," Riaz said in a university press release. "The ancient genes could offer valuable sources of disease resistance or drought tolerance."

NAS Reviews Experience with GE Crops and Looks to Future Technologies

In May, the National Academies of Sciences, Engineering, and Medicine released a report about experiences with genetically engineered (GE) crops. The Committee on Genetically Engineered Crops reviewed published literature, read more than 700 comments from members of the public, and heard from 80 speakers. The committee "concluded that sweeping statements about GE crops are problematic because issues related to them are multidimensional." Fair enough.

With regard to potential effects of GE crops on animal health, the group decided that "the large number of experimental studies provided reasonable evidence that animals were not harmed by eating food derived from GE crops." They also did not find evidence that GE crops adversely affected the health of livestock. The committee's review of epidemiological

data on the incidence of cancer and other human health disorders revealed "no substantiated evidence that foods from GE crops were less safe than foods from non-GE crops."

The group found that the cultivation of GE soybeans, GE cotton, and GE maize has generally produced favorable economic outcomes, such as higher yields, for producers who adopted the crops. The committee noted that, under certain conditions, GE crop cultivation can trigger resistance problems. If farmers did not follow resistance management strategies with *Bacillus thuringiensis* toxin-producing GE crops, then target insects developed "damaging levels of resistance." Similarly, some weed populations evolved resistance to glyphosate if the cultivation of glyphosate-tolerant GE crops led to a heavy reliance on glyphosate. The committee suggested that the sustainable use of GE crops that produce *Bacillus thuringiensis* toxin or that were engineered for glyphosate tolerance will require the application of integrated pest-management strategies to avoid the selection of resistant insects or weeds.

The committee also considered new techniques that are being used to engineer traits in plants. "Emerging genetic technologies have blurred the distinction between genetic engineering and conventional plant breeding to the point where regulatory systems based on process are technically difficult to defend," they said. "The committee recommends that new varieties—whether genetically engineered or conventionally bred—be subjected to safety testing if they have novel intended or unintended characteristics with potential hazards."

Glyphosate Safety: A Pressing Concern or Much Ado About Nothing?

Glyphosate is a non-selective herbicide that targets the shikimate pathway enzyme 5-enolpyruvylshikimate 3-phosphate (EPSP) synthase. As a result, glyphosate blocks the synthesis of three amino acids essential for growth. EPSP synthase occurs in plant cells and many bacteria; animals lack the enzyme.

In 1974, Monsanto Company developed Roundup®, which contains glyphosate as the active ingredient. Because glyphosate killed both weeds and crops, farmers' use of Roundup® was initially limited. This changed in 1996 with the availability of glyphosate-tolerant GE crops, which enabled farmers to spray Roundup® after crops started to grow. Since the introduction of Roundup Ready® crops, glyphosate use increased about 15-fold. In the US, two-thirds of glyphosate used from 1974 to 2014 was applied during the last ten years. Today, glyphosate is the most widely applied herbicide worldwide. The massive application of glyphosate has raised questions about the safety of the chemical.

During March 2015, the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) issued a report that classified glyphosate as "probably carcinogenic to humans." The basis for the classification was not uncomplicated. The group said that several studies indicate that people who work with glyphosate seem to be at increased risk of non-Hodgkin lymphoma. Yet they also mentioned that a large US study failed to find a connection to non-Hodgkin lymphoma. In the end, studies that linked glyphosate to tumors in rats and mice tipped the balance for IARC's classification.

What does the IARC report mean? *The New Yorker*'s Michael Specter placed the significance of the classification into context with a comment by Andrew Maynard, who was the director of the Risk Science Center at the University of Michigan School of Public Health. "It is the equivalent of saying a rock could kill you," Maynard said, "but not pointing out that it probably needs to be dropped on your head from a great height first."

Still, the IARC report forged a link between glyphosate and cancer in the minds of many. The November announcement by the European Food Safety Authority that glyphosate was unlikely to cause cancer seems to have had little effect to reduce fears about the chemical.

On Friday, April 29, the US Environmental Protection Agency posted an 86-page internal document on its website stating that the agency's cancer assessment experts decided that glyphosate is "not likely to be carcinogenic to humans." On the following Monday, the EPA deleted the memo from its website; the agency said that the assessment was not

final. Despite this explanation, Reuters reported that "FINAL" was printed on each of page of the memo, which was dated October 1, 2015. The EPA promised that its final, final assessment will be completed by the end of 2016.

On the other side of the Atlantic, scientists discussed the issue of pesticide safety. The Food and Agriculture Organization of the United Nations Panel of Experts on Pesticide Residues in Food and the Environment met with the WHO Core Assessment Group on Pesticide Residues at WHO Headquarters in Geneva, Switzerland. The group's summary report stated that "[i]n view of the absence of carcinogenic potential in rodents at human-relevant doses and the absence of genotoxicity by the oral route in mammals, and considering the epidemiological evidence from occupational exposures, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet."

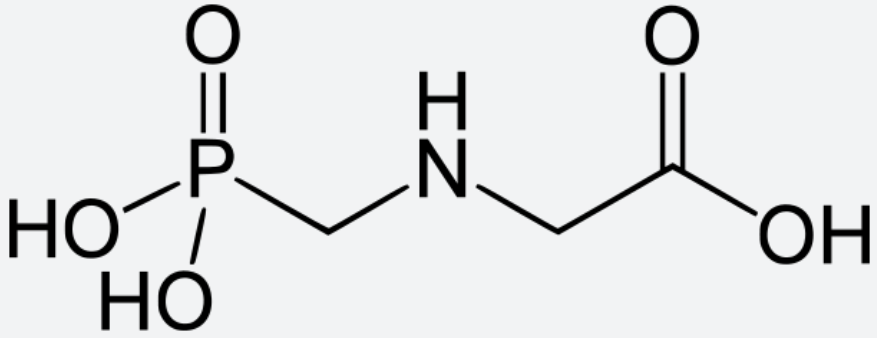
Another type of venue will focus on glyphosate safety: courts. During the spring, plaintiffs filed more than a dozen lawsuits across the US, alleging that glyphosate exposure caused cancer and other health disorders. Some claim that Monsanto hid evidence about glyphosate safety and manipulated regulators.

In March, a group of European non-governmental organizations sued Monsanto and the European Food Safety Agency for allegedly distorting scientific data on the carcinogenic effects of glyphosate to keep the herbicide in the European market. The plaintiffs filed the lawsuit days before European Union representatives were scheduled to vote on whether the EU should renewal approval for glyphosate.

The glyphosate license renewal has sparked controversy since the European Commission proposed in February to re-approve the license for another 15 years. The license had to be renewed by the June 30 deadline, or glyphosate would no longer be authorized in the EU and Member States would have to withdraw authorizations for all glyphosate-based products.

The vote on re-approval was postponed in March after four Member States raised objections. The European Parliament then proposed a compromise: The glyphosate license should be approved for another seven years. But a May meeting of the EU standing committee on plants, animals, food and feed failed to achieve a vote.

On June 27, the EU Commission failed for a third time to convince a majority of EU governments to extend the glyphosate license. France and Malta reportedly voted against re-approval, and seven countries abstained from the vote. Wanting to devote attention to the consequences of Brexit (British exit from the EU), the Commission extended the glyphosate license for 18 months.



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Detection of GE Wheat Volunteer Plants in Washington State

USDA has confirmed the discovery by a farmer of 22 genetically engineered (GE) wheat plants growing in an unplanted agricultural field in Washington State. The GE wheat in question is resistant to the herbicide glyphosate, commonly referred to as Roundup®. APHIS has taken prompt and thorough action in response to this discovery and has no evidence of GE wheat in commerce.

The GE wheat was developed by the Monsanto Company and is referred to as MON 71700, containing the CP4-EPSPS protein. The U.S. Food and Drug Administration (FDA) previously evaluated crops containing the CP4-EPSPS protein for safety through its voluntary biotechnology consultation process. Due to the small number of affected plants, and based on the available information about MON 71700 and CP4-EPSPS, FDA concluded it is unlikely that the wheat would present any safety concerns if present in the food supply as a result of this incident.

Working with the farmer, APHIS has taken measures to ensure that no GE wheat moves into commerce. Out of an abundance of caution, APHIS is testing the farmer's full wheat harvest for the presence of any GE material. The farmer's harvest is complete, and it continues to be held while USDA completes tests of the grain. So far all samples continue to be negative for any GE material. If any wheat tests positive for GE material, the farmer's crop will not be allowed in commerce.

Monsanto has developed a test that will identify MON 71700 in commercial grain shipments, and USDA has validated the test and its sensitivity level so that trading partners can use the test for wheat imports, if they choose.

USDA is collaborating with our state, industry and trading partners, and we are committed to providing all our partners with timely and transparent information about our findings.

There are no genetically engineered (GE) wheat varieties for sale or in commercial production in the United States at this time, as APHIS has not deregulated any GE wheat varieties.

In recent years, USDA has taken steps to strengthen its oversight of regulated GE field trials. APHIS now requires developers to apply for a permit for field trials involving GE wheat beginning with GE wheat planted on or after January 1, 2016. The decision to require the more stringent permit process rather than the notification process employed in the past, provides added protection that GE wheat will remain confined during field trials.

Source: USDA APHIS BRS News.
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/ge+wheat+washington+state