AFRICAN CENTRE FOR BIODIVERSITY

Application to the Executive Council: GMO Act to review its decision to approve GM wheat for import into South Africa as food, feed, and processing

May 2023

Table of Contents

Introduction

The African Centre for Biodiversity (ACB) is a research and advocacy organisation working towards food sovereignty and agroecology in Africa, with a focus on biosafety, seed systems, and agricultural biodiversity. The ACB has been engaging with biosafety issues for the past 20 years at national, regional, and international levels. It has a long and established track record of interacting with the Executive Council (EC) established in terms of the Genetically Modified Organisms Act. This includes the ACB having submitted more than 60 objections in respect of various applications for approval, involving diverse genetically modified organisms (GMOs), for various purposes. It has also participated in various stakeholder consultations over the years as well as having been involved in administrative appeals and a review to the High Court involving Monsanto's GM drought-tolerant maize. This matter is awaiting judgment.

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We are making this application in terms of Section 4 (2)(g) of the GMO Act (as amended), read together with related provisions, which deals with the review of decisions by the EC, on the grounds that it has failed to consider relevant scientific evidence concerning the adverse impacts posed by the genetically modified (GM) wheat event HB4. We argue that if taken into account, this evidence would have had an influence on the outcomes of the risk assessment upon which the decision of the EC was made to grant the approval.

We are of the respectful view that the members of the EC accepted, at face value, the extreme paucity/lack of data to justify its decision in granting the approval, without applying their minds critically to the lack of data and without ensuring that the necessary health and safety risks associated with the GM wheat had been assessed thoroughly and independently. This is particularly pertinent in the light that wheat is an important staple food in South Africa, consumed by millions of people on a daily basis. Wheat is a major source of carbohydrates, in the form of starch, with its seeds also providing an important source of protein. It is used ubiquitously in everyday food (including staple foods), such as bread, noodles/pasta, couscous, cakes, muffins, biscuits, snack foods, puddings, and sauces in confectionery.

Further to this, it is our contention that the EC as decision-makers failed to properly apply their minds to the material before them as they are required to do in terms of the GMO Act, and as such their decision to grant the approval is procedurally flawed. In this regard, the EC failed to consider the grave concerns raised by the research community, with 1 400 scientists warning that GM wheat introduction would perpetuate an agribusiness model that is harmful to the environment and biodiversity while failing to solve the problems of the food system. They cautioned that GM wheat will further threaten the health of people and jeopardise food security and sovereignty (Biodiversidad, 2021).

The ACB contends that the precautionary principle dictates that a GMO should be approved only where such approval is supported by positive and convincing scientific evidence. Where there is any uncertainty as to the risks of harm posed by the GMO then it ought not to be approved unless and until these risks can be positively discounted.

The ACB's reliance on the precautionary principle is informed by the paucity of reliable scientific evidence of the safety of the GM wheat in question that was before the EC when it made its decision. It is our contention, that at best, there is a great deal of uncertainty around the use of GM wheat and that more scientific evidence is required before it can conclusively be considered to be safe. It is this uncertainty that triggers the application of the precautionary principle.

The principle has been reaffirmed in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity ("Cartagena Protocol"), the objective of which is set out in Article 1 as follows:

> *"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements."*

In line with this objective, the Cartagena Protocol makes clear that where there exists insufficient relevant scientific information and knowledge regarding possible adverse effects of a GMO, this cannot be relied upon in order to establish a particular level of risk, the absence of risk or a particular level of risk, nor does it preclude decision-makers from taking decisions that avoid or minimise potential adverse effects.

Further to this, we remind the EC that there is no onus upon the ACB to introduce conclusive scientific evidence to trigger the application of the precautionary principle. To require the ACB to furnish such evidence would render meaningless the very essence of the precautionary principle, which dictates that where there may be a threat of harm, it is the applicant that bears the onus of establishing that the threat is negligible. It is our contention, based on the concerns raised below, particularly in regard to food safety issues, that the applicant failed to discharge this onus.

The EC's decision document is an exceptionally cursory one, and there is no indication that the EC evaluated and engaged critically with the paucity of information and lack of data, assessments, and evidence before it. Indeed, the EC's decision that there was no need to pursue whole food and feed studies suggests that there was no rigorous scientific assessment conducted in relation to the safety and efficacy of GM wheat. To make matters worse, the EC failed to call for an independent risk assessment despite there being no data at all on the safety of the GM wheat in question, particularly since no feeding studies had been undertaken.

Risks of HB4 trait in wheat

We set out below, the risks associated with GM wheat, which we argue, should have been taken into account by the EC and which it failed to do.

Food Safety Assessments not performed

First, we point out that the most standard and basic food safety assessments were not performed. Despite GM wheat being destined for the human food supply, there appears to be no published toxicity data in the scientific or regulatory records, including the risk assessment submitted to the EC. Indeed, no toxicity feeding studies were conducted at all for the risk assessment, neither to the EC nor the Argentinian biosafety authorities, even of the rudimentary tests routinely submitted by industry, where bacterially produced versions of the introduced proteins are tested in mice for risk assessment. Indeed, we have ascertained that no feeding studies have been conducted anywhere in the world.

The only assessments done to justify the claims of safety are:

1. An allergenicity study that involves assessing if the proteins intended (not any unintended) for introduction can break down in simulated digestive juices.
2. Computer-based bioinformatics analyses that assess whether the introduced HaHB4 protein and PAT protein confer glufosinate ammonium tolerance; and
3. Compositional analysis where levels of just 41 different components, e.g. vitamin levels, were analysed in the plant, and two anti-nutrients were assessed.

It is our view that the risk assessment makes completely unfounded assertions that feeding studies are not needed due to the above tests being performed, and the fact that conventional wheat has a history of safe use.

Such omissions fail to meet the requirements for a precautionary principle approach to risk assessment for a food that is destined for high levels of human food consumption. Moreover, it completely fails to consider important additional aspects of the risk assessment that indicate potential risks of HB4 wheat. In this regard, the risk assessment report noted that there are several unintended insertions of genetic

material in GM wheat. Unintended insertions of the vector backbone mean that the wheat carries genetic sequences that it was not intended to carry.

As stated in the risk assessment:

> *"In summary, the insertion contains three copies of HaHB4 (two complete and one incomplete) and eight copies of bar (seven of them complete and one incomplete). In addition, the insertion contains 19 copies of the bla gene (12 complete and seven incomplete), four copies of gus (all incomplete). Among all these sequences, only one copy of HaHB4 and three copies of bar re functional, e.g.: have their regulatory sequences in the right position and direction to allow expression in HB4 wheat."*

These unintended insertions include a gene that encodes for a truncated version of the gus gene, which was not supposed to be introduced, and further has resulted in a truncated protein, which has not been assessed in any way, because the risk assessment only assessed HaHB4 and PAT proteins for potential allergenicity and digestibility analysis. No proteins that have been unintentionally introduced have thus been assessed, due to a complete lack of assessment of the whole plant.

Moreover, the risk assessment states that bioinformatics analyses assess if any novel proteins are potentially expressed in the plant, stating that there were 67 putative novel proteins potentially produced in HB4 wheat. None of these have been empirically assessed, but instead only assessed to determine whether they shared sequence similarities to known toxins using computational bioinformatics analyses.

Lack of understanding of how the HB4 functions

We have taken note that the developers themselves acknowledge that they do not fully understand how the trait is functioning in the plant. The HB4 trait involves the introduction of a gene from sunflower plants, called HAHB4. This gene's function is to control and regulate the activity of other genes (called a 'transcription factor'). Its function in sunflowers is thought to manage responses to abiotic stresses such as drought, saline exposure, mechanical damage, and herbivory. The rationale of the developer is that this gene may turn on/off genes in the event of drought, allowing the plant to cope by altering its genetic activity, including broader networks of genes. In their 2020 publication, it is acknowledged that they do not know what genes in the wheat the HB4 protein is regulating, stating that, "the way this TF is affecting such transcriptome is yet unknown". The unintended insertions may also have impacts on gene expression in the plant (González et al., 2019).

This raises additional concerns for food safety, as the trait is designed to change the activity of hundreds, or potentially thousands, of genes. The field trial publication for soybean (Ribichich et al., 2020) reported that introducing HAHB4 into the HB4 soybean resulted in the altered expression of 743 identified genes, including those involved in a variety of plant processes, including metal binding, protein metabolism, and inhibitors of trypsin, a protein digestive enzyme (also present in human stomachs), among other functions. Such information is lacking for wheat and thus warrants further investigation.

The implications for food safety are completely unknown, e.g., whether altering the activity of any of these genes may lead to increases in toxic metabolites, anti-nutrients, or allergens, and/or decreases in important nutrients. Such a trait that is designed to perform widespread alterations to genetic activity in the host plant clearly warrants further safety assessment regarding molecular and compositional characterisation. Such biosafety considerations could have been assessed with, for example, the use of 'omics' profiling techniques that perform unbiased analysis of the activity of thousands of genes, proteins, and metabolites.

In summary, considering that:

- Unintended proteins have been introduced due to unintended insertions of genetic material into the wheat; and
- The introduced trait is aimed to alter gene expression in the plant, but which genes it targets are currently unknown,

It is our contention the EC has failed to exercise due diligence when assessing the application and granting the approval including and especially, its failure to apply the precautionary principle.

Further to the concerns raised above, we would mention additional concerns relating to possible herbicide residues from the spraying of glufosinate on the GM wheat plant during cultivation. Glufosinate is linked to a range of adverse health and environmental effects, including brain damage, developmental disability (autism), and developmental defects following paternal exposure (e.g. Calas et al., 2008; García et al., 1998; Lantz et al., 2014; Laugeray et al., 2014; Meme et al., 2009), which has led to partial bans and restrictions to various countries.

Finally, we raise concerns about the contamination of the South African wheat supply and the possible adverse impacts if such GM wheat is to be imported into South Africa. Conventional and organic varieties will require entirely separate processing and supply chains to provide protection against contamination. However, even with such measures in place, contamination may become inevitable if widespread commercialisation does indeed occur. There is nothing in the decision of the EC that indicates members have applied their minds to these issues.

Further to this, we point out that consumers in South Africa have the right to know what is in their food and to make informed choices about what they eat. The Consumer Protection Act only requires food containing 5% or more GM content to be labelled. Food containing less than 5% GM content will thus not be labelled and consumers will have no idea that they are consuming risky and unsafe GM wheat.

South Africa is both an importer and exporter of wheat. It exports wheat to several African countries, including Botswana, Zimbabwe, Lesotho, Zambia, and Namibia. We have found no mention in the decision of the EC, of the risk management measure it would put in place to secure GM-free wheat exports to these African countries, none of which have approved GM wheat for human consumption. At a minimum, there would be the requirement of extensive use of silo bags and strict segregation and labelling measures would need to be put in place and adhered to.

Conclusion

The potential rollout of GM wheat in South Africa is occurring under circumstances where there is a complete dearth of safety assessment for human consumption, risking the safety of a vitally important food in the country. Such approval should not have gone ahead without ensuring against the harm to the citizenry and suggests a widespread failure in governance on the part of the EC.

The South African regulators are under an obligation to adopt a risk-averse and cautious approach to decision-making regarding GM approvals, relating to novel GM traits and crop plants involving staple food. We are of the view that such an approach was not taken. Considering the serious concerns raised in this submission regarding the paltry nature of the food safety assessment conducted by the applicant, we are of the view that it is incumbent upon the EC to review and reassess its decision and set the approval aside.

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