AFRICAN CENTRE FOR BIODIVERSITY

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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 organisation is committed to dismantling inequalities and resisting corporate industrial expansion in Africa's food and agriculture systems.

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ACRONYMS AND ABBREVIATIONS

BCH	CBD's Biosafety Clearing House
CBD	Convention for Biological Diversity
DAFF	South African Department of Agriculture, Fisheries and Forestry
EC	Executive Council: GMO Act
GM	genetically modified
GMO	genetically modified organism
ISAAA	International Service for the Acquisition of Agri-biotech Applications
SA	South Africa
USDA	United States Department of Agriculture

KEY FINDINGS

The converging multiple global crises are being exploited by a failed biotechnology industry, to promote the latest GM technofix – GM wheat – touted as drought-tolerant and a climate change solution. Yet, complex traits such as drought tolerance in GM crop plants remain an unfulfilled promise.

The biotechnology industry has been unable in the last 25 years, to move beyond two dominant traits: herbicide tolerance and insect resistance, both of which are now facing widespread efficacy challenges. The incursion into GM wheat is a desperate attempt at survival, by making a bid for control over lucrative wheat markets including the African region, in a classic disaster capitalist manoeuvre.

There is considerable pressure on Africa to diversify its wheat sources and lessen its dependency on Russia, thereby also decreasing the influence geopolitically that Russia has over Africa. Argentinian wheat exports have been suggested to replace much of the global demand. Noteworthy is that Nigeria, the world's second largest wheat importer, approved the GM wheat in July 2022.

The risk assessment furnished in respect of which the South African biosafety authorities (Executive Council: GMO Act) approved the GM wheat for importation into the South African food supply lacks pertinent and crucial food safety data, assessments, and evidence. Astonishingly, no feeding studies have been undertaken anywhere in the world regarding the GM wheat and thus it poses unacceptable risks to human and animal health as well as undermining food sovereignty and nutrition security.

GM wheat prolongs and perpetuates the destructive nature of GM monocultures and the spraying of toxic chemicals and forecloses a just transition to agroecological practices.

The South African biosafety regulators have failed to adopt a risk averse and cautious approach in assessing the application as it is required to do, in granting approval for the importation of GM wheat to enter the South African food system.

There are serious concerns about contamination of the South African food supply. These concerns also extend to Botswana, Zimbabwe, Lesotho, Zambia, and Namibia, countries in the region that import wheat from South Africa.

Considering the serious concerns raised, the Executive Council must review and reassess its decision and set the approval aside.

ABOUT THIS PAPER

In this paper, we scrutinise the application and risk assessment submitted by Trigall Genetics to the South African biosafety authorities with respect to its genetically modified (GM) wheat variety, HB4, and in respect of which it has received a commodity import approval. Such approval means that GM wheat will be imported into South Africa as food, feed, and for the purposes of industrial food and feed processing, as soon as this becomes commercially available in Argentina.

Our scrutiny, while focusing on food safety issues, is cognisant of the converging multiple global crises that are being exploited by a failed biotechnology industry, to promote the latest GM technofix – GM wheat – touted as being drought-tolerant. This is particularly pertinent in light of the biotechnology industry's inability over the last 25 years to move beyond the two dominant traits: herbicide tolerance and insect resistance, both of which are now facing widespread efficacy challenges. Taken together with

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the long-term plateauing of genetically modified organism (GMO) adoption rates globally in the last decade (GeneWatch UK, 2022; Sirinathsinghji, 2022), the viability of the biotech industry appears by all accounts to be seriously in question.

Further to this, the timing of this approval in South Africa points to the biotechnology industry's desperate attempts at survival, by making a bid for control over lucrative wheat markets including the African region, in a classic disaster capitalist manoeuvre.

GM WHEAT TO ENTER SOUTH AFRICA'S FOOD SYSTEM

On 30 August 2022, the Executive Council (EC): Genetically Modified Organisms Act, (Act 15, of 1997 as amended), approved an application by Trigall Genetics for the importation of a GM wheat variety, HB4, for the purposes of use in South Africa as food, feed and processing. The EC is of the opinion that adequate scientific support exists to conclude that the GM wheat variety is safe for human and animal consumption. At the time the decision was made, the GM wheat variety was not grown commercially anywhere in the world. Nevertheless, at the time of writing, the GM wheat variety has been approved for commercial growing in Argentina and Brazil, but nowhere else in the world.

This GM wheat variety is the product of a 20-year Argentinian public-private partnership between the National Commission for Science and Technology (CONICET) and Bioceres. Bioceres co-owns Trigall

Genetics as part of a joint venture with Florimond Desprez, a French seed company. CONICET researchers have as far back as 2004, patented the technology, that was subsequently licensed to Bioceres, the latter which has commercial ties to Bayer, Corteva, and Syngenta, the latter which is now part of the merged entity ChemChina.

Wheat is South Africa's most important grain crop after maize (Naledzani et al., 2019), and is widely cultivated across three regions of the country. South Africa is both a wheat importer and an exporter. South Africa imports wheat primarily from Australia, Lithuania, Latvia, Poland, and Russia. It exports wheat to several countries in Africa, including, Botswana, Zimbabwe, Lesotho, Zambia, and Namibia.[1]

1. https://oec.world/en/profile/bilateral-product/wheat/reporter/zaf#:~:text=The%20fastest%20growing%20export%20markets,of%20Wheat%20in%20the%20world

INSTRUMENTALISATION OF WHEAT IN AFRICA AND EXPEDIENCY OF BIOTECH INDUSTRY IN DECLINE

The centre-of-origin of wheat is the Fertile Crescent, where it was domesticated more than 10 000 years ago. Wheat is a major source of carbohydrates for humans in the form of starch, with its seeds also providing an important source of protein. Globally and in South Africa, wheat 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. Today, wheat is grown on more land area than any other commercial crop. (Curtis, undated). It is grown in nearly every region of the world and represents a main source of food and income for millions of smallholder farmers (CIMMYT, 2018), therefore being critical for ensuring food sovereignty and nutrition security worldwide. In 2021, the top exporters of wheat were Russia, the United States, Australia, Canada, and Ukraine. The top importers were Egypt, Nigeria, Indonesia, China, and Turkey (OEC, 2021).

Russia and Ukraine are thus significant global players in the agri-food market and control 27% of the global trade in wheat. Around 32% of Africa's total wheat imports are from Ukraine (UNCTAD 2022) with Russia covering about 32% of the continent's wheat consumption (The Argus, 2022).

Following Russia's invasion of Ukraine in February 2022, prices of key commodities – many of which had already been on the rise as the world recovered from the Covid-19 pandemic – rose exponentially,[2] including the price of grains, fuel, and chemical fertilisers. While it is widely acknowledged and reported that at least 10 hedge funds made obscene profits from the food hike price (The Guardian, 2023; UnEarthed, 2023), there is considerable pressure on Africa to diversify its wheat sources and lessen its dependency on Russia, thereby also decreasing the influence geopolitically that Russia has over Africa. (The Conversation, 2022). Argentinian wheat exports have been suggested to replace much of the global demand, with the Argentinian President stating in 2022, that they are ready to seize the "formidable opportunity" to meet the shortfalls (FT, 2022).

It is worth noting that in July 2022, Nigeria approved the importation of GM wheat from Argentina's Bioceres, for food, feed and processing (Reuters, 2022), after becoming the world's second largest wheat importer in 2021, importing from Lithuania, Latvia, the United States, Russia and Ukraine.[3]

Noteworthy too is that severe droughts and a struggling economy have limited Argentinian outputs for the 2022/2023 season, with steep drops in the production of maize, soybean, and wheat. Moreover, the HB4 wheat itself is yet to prove itself under the drought conditions currently prevailing in the country, after disappointing harvests a year earlier (see further below).

In any event, complex traits such as drought tolerance have yet to be widely commercialised, due to the yet unfulfilled long-held promises by the biotechnology industry that drought-tolerant GMOs would be a climate change solution. A case in point is Bayer's (formerly Monsanto) MON 87460 'drought-tolerant' GM maize, which has been the subject of litigation by the ACB in the High Court of South Africa since 2017.[4] In this case, the ACB has consistently argued that there is insufficient data to demonstrate the claimed drought-tolerant benefit, based on either yield or agronomic performance advantages. Curiously, Monsanto sought approval for the commercial growing of a triple-stacked GM maize variety that included the contested drought-tolerant trait, combined with

2. https://www.theguardian.com/business/2022/aug/01/food-prices-soar-across-world-amid-ukraine-crisis-world-bank-finds
3. https://oec.world/en/profile/bilateral-product/wheat/reporter/nga
4. https://acbio.org.za/gm-biosafety/landmark-legal-challenge-against-monsanto-bayers-bogus-drought-tolerant-gm-maize-finally-to-be-heard-in-south-african-high-court/

Table 1. Approvals of HB4 wheat and soybean for import and cultivation

COUNTRY	WHEAT	SOYBEAN
Argentina	Cultivation	Cultivation
Brazil	Cultivation	Cultivation (combined with herbicide tolerance)
Nigeria	Import	-
South Africa	Import	-
Australia	Import	-
New Zealand	Import	-
Colombia	Import	-
United States	Import	Cultivation
Canada	Import	-
China	-	Import
Paraguay	-	-

Monsanto's ancient and failed herbicide-tolerant and insecticidal traits, respectively (MON 89034 and NK 603). This application was rejected by the very same South African biosafety authorities that had approved the single trait, on agronomic and biosafety grounds.[5]

The data in the table is based on information submitted to the Convention for Biological Diversity's (CBD) Biosafety Clearing House (BCH), International Service for the Acquisition of Agri-biotech Applications (ISAAA.org), and United States Department of Agriculture (USDA) data.

5. https://acbio.org.za/gm-biosafety/sa-government-rejects-monsantos-triple-stacked-gm-drought-tolerant-maize/

SEARCH FOR GM WHEAT MARKETS AND PUSHBACK FROM SCIENTIFIC COMMUNITY

While GM wheat has thus far only been approved for commercial cultivation in Argentina and Brazil, Bioceres has set its sights beyond South America. A recent joint venture with Florimond Desprez, and more recently with S&W Seed company in Australia is set to integrate the HB4 technology in a new breeding programme, as part of an international expansion strategy into major wheat-producing regions. S&W already has an existing germplasm library with seeds from Europe, Middle East and North Africa (Florimond Desprez, n.d.; World-Grain.com, 2023).

However, the projects recently faced sharp opposition from within the immediate research community, with 1 400 scientists including from CONICET itself 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). Despite the controversy, small amounts of GM wheat are now entering the Argentinian food supply. With Argentina lacking mandatory labelling of GM crops, HB4 wheat is reportedly due to be processed in 25 mills in the country, alongside other conventionally-bred wheat varieties, with no intention to keep supply chains separate (Bichos de Campo, 2023).

This trait is set to thus prolong and perpetuate the widely understood destructive nature of GM monocultures that include blanket spraying of known toxic chemicals. The commercialisation of HB4 soybean in Argentina was dependent on Chinese import approvals, which it received in 2022. However, unlike wheat, the soybean market, particular for products destined for animal feed, is already largely saturated with GM varieties.

Bioceres is pushing for approvals among wheat-importing nations to guarantee markets, before it expands to full-scale production. This despite the company itself acknowledging that it still requires several years of further testing and seed multiplication before the product may be ready for wider cultivation in Argentina (and additionally elsewhere e.g., Brazil, for the soybean varieties). Reports of low yields in initial harvests also raise serious questions about how 'market ready' the crop is, and further, how effective it indeed is, to improve yields in real-world conditions.

RISKS OF HB4 TRAIT IN WHEAT

Standard food safety assessments not performed despite unintended effects

According to the Department of Agriculture, Fisheries and Forestry (DAFF), "...there was no need to pursue whole food and feed studies" (2022). Despite the 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 South African biosafety authorities. Indeed, no toxicity feeding studies were conducted at all for the risk assessment, neither to the South African nor Argentinian 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.

The only assessments done to claim 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.
3. Compositional analysis where levels of just 41 different components e.g. vitamin levels were analysed in the plant, and 2 anti-nutrients were assessed (see Ayala et al., 2019; DAFF, 2022).

As discussed above, the risk assessment makes completely unfounded assertions that feeding studies are not needed due to the above tests having been performed, and the fact that conventional wheat has a history of safe use.

Such omissions fail to meet the requirements for a precautionary approach to risk assessment for a crop that is destined for high levels of human food consumption. Moreover, it completely fails to consider other 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 the GM wheat. Unintended insertions of the vector backbone means 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 to 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 HB4 trait functions

The developers 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), amongst 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 into the wheat 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 appears regulators have failed to exercise due diligence when assessing the application and granting the approval.

Glufosinate tolerance will pollute staple food supply

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. The incorporation of glufosinate tolerance will inevitably promote blanket spraying of wheat plants, risking the safety of one of the world's most staple food crops and causing adverse environmental impacts.

Contamination of the wheat supply

GM wheat raises particular concern about the potential wider contamination of the food supply. 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. Genetic contamination of conventional wheat has already been documented despite no commercial approvals anywhere in the world, and instead stemming from research by Monsanto on glyphosate herbicide tolerant varieties that never made it to market (NPR, 2013).

EFFICACY CLAIMS DUBIOUS FOR BOTH WHEAT AND SOY 'HB4' VARIETIES

Yield data for HB4 wheat was published by the developers in 2019 claiming a 6% yield improvement under dry and hot conditions (González et al., 2019). However, this figure hides some of the variation in results of the trials that were conducted, with 12 of the 37 trial sites showing no yield benefits, and 8 of those showing negative yield results with an average of -7% decrease.

Moreover, the wheat cultivar used for the trials, called Cadenza, is a British variety that does not perform well in Argentine conditions. As stated in their publication:

> “[T]he mentioned benefit allowed the transformed variety to achieve grain yields similar to different commercial controls included in experiments, which were comparatively modern local varieties expected to have improved adaptation as well as yield potential (Cadenza was released to the UK market in 1995, and is not among the best adapted cultivars to Argentine wheat environments mainly due to its long cycle).” (González et al., 2019)

The results of comparisons to other commercial cultivars does not appear in the study for analysis. However, this quote suggests that the new HB4 trait in Cadenza does not offer yield benefits above already existing varieties, and data to suggest that the HB4 trait would improve yields in these better performing varieties appears not to exist in the public domain.

Questions over the veracity of yield benefit claims is compounded by the underwhelming performance of the HB4 wheat in its initial harvests since it was approved in Argentina. Reports of low yield surfaced in 2022, averaging two thirds of that of the average for non-GMO wheat (Canal Abierto, 2022). Moreover, Bioceres financial reports also reveal a more complex picture. It appears that the recent droughts in the region have also impacted the HB4 trait, with 3% of harvests expected to be lost, and 86% estimated to reach yields of 1500-2000 kg/ha, below the USDA estimate of Argentine average wheat yield for 2022/2023 of 2086 kg/ha reported in the first quarter. Droughts are also impacting the seed multiplication that is needed for planting to assess performance in new regions such as Brazil. Their second quarter report begins to reference a ‘2nd generation variety’ of wheat (Bioceres Crop Solutions, 2023) though no further information was found on what this variety is. The development of a second variety does not raise confidence for the new crop that is fresh from international approvals for a supposed ability to increase yields by 20%, as stated by the developers, despite the data to back up this increase being unclear (Bioceres Crop Solutions, 2023).

HB4 soybean approved alongside HB4 wheat

In parallel to developing the GM wheat, Bioceres has also released the same 'HB4' trait into soybeans, which have also been approved by SA and several other countries for import, as well as cultivation by countries that already widely grow GM soybeans, such as Brazil (see Table 1 for approvals for wheat and soybean products). Potential future applications for commercial cultivation appear in the pipeline, with the company reporting that they plan to breed the HB4 trait into South African soybean varieties (along with American, Argentinian and Brazilian varieties) (Bioceres Crop Solutions, 2023). It is noteworthy that Brazil, according to the CBD's BCH, has only approved the soybean trait in combination with herbicide (glyphosate) tolerance, and not the single 'drought' tolerant trait alone. The addition of glyphosate tolerant traits perpetuates the use of an herbicide linked to an array of environmental and health effects that have resulted in several bans and restrictions on its use. Moreover, it reveals an industry that must rely heavily on herbicide tolerance as a commercially viable product.

Efficacy questions surround the soybean variety, with potential implications for the efficacy of the HB4 trait in general. For example, developers recently published a study reporting a 4.05%–10.5% increase in 'grain productivity' in Argentinian trials (Minussi Winck et al., 2022). However, recent reports suggest that yield gains are restricted to low yielding regions. HB4 soy has demonstrated significant yield benefits in highly restricted environments, where average yields are below 1.5 tons per hectare. However, the benefit was not being realised in moderate to highly productive environments, where average yields were greater than 2.5 tons per hectare (Yahoo Finance, 2022).

CONCLUSIONS

The potential roll out of GM wheat in South Africa sets a precedent for this staple crop on the continent, which has long been a target for GMO developers. This is occurring under circumstances where there is a complete dearth in safety assessment for human consumption, risking the safety of a vitally important food in the country. Such an approval should not go ahead without ensuring against harm of the citizenry and suggests a widespread failure in governance across the globe thus far for this crop. Moreover, the economic viability of maintaining dependence on imports at times of high volatility needs to be carefully assessed, especially for a crop that is yet to be fully market ready.

HB4 wheat is nonetheless being pushed for global acceptance, with concerted efforts to gain approvals, such as the latest one from SA, even before the product is market ready. Despite disappointing reports of first

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harvest yields, the company is developing a second-generation variety and may be able to sit patiently and wait for approvals, taking advantage of the latest crises. Any widespread roll out within Argentina would expose the public to a crop with minimal, if indeed any, toxicity data to ensure food safety. This simply cannot be the precedent that we wish to set for the world's most fundamental stable crop.

The South African regulators are under an obligation to adopt a risk averse and cautious approach to decision making regarding GM approvals, in particular 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 briefing 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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