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Attention: The Registrar: Genetically Modified Organisms
Directorate Genetic Resources
Department of Agriculture, Forestry and Fisheries
By email: GMOAppComments@daff.gov.za

Objection to the Application for General Release of Pioneer Hi-Bred's GM Maize TC1507xNK603

Please find our objection submission on the permit application for general release of **Pioneer Hi-Bred's GM Maize TC1507xNK603**, which consists of:

- Background on Biowatch South Africa
- Comments on the application

Yours sincerely

Rose Williams
Director

Biowatch South Africa

Biowatch is a non-governmental organisation established in 1999, which strives for social and environmental justice within the context of food sovereignty. Biowatch works to challenge unsustainable agricultural practices and to advocate for agroecology as an ecologically viable alternative that safeguards people and land. This includes supporting smallholder farmers; working with civil society to create joint understanding and action; and constructively engaging with government in implementing policies and practices that promote, facilitate and actively support agroecology and farmers' rights. We have a long track record of working on policy issues concerning agriculture, biodiversity and indigenous knowledge systems.

Comments on the application

Biowatch SA strongly objects to the granting of a permit for the general release of GM Maize **GM Maize TC1507xNK603**. The reasons for our objection follow.

Objection to placing South Africans at risk [RW1]

Although the permit application is not intending a commercial release, the granting of this permit will allow this maize to be planted in the South African environment, and according to the application advert, the maize will be planted "in many commercial maize growing regions in South Africa for the purposes of research, development and seed bulking". As maize is open-pollinated, there is a strong likelihood that South Africans or other consumers will in fact be eating this maize at some point in time. Our environment will be exposed to these genes and related herbicides for the duration, and beyond the duration of this research, development and seed bulking.

We object to this general release in that it unnecessarily exposes the South African environment and agricultural system to the risks associated with these events and may lead to an unintended introduction of these genes into commercially grown as well as farmer varieties of maize through cross-pollination. The South African environment and people carry the risks of this technology, and the costs related to the regulatory process as well as any damages to health, the environment or seed systems that may occur while the multinational companies that own the technology will benefit from any profits that accrue. Government should not allow the subsidising of multinational companies in this way.

Concerns with health and environmental safety of the events

Although NK603 has been approved for commercial growing in South Africa the permitting of this event should be reviewed as new information and questions regarding its safety come to light. There are many concerns with each of these events, including but not limited to the following.

We note the toxicity research by Séralini *et al* that was re-published in 2014 (after industry pressure precipitated the withdrawal of the 2012 peer-reviewed study in the journal Nature). This research documented the effects on three groups of mice over two years either being given glyphosate in their drinking water or being fed with NK603 maize grown with and without the use of Roundup herbicide compared to a control group. Alarming health effects occurred in all three test groups including significant chronic kidney deficiencies, liver congestions and necrosis, hormonal disruption, earlier mortalities, and greater incidence of tumours.[i] Although the results relating to tumours could be

dismissed due to the small sample of animals, many scientists have confirmed the study's soundness as a toxicological assessment and that the findings on organ damage and hormonal disturbances are statistically significant.[ii] This should be enough reason for precaution and require further independent verification of safety based on longer term feeding trials.

Given that maize is our staple food we note with alarm the potential for increased allergenicity and immune reactions of these events, which are increased when stacked. Studies with mice have demonstrated that Cry1Ac raises specific immune reactions, and also possesses adjuvant properties by increasing the immunogenicity of other dietary antigens/allergens that may be present in food. [iii] Allergenicity, toxicity and disruption of protein synthesis is also associated with events such as NK603 using the CaMV S35 promoter resulting from the encoding of a fragment of a gene from the Cauliflower mosaic virus (CaMV).[iv]

The genetic stability of both these events has not been maintained in the genetic engineering process: an independent study by Morisset et al. found a single nucleotide polymorphism (SNP) in the promoter region of TC1507 maize[v] and Monsanto's own research into NK603 identified an inverted piece of the rice gene promoter, but also two-point mutations in one of the genes conveying glyphosate resistance.[vi]

Prior authorisation of single traits should also not assume their safety in stacked gene constructs – the issue of unpredictable synergistic or combinatorial effects with stacked traits has been a concern instability of stacked GMOs has been a concern for the past decade. This includes cross-reactivity of Bt proteins in stacked traits that may reduce their efficacy leading to higher rates of resistance evolution in targeted insects.[vii]

Increasing evidence of the harm of glyphosate

Studies into the long-term use of GMOs have found that herbicide use has increased with the use of herbicide resistant GM crops. Biowatch has consistently objected to the use of glyphosate in agriculture, and the GMOs which encourage its use, due to the dangers to health and the environment that glyphosate poses.

The recent ruling of a Canadian Court in favour of cancer victim Dwayne Johnson, based on evidence from Monsanto's internal records that showed it knew and covered up evidence of glyphosate's harm[viii], has highlighted the need to review glyphosate's safety and should discourage authorisation of GM permits that encourage its use.

The use of Glyphosate herbicide has substantially increased with the introduction of Roundup Ready crops.[ix] In South Africa Glyphosate use rose from 12 million litres in 2006 to 20 million litres in 2011, and imports increased by 177%.[x]

Although the industry claims that Glyphosate is a safe herbicide, a growing body of research shows that it is toxic to humans and in the environment. Additional ingredients in formulations such as Roundup increase the toxicity. Known human health impacts include disruption of the endocrine system and exposure is associated with increased risk of miscarriages, premature birth, chronic kidney disease and the cancer non-Hodgkin's lymphoma.[xi] The most recent studies link exposure to commercial concentrations of Glyphosate to resistance of common medical antibiotics.[xii] In March 2015 the World Health Organisation's cancer research arm, the IARC, declared Glyphosate to be

'probably carcinogenic' based on evidence in agricultural workers and convincing evidence in animal experiments.[xiii]

Glyphosate is very mobile in water systems and is highly toxic to aquatic life. Glyphosate is also toxic to earthworms and weakens plants by inhibiting their ability to take up nutrients. It also increases susceptibility to plant diseases, especially fungal diseases.[xiv]

Objection to the introduction of new forms of herbicide resistant GMOs

Given that herbicide use is increasing with the use of GMOs, Biowatch strongly objects to the introduction of new GM crops resistant to different and more toxic herbicides to manage inevitable pest resistance. GM maize TC1507 is not only resistant to glyphosate but also to the herbicide glufosinate-ammonium. There are severe documented and known environmental and health risks associated with glufosinate[xv], the use of which should be phased out in South Africa rather than being encouraged through the introduction of resistant GM crops.
Glufosinate is harmful to soil bacteria and aquatic animals; and UK farm-scale evaluations show that glufosinate-resistant crops reduce the number and diversity of wild plants and the arthropods and other species dependent upon them, thereby threatening biodiversity.

Glufosinate is extremely toxic when swallowed, inhaled or when it comes in contact with skin. There are many cases of suicide using glufosinate formulation Basta as well as accidental poisoning. Clinical findings of poisoning cases show the chemical damages the central nervous system: causes disturbed consciousness, convulsions, pyrexia, and respiratory failure. Death is often caused by circulatory failure, which may be caused by the surfactant in formulations.

Glufosinate is rapidly but poorly absorbed in the exposed body where it is widely distributed; the highest concentrations were found in the liver, kidneys and testes.

EU experts conclude that there are possible long-term health risks for all mammals from glufosinate usage. Risks include damage to fertility and abnormalities in the development of embryos in mammals, in vitro and in vivo. Prolonged or repeated exposure causes damage to organs.

Mouse embryos exposed to glufosinate in vitro developed apoptosis (fragmentation of the cells leading to cell death) in the neuroepithelium of the brain. Another study found that all the embryos in the glufosinate treated groups had specific defects including overall growth retardation, increased death of embryos, and hypoplasia (incomplete development) of the forebrain.

References

[i] Gilles-Eric Séralini et al, 2014. *Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*. Environmental Sciences Europe 2014, 26:14. See https://enveurope.springeropen.com/track/pdf/10.1186/s12302-014-0014-5

[ii] See for example:

- EndScienceCensorship.org. *Statement: Journal retraction of Séralini GMO study is invalid and an attack on scientific integrity*. 2014. Available at: http://www.endsciencecensorship.org/en/page/Statement#.UwUSP14vFY4.
- European Network of Scientists for Social and Environmental Responsibility (ENSSER). *Journal's retraction of rat feeding paper is a travesty of science and looks like a bow to industry: ENSSER comments on the retraction of the Séralini et al. 2012 study*. 2013. Available at: http://bit.ly/1cytNa4.

[iii] See GENOK Centre for Biosafety (2010). *Impact assessment of maize hybrid MON 89034 x 1507 x NK603 from Monsanto and DowAgroSciences (EFSA/GMO/NL/2009/65)* for in-depth review of the scientific literature in this regard.

[iv] Podevin N, du Jardin P. *Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants*. GM Crops Food. 2012;3:296–300. doi:10.4161/gmcr.21406.

[v] Morisset, D., et al. 2009. *Detection of genetically modified organisms—closing the gaps. Nat. Biotechnol. 27, 700–701 (2009)*. Accessed: https://media.nature.com/original/nature-assets/nbt/journal/v27/n8/extref/nbt0809-700-S1.pdf

[vi] See https://biotechsalon.com/2018/02/09/update-on-extra-dna-and-other-problems-with-crop-genetic-engineering/

[vii] See again GENOK Centre for Biosafety (2010). *Impact assessment of maize hybrid MON 89034 x 1507 x NK603 from Monsanto and DowAgroSciences (EFSA/GMO/NL/2009/65)*

[viii] See US Right to Know. *The Monsanto Papers: Roundup (Glyphosate Cancer Case Key Documents & Analysis.* Accessed https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/

[ix] Benbrook C. *Impacts of genetically engineered crops on pesticide use in the US – The first sixteen years*. Environ Sci Eur. 2012;24. doi:10.1186/2190-4715-24-24.

[x] African Centre for Biosafety. (2012). *Glyphosate in SA: Risky pesticide at large and unregulated in our soil and water*.

[xi] For an extensive list of references and discussion relating to health impacts of Glyphosate see Fagan, J., Antonio, M., and Robinson, C. (2014) *GMO Myths and Truths*, Second edition, Version 1.0. London: Earth Open Source. Pages 204 - 218.

[xii] Kurenbach, B., Marjoshi, D., Amábile-Cuevas, C.F., Ferguson, G.C., Godsoe, W., Gibson, P., Heinemann, J.A. (2015). *Sublethal exposure to commercial formulations of the herbicides dicamba, 2,4-dichlorophenoxyacetic acid, and glyphosate cause changes in antibiotic susceptibility in Escherichia coli and Salmonella entericaserovar Typhimurium*. mBio 6(2):e00009-15. doi:10.1128/mBio.00009-15.

[xiii] International Agency for Research on Cancer. (20 March 2015) *IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides*. Lyon: World Health Organisation.

[xiv] African Centre for Biosafety. (2012). *Glyphosate in SA: Risky pesticide at large and unregulated in our soil and water*.

[xv] See the following:

- US Geological Survey. 2007. *Concentrations of Glyphosate, its degradation product, Aminomethylphosphonic Acid, and Glufosinate in ground- and surface-water, rainfall, and soil samples collected in the United States 2001-2006*. Accessed: https://pubs.usgs.gov/sir/2007/5122/pdf/SIR2007-5122.pdf
- Beyond Pesticides. *Pesticide gateway: Glufosinate ammonium.* Accessed:
- https://www.beyondpesticides.org/resources/pesticide-gateway?pesticideid=190
- Pesticides News. 2017. *Glufosinate-ammonium — toxicity, side effects, diseases and environmental impacts.* Accessed: http://www.pesticides.news/2017-12-02-glufosinate-ammonium-toxicity-side-effects-diseases-and-environmental-impacts.html
- Journal of Pesticide Reform. 1996. *Herbicide Factsheet: Glufosinate*. Accessed: https://d3n8a8pro7vhmx.cloudfront.net/ncap/pages/26/attachments/original/1428423375/glufosinate.pdf?1428423375

- Journal of Korean Medical Science. 2013. *Glufosinate Herbicide Intoxication Causing Unconsciousness, Convulsion, and 6th Cranial Nerve Palsy.* Accessed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3835516/
- Stop the Crop Campaign, *Toxic Chemicals. Accessed:* http://www.stopthecrop.org/toxic-chemicals
- Pesticide properties database. Accessed: https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/372.htm
- Pesticides Action Network UK 2001. Accessed: https://friendsoftheearth.uk/sites/default/files/downloads/impacts_glufosinate_ammon.pdf
- EFSA Scientific Report 2005, 27, 1-81, *Conclusion on the peer review of the pesticide risk assessment of the active substance of glufosinate*.