



South Africa and 2,4 D stacked GM maize: biosafety, socio-economic risks

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Contents

| | |
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| Acronyms | 3 |
| Key findings | 4 |
| Introduction | 5 |
| New 2,4-D crops: admittance to failure of herbicide-tolerant crop systems | 5 |
| South Africa's openness to 2,4 D GM maize | 9 |
| Parliamentary hearings | 9 |
| SA's field trials of GM maize | 10 |
| Data on field trials show failure to increase yield | 11 |
| Biosafety assessment inadequate and outdated | 11 |
| Conclusions | 13 |
| References | 14 |



On 7 April 2015 the African Centre for Biosafety officially changed its name to the African Centre for Biodiversity (ACB). This name change was agreed to by consultation within the ACB, to reflect the expanded scope of our work over the past few years. All ACB publications prior to this date will remain under our old name of African Centre for Biosafety and should continue to be referenced as such.

We remain committed to dismantling inequalities in the food and agriculture systems in Africa and to our belief in peoples' rights to healthy and culturally appropriate food, produced through ecologically sound and sustainable methods, and to define their own food and agriculture systems

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Acronyms

| | |
|--------|--|
| 2,4-D | 2,4-Dichlorophenoxyacetic acid |
| AGRA | Alliance for Green Revolution in Africa |
| EFSA | European Food and Safety Authority |
| EU | European Union |
| GM | Genetically Modified |
| IAASTD | Assessment of Agricultural Knowledge, Science and Technology for Development |
| IARC | International Agency for Research on Cancer |
| RR | Roundup Ready |
| WHO | World Health Organisation |

Key findings

- The advent of 2,4-D tolerant GM crops is testament to the failure of the most popular GM trait – glyphosate-tolerance, to combat weeds with reduced environmental and economic burden. Glyphosate-tolerant crop cultivation has led to sharp rises in glyphosate use and subsequent epidemics of glyphosate-tolerant weeds that are threatening yields, increasing farmer costs on additional weed protection products. High herbicide use has been a public health disaster in areas of high cultivation, such as Argentina, where pesticide use has risen by 858% (1994–2010), with rises in birth defects, cancers and other illnesses. The dire situation in Argentina is a warning of the human costs of intensive chemical/GM agricultural systems.
- To combat weed resistance, GM producers are commercialising crops tolerant to other herbicides, including 2,4-D, as well as stacked crops with tolerance to multiple herbicides. The commercialisation of 2,4-D tolerant GM crops, such as maize DAS-40278-9 developed by Dow AgroSciences is predicted to lead to a 30-fold rise in 2,4-D pesticide use. A synthetic auxin (plant hormone), 2,4-D is a war chemical that has long been linked to wide-ranging toxicity, including cancers, birth defects and reproductive toxicity. Research suggests its potential to disrupt endocrine systems. Its toxicity has led to total national bans in Scandinavian countries and partial bans in Canada as well as South Africa.
- Dow Agrosience’s 2,4-D maize event DAS-40278-9 was approved for import in SA in 2012, for food, feed and processing, despite lack of testing for long-term toxicity. Short-term toxicity data is severely limited and outdated. There is, therefore, insufficient data to conclude safety of DAS-40278-9.
- Dow Agrosiences Southern Africa performed field trials in South Africa in 2015–2016 on 2,4-D tolerant maize (DAS-40278-9) and stacked events tolerant to 2,4-D and glyphosate, and events with multiple insecticidal Bt toxins. Trial data showed no evidence of collection of biosafety data to assess risk assessment as stated in the Executive Council Decision Documents that approved the trials. No considerations of the harms of pesticides, combinatorial or synergistic effects of multiple pesticides to human health have been addressed before commencing trials. Nor were considerations given to the effects of Bt toxins to non-target organisms and the environment.
- Trial data generated in South Africa completely failed to show any increase in yield of GM varieties in comparison to the non-GM control, highlighting a lack of proven efficacy of these crops. Trials show a slight yield reduction for herbicide-tolerant varieties in comparison to the control.
- Maize is a staple crop in South Africa, unlike Argentina, for example, whose GM produce is primarily destined for animal feed exports. A shift away from the vicious cycle of GM monocultures, weed resistance and rising chemical dependency is urgently need to protect the human and environmental health of South Africa and the long-term sustainability of its food system.

Introduction

In 2015–2016 Dow AgroSciences Southern Africa (Pty) Ltd performed field trials on maize tolerant to 2,4-D (event DAS-87078-9) and stacked varieties carrying not only 2,4-D tolerance, but also glyphosate tolerance and/or Bt insecticidal toxins. The trial followed the approval for import for food, feed and processing in 2012, despite the crop not having been approved anywhere in the world for cultivation.

This paper reports on the global failings of GM crops to date to do their stated job: to control weeds and pests, reduce environmental burden of toxic pesticides and improve farmer costs. The spread of glyphosate resistant weeds proliferated after the adoption of glyphosate-tolerant crops, with the herbicide now practically ubiquitous in the environment in high cultivation areas such as the US and Argentina. Farmers are paying the price with having to use additional weed control measures, while people are being exposed to ever increasing amounts of toxic chemicals. This has come with catastrophic human costs. Argentina for example, is witnessing a reported 2-4-fold rise in birth defects and cancers amongst other illnesses. The recent decision by the World Health Organisation's (WHO) International Agency for Research on Cancer (IARC) to classify glyphosate as a 'probable human carcinogen' corroborates these clinical findings.

The failure of glyphosate-tolerant crops serves as a clear warning of the limited, short-term effectivity of such industrial farming systems. We are now faced with more of the same, with 2,4-D stacked maize being commercialised in South Africa in attempts by the industry to combat the issue.

This paper urges a shift away from a failed GM maize system that is burdening human and environmental health as well as farmers' pockets. South Africa is the only country in the world to have commercialised GM cultivation of their staple food crop, maize. This raises serious public health concerns about extending the GM monocultures that also remain untested for long-term health effects, and are laden with ever increasing quantities of toxic chemicals. We have a choice to adopt yet more GM crops and chemical usage, or transform our food system to one that is equitable and biodiverse, in support of seed sovereignty and agroecological methods to provide sustainable health for the people and environment of South Africa.

New 2,4-D crops: admittance to failure of herbicide-tolerant crop systems

In 1996, Monsanto's first generation of genetically modified (GM) crops, so-called 'Roundup Ready' (RR), engineered to tolerate glyphosate-based herbicides, were approved for planting in the US. RR crops were sold as progressive technology set to improve environmental sustainability by reducing overall use of herbicides and soil erosion, with superior ability to tackle weeds – an economic gift to farmers. The use of glyphosate, purportedly claimed to be 'as safe as table salt', but now classified by the WHO's oncology agency the IARC as a 'probable human carcinogen', was supposed to replace the older, more toxic herbicides such as dicamba and 2,4-D. Twenty years on, however, huge rises in glyphosate use has resulted in an epidemic of glyphosate tolerant weeds, which are rapidly rendering RR crops obsolete.

Latest figures from the US document a staggering 15-fold rise in glyphosate use since RR crop introduction. Two-thirds of all glyphosate usage applied in the US from 1974 onwards was applied in the last 10 years alone, corresponding to 74% of the world's usage (Benbrook, 2012).

RR crops account for 56% of the world's glyphosate use. Such high use has led to its detection in rain, water and air samples, suggesting it is practically ubiquitous in the environment in high use regions. Argentina has documented an 858% rise in pesticide use from 1994 to 2010, with glyphosate consisting of 64% of total sales, having a devastating effect on the health of the local residents who are now suffering a shocking rise in birth defects, cancers, and other illnesses. 30% of deaths in towns located in and around GM crop farms are now caused by cancer, compared with 20% nationwide. Local clinicians report high rates of miscarriages (23%) and 4-fold increases in birth defects (1997–2008) (Ávila-Vázquez, 2014). The situation in Argentina serves as a clear warning of the tragic human costs of intensive chemical/GM agriculture.

A rapid proliferation of resistant weeds predictably followed RR crop commercialisation and over-reliance on glyphosate, with 16 species observed by 2009, rising to 21 species by 2011, totalling 36 as of January 2017 (International Survey of Herbicide Resistant Weeds). Over 260 independent cases of glyphosate resistance have been documented in the world. As of 2012, 49% of US farmers surveyed by Agri-business market research firm Stratus said they had glyphosate-resistant weeds on their farms. By 2013 glyphosate resistant weeds had spread over 28 million hectares of land. Monsanto acknowledges the problem in attempts to protect profits from their failing products, stating: 'Roundup agricultural warranties will not cover the failure to control glyphosate resistant weed populations' (Monsanto (a)).

In South Africa alone, three glyphosate-tolerant species have so far been documented: *Conyza bonariensis* (hairy fleabane), *Lolium rigidum* (rigid ryegrass), observed in two independent cases, and *Plantago lanceolata* (buckhorn plantain). South Africa is also one of the few places to have detected pest resistance to Bt toxins in the field, as a result of large-scale GM Bt crop cultivation (Van Rensburg, 2007). Indeed, new research suggests that South Africa has the necessary environmental conditions for the spread of Bt pesticide resistance in corn borers, a major pest for South African farmers (Campagne, 2016). Such examples serve to show the limited, short-term solution of crude chemical weed and pest management systems, predicted by basic evolutionary biology and even acknowledged by GM producers themselves, with Monsanto stating it is 'natural and expected' (Monsanto(b)).

Resistant weeds are now a major economic concern for farmers. By 2014, resistant weeds cost US farmers an estimated \$1 billion in total crop damages. 2012–2015 statistics from the US National Agricultural Statistics Survey (NASS) also reveal that soybean producers spend 88% more on crop protection products than they did six years ago. Indeed, studies have linked the spread of glyphosate resistant weeds to increased glyphosate application by farmers, driving up usage by an estimated 25% each year in the US. Farmers are also turning to additional, alternative herbicides to mitigate damages.

The failure of a technology can be a marketing opportunity for those who claim to provide the solution. In such a circumstance, it can be reasonably expected that the solution to tackle the problem is not simply a repeat of the very mistakes that led to its demise. However, this is what is being proposed with the next round of stacked herbicide-tolerant crops. There may be short-term business logic to such a strategy, but the scientific and biological logic is flawed as clearly exposed by the current failures. Already, many weeds are resistant to multiple herbicides, so stacking multiple herbicide resistant traits into one crop is unlikely to reduce selection pressures on weeds, or lower herbicide use. Nonetheless, ruthless marketing of stacked herbicide tolerance traits, including combinations of glyphosate; 2,4-D; numerous Bt toxins; drought-tolerance and biofortified foods are being aimed at the African continent. In 2015, South Africa planted 940 000 hectares of stacked Bt and herbicide tolerant maize (ISAAA).

The experiences of RR crops allow sensible predictions on the prospects of 2,4-D tolerant crops. In the US, based on an upward trajectory of 55% 2,4-D HR corn being planted by 2019, research

has estimated an expected 30-fold increase in 2,4-D use (Benbrook, 2016; ACB, 2012a). This is likely to pave the way for the spread of 2,4-D resistant weeds and increase the economic burden for farmers, while exposing the environment and people to increasing combinations and levels of chemical cocktails (see Box 1 for summary of 2,4-D toxicity). Indeed, there are already 34 documented weed species resistant to synthetic auxins, including *Chenopodium album*, or bloubossie, an economically important weed for maize farmers in South Africa. It is only a matter of time before such cases will be documented in SA, if approval for commercial cultivation goes ahead.

2,4-D – a war chemical, not a food ingredient

2,4-Dichlorophenoxyacetic acid, commonly known as 2,4-D, is a synthetic hormone that mimics auxins – a type of plant hormone essential for plant development. While low doses promote plant growth, high dose herbicide application to broad leaf plants leads to uncontrolled growth, stem curl-over, leaf withering and eventual death. 2,4-D is mobile and easily travels throughout the plant tissue, and runs off into water supplies.

Invented as a war chemical by the British during World War II, it was first used in Malaysia in the 1950s against the Malaysian independence fighters. The chemical destruction of the Malaysian fighters' food supply by the British government set a precedent for the US to repeat and extend the chemical warfare programme, later using the notorious 2,4-D-containing 'Agent-Orange', in the Vietnam war. The use of Agent Orange had devastating effects on Vietnamese people, including thousands of deaths, cancers and birth defects. Much of this toxicity was attributed to dioxins, which widely contaminated the herbicide mixtures during the manufacture process. Though dioxins have been regulated since, they were detected in herbicide products as recently as 2014, questioning confidence that such formulations can be produced free of dioxin contaminants.

2,4-D itself has also been shown to exert a wide range of toxic effects, including carcinogenicity, endocrine disruption, reproductive toxicity and neurotoxicity, that have led to various restrictions on its use by governments, including complete bans in Norway, Denmark and Sweden. In Canada, the use of pesticides containing 2,4-D on lawns is banned in Quebec, Newfoundland and Labrador and Nova Scotia. In 1990, a group of fresh vegetable producers from the Tala valley in KwaZulu-Natal took legal action against a herbicide manufacturer, after their crops were damaged by herbicides, including 2,4-D. This ultimately led to a ban on the aerial application of 2,4-D (in its diethylamine salt form) in KwaZulu-Natal and a total ban in the magisterial districts of Camperdown, Pietermaritzburg and Richmond. In its ester form, 2,4-D was completely prohibited from use in the province. In 1980 2,4-D was withdrawn from agricultural use in the Western Cape.

Studies have shown raised incidence of illnesses in farmers and farmworkers, including non-Hodgkin lymphoma, a cancer of the white blood cells. A new 2017 study on farmers in Iowa detected 2,4-D in their urine, who also showed elevated levels of oxidative stress linked to DNA damage, an important factor in cancer development (Lerro *et al.*, 2017). The WHO International Agency for the Research on Cancer (IARC), classified it as a 'possible carcinogenic to humans' in 2015, based on *limited evidence* in experimental animals and *inadequate evidence* in humans. Though it was not placed in the 'probable carcinogen' category, a substantial minority of the IARC working group would have done so, based on *sufficient evidence* in animals and *limited evidence* in humans, though the group could not agree on this. A problem for such agencies who only assess herbicides individually, is the limited data from epidemiological studies on 2,4-D alone, with data more available from case-control studies linking exposure to the wider category of phenoxy herbicides to cancer of the immune system. The dilution of information

on 2,4-D carcinogenicity by industry supported studies, a tactic adopted by the tobacco industry, also deliberately confuses the matter.

With 2,4-D being a synthetic hormone, studies have shown it to function as an endocrine (hormonal system) disrupter. Endocrine disrupters are of increasing concern to health professionals and governments, now linked to rising incidence of illnesses and health problems. A recent study estimated that the effects of (only already known) disrupters is costing the European Union (EU) an estimated 1.3% of its total GDP (\$209 billion), attributed to IQ loss and associated intellectual disability, autism, attention-deficit hyperactivity disorder, childhood obesity, adult obesity, adult diabetes, cryptorchidism, male infertility, and mortality associated with reduced testosterone (Trasande, 2015). Indeed, 2,4-D has been suggested to interfere with male reproduction, with effects including disrupted testosterone levels and spermatogenesis; reduced mortality of human sperm; and increased sperm abnormalities, reduced testosterone and increased leutinising and follicle-stimulating hormones in male rats (both involved in male and female reproduction).

Metabolites of 2,4-D, including 2,4-DCP is also categorised as ‘possibly carcinogenic to humans’ by the IARC, adding an additional mechanism of 2,4-D toxicity.

2,4-D is highly volatile, turning into a gaseous vapour and is one of the herbicides known for its ability to cause pesticide drift, travelling up to a documented 10–50 miles from its point of application under certain conditions (Robinson et al, 1978). The latest formulation by Dow to be used in conjunction with the crop has improved performance for drift according to Dow, and comes with different nozzles for application, though whether farmers will adopt them cannot be assumed. As we are now seeing with the introduction of a parallel crop – dicamba-tolerant crops now being planted in the US – many farmers are facing crop damage from the spraying of nearby fields due to its similarly volatile properties, and are even suing Monsanto for damages. A farmer was reportedly recently murdered by his neighbour for crop destruction from dicamba drift.

2,4-D has also been linked to ecological toxicity, including toxicity to bees and other pollinator species, such as lady beetles, which could also have knock-on effects on farmer yields.

For a comprehensive review on 2,4-D toxicity, please refer to ‘The risks of the herbicide 2,4-D’ (Testbiotech et al, 2014), a joint publication by Testbiotech, GeneWatch UK and Pesticides Action Network (PAN) Europe.

South Africa's openness to 2,4 D GM maize

In May 2012, South African GMO authorities granted approval for the importation of Dow AgroSciences's highly controversial 2,4-D tolerant maize variety, DAS-40278-9 for direct use as feed, food and processing (ACB, 2012a). The crop is being marketed to replace the RR system. This approval, along with approval of the 2,4-D tolerant soybean variety DAS-44406-6 in 2013, was made even though the crops were yet to be approved for cultivation anywhere in the world. See Table 1 for details on the DAS-40278-9 event. These crops are designed to be used alongside Dow's Enlist herbicide formulation, which contains both glyphosate and 2,4-D. The transgene for 2,4-D tolerance also confers tolerance to aryloxyphenoxypropionate herbicides (e.g. haloxyfop, cyhalofop, quizalofop).

The ACB, then supported by more than 20 organisations, 7 000 individuals, 18 health professionals from South Africa and Cheryllyn Dudley of the African Christian Democratic Party submitted a petition to the National Assembly on 7 August 2012 to overturn the decision of the Executive Council and ban imports for food, feed and processing of Dow's 2,4-D GM maize (ACB, 2012b). On 19 March 2013 ACB, together with the Network for a GM free Latin America, the Pesticide Action Network, North America, GRAIN, Aqui el logo de la Red Nacional de Accion Ecologista (RENACE), Terra de Direitos and AS-PTA Agricultura Familiar e Agroecologia appealed to the UN High Commission for Human Rights, Secretary General of CBD to intervene. It is unclear what if any, action was taken by these international bodies.

Parliamentary hearings

After ACB persistently pursued the issue, a year later on 13 September 2013, the Portfolio Committee on Agriculture held a joint briefing with the Portfolio Committee on Health on the issue of GMOs in South Africa. The Agriculture Chair, Mr Lulu Johnson, opened proceedings by stating that three public hearings were planned in response to the petition lodged by the ACDP on behalf of the ACB, to update parliamentarians on the current status of GMOs and GM regulation in South Africa. The first hearing was called so that the Executive Council: GMO Act could update Members of Parliament on the status and administration of GMOs in the country and, although it was open to the public for observation, no public participation was allowed. The hearing was well attended by public observers, so well in fact that the meeting had to be moved to a larger venue. Included in the public were farmers from the Agrarian Reform for Food Sovereignty Campaign, who travelled at least four hours to participate.

However, except for the ACB, none of the people that attended the first hearing was given notice of the second hearing, held on 26 February 2014, despite having registered their contact details and indicating that they were interested parties. ACB researchers, Haidee Swanby and Gareth Jones gave presentations, focusing on ACB's concerns as laid out in a petition against 2,4 D GM crops, as well as giving a broader context and background to the issue of GMOs. Their presentations were hurried along and largely dismissed. Comments from MPs suggested that the narrative that we must use is that only industrial agriculture can feed a burgeoning population and deal with climate change.

There was, however, concern about the lack of capacity for research and monitoring into GM safety and pesticides and a feeling that resources must be allocated to address this. By contrast, Mr Lombard, a consultant to the industry lobby group Africabio was allowed to address the hearing, followed by scientists from Biosafety Africa and AfricaBio, the US embassy

attaché and a ‘small-holder’ (who farms on 500 hectares) – all lauding GM crops. Afterwards, the Biotech team had their photo taken with the portfolio committee, the meeting was adjourned.

ACB has not pursued any further parliamentary hearings.

SA’s field trials of GM maize

In July 2015, Dow AgroSciences Southern Africa (Pty) Ltd was granted approval for importing a trial release of DAS-40278-9 2,4-D tolerant maize, along with stacked varieties (see Table 1) combining 2,4-D and glyphosate tolerance, as well as 2,4-D, glyphosate tolerance and Bt insecticidal traits. Approval was granted, despite a complete failure by the applicant to discuss potential effects of the herbicide use on humans (particularly farmers, who are exposed to these herbicides, even when over one growing season), animals and the environment. Exposure to commercial formulations, as well as to the multiple Bt toxins present in the stacked varieties were also not discussed. There was an astonishing lack of information on trial management, including how much maize was to be planted, isolation from maize farms, or plans for assessment of gene flow.

Despite biosafety concerns, trials were approved and performed over the 2015–2016 summer growing season, taking place across four sites at undisclosed locations. The only information disclosed on the locations was that the trials were conducted between 80 and 2 000 metres away from human settlements. One site was also located 80 metres from surface water, and the immediate surroundings of the four sites included grasslands and cultivated fields, irrigation farms, dwellings and farmlands, pastures and maize fields. It is not specified whether these dwellings were occupied.

Table 1: Description of crop events under field trials in SA

| Crop variety | Trait/s of interest | Gene/s introduced |
|--|---|---|
| DAS-40278-9 | 2,4-D & aryloxyphenoxypropionate herbicide tolerance | <i>aad-1</i> |
| NK603 x DAS-40278-9 | glyphosate & 2,4-D, aryloxyphenoxypropionate herbicide tolerance | <i>Cp4 epsps (aroA:CP4)</i> , <i>aad-1</i> |
| MON 89034 x 1507 x NK603 | insecticidal activity, glyphosate herbicide tolerance | <i>Cry2Ab2</i> , <i>Cry1A.105</i> , <i>Cry1Fa2</i> , <i>Cp4 epsps (aroA:CP4)</i> |
| MON 89034 x 1507 x NK603 x DAS-40278-9 | Glyphosate, 2,4-D & aryloxyphenoxypropionate herbicide tolerance, insecticidal activity | <i>Cp4 epsps (aroA:CP4)</i> , <i>aad-1</i> , <i>Cry2Ab2</i> , <i>Cry1A.105</i> , <i>Cry1Fa2</i> |

Data on field trials show failure to increase yield

The field trial report, entitled 'Agronomic Characteristics of Maize Hybrids Containing DAS-40278-9, NK603 × DAS-40278-9, MON 89034 × 1507 × NK603, and MON 89034 × 1507 × NK603 × DAS-40278-9', completed on 11 July 2016, reports on data gathered across four sites. Information on the site, planting and plot maintenance, and results from agronomic evaluations were recorded. Trials tested the agronomic performance of the four hybrid GM crop varieties either unsprayed with pesticides, sprayed with 2,4-D or sprayed with both 2,4-D and glyphosate (for the hybrids expressing both glyphosate and 2,4-D tolerance). They were then compared with an isoline non-GM control variety.

Two key parameters measured for assessing agronomic performance of crops were corn borer pest damage and yield. Bt hybrids showed a significant reduction in percentage of plants showing leaf feeding damage and percentage of plants with stalk feeding damage. **However, despite a significant reduction in pest damage, this did not translate into statistically higher yields when compared to the non-Bt hybrid control**, or to herbicide tolerant varieties. Further, all four herbicide samples (sprayed and unsprayed), despite showing pest damage that was non-significantly different to the isoline control for three of the four samples tested, had a **significant reduction in yield** compared to the control.

The results from the field trial data therefore fail to demonstrate the efficacy of GM crops to prevent yield loss due to pest or weed damage. These results report a reduction of pest damage and a tolerance to the herbicides, allowing Dow to conclude efficacy of the varieties, stating the results '*demonstrate agronomic equivalence between MON 89034 × 1507 × NK603 and non-transgenic maize; further the lepidopteran insect pest protection and herbicide tolerance provided by MON 89034 × 1507 × NK603 is demonstrated*'. They also state that '*no herbicide injury was observed with DAS-40278-9, NK603 × DAS-40278-9, and MON 89034 × 1507 × NK603, while 5% injury was observed in one plot for MON 89034 × 1507 × NK603 × DAS-40278-9. These results demonstrate the efficacy of the herbicide tolerance provide by DAS-40278-9 and NK603.*'

However, without demonstrating a reduction in yield loss compared with non-GM varieties, Dow have failed to demonstrate any efficacy in terms of yield. **If anything, the results suggest a potential yield drag for herbicide tolerant varieties.**

Biosafety assessment inadequate and outdated

Field trials did not gather biosafety data, so no conclusions on a lack of biosafety risk can be made from such trials. This is despite the fact that the executive council decision document approving the trial stated that, in addition to testing efficacy of the crops, the trials were also to 'generate safety data needed for subsequent risk assessment and general release approval'. Limited data submitted to the European Food and Safety Authority (EFSA) was published by EFSA in 2016, while a compositional analysis and short-term mouse toxicity study was published in the scientific literature (EFSA, 2016). The publications included agronomic data, compositional data, molecular characterisation and acute toxicity data. In summary:

- **No comprehensive testing has been done on short-term or acute toxicity of plant-derived AAD-1 transprotein.** All toxicity tests were performed on the bacterially derived AAD-1 protein, with limited relevance to toxicity of the GM plant derived protein.
- **There is no data on long-term toxicity, including transgenerational effects available on DAS-**

40278-9. This is crucial in reflecting the real-world levels people would be exposed to in their daily diets. In order to detect reproductive toxicity, or chronic diseases, such as cancer and metabolic disease, long-term tests are essential.

- **There is no data available on survivability of the plant-derived transprotein AAD-1.** GM producers often claim that proteins do not survive digestion, thus minimising potential toxicity. This goes against peer-reviewed scientific literature that has detected GM proteins in humans and other mammals (Aris and Leblanc, 2011).
- **There is no data available on global compositional data, including ‘omics’ analysis of gene expression, protein and metabolite levels. Compositional data is limited to arbitrary constituents.** Nutritional analysis ranging from 59–82 analytes is not sufficient to detect potential toxicants, altered nutrient profile, or novel proteins produced via the genetic engineering process. ‘Omics’ technologies that allow for analysis of hundreds to thousands of gene expression levels, and protein and metabolite levels are becoming routine in the molecular biology field and should be employed for GM risk assessment. A recent publication on NK603 exemplifies this notion (Mesnage *et al*, 2016). Published in the respected journal *Scientific Reports*, researchers revealed metabolism disturbances, including huge spikes in levels of potentially toxic polyamines. Data also showed imbalances in energy metabolism and increased oxidative stress, concluding that NK603 is not substantially equivalent to its non-GM counterpart. These effects are likely to be specific to each event, in each genetic background. Therefore risk assessment of each event should be performed every time it is bred into a new variety.
- **No short- or long-term data is available on the combinatorial effects of stacked traits, or pesticide mixtures.** This is of great importance when considering most crops are stacked and often outbred into local breeds. For example, plant co-stressors can alter Bt toxicity specificity, such as cadmium and nematodes, and certain pesticides (e.g. pyrethroids) can make Cry Bt toxins toxic to slugs. The crop varieties tested include up to three Bt toxins and tolerance to multiple herbicides, the combinatory effects of which remain untested.
 - Pesticide mixtures and formulations were not taken into account. Combinatorial effects of multiple pesticides and their commercial formulations should be taken into account, instead of the active ingredient alone as performed in risk assessment.
 - Analysis of epigenetic regulation of transgene expression in single versus stacked events revealed differences in epigenetic tags between different Bt hybrid varieties, as well as differences in epigenetic patterns of Cry2Ab2 transgenes in single versus stacked events (Vilperte *et al*, 2016). Differing expression levels of transgenes may alter the efficacy of the transgene, which should be tested for each hybrid variety. This shows again that genetic background and stacked events can alter the molecular physiology of GM plants, the safety implications of which are yet to be understood.
- **No assessments of environmental effects were performed in the trial.** There are no assessments of gene flow or on the effects on off-target organisms.
- **Only descriptive results of molecular characterisation are available.** No data was provided on the molecular characterisation of the transgenic modification. The report claims ‘no evidence was found for the interruption of known endogenous gene[s] in the maize genome’. It is mentioned though, that the transgene has integrated into a grande transposon, a type of mobile genetic element increasingly recognised in the latest molecular biology field to be an important player in regulating expression of genes. Suggesting that insertion into such a region of the genome is somehow safe, is unfounded.

Conclusions

Proponents of the industrial agriculture claim that advanced, intensive agricultural techniques are needed to 'feed the world'. Yet, this is a flawed system that has thus far failed to alleviate hunger, malnutrition, food insecurity and protection of agricultural sustainability for future generations. Soils are nutritionally deficient and lacking resilience at a time of unpredictable climate change. Focus on monocrops, instead of a biodiverse farming and dietary model, has left South Africans suffering a double burden of malnutrition and obesity, due to the reliance on cheap, over-processed, single-food diets, while food insecurity is a major issue, despite South Africa's ability to produce sufficient quantities of food (ACB, 2016). The GM/chemical monocropping model, instead of supporting a healthy food system, is only exacerbating public health issues, and serving to contaminate South Africa's major food staples with toxic chemicals and untested GM food products. We need a shift to non-GM maize and a diversification of diets to include indigenous crops that are culturally, nutritionally and climatically appropriate to reverse this health crisis.

There is a growing recognition that the status quo of high chemical inputs and mass-produced monocultures is untenable. Climate change, hunger and poverty, loss of biodiversity, forest destruction, water crises and food safety are all, at least in part, caused by our current agricultural models. The example of RR crops serves to illustrate the problem that will only be extended through the introduction of 2,4-D tolerant maize. The ground-breaking International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), the largest study on agriculture undertaken to date, rightly prompted Greenpeace International to call for a 'thorough and radical' overhaul of agricultural policies in the 21st century (Greenpeace International, 2009). This means: transitioning to policies that prioritise the resources needs and knowledge of the small-scale farmers; supporting ecological farming systems with policy research; implementing policies that address climate change via ecological farming methods and recognising the inter-related principles of the right to food and food sovereignty.

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