

No Safe Limits for Toxic Pesticides in Our Foods:

Comments on Draft Regulations for MRLs

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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 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 our belief in people's right to healthy and culturally appropriate food, produced through ecologically sound and sustainable methods, and their right to define their own food and agricultural systems.

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Acronyms

2,4-D	2,4-Dichlorophenoxyacetic acid
ACB	African Centre for Biodiversity
ADI	Acceptable Daily Intake
EU	European Union
EFSA	European Food and Safety Agency
GM	Genetically Modified
IARC	International Agency for Research on Cancer
MRL	Maximum Residue Level
RR	Roundup Ready

About this paper

The African Centre for Biodiversity (ACB) is making this submission to the Department of Health in response to the draft amendments to regulations (Foodstuffs, Cosmetics and Disinfectants Act, 1972), governing the 'maximum residue levels' (MRLs) for pesticides that may be present in foodstuffs, published on 7 April 2017.

The submission primarily focuses on food safety and human health, highlighting the public and scientific concerns surrounding the widespread cultivation of herbicide-tolerant, genetically modified (GM) crops in South Africa, and the concomitant use of herbicides that are contaminating staple food crops in the country.

Converging evidence from the scientific literature, as well as farmer and clinical experiences show that current regulations are insufficient to protect human health and the environment from toxic pesticides, to the extent that no safe levels have yet been clearly determined for herbicides, including glyphosate, 2,4-Dichlorophenoxyacetic acid (2,4-D) and glufosinate. Indeed, both glyphosate and 2,4-D are classified as 'probable human carcinogens' by the World Health Organisation's oncology arm, the International Agency for Research on Cancer (IARC). Regulatory data determining safe levels are widely criticised for being outdated and often heavily influenced by industry needs and an unscientific understanding of toxicity, highlighting their inadequacy in ensuring safety for consumers.

Considering the accumulating evidence of harm, the new draft MRLs set by government are not stringent enough to ensure the safety of South African food products. Indeed, it appears that no MRLs are even set for glufosinate on maize, while this the first time an MRL has been set for glyphosate residues on soybean, despite glufosinate-tolerant maize and glyphosate-tolerant soybean being cultivated in South Africa. The ACB therefore calls for a ban on GM crops and their associated chemicals. A paradigm shift away from the industrial, chemical,

monoculture model of South Africa's current food system, towards an agroecology and sovereignty is urgently required to protect the health of the citizens of South Africa and the rich biodiversity of the country.

Introduction

South Africa's food system is heavily based on an industrial, chemical-based system. Indeed, the country has more than 500 registered pesticides (PAN, 2010) and is one of the four largest importers of pesticides in sub-Saharan Africa (Osibanjo et al., 2002), totalling US\$170 056 000 in 2006. Publicly available data already links pesticide use in South Africa to health problems, including birth defects, endocrine disruption and organophosphate poisoning, as well as to ecotoxicological effects in aquatic organisms, exposing biodiversity to environmental hazards and the contamination of South Africa's limited water supplies (Quinn et al., 2011). Indeed, in an era of unpredictable climate change and unprecedented drought, increased chemical use is predicted to exacerbate water quality degradation (Quinn et al., 2011).

A key factor promoting chemical use is the widespread cultivation of herbicide-tolerant GM crops. According to the Department of Agriculture in the United States (2015), approximately 2.9 million hectares of GM crops were grown in 2014. GM maize represented 79% of GM crops, while GM soybeans represented 21%, with GM cotton making up less than 1%. Herbicide-tolerant GM maize accounted for an estimated 17% of GM maize, with insect resistance at 25% and stacked GM maize (meaning both herbicide-tolerant and insect resistant) at 58%. Thus 75% of GM maize in South Africa is herbicide-tolerant. Some of this GM maize will be tolerant to glyphosate, but some will be tolerant to a different herbicide, glufosinate, because GM crops tolerant to either herbicide are approved for cultivation in South Africa (DAFF, 2015). It is not possible to determine the exact area of glyphosate-tolerant GM maize, but it is likely to be a substantial

proportion of the GM herbicide-tolerant maize grown. With GM soya, all of it is glyphosate-tolerant, with the only approved GM crop being Monsanto's Roundup Ready (RR) variety (DAFF, 2015).

Rising glyphosate resulting from GM crop cultivation in South Africa reflects the global trend with glyphosate-tolerant crops. The use of glyphosate with maize and soya has increased as the area of GM glyphosate-tolerant crops has increased (Gouse, 2014). For example, in 2006 approximately 2 million litres of glyphosate was used and 11% of the national maize area was planted to GM herbicide-tolerant (predominantly glyphosate-tolerant) maize. By 2012, the area planted to GM herbicide-tolerant maize had grown to 56% and glyphosate use had increased to 10.6 million litres (Gouse, 2014). Similarly, in the United States, RR crops have been directly attributed to rises in overall herbicide use, and a 15-fold rise in glyphosate use specifically, since the introduction of RR crops (Benbrook, 2012). An 858% rise in agrochemical use in Argentina has also been documented (Ávila-Vázquez, 2014). As a result, foodstuff, groundwater, rainwater, rivers, medical equipment, and sanitary products, as well as human bodies are contaminated with glyphosate residues (see *Banishing Glyphosate*, 2015).

In 2017, the South African government approved the cultivation of 2,4-D-tolerant crops, which will only serve to further contaminate our food supply (ACB, 2017). The approved crop is a stacked event, engineered to also tolerate glyphosate, exposing consumers to a 2,4-D-glyphosate chemical cocktail yet to be assessed for combinatorial effects anywhere in the world. A United States study has estimated that the introduction of 2,4-D-tolerant crops to the United States will result in a 30-fold rise in 2,4-D use (Benbrook, 2016).

What is the 'maximum residue level'? (MRL)

The 'maximum residue level' is the legal limit for pesticide residues in food for human consumption and animal feeds, when a pesticide is applied in accordance with its authorised conditions of use. Each foodstuff has its own limit; an MRL for soybean, for example, may be different to that set for chicken liver or maize. MRLs are generally based on formulas that determine the actual level of pesticides found in the diet, and the accepted daily intake (ADI) of a specific pesticide. The ADI is the safety limit determined by regulators, based on long-term toxicity studies on the active ingredient of the pesticide, and, in theory, is meant to represent safe levels to be consumed over an entire lifespan. As expanded below however, there is widespread scrutiny of the safe levels determined by regulators. The weight of evidence from independent literature shows that such levels set by various national and regional regulators are outdated, inadequate and often influenced by industry.

International levels for MRLs are established by the World Health Organisation Codex Committee on Pesticide Residues, though individual nations set their own, which may be lower or higher than the recommended Codex level.

In South Africa, the MRL is determined by a number of factors, including: the minimum effective dose; the standard application dose rate; the interval between harvest and consumption; and climatic conditions that may influence the efficacy of the pesticide. Once the most appropriate MRL has been selected by the Department of Agriculture, Forestry and Fisheries, (DAFF) this is sent to the Department of Health, which determines whether or not it will compromise human health and safety. If the MRL is not deemed a health risk, it is published under the Foodstuffs, Cosmetics and Disinfectants Act (no. 54 of 1972).

Questionable scientific rationale of MRLs

Over the last two decades, the MRLs for glyphosate in numerous staple crops and in the Codex Committee levels have been increased by authorities in countries where glyphosate-tolerant crops are produced. For example, in Brazil, the MRL in GM soybean increased from 0.2 mg/kg to 10 mg/kg (a 50-fold increase). Similarly, in Europe it was raised from 0.1 mg/kg to 20 mg/kg (a 200-fold increase). In 1999, the same value was adopted by the United States. In 2012, Monsanto in the United States applied to increase the glyphosate MRL for lentils by 150-fold, in order to allow the use of glyphosate as a pre-harvest desiccant.

In all these cases, the raising of levels does not appear to be associated with new scientific evidence of safety, but instead in response to agronomic usage of ever-increasing amounts of pesticides with GM crops, as well as for other uses.

South Africa's MRL levels yet to be fully established or tested

South Africa's MRLs for the staple GM herbicide-tolerant crops are shown in Table 1, alongside Codex and EU levels for comparison.

There is no single database containing all the MRLs, making information extremely difficult to obtain and verify. The information obtained was collected both from the DAFF website and the amendments from October 2006, the only references found for a glyphosate MRL for maize. No values could be found for glufosinate levels for maize, despite the cultivation of glufosinate-tolerant maize. The latest draft amendments (2017) are the first record found that places a value on glyphosate MRLs for soybean. As shown, there is no consistency in the levels set for

various crops or pesticides. It is inexplicable that MRLs have yet to be established for crops that are grown in conjunction with herbicides, and reflects a lack of thorough regulatory implementation to ensure the public are not exposed to harmful pesticide residues in foods.

Incomplete information may be explained by the gap in the South African government's capacity to ensure due oversight of our food system, with the role fragmented across 14 separate Acts of Parliament and with policy execution hampered by a lack of clear demarcation regarding mandates, responsibilities and accountability. Indeed, there is no clear information showing that government regulators are required to test local food products before they reach the shelves. Conversely, regulations for MRLs for food exports, and their enforcement, are established by DAFF, the South African Bureau of Standards, the Perishable Products Export Control Board, industry working groups, agrochemical companies and other technical experts. It therefore appears that the position of DAFF is to ensure that export products meet international requirements, while neglecting tests on local foods, putting international trade before the health of the nation.

In December 2010, DAFF published a Pesticide Management Policy for South Africa (DAFF, 2010). The Policy acknowledges current legislative problems, including that Act 36 of 1947 does not address Constitutional requirements with regard to our rights to an environment that is not harmful to human health, access to information, openness and transparency, and public participation in decision-making. The Pesticide Management Policy sets out various proposed measures that need to be taken to substantially reform Act 36. However, to date, little progress has been made in implementing these measures.

In summary, current legislation and monitoring of pesticide residues on herbicide-tolerant GM crops is not sufficient to prevent exposure to harmful pesticide residues. The public remain in the dark to the extent of chemical contamination of their food.

Table 1: MRLs for herbicides used on GM maize and soybean GM. All values are in mg/kg.

		European Union	South Africa	Codex
Maize	Glyphosate	1	2	5
	Glufosinate	0.1	-	0.1
	2,4-D	0.05	0.5	0.05
Soybean	Glyphosate	20	Currently n/a. New draft sets it at 10	20
	glufosinate	2	-	2
	2,4-D	0.05	-	0.01

No established safe levels for toxic pesticides

The safe levels for pesticides that are determined by regulators have been widely scrutinised for being outdated, inadequate and heavily influenced by industry, which has even participated in the regulatory approvals of glyphosate for the EU, making the integrity of the entire process questionable. Some of the concerns surrounding the approval process and the acceptable daily intake (ADI) doses include:

1. Tests rely on industry studies alone, which remain unpublished and kept as confidential commercial secrets. This means that data cannot be independently scrutinised and comes with clear conflict of interest.
2. Only the active ingredient is tested, despite the fact that certain adjuvants added to commercial formulations are toxic and has also been shown to increase toxicity of the active ingredient itself (Mesnage et al., 2014).
3. Most regulatory tests are more than 20 years old for glyphosate, 2,4-D and glufosinate and therefore have not taken into account recent independent data showing toxicity.
4. No tests are done on low doses that are below the ADI.
5. Combinatorial effects of multiple pesticides are not tested.
6. The ADI differs in various regions, from the EU to China, the United States and South Africa, questioning a scientific consensus on safety.

With regards to glyphosate, independent data disputes the validity of current ADIs, even for the EU, which has the lowest permitted levels in the world of 0.3 mg/kg body weight per day, compared to 1 mg/kg body weight per day in South Africa.

The most recent evidence of glyphosate harm was a major study published in the nature journal *Scientific Reports*; the first study to show a causative link between glyphosate consumption at real world, permitted levels, and a serious disease. Mesnage et al., (2016) showed that doses of 0.1 parts per billion, equivalent to 0.4 ng/kg of body weight per day, led to non-alcoholic fatty acid liver disease in rats over a 2-year feeding trial. This dose amounts to 75 000 and 250 000 times below the ADI for the EU and South Africa, respectively.

Numerous studies have also linked glyphosate to endocrine disruption associated with birth defects and reproductive problems, leading scientists to call out regulators for the divergence of regulatory decisions from scientific evidence (Antoniou et al., 2012). It is well known that endocrine disruptors can have effects at very low doses, not seen at higher doses, but regulators dismissed such evidence.

The public health debate on glyphosate's carcinogenic potential only intensified since the IARC used publicly available data to classify the herbicide as a probable human carcinogen; not only the active ingredient itself but also commercial formulations that contain ingredients that have been shown to increase glyphosate toxicity (Mesnage et al., 2013). This classification led to the ban of one additive, Polyethoxylated tallow amine, from

glyphosate formulations by the EU, following conclusions by the European Food and Safety Agency (EFSA) that ‘compared to glyphosate, a higher toxicity of Polyethoxylated tallow amine was observed on all endpoints investigated’.

Following its own assessment, the EFSA, however, disagreed with the IARC’s decision, claiming that glyphosate showed a lack of carcinogenic potential. Unfortunately, there was controversy over the methodology and conflict of interests involved in EFSA’s assessment, which included unpublished industry data, and the placing of greater weight on industry studies, as well as exhibiting cherry-picking of data (Bleaney, 2017). The IARC, by comparison, excluded unpublished data or studies with a clear conflict of interest. As a result of the IARC findings, the EU delayed its decision (which was due to be made in 2016) on glyphosate re-approval. Further pressure on authorities has come from a European Citizen’s Initiative that collected over a million signatures to call for an outright ban, which will force a formal legislative response from the EU, prior to making any decision.

Evidence of glyphosate toxicity has become impossible to ignore, with over a hundred studies showing harm to human health and the environment, including industry data itself that reported carcinogenic and teratogenic effects dating as far back as the 1980s (see *Banishing Glyphosate*, I-SIS Special Report, for a review).

The regulatory data for 2,4-D and glufosinate also requires widespread scrutiny; as with glyphosate, outdated, unpublished industry studies are used to determine current safe levels. Indeed, regulatory data for 2,4-D was not able to establish a non-toxic dose from which the ADI is then calculated, because toxic effects were seen at the lowest dose tested. In independent studies, 2,4-D has been linked to cancers, and has been classified as a possible human carcinogen by the IARC. Although a higher category was suggested by members of the IARC working group, too few studies in humans limited the evidence available to raise its classification (see ACB, 2017 for a summary of 2,4-D toxicity). Independent data and United

States Environmental Protection Agency data has also linked 2,4-D to endocrine disruption, as well as to reproductive toxicity and birth defects.

Major gaps in toxicity studies are available for glufosinate, begging the question of how accurate the established safety levels are for the herbicide. It has been associated with severe reproductive and developmental toxicity in both regulatory and independent studies, including at permitted doses, which resulted in neurodevelopmental problems in mice associated with autism-like symptoms following exposure to commercial formulations (Herzine et al., 2016; Laugeray et al., 2014). As with glyphosate, glufosinate and 2,4-D have been detected in the urine of people in North America (Aris and Leblanc, 2011; CDC, 2017), including those on a standard Canadian diet, showing us the extent of contamination of global food systems, particularly regions that cultivate and consume GM foods.

Tests commissioned by ACB detect glyphosate in soy and maize products at levels associated with toxicity

Due to the lack of monitoring by the South African government, ACB commissioned tests on soy and maize products for the presence of glyphosate residues (the list of ingredients tested is given in Appendix A). The samples assessed by ACB were sent to an independent commercial analytical laboratory that is both ISO17025 and ISO9001 accredited, for the determination of glyphosate and metabolites using liquid chromatography combined with mass spectrometry (LC-MS/MS). The limit of quantification was 0.05 mg/kg.

As shown in Table 2, glyphosate was detected in all samples tested, which were all within permitted MRL levels set by the government. However, as reviewed above, MRLs that are set to ensure consumption lie within the

Table 2:

Product tested	Principle ingredient(s)	Glyphosate (mg/kg)	% of South African MRL
Ace maize meal	maize	0.07	3.5
White Star maize meal	maize	0.08	4
Top Class soya mince	soya and maize	1.7	11.8
Knorrox soya mince	soya and maize	0.29	2.2
Imana soya mince	soya and maize	0.71	5.5
PnP soya mince	soya and maize	0.59	4.2

established ADI, are based on questionable and outdated regulatory data that does not incorporate the latest scientific evidence of toxicity. As previously highlighted, glyphosate has been shown in a recent study to induce liver disease at levels of 4 ng/kg body weight per day (Mesnage et al., 2016). This means that for a person weighing 60 kg, only 240 nanograms a day would be sufficient to induce liver disease. Currently, the ADI set by South Africa is 1mg/kg body weight per day, which would mean that a 60 kg person could consume up to 60 mg a day, which is far above the dose conferring liver toxicity. This is also far below even the lowest level of glyphosate detected in (Ace) maize meal, which, if consumed as a staple crop at 500 g a day, would amount to 0.035 mg, or 35 000 nanograms.

Conclusions

The detection of glyphosate in South African food products raises alarm bells about the integrity and safety of South Africa's food system. The current MRLs have been set far above doses that have been linked to causing serious disease in chronic feeding studies.

Further, current legislation and capacity appears insufficient to set and regulate safe pesticide levels in our food system. Ongoing scrutiny over the safety of GM crops and their associated pesticide is intensifying. The EU is unable to agree on re-approval of glyphosate. Multiple court cases in the United States are ongoing, as farmers take Monsanto to court, due to suffering from cancer after years of glyphosate use. The EU has also recently rejected approval of both glufosinate and 2,4-D-tolerant GM crops, based on concerns over their toxicity and the predicted rise in their global use as a result of GM crop cultivation. Regulatory agencies are also in the process of increasing the identification and testing of potential endocrine disruptors, as well as combinatorial effects of multiple pesticides. All three herbicides discussed have been banned by various regional or national governments over toxicity concerns.

With the current scientific evidence exposing the shortcomings of regulatory agencies to thoroughly test and accurately estimate safe levels of pesticides in our food, the ACB calls for a ban of such products in order to protect the public and environmental health of South Africa.

Appendix A: Printed information from the labels of products tested

ACE Maize Meal

Super Maize Meal (may contain genetically modified ingredients), mineral salts, (electrolytic iron, zinc oxide) and vitamins.

May contain wheat gluten.

Product of South Africa.

Amount to use: 300 g (not known how many this would feed).

White Star Maize Meal

Super Maize* Meal, vitamins and mineral salts (electrolytic iron, zinc oxide). (*Maize is produced using genetic modification.)

Produced in South Africa.

Daily portion size is 100 g.

Top Class Soya Mince

Texturised vegetable protein (soybean), maize, wheat flour (gluten), rice, maltodextrin, salt, vegetable fat (palm fruit (TBHQ) [E319]), sugar, maize starch, colourants (E124, E153, E172, E110, E150c), monosodium glutamate (flavour enhancers [E621]), dextrose acids [E330, E262], anticaking agents (E551, E341), capsicum extract (TBHQ [E319]), chilli extract, flavourings, flavour enhancers (E631, E627) and spices (Irradiated).

Product of South Africa.

Suggested single serving is 25 g.

Knorrox Soya Mince

Texturised vegetable protein (40%), maize flour, corn flour, salt, radurised spices, sugar, vegetable oil (palm fruit) (contains antioxidant TBHQ), flavour enhancer (monosodium glutamate), radurised chillies, colourants (E150c, E110), flavouring.

Product of South Africa.

Suggested single serving is 50 g.

Imana Soya Mince

Texturised vegetable protein (soybean), maize, vegetable fat (palm fruit, TBHQ), rice, salt, sugar, monosodium glutamate (flavour enhancer (E621)), dehydrated carrot pieces (irradiated), colourants (E150c, E124, E110), dextrose, wheat flour (gluten), flavour enhancers (E631, E627), maize starch, herbs (irradiated), spices (irradiated), anticaking agent (E551), acidity regulator (E339), flavourings and acids (E330, E363, E262).

Product of South Africa.

Suggested single serving is 25 g.

Pick n Pay Soya Mince

Texturised vegetable protein* (44%) (soya), thickeners (maize*) vegetable fat (palm fruit, TBHQ [E319], BHT [E321], salt, sugar, maltodextrin, hydrolysed vegetable protein (soya), monosodium glutamate (E621) (flavour enhancer), colourant (E150), irradiated onion, irradiated spices and herbs, yeast extract, irradiated garlic powder, acidity regulator (E330), thickener (E412), flavour enhancers (E627, E631), flavouring. *May be genetically modified.

Produced in South Africa.

Suggested single serving is 25 g.

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