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COMMENTS ON REGULATIONS RELATING TO THE DRAFT AGRICULTURAL REMEDY: GNR 541 OF 18 JUNE 2021- UNDER FERTILIZERS, FARM FEEDS AND AGRICULTURAL REMEDIES ACT (36 OF 1947.

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EXECUTIVE SUMMARY

The draft regulations are to be welcomed, but they essentially retain the status quo of weak management of pesticides and agricultural remedies, by failing to comply squarely with section 24 of the Constitution, the regulatory scheme under the National Environmental Management Act (NEMA) for the protection of public health and the environment, and fail to implement, or even pay attention to the 2010 Pesticide Management Policy. Under the section 24 of the Constitution the public health and environment is guaranteed to be protected by "reasonable measures."[1] The failure to do so through the regulations for the registration of pesticides and agricultural remedies under the Fertilizers Farm Foods and Agricultural Remedies act[2] (FFFAR Act)[3] renders these draft regulations unconstitutional, if promulgated in their current form.

At the heart of the deficiencies in the draft regulations is a failure to allow for public participation, and transparent access to information in the registration process. However there are many more areas that are problematic.

[1]The constitution states:
Section 24 :Everyone has the right - (a) to an environment that is not harmful to their health or well-being; and (b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that - (i) prevent pollution and ecological degradation; (ii) promote conservation; and (iii) secure. ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

[2] Act 36 of 1947
[3] Published in GNR 541 published in GG 44 726

The Pesticide Management Policy clearly identified the deficiencies in current legislation ten years ago, but its recommendations have been ignored. The Registrar's powers to refuse registration or re-evaluate and terminate existing registrations are unduly fettered by provisions that favour the applicant or registration holder or are unduly vague, whereas the duty should be on the applicant to prove that the chemical and its general use do not pose an unacceptable risk to society, the vulnerable and the environment.

The Pesticide Policy drew attention to a number of deficiencies in current legislation and gave an indication of how to address these, none of which have been reflected in the draft legislation. One of the most important regulatory places to achieve this is through product labelling, as in practice "the label is law." The following deficiencies were identified.

- Failure to protect non-target areas (e.g. residential areas, schools, hospitals, etc) from exposure to activities spraying activities;
- Failure to require prior training and certification to use/apply the most toxic pesticides (e.g. WHO hazard class 1 and II);
- lack of awareness raising, education and training appropriate to the public and the user
- failure to address the problem of obsolete stockpile pesticides and their disposal;
- failure to adequately address the issue of pesticide container management;
- criminal penalties having a limited deterrent effect. [4]

Much of what the Pesticide Management Policy recommended can be achieved through product labelling and hence the draft regulations are a critical component in the implementation of this policy. The FFFAR[5] Act, through product registration and labelling creates the legal requirements for lawful pesticide use. The draft regulations seek to amend and amplify these regulations, making provision for the review of existing agricultural remedy registrations but provide no guidance as to how to impose label requirements that would bring pesticide management in line with best practice internationally, for example through the establishment of buffer zones and restrictions on aerial spraying. Highly hazardous chemicals can still be registered for use as pesticides and agricultural chemicals with no regulatory guidance given for the drafting of product labels for use where such chemicals are permitted.

International developments in the definition of "substances of concern" are not followed and only a very limited group of chemicals is to be excluded under this heading, which also does not include "highly hazardous chemicals." The draft regulations define these substances too narrowly and must at a minimum include Category IB of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) presumed toxicants. Category 1A of the GHS, which is the category specified in the draft regulation's definition of substances of concern from the GHS is extremely narrow, encompassing only 'known' toxicants, and does not include the broader categories of 'presumed' toxicants.

[4] Paragraph 2 – Problem Statement
[5] Act 36 of 1947

There is a lack of provision for education and safe disposal of containers, and continued lack of provision for effective enforcement provisions.

The Registrar's powers to refuse authorisation or renewal of a pesticide or agricultural chemical are constrained, whereas the duty should be on the applicant to prove that the chemical and its general use do not pose an unacceptable risk to society, the vulnerable and the environment. The provisions contained in PART III of the regulations for renewal are inconsistent, and unreasonably fetter the discretion of the Registrar. Regulation 10(1) states that if the Registrar is satisfied that the application for renewal meets the application requirements he SHALL renew the registration. The application requirements are set out in regulation 8(3) and say nothing about assessment of public health and environmental consequences of the chemical used in agriculture, or updated information as to environmental and health risks associated with the remedy. This is an unreasonable restriction on the discretion of the Registrar to deny renewal based on public health or environmental sustainability requirements. The regulation should be drafted in order to grant the Registrar an overall discretion to apply the precautionary principle of not renewing a registration in the absence of scientific certainty.

The Pesticide Management Policy recommends a proactive approach that bans or restricts chemicals that pose an unacceptable risk. The draft regulations are the appropriate place for this to take place.

We call upon the Registrar to ban any active ingredient that is banned in more than 25 countries, by defining such ingredient as a "substance of concern" as per regulation 1 of the draft regulations. Since the European Union comprises of 27 countries, if South Africa were to ban any active ingredient banned by more than 25 countries it would include 208 ingredients not approved for use in the EU.

For all of the above reasons as well as the further detailed submissions contained below, the draft regulations cannot be considered to be a reasonable measure as envisaged by section 24 of the Constitution, to protect the public health and the environment. They need to be substantially redrafted or face legal challenge for being not constitutionally compliant.

A. INTRODUCTION

1. Unpoison is a civil society movement made up of concerned citizens, educational institutions, and other multi-sector organisations that are united behind the common goals of effecting legislative reform of agrichemical policy, ensuring effective regulation and monitoring of agrichemical use, transparent registration processes, access to product information, and ensuring a healthy, clean, just, and safe South Africa for all.

2. This submission responds to the invitation to comment on the draft regulations published by the Registrar under the Fertilizers Farm Foods and Agricultural Remedies

act[6] (FFFAR Act) on 18th June 2021[7] which proposes changes in the regulation of registration of pesticides and agricultural remedies.

3. Unpoison welcomes legislative reform in this sector. However, we submit that the proposed regulations fall short of complying with the regulatory scheme for environmental governance under the Constitution and National Environmental Management Act.[8] (NEMA) and is out of sync with the South Africa Pesticide Management Policy.[9] It is submitted that it needs to be substantially amended, for regulatory compliance, based on what is set out in this submission.

4. The draft regulations do not sufficiently empower the Registrar to protect public health and the environment. They enable the review of existing registrations of agricultural chemicals and authorization of new ones, and enable the Registrar to obtain information needed to do so. However they do not provide a framework for the assessment of risk to public health and/or the environment, an essential requirement if these regulations are to constitute a reasonable measure for the protection of the environment as envisaged in section 24 of the constitution. Where existing registrations are reviewed the powers of the registrar are limited regarding possible refusal of further registration if all information that he/ she seeks has been provided. The onus is more on the Registrar to justify why the chemical should **not** be allowed to continue, as opposed to being on the applicant to prove it is safe. The regulations essentially confirm the status quo and that is unacceptable 27 years after the birth of the new constitution.

5. The Pesticide Management Policy correctly identifies the deficiencies in the current legislation for the governance of agricultural chemicals. But the regulations do not follow the policy as to how to address this deficiency which has led to widespread contamination.

6. Currently the FFFARA is legislation that governs sale and use of pesticides n South Africa. Under the Act, the registration process, through product labelling creates the legal requirements for lawful pesticide use. Product labels are used throughout the world to set out the main duties and responsibilities of pesticide users. The result is that controls over pesticide use are largely dependent on what is contained in the label – which sets out the applicable restrictions on lawful use. USA labels for the same product will for example differ widely from RSA labels. "The label is the law" in other words.

7. New regulations for the registration and labelling of pesticides must be consistent with the Constitution, FFARA, NEMA and the Pesticide Management policy.

8. This submission will argue that the draft regulations fail to comply with the Constitution, FFARA, NEMA and the Pesticide Management policy in material respects and that they need to be substantially redrafted.

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[6] Act 36 of 1947
[7] Published in GNR 541 published in GG 44 726
[8] Act 107 of 1998
[9] Pesticide Management Policy for South Africa - GN 1120 of 2010 published in GG 33 899 on 24 December 2010.

B CURRENT CONTEXT – THE EXAMPLE OF THE WESTERN CAPE MAIN CATCHMENTS

9. Widespread non-compliance with current label requirements for pesticides and other agricultural chemicals is an acknowledged problem in South Africa, and policy changes in the governance of agricultural chemicals in order to address this problem commenced in 2010 with the introduction of the Pesticide Management Policy.[10] This policy notes:

> "The absence of effective management of pesticides to ensure that pesticides are used in ways that lead to the minimisation of significant adverse effects on human health and the environment is of concern."[11]

10. A 2019 study of the presence of pesticides in river water samples in a number of typical fruit farming areas in the Western Cape depicts the scale of the problem of pesticide drift very clearly.[12] The conclusion is inescapable that there is widespread non-compliance with the label requirement that pesticides and herbicides not be allowed to drift into non target areas and water bodies. Clearly there is a need for reform to bring the labels and practices of pesticide and herbicide application in line with international best practice, which includes severe restrictions on aerial spraying.

11. The study included the Krom, Breede and Hex River catchments.[13] Using passive water samplers 248 chemicals, including 187 pesticide compounds were detected.[14] Analysis 53 of pesticides showed that the insecticide imidacloprid exceeded the environmental quality standards (EQS) up to 558 - fold. Additionally, thiacloprid, chlorpyrifos, acet-amiprid and terbuthylazine were detected at least once 12, 9, 5 and 3-fold above the EQS, respectively.

12. Since such environmental quality standards for surface waters are only available for two pesticides in South Africa (atrazine, endosulfan (Department of Water Affairs and

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[10] Pesticide Management Policy for South Africa - GN 1120 of 2010 published in GG 33 899 on 24 December 2010.

[11] id section 1.

[12] Temporal variation of pesticide mixtures in rivers of three agricultural watersheds during a major drought in the Western Cape, South Africa. lLouCurchod[abcd]ChristelleOltramare[c]MarionJunghans[d]ChristianStamm[c]Mohamed AqielDalvie[e]MartinRöösli[ab]SamuelFuhrimann[ef] available: https://www.sciencedirect.com/science/article/pii/S2589914719300751

[13] Out of the 248 analyzed compounds (187 pesticide compounds and 61 TPs), 34 parent compounds (18% of the analyzed active in- gredients) and 19 TPs (31% of the analyzed TP) were detected (Table S4 of the SI). The 34 pesticide compounds detected above LOD consisted of 13 fungicides, 12 herbicides and nine insecticides (Fig. 3). Out of the 96 pesticide compounds that have been reported on the spray records, 35 compounds were covered by the analytical method. These included six out of the eight dominating compounds in the spraying records (Tables S3 and S4 of the SI). Only the fungicide mancozeb and the herbicide glyphosate, which are hardly stable in the environment or require particular analytical methods, were not covered (paragraph 3.2.2)

[14] Out of the 248 analyzed compounds (187 pesticide compounds and 61 TPs), 34 parent compounds (18% of the analyzed active ingredients) and 19 TPs (31% of the analyzed TP) were detected (Table S4 of the SI)

Forestry, 1996)), a consistent set of EQS from the Switzerland or the EU were used in the study.[15]

13. Out of 34 compounds from the spraying records, which were analyzed, 13 compounds (39%) could be detected. Out of these compounds three (chlorpyrifos, penconazole, spiroxamine) belong to compounds sprayed in the highest quantities according to the spray records.[16] The study stated that the following pesticides were used in high quantity: the fungicides mancozeb, ametoctradin and dimethomorph; the herbicides glyphosate, trifluralin and paraquat and the insecticides prothiofos, omethoate and indox-acarb).

Mancozed , trifluralin, paraquat, prothiofos, and omethoate are all banned for use in the European Union.

14. Apart from the above pesticides and agricultural remedies profenofos, diafenthiuron chlorothalonil, and atrazine, all banned for use in the EU are routinely used in South Africa.

C. THE POLICY CONTEXT

15. The Pesticide Management Policy correctly identifies the serious risk that the lack of proper pesticide management can cause and sets out how the state must address and remedy this.

16. But the draft regulations fail to comply with the Pesticide Management Policy in at least four respects:
    a. Lack of provision for public participation in the registration and review of agricultural chemicals
    b. Lack of guidance for product labels provisions to reduce non target exposure and contamination of people and water bodies
    c. Lack of provision for education and safe disposal of containers.
    d. Lack of provision of effective enforcement provisions.

17. The Pesticide Management Policy states that its purpose is to guide legislation:

> "This Policy provides information and will serve as guidelines to support the legislation and regulations. It provides decision-makers with direction by setting out a framework to ensure improvements that are aimed at ensuring that pesticides are produced, used and disposed of throughout their full life-cycle in ways that pose no significant adverse effects on health and the environment." [17]

[15] Id paragraph 2.6
[16] Id 3.2.2
[17] Paragraph 1

18. Hence all legislation, including subordinate legislation in the form of regulations should align with the guidance set out in this policy. However the draft regulations fail to do so.

19. The overall objectives of the policy include the tightening up of the legislative framework and promotion of transparency in pesticide registration:

> "The objects of this policy are to
> - improve legislative framework to ensure that South Africans are better protected from health and environmental risks posed by pesticides; ….
> - Increased transparency, access to information and improve public participation in the registration of pesticides." [18]

20. The Pesticide Management Policy states that these objectives can only be achieved effectively through partnerships.

> "between Government, the agro-chemical industry. farmers, Community Based Organizations, labor, Non Governmental Organizations, consumer groups and other stakeholders nationally and through international initiatives." [19]

21. The Pesticide Management Policy identifies key deficiencies in current pesticide management including i*nter alia:*

- Failure to protect non-target areas (e.g. residential areas, schools, hospitals, etc) from exposure to activities spraying activities;
- Failure to require prior training and certification to use/apply the most toxic pesticides (e.g. WHO hazard class 1 and II);
- lack of awareness raising, education and training appropriate to the public and the user
- failure to address the problem of obsolete stockpile pesticides and their disposal;
- failure to adequately address the issue of pesticide container management;
- criminal penalties have a limited deterrent effect. [20]

22. The Pesticide Management Policy sets out a number of steps to address the problem. Two important areas of focus that are critical to addressing the above identified deficiencies are the focus on the protection of water bodies and worker safety. Neither are addressed in the draft regulations. The Policy states:

    a. WATER ISSUES

    > "An effective approach to reducing pollution of water by pesticides would be, first, to release fewer pesticides and/or less toxic pesticides into the environment and, second, to use practices that minimize the movement of pesticides to surface water

[18] Id paragraph 3
[19] Id paragraph 3
[20] Paragraph 2 – Problem Statement

and groundwater. Where necessary, the DAFF, through the regulatory system, shall place requirements or restrictions on users to limit the movement of pesticides to water. These will include instituting buffer zones, restricting aerial spraying in a certain proximity to water sources."[21]

b. WORKER PROTECTION

"The DAFF shall, in accordance with OHSA Act, engage with employers and employees to raise awareness, institute educational and training and programmes appropriate to the public and users. Training and information programmes should include all sectors handling and using pesticides. Aside from farmers, pesticide retail store-owners and attendants. Government technicians and extension workers, pest control operators, and even medical doctors, environmental health officers, nurses and paramedics should also be trained on the safe use of pesticides. Also, the DAFF shall require that any person applying and selling pesticides must be certified in order to apply or sell pesticides in South Africa."[22]

(i) Legislative measures to control pesticide drift to non target areas and water bodies are mandatory.

23. The Pesticide Management Policy identifies the need for the revision of the outdated FFFAR Act and its regulations. It requires new legislation to protect vulnerable populations, support sustainable pest management, mandate buffer zones for pesticide use areas and prohibit the registration of pesticides that pose an unacceptable risk to people's health and the environment.[23] This means that the regulations under the FFFAR Act must contain these reforms. However the draft regulations fail to address any of these requirements for legislative reform.

24. The policy states:

"The Policy considers that the current legislation, the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) and its regulations that sets up framework for regulations of pesticides is outdated and therefore will need to be revised/repealed. Thus new legislation is needed that will:

(i) Strengthen health and environmental protection by:

- Introducing special protection for vulnerable populations (e.g. children, women,):
- Taking into account pesticide exposure from all sources, including, food and water;
- Consider cumulative effects of pesticides that act in the same way;
- Support sustainable pest management;
- Prohibiting registration of products that poses unacceptable risk to people's health or the environment;
- Expediting the registration of lower-risk products;
- Mandate buffer zones for pesticides use areas; …"

[21] Section 4(i)
[22] id
[23] Section 5 (i) - Legislation

25. Clearly the Pesticide Management Policy requires regulations under the FFFRA to contain measures to control pesticide drift, and create buffer zones to protect vulnerable populations such as women and children, whether they reside on farms as farm workers and their families, or in adjacent communities. It has failed to do so.

(ii) Suggested regulatory provisions for preventing pesticide drift:

26. The draft regulations could have included overarching principles coupled and clear criteria, enabling labels to be crafted with provisions that are capable of enforcement. Currently the provisions in most labels are so vague as to be unenforceable. For example the label for chlorpyrifos[24] has the following virtually unenforceable provisions, due to use of vague terms such as "immediate area" and "nearby" as well as the general difficulty of obtaining evidence that links contamination without reaonsable doubt to particular sources of spraying:

    a. Notify all inhabitants of the immediate area to be sprayed and issue the necessary warnings. Do not spray over or allow drift to contaminate water or adjacent areas.
    b. Prevent drift onto other crops, grazing, rivers, dams or areas not under treatment or to nearby water sources.

27. Other jurisdictions, for example the European Union, have developed regulatory measures that guide member countries in developing legislation aimed at limiting non targeted contamination. The EU directive of 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[25] severely restricts and controls aerial spraying, (ie from helicopters and aeroplanes) which is one of the principle causes of pesticide drift. It states:

> "(14) Aerial spraying of pesticides has the potential to cause significant adverse impacts on human health and the environment, in particular from spray drift. Therefore, aerial spraying should generally be prohibited with derogations possible where it represents clear advantages in terms of reduced impacts on human health and the environment in comparison with other spraying methods, or where there are no viable alternatives, provided that the best available technology to reduce drift is used." [26]

28. Water bodies near farming areas where there is significant aerial spraying of pesticides and herbicides are particularly susceptible to contamination through drift. This issue can be addressed through label requirements that make sure that there is little prospect of the drift into water bodies through the use of buffer zones. The draft regulations make no mention of concepts such as buffer zones, and how the Registrar can utilize these measures through product labels. In the European Union the 2009 directive makes provision for this issue as follows:

[24] https://za.uplonline.com/download_links/mjwXAbLCISAnqOLjJy3qDcISkom5g8HjBRe5XVVZ.pdf
[25] DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 available at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:en:PDF
[26] id

> "(16) Use of pesticides can be particularly dangerous in very sensitive areas, such as Natura 2000 sites protected in accordance with Directives 79/409/EEC and 92/43/EEC. In other places such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds, and in the close vicinity of healthcare facilities, the risks from exposure to pesticides are high. In these areas, the use of pesticides should be minimised or prohibited. When pesticides are used, appropriate risk management measures should be established and low- risk pesticides as well as biological control measures should be considered in the first place."

29. A typical example of a preventative provision in FFFAR regulations that could be included in product labels would be to prohibit aerial (aeroplane or helicopter) spraying, save under clearly identified circumstances, and with buffer zones of at least a kilometer from residential areas, water bodies, schools, creches and hospitals. Where mechanical spraying is used (ie apart from backpack spraying) a buffer zone of at least 100 meters from these areas should be imposed. This would apply to mistblowers, for example.

30. The particular area buffers could be defined more closely in these regulations by reference to town planning zonings, forested areas, flood plains, nature reserves and other existing delineations. See for example the restrictions on pesticide use contained in the example from Maine, USA.[27]

(iii) Measures to ensure public education and training in sectors handling

31. As stated above, the Pesticide Management Policy identified key deficiencies in current legislation to include :

- Failure to require prior training and certification to use/apply the most toxic pesticides (e.g. WHO hazard class 1 and II);
- lack of awareness raising, education and training appropriate to the public and the user

32. Notwithstanding the highly hazardous nature of the chemicals concerned, the regulations make no provision for training and support for users. Some examples of how to integrate such requirements into product labels under the regulations could include a provision that states that labels may require:

a. Restrictions on sale of certain pesticides unless to persons who have undergone training and are certified as having done so. Further regulations and guidelines could set out the training requirements in more detail.
b. Record keeping of training, disposal etc by users coupled with administrative fines for non compliance. Further guidelines and/or regulations could also provide detail as to the measures envisaged.

[27] In addition to bans of a product, there are laws that prohibit certain applications or applications in specific areas. See for example this list of specific use regulations for pesticides in municipalities in the state of Maine:https://www.maine.gov/dacf/php/pesticides/public/municipal_ordinances.shtml

33. The European Union provides that education should include all sectors handling and using pesticides. See for for example the provision in the 2008 EU directive - **framework for Community action to achieve the sustainable use of pesticides**

> "(8) It is essential that Member States set up systems of both initial and additional training for distributors, advisors and professional users of pesticides and certification systems to record such training so that those who use or will use pesticides are fully aware of the potential risks to human health and the environment and of the appropriate measures to reduce those risks as much as possible. Training activities for professional users may be coordinated with those organised in the framework of Regulation (EC) No 1698/2005."[28]

(iv) Measures to ensure public education

34. The highly toxic nature of these chemicals makes it incumbent on government and the producers of the chemicals to make the public aware of the dangers of their use. Training at the point of sale, through supporting information as well as information on publicly available ie state websites is critical to ensuring the promotion of their safe use. Yet the regulations make no provision for this to be included in the registration and product labelling process.

35. Compare for example the provisions of the 2008 EU directive which show the importance of this kind of governance.

Education at point of sale

> "(6) Sales of pesticides, including Internet sales, are an important element in the distribution chain, where specific advice on safety instructions for human health and the environment should be given to the end user at the time of sale, in particular to professional users. For non-professional users who in general do not have the same level of education and training, recommendations should be given, in particular on safe handling and storage of pesticides as well as on disposal of the packaging."

36. Education at the public level:

> "(10) Considering the possible risks from the use of pesticides, the general public should be better informed of the overall impacts of the use of pesticides through awareness-raising campaigns, information passed on through retailers and other appropriate measures."

F LACK OF CONTROL OVER PESTICIDE APPLICATION EQUIPMENT.

[28] **DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides**

37. The manner in which pesticides are applied can have a significant impact on how they spread through the air into non target areas. For example provisions which require labels to indicate restrictions on droplet size and types of technology employed can play a big part in reducing pesticide drift. Yet the regulations are silent on controls over application equipment, best available technology and the like.

38. Compare for example the provisions of the 2008 EU directive which show the importance of this kind of governance.

> "(13) Since Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery ([4]) will provide for rules on the placing on the market of pesticide application equipment ensuring that environmental requirements are met, it is appropriate, in order to minimise the adverse impacts of pesticides on human health and the environment caused by such equipment, to provide for systems for regular technical inspection of pesticide application equipment."

D. NO PROVISION FOR PUBLIC PARTICIPATION

39. There is no opportunity for public participation in the Registration of an Agricultural Remedy (Part II), and the renewal of a Registration of an Agricultural Remedy. The applicant submits the information required (under Rule 4 for registrations, and Rule 8 for renewals), and the public is shut out of the process while the Registrar makes his or her decision.

40. This is contrary to the Pesticide Management Policy which states as one of its objectives:

> "Increased transparency, access to information and improve public participation in the registration of pesticides."[29]

And

> "These objectives can only be achieved effectively through partnerships between Government, the agro-chemical industry, farmers, Community Based Organizations, labor, Non Governmental Organizations, consumer groups and other stakeholders nationally and through international initiatives."

And

> "4. POLICY TO ADDRESS THE PROBLEM The objectives of the policy will be achieved through the application of relevant and existing international agreements, policies and regulatory frameworks, with particular reference to the following
>
> "According to section 32, (Access to Information), of the Constitution of Republic of South Africa, Act No. 108 of 1986, the public has a right to access to information on pesticides to which they are exposed. To ensure transparency and access to information, the DAFF shall

[29] Section 3 - Objectives

> incorporate all aspects of the regulatory system and also avail the opportunity for public involvement in the development of new aspects of the regulatory decision in the new legislation."[30]

41. The approach of the Draft Regulation is contrary to the duty to promote participation contained in the regulatory scheme for environmental governance in South Africa. This will be explained in detail below:

LEGISTLATIVE CONTEXT

(i) The Constitution

42. The Constitution requires the state to take reasonable measures to protect the environment. Read together with the constitutional duty to promote fair administrative action,[31] it becomes clear that the state has a duty to take reasonable measure both of a procedural, as well as a substantive nature, to protect the environment, and especially when regulating hazardous agricultural chemicals, that are detrimental to health. A reasonable procedural measure would include provisions promoting public participation in the chemical registration process contemplated under these regulations.

43. The constitution states:

> Section 24
> Everyone has the right - (a) to an environment that is not harmful to their health or well-being; and (b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that - (i) prevent pollution and ecological degradation; (ii) promote conservation; and (iii) secure. ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

44. When interpreting a provision in the bill of rights, international law must be considered and foreign law may be considered. See:

> Interpretation of Bill of Rights
>
> 39. (1) When interpreting the Bill of Rights, a court, tribunal or forum - (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom; (b) must consider international law; and (c) may consider foreign law.

(ii) International Law

[30] Id section 4(vii) – Increasing Transparency
[31] Constitution section 33

45. International law, such as the Rio Declaration[32] requires states to promote public participation. See – Principle 10 which states:

> "Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided."

(iii) Foreign Law – examples from Europe and North America

46. This submission does not advocate for the adoption of any specific piece of foreign legislation into South Africa. However under section 39(1)(c) of the Constitution the state may consider foreign law as an interpretative tool, to guide it as to what a reasonable procedural measure under section 24 of the Constitution should be. Foreign legislation in jurisdictions such as the USA and directives in the European Union protect the public right to participate in in the registration of agricultural remedies and pesticides.

47. The European Union issued a directive[33] in 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. It builds on the general approach adopted in an earlier EU directive of 2002[34] that aimed to provide a framework to meet the general environmental objectives and targets already established by the Community. The importance of public participation in decision making is repeatedly emphasised in the 2002 directive, and is incorporated in the 2009 directive.[35]

For example the preamble to the 2002 directive states:

> "(15) Provision for access to environmental information and to justice and for public participation in policy-making will be important to the success of the Programme."

The programme places "an emphasis" on:

[32] RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT 1992; https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_CONF.151_26_Vol.I_Declaration.pdf

[33] DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 availble at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:en:PDF

[34] Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme (4), a common legal framework for achieving a sustainable use of pesticides should be established g account of precautionary and preventive approaches.

[35] (1) In line with Articles 2 and 7 of Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme (4), a common legal framework for achieving a sustainable use of pesticides should be established, taking account of precautionary and preventive approaches.

"(3).....extensive dialogue with stakeholders, raising environmental awareness and public participation"

and

"(5)… - cooperation with civil society, environmental non-governmental organisations (NGOs) and business in the Candidate Countries to help raise public awareness and participation"

48. The USA: Public Participation Process for Registration Actions https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions

(iv) The National Environmental Management Act

49. The National Environmental Management Act provides the overarching framework for the implementation of section 24 of the Constitution. Its principles[36] are binding on all organs of state and include a duty to promote public participation. They apply to the Department of Agriculture in promulgating regulations under the FFFAR Act given the potential significant effect that the regulation of these substances can have.

50. They state:

Section 2. Principles

(1) The principles set out in this section apply throughout the Republic to the actions of all organs of state that may significantly affect the environment and- (a) shall apply alongside all other appropriate and relevant considerations, including the State's responsibility to respect, protect, promote and fulfil the social and economic rights in Chapter 2 of the Constitution and in particular the basic needs of categories of persons disadvantaged by unfair discrimination; (b) serve as the general framework within which environmental management and implementation plans must be formulated; (c) serve as guidelines by reference to which any organ of state must exercise any function when taking any decision in terms of this Act or any statutory provision concerning the protection of the environment;…(e) guide the interpretation, administration and implementation of this Act, and any other law concerned with the protection or management of the environment.

51. Some of the principles directly relevant to public participation include:

(f) The participation of all interested and affected parties in environmental governance must be promoted, and all people must have the opportunity to develop the understanding, skills and capacity necessary for achieving equitable and effective participation, and participation by vulnerable and disadvantaged persons must be ensured. (g) Decisions must take into account the interests, needs and values of all interested and affected parties, and this includes recognising all forms of knowledge, including traditional and ordinary knowledge. (h) Community wellbeing and empowerment must be promoted through environmental education, the raising of environmental awareness, the sharing of knowledge and experience and other

[36] NEMA principles - section 2

> appropriate means. (i) The social, economic and environmental impacts of activities, including disadvantages and benefits, must be considered, assessed and evaluated, and decisions must be appropriate in the light of such consideration and assessment. (k) Decisions must be taken in an open and transparent manner, and access to information must be provided in accordance with the law.

52. Agricultural chemicals in South Africa, through their use disproportionately affect workers and persons living on farms who are exposed to them in the workplace, and often where they live. Children and lactating mothers are also disproportionately exposed making it critical that their interests needs and values are heard in the pesticide regulation process.

(v) The National Environmental Air Quality Act

53. South Africa knows how to insure public participation in environmental decision-making because it provides for such in decisions for atmospheric emission licenses (for example).

https://cer.org.za/wp-content/uploads/2018/10/National-Environmental-Managerment-Air-Quality-Act-39-2004-the-2017-National-20181026-GGN-41996-01144.pdf

E THE REGULATIONS PROVIDE NO GUIDANCE ON HOW TO PROTECT PUBLIC HEALTH AND THE ENVIRONMENT

"Substances of concern" and "highly hazardous agricultural remedies"

54. The definition and designation sections (regulations 1 and 2) of the draft regulations do not clearly define, and limit the use of substances that pose a threat to public health and/or the environment.

55. There is no explanation, nor is there good reason for why "substances of concern should" do not include "highly hazardous agricultural remedies" in the definition section. They are defined separately. "Highly hazardous agricultural remedies" are defined to include a wider group of substances than "substances of concern." No memorandum accompanying the draft regulations explains this and it is not acceptable. What is required is a reasonable measure in order to protect the public health and environment as envisaged in section 24 of the Constution. A further critique of this issue and the shortcoming in the definition of "substances of concern" is contained in section G below.

56. The regulations are not clear as to how these two groups of chemicals sync with eachother to protect public health and the environment. This deficiency needs to be addressed:

a. "Highly hazardous agricultural remedies" seem to be allowed to be registered for sale and use provided the labels make it clear what restrictions should be placed on their use. See regulation 2(1)(c) which defines "restricted" chemicals as including those containing "highly hazardous agricultural remedies." As stated below, however there is little guidance on the contents of labels provided in the draft regulations.
b. Regulation 4 which defines what information must be submitted does not require the applicant to state whether the agricultural chemical contains ingredients that are "substances of concern" and/or "highly hazardous agricultural remedies." These requirements need to be included in section 4.
c. In terms of regulation 6 the Registrar needs to be satisfied of certain factors, including that the agricultural remedy does not contains "substances of concern", but there is no mention of the need to know whether the product contains "highly hazardous agricultural remedies."
d. If the Registrar is satisfied that the requirements set out in these regulations are met he or she **must** register the agricultural remedy. This provision fetters the powers of the Registrar unacceptably. Given that the group of substances defined as "substances of concern" is far narrower than the group defined as "highly hazardous agricultural remedies" it is not clear that the Registrar is being required to look closely enough at whether an application for registration will pose a threat protect public health and the environment. (see section F and G below).
e. Regulation 7 concerns grounds of refusal but does not mention as a basis for refusal that the remedy contains "substances of concern" or "highly hazardous agricultural remedies." These categories should be added.
f. Once registered the registrar in terms of regulation 11(b) may refuse the renewal of an agricultural remedy which contains active ingredients and/or co-formulants or biological substances regarded as substances of concern. However this section does not state that the registrar may refuse renewal if the application for renewal concerns an agricultural remedy which contains a "highly hazardous agricultural remedy". This means that the regulation fails to protect public health and the environment.

Lack of guidance on labels

57. The use of the registration process and product labeling under the FFFRA is the principle means for the control and regulation of the use of highly hazardous agricultural chemicals. Yet these regulations provide **inadequate guidance** to the Registrar for the evaluation of new pesticides and the design of **product label requirements** that would ensure the protection of public health and the environment in the registration and review process. The regulations seem to be focused on the enabling the Registrar to obtain information on the chemicals, but not on how to assess this information.

58. Draft regulation 4 requires toxicological and ecotoxicological data to be supplied on application for registration, as well as scientific information to demonstrate the safety

efficacy and quality of a product.[37] But these provisions does not go far enough to ensure the protection of public health and environment. The terms "safety" and "quality" of a product are vague, and cannot enable consistency and the protection of public health in the evaluation of risks to the environment.

59. The regulations need provisions for the evaluation of human health and environmental risks based on **data and peer review**, including a review of alternative less harmful methods and mitigation measures. In this regard the US EPA is instructive in describing an evaluation process, which is missing from our regulations. This submission does not advocate for the adoption of USA legislation or any foreign law but includes this information for consideration given the Constitutional provision that foreign law can be considered in the interpretation of rights including the environmental right in the Bill of Rights.[38]

60. As an example, USA EPA publication on pesticide registration states:[39]

"The Evaluation Process

- We evaluate human health risks (including sensitive groups such as children and immune-suppressed individuals), by reviewing data on:
  - Aggregate risks–through food, water, and residential uses
  - Cumulative risks–from different pesticides with the same effects
  - Occupational risks to those applying the product during their work
- We evaluate environmental risks by reviewing data on:
  - Potential for ground water contamination
  - Risks to endangered and threatened species
  - Potential for endocrine-disruption effects
- We implement risk assessment and peer review:
  - We review all the scientific data on the pesticide product and develop comprehensive risk assessments that examine the potential effects of the product or ingredient on the human population and environment.
  - The health and environmental risk assessments undergo a process of peer review by scientific experts.
- We make risk management and regulatory decisions, where we:
  - Consider the results of the risk assessments and the peer review
  - Research alternative pesticides that are already registered
  - Review any measures needed to mitigate any identified risks
  - Discuss with the applicant if modifications to the product or labeling must be made to mitigate risk
  - Establish new food tolerances if needed, after publishing notices for comment in the Federal Register
  - Grant the registration if no changes are needed, or if necessary modifications are accepted by the applicant

[37] Draft regulations 4(1)(h)(viii) onwards.
[38] Constitution section 39 - Interpretation
[39] https://www.epa.gov/pesticide-registration/about-pesticide-registration

- Publish in the Federal Register a notice of issuance of the registration."

61. It is suggested that the draft regulations include similar risk evaluation provisions.

62. By way of comparison, in the USA there are also significant requirements for registration applicants to provide information on toxicological data, terrestrial and aquatic non target organisms data, and data on applicator exposure. Similar information should be specified as required under the draft regulations. See:

    40 CFR § 158.500 - Toxicology data requirements table. https://www.law.cornell.edu/cfr/text/40/158.500

    40 CFR § 158.630 - Terrestrial and aquatic nontarget organisms data requirements table https://www.law.cornell.edu/cfr/text/40/158.630

    40 CFR § 158.1000 - Applicator exposure - general requirements. https://www.law.cornell.edu/cfr/text/40/158.1000

F. REGULATION 4 DOES NOT GIVE SUFFICIENT GUIDANCE TO THE REGISTRAR TO PROTECT HEALTH

The regulation is too vague as to what data is required

63. The provisions of regulation 4 are too vague to ensure that sufficient data will be placed before the Registrar, and therefore cannot constitute reasonable measures as envisaged under section 24 of the Constitution or the FFFAR Act. By being so vague an undue burden is placed on the Registrar to demonstrate, if challenged, why information is "relevant" or "necessary" or what "sufficiently safe" means. What a regulation of this nature should instead provide is clear and precise regulatory provisions or criteria for the exercise of discretion. The following provisions of regulation are particularly vague:

64. Regulation 4 (1) (b) refers to all information "where relevant" and "all necessary information as indicated on the application form." There is no clarity provided on what is to be indicated on the application or how to determine relevance.

65. Regulation 4 (1) (h) similarly states the requirements in the most general of terms:

    "where relevant in addition to the information required by regulation 4 all scientific documentation required to demonstrate the safety quality and efficacy of the product in respect of any of the following as set out in the guidelines issued by the Registrar Office."

66. By merely listing the kinds of information that is required (toxicological data, ecotoxicological data, etc.) is not sufficient because it may allow registration decisions to be made based on very limited information as long as they merely touch on all of the topics above.

67. This submission does not advocate for the adoption of USA legislation. But by way of the comparison, the U.S. EPA in regulations applicable to pesticide registration decisions clarifies what data is necessary to *sufficiently* address each topic.

    40 CFR § 158.310 - Product chemistry data requirements table.
    https://www.law.cornell.edu/cfr/text/40/158.310

    40 CFR § 158.400 - Product performance data requirements table.
    https://www.law.cornell.edu/cfr/text/40/158.400

    40 CFR § 158.500 - Toxicology data requirements table.
    https://www.law.cornell.edu/cfr/text/40/158.500

    40 CFR § 158.630 - Terrestrial and aquatic nontarget organisms data requirements table
    https://www.law.cornell.edu/cfr/text/40/158.630

    40 CFR § 158.1020 - Applicator exposure data requirements table.
    https://www.law.cornell.edu/cfr/text/40/158.1020

    40 CFR § 158.1070 - Post-application exposure data requirements table.
    https://www.law.cornell.edu/cfr/text/40/158.1070

    40 CFR § 158.1100 - Spray drift data requirements table
    https://www.law.cornell.edu/cfr/text/40/158.1100

    40 CFR § 158.1300 - Environmental fate data requirements table
    https://www.law.cornell.edu/cfr/text/40/158.1300

68. Applicants for registration of agricultural remedies should be required to submit all of the date required in the above data requirements tables, unless an exemption is warranted.

Information submitted by the applicant should be peer reviewed

69. Peer-reviewed studies should also be included as part of the data requirements. That is, the applicant should be required not only to submit its own data, but also any studies from the peer-reviewed scientific literature about the agricultural remedy for which a registration is being sought that relate to one or more of the data requirements.

Regulation of nano-pesticides (and nano-technology)

70. After regulation 4(1)(g) information as to the introduction of **nanoformulations** should be included and the term “nanoformulation” should be defined in the regulations. The following possible formulation of the text after the end of paragraph 4(1)(g) is suggested:

> "In the case where an applicant intends to introduce nanoformulations as part of the formulated product, the applicant shall provide to the Registrar scientific documentation required to demonstrate the safety for health and the environment, quality and efficacy of the products, including particle number concentration and particle size distribution in the environment."

71. Nanotechnology is a novel and largely unregulated area of technological evolution. As such it requires careful consideration in regulation and authorisation of all and any substances derived from this technology. In the case of nano-pesticides, over and above the regulations and authorisation required for conventional chemical pesticides, the following should be required in order to protect public health and the environment:

    a. A risk analysis for all nano-materials and nanotechnology-derived ingredients. This must provide specific detail of both *in vitro* and *in vivo* studies, as well as all other supporting studies and documentation, including all relevant published peer reviewed literature on each of these substances or relevant to the application of these substances in general.
    b. All assessments must be based on current state of the art analysis as it may evolve in both industry and in peer reviewed literature. The regulators must refrain from using unscientific terminology, such as "safe for design", "sound science" or "good epidemiology,"[40] as enabling of regulation and/ or permissability of nano-based substances. Rather, the regulation of nano-particles must assume a risk averse and precautionary approach due to the novelty and lack of international oversight mechanisms of these substances, and in order to prevent harm.
    c. All existing information and data on the substances under contemplation must be provided. Information and data provision cannot be excluded under CBI or proprietary claims if that information is in any way relevant to the assessment of the product or substance.
    d. Full disclosure of full life-cycle impacts of all ingredients, management of nano particles, cleanup and handling directions must be divulged for each substance.
    e. Failure to provide such data or revelation of any further untoward impacts of these nano-particles have revealed in either industry research, published literature or other studies must result in the immediate suspension of the product or range of products until a full and transparent assessment of the implications can be made, which demonstrates that the substance does not pose of risk.
    f. Any chemicals or pesticides in use in SA which use nano-particles or technology as ingredients or adjuvants must be regulated as novel products with each and any adjuvant subject to full evaluation as above.

[40] These are terms emanating from within industry to circumvent and/ or undermine conventional peer reviewed science and to instead rely on industry generated research as is common in chemical and pesticide regulation.
Ong, E.K. & S. A. Glantz. 2001. Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms. American Journal of Public Health. 91(11), 1749-1757.

g. South African law must remain the supreme guiding principle in the regulation of these substances, and no measures preventing public participation, access to information and access to fair administrative action can be imposed through standards set at FAO, Codex or other external regulatory regimes. Our constitutional rights may not be subordinated to international regulation.

Important aspects of the regulation are ambiguous

72. There is an ambiguity or contradiction in regulation 4(1)(h)(xv)(c) – which is an important section dealing with information that could be useful to the Registrar in considering whether to authorize a chemical. It is ambiguous, and therefore of doubtful regulatory value.

It states

"in the case where the agricultural remedy has been registered or approved (however described) for use in a foreign country –
(a)…….
(b)…….
(c) the limitations, if any imposed in the foreign country on the use of the agricultural chemical, and if refused, reasons for such decision"

COMMENT: clearly this formulation of the regulation means that an agricultural remedy can at the same time be both registered in a foreign country and also refused registration, which is a contradiction.
This is unacceptable in legislative drafting and must be corrected.

It is suggested that a further subheading be included to state:

"if an agricultural remedy has applied for and been refused approval in a foreign country reasons for such decision should be stated. If the agricultural remedy is banned or restricted for use in a foreign country this should be indicated."

73. There is also a concern with ambiguity in the definition of IPM (Integrated pest management): the words "subsequent integration" do not relate clearly to the definition.

Insufficient requirements are set for information on the contents of labels

74. Regulation 4(1) (e) relates to the requirement for the applicant to prepare draft labels. Labels submitted by the applicant should be required to present feasible methods of preventing pesticide drift, for example reasonable buffer zones related to verifiable objects, such as water bodies, residential zonings, schools, dwellings on farms. Currently they are too vague to be enforceable except at considerable expense by the state.

75. In some respects the draft regulations refer to details that will be included in guidelines – which are not law, and where there is no obligatory provision or guidance. Ideally any

guidance should be in the regulation itself and guidelines be issued for issues not appropriate to regulation.

No guidance is given as to risk management requirements

76. Reg 6 (1) (e) refers to "every risk must be manageable." This provision does not guide the Registrar in the assessment of the chemical concerned. The sentence is ambiguous, or alternatively does not have a clear and simple meaning. For example it is not clear what "management of a risk" means in practice. What is required in a regulation of this nature are enforceable provisions for the management and mitigation of risks by measures that ensure that the chemical will not be used or disposed of in a manner that could pose a threat to public health and the environment. Such measures could include buffer zones, avoidance of aerial spraying and the use of specified technology for application. The Registrar should be able to determine from the application whether every risk is capable of being managed and mitigated to remove any threat to health and the environment by enforceable provisions on labels.

77. Similarly the requirement in regulation 6(1)(a) is vague given that there is no regulatory guidance given on what "criteria for "safety" actually means in terms of this statute, once again placing the burden on the Registrar to justify and defend its views on safety, instead of giving the Registrar clear and justiciable criteria.

G. SUBSTANCES OF CONCERN ARE TOO NARROWLY DEFINED

78. "Substances of Concern" is defined too narrowly, and must include Category IB presumed toxicants.

79. Under proposed Regulation 6(1)(d), the Registrar must be satisfied that an agricultural remedy for which a registration is being sought does not contain substances of concern. The term "substances of concern" is defined in Regulation 1 (definitions) with reference to Category 1A of the GHS

80. However, **Category 1A** of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is extremely narrow, encompassing only 'known' toxicants, and do not include the broader categories of 'presumed' toxicants. See below classifications under the GHS for chemicals that are *carcinogens, mutagens and reproductive toxicants*:

Hazard categories for carcinogens

> **CATEGORY 1:** Known or presumed human carcinogens
>
> The placing of a substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual substance may be further distinguished:
>
> **Category 1A**: Known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence.

Category 1B: Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence.

Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

Hazard categories for germ cell mutagens

CATEGORY 1: Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.

Category 1A: Substances known to induce heritable mutations in germ cells of humans
Positive evidence from human epidemiological studies.

Category 1B: Substances which should be regarded as if they induce heritable mutations in the germ cells of humans.

(a) Positive result(s) from in vivo heritable germ cell mutagenicity tests in mammals; or
(b) Positive result(s) from in vivo somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxic tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of
germ cells; or
(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.

Hazard categories for reproductive toxicants

CATEGORY 1: Known or presumed human reproductive toxicant

This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

CATEGORY 1A: Known human reproductive toxicant: The placing of the substance in this category is largely based on evidence from humans.

> **CATEGORY 1B**: Presumed human reproductive toxicant: The placing of the substance in this category is largely based on evidence from experimental animals. Data from animal studies should provide clear evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

81. Many presumed toxicants are in Category 1B because it is unethical to conduct experiments on humans to test whether human exposure to such toxicants causes cancer, mutations, or adverse effects on sexual function, fertility or on development. The Draft Regulations Under the FFFAR Act should not permit the registration of presumed carcinogens, mutagens and reproductive toxicants. The definition of Substances of Concern needs to be amended to include both Category 1A **and Category 1B** carcinogens, mutagens and reproductive toxicants.

H REFUSAL AND RE- ASSESSMENT PROVISIONS ARE TOO LIMITED

Refusal or Authorisation

82. Regulations 7: The provisions for refusal of registration do not empower the Registrar to protect public health and the environment, either because they are too vague or because they place an undue burden on the Registrar to justify the refusal in the face of a **mandatory requirement** that the registration is granted if requirements set out in regulation 6 are complied with. Note as discussed above that the requirements for approval are vague and too weak to protect public health and the environment. The entire regulatory process is weighted in favour of granting registration and burdening the Registrar with an unacceptable administrative burden of justifying why it should not be granted – where the Registrar does not have clear standards he or she can use do justify refusal.

83. For example the following sub regulations are unacceptably vague for the regulation of highly hazardous chemicals, released into the environment often from aeroplanes and near residential areas and water bodies:

    The Registrar may refuse an application if:

    a. Information is insufficient to enable assessment - (regulation 7(b));
    b. Product is not sufficiently effective for purpose - (7(c));
    c. Establishment for manufacture is not suitable - (7(d));
    d. Product does not comply with established standards for the active ingredient (are these local standards?) - (7(f));
    e. Use of the chemical according to the label will be detrimental to humans, animal, plant and or the environment. - (7(g));

84. Regulation 7(g) is of particular concern. It has very little value to the Registrar. Product labels presented for registration usually include vague instructions to the user that limit the liability of the manufacturer but are near impossible to enforce. On the face of it

use of the chemical according to the label might not be detrimental to humans and the environment, but the label is virtually unenforceable. See for example the label for chorpyrifos.[41]

> "Avoid drift of spray onto other crops, grazing, rivers, dams and areas not under treatment."

85. What is needed are clear and justiciable provisions enabling the exercise of the Registrar's discretion to refuse a remedy, such as the availability of a less hazardous remedy or agricultural practice. At the very least the Registrar should be entitled to refuse regulation, or renewal of any pesticide or agricultural remedy falling into the category of "highly hazardous agricultural remedy" and provision should be made for the Registrar to refuse authorisation or renewal of an agricultural remedy in the absence of scientific certainty if in his or her opinion a precautionary approach is justifiable.

Renewal of authorisation

86. The provisions contained in PART III of the regulations for renewal are inconsistent, and unreasonably fetter the discretion of the Registrar. Regulation 10(1) states that <u>if the Registrar is satisfied that the application for renewal meets the application requirements he SHALL</u> renew the registration. The application requirements are set out in regulation 8(3) and say nothing about assessment of public health and environmental consequences of the chemical used in agriculture, nor any requirement for updated information as to its impact on public health and the environment. This is an unreasonable restriction on the discretion of the Registrar to deny renewal based on public health or environmental sustainability requirements.

87. Regulation 10(1) is also inconsistent with regulation 11 as it says that:

> "11 the Registrar may refuse the renewal application if –
> (a) All conditions as determined by the Registrar are not met."

It is not clear what conditions are being referred to. They could be conditions in the existing certificate of registration. Alternatively they could be conditions that the Registrar imposes on certain agricultural chemicals eg they may not be toxic to bees. The regulation needs to be clear on what is meant by conditions and needs to define what conditions can be imposed under these regulations. If not the Registrar may be challenged by applicants who say he does not have the power to impose certain conditions.

88. The inconsistency between regulation 10 and 11 arises because regulation 10 <u>compels registration</u> whereas regulation 11 <u>allows for refusal,</u> and the two regulations are not properly harmonised.

[41] https://za.uplonline.com/download_links/mjwXAbLCISAnqOLjJy3qDcISkom5g8HjBRe5XVVZ.pdf

89. The much more important issue, however is the absence in regulation 11 of a provision giving the Registrar a general discretion to refuse renewal in the interests of protecting protect public health and/or the environment. Such a clause should be based on the precautionary approach which is mandated by the NEMA principles, namely that in the absence of scientific certainty a precautionary approach is justified, and this should be a matter for the opinion of the Registrar.

90. A draft clause could be phrased as follows:

> "The Registrar may refuse to renew a registration if in his/her opinion the pesticide or agricultural chemical poses a risk or threat to public health and/or the environment. The registrar may refuse such renewal if in the absence of scientific certainty a precautionary approach is justifiable."

This could also be stated as:

> "The registrar may refuse to grant or renew a registration of an agricultural remedy if in his or her opinion there is an absence of scientific certainty that remedy will not be detrimental to the public health and the environment, and the chemical has certain toxicological features."

91. Both renewal and application for registration of a pesticide or agricultural remedy, should be refused if the agricultural remedy or any of its active ingredients is banned in the country where the company, or its parent company or holding company is headquartered, and where the reason for the ban are related to the protection of public health and the environment.

92. As they are currently written the regulations entrench the agricultural chemical sectors' interests and do not balance these with the protection of the environment. The onus must always be clearly on the applicant to show that a chemical is safe, rather than on the registrar to justify why he or she considers it unsafe, given that our constitution guarantees an environment that is not detrimental to health and well being.

Reassessment on new information

93. Following established scientific practice it is incumbent upon the Registrar to allow and enable the timeous re-assessment of any chemicals and pesticides, in light of publication of peer reviewed literature which calls the safety of these substances into question, and to then allow and enable public participation in any such reassessment, re- or de-regulation of the substances being reviewed.

I. SUPPORT FOR ENFORCEMENT AND PROPER USE

94. The regulations use the criminal justice system to ensure compliance, nothwithstanding the fact that the Pesticide Management Policy had identified this as a deficiency in current legislation. It stated:

> "Under the current Act, anyone contravening a provision of the Act or the regulations is guilty of an offence and will be summarily convicted and liable to a fine not exceeding R1000, and such penalties have limited deterrent effect; [42]

95. Under the draft regulations non-compliance with the regulations remains a criminal offence. In terms of regulation 41 any person contravening these regulations shall be liable for a fine or imprisonment on conviction or both. This means that the state must prosecute the offender beyond reasonable doubt in a criminal court and rely on a magistrate to levy an appropriate fine.

96. It is readily apparent from the lack of prosecutions under the FFFAR Act to date that this mechanism for enforcement is simply not workable, and hence there is an absence of deterrence under the Act. Some of the features that limit the success of this approach, include an overburdened criminal justice system, a lack of resources and capacity to prosecute environmental violations, the fact that South Africa is overwhelmed with violent crime which has dominated the criminal justice system, the specialised nature of prosecutions for offences of this nature and the fact that courts in rural areas are often small ones, and have limited capacity given the rural nature of most of our agriculture.

97. There is however a solution. Having regard to comparative international experience, a paper written by Melissa Fourie of the Center for Enironmental rights[43] analyses in detail how administrative penalty systems can provide for the adjudication of contraventions of environmental laws, and the determination of a monetary penalty (having regard to a range of factors) on a balance of probabilities by either an administrative body, civil courts, or both. This is not only a feasible innovation in South African legislation, but will significantly improve environmental compliance according to her analysis.

98. Provisions for administrative penalties need to be included in the regulations. In order to facilitate proper enforcement through a system of administrative penalties, and product labels for pesticides need to be designed to facilitate prosecution for non compliance. For example simple requirements such as record keeping and training can enhance compliance, and proof of non-compliance is relatively simple to prove. Specifications for permissible equipment type, protective equipment, sizes of buffer zones and ban on aerial spraying are likewise provisions that are easier to enforce than the current typical label requirements that "no drift be allowed to enter non target areas". These criteria and provisions need to be included in the draft regulations.

Examples would be:

[42] Pesticide Management Policy – section 2 – problem statement

[43] HOW CIVIL AND ADMINISTRATIVE PENALTIES CAN CHANGE THE FACE OF ENVIRONMENTAL COMPLIANCE IN SOUTH AFRICA - Melissa Fourie. Available at https://cer.org.za/wp-content/uploads/2011/11/Fourie-M-SAJELP-Paper-June-2009-Final.pdf

a. No one may apply pesticides within XXX (specified distance) meters of a water body, with the water body being defined as channels, rivers, wetlands, ponds lakes and dams.
b. No one may apply pesticides aerially save with the permission of the relevant authority and after satisfying it that a set of criteria have been met; these criteria must be set out in the regulations;
c. Employees may not apply pesticides without wearing stipulated personal protective equipment. Employers can be fined;
d. Records must be kept of disposal of containers to a permitted waste disposal facilities or operators, which are defined by reference to other related legislation.

J. PROHIBITION OR RESTRICTIONS ON CERTAIN AGRICULTURAL CHEMICALS

99. The policy states that certain agricultural remedies and pesticides should be banned:

> "The Policy takes into cognisance the fact that special attention should be given to pesticides that pose unmanageable risk, with an understanding that such pesticides should be considered for phase out, severe restriction and bans. Those that will be considered include those with Endocrine Disrupting Properties (EDP), Persistent Organic Pollutants (POPs), carcinogenic and immunotoxic potential, formulations classified by WHO as Extremely Hazardous (class 1a) and Highly Hazardous (class 1b), as well as pesticides associated with frequent and severe poisoning incidents."

100. The regulations are the place to do so. However they fail to.

101. It is suggested that a ban on specific products should be included in the regulations. Certain remedies, for example glyphosate require immediate attention. At least forty countries and local jurisdictions have banned or restricted glyphosate.[44] For example Mexican President Andres Manuel Lopez Obrador issued a decree late last year that seeks to ban the herbicide completely by 2024, joining several other governments that have sought to restrict its use, including Germany. He has described the chemical as toxic. Recently a court upheld Mexico's glyphosate ban.[45] The following site lists information about some bans on glyphosate: In addition to bans of a product, there are laws that prohibit certain applications or applications in specific areas. See for example this list of specific use regulations for pesticides in municipalities in the state of Maine:

https://www.maine.gov/dacf/php/pesticides/public/municipal_ordinances.shtml

102. In addition hereto we call upon the Registrar to ban any active ingredient that is banned in more than 25 countries, by defining such ingredient as a "substance of concern" as per regulation 1 of the draft regulations. We refer you to the Consolidated List of

[44] https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/where-is-glyphosate-banned-/

[45] https://www.reuters.com/business/healthcare-pharmaceuticals/mexican-court-strikes-down-bayers-legal-challenge-over-glyphosate-ban-2021-05-08/

Banned Pesticides published by the Pesticide Action Network, available at https://pan-international.org/pan-international-consolidated-list-of-banned-pesticides/

Since the European Union comprises of 27 countries, if South Africa were to ban any active ingredient banned by more than 25 countries it would include 208 ingredients not approved for use in the EU. See https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en

K. PART VI. MANUFACTURING ESTABLISHMENTS

103. South Africa has experienced a recent devastating industrial accident as a result of unrest in KwaZulu Natal, the explosion and fire at the UPL warehouse.[46] This has highlighted the need for particular controls on manufacturing and warehousing of pesticides and agricultural remedies. The following submissions should be considered in the light of these events

104. Regulation 27(1) should include 'warehoused'.

105. Regulation 27 (3) should include some detail on what "adequate" means with reference to clear and justiciable criteria, in order for this provision not to be so vague as to be meaningless. From the UPL fire and previous Transnet warehouse fire in Durban in 2017[47] it is suggested that such measures could include:

- measures to contain fire, including preventing the spread of fire between adjacent sections of storage; well-maintained sprinkler systems; run-off containment on the boundaries of the site in the event of flooding and fire management and other appropriate fire management provisions;
- annual inspections for all these requirements and for general safety;
- the onus should be placed on any business or entity setting up such a facility to provide notice of the intention to establish the facility to both the Registrar as well as provincial environmental, and water departments and municipal environment, water, fire and emergency services departments.
- submission of products and quantities stored should be made to the Registrar annually as well as to the local authority's departments of environment, water, fire and emergency services, and this should include detailed lists of specific chemicals and not generic categories.
- in the event of a fire, flood or any other event that disperses pesticides into the environment, the owner or person in control of the premises should be required to make a detailed list of chemicals and quantities thereof under storage or production available to authorities immediately in order to enable action, remediation, and to alert affected areas.

[46] https://www.google.com/search?q=maverick+upl&oq=maverick+upl&aqs=chrome..69i57j33i160.5260j0j7&sourceid=chrome&ie=UTF-8

[47] https://www.iol.co.za/mercury/news/transnet-cleared-of-wrongdoing-in-2017-warehouse-blaze-43362145

UNPOISON

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