UNPOISON

EARTH • AIR • WATER

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COMMENTS ON REGULATIONS RELATING TO THE AGRICULTURAL REMEDIES: GNR 51386 UNDER FERTILISERS, FARM FEEDS AND AGRICULTURAL REMEDIES ACT (36 OF 1947).

This comment is made by UnPoison, a civil society collective made up of multi sector organisations, educational institutions, NPOs, agronomists, researchers, advocacy groups, communities, environmental practitioners, scientists, doctors, and concerned citizens, committed to a sustainable, healthy, clean, safe, just and thriving agricultural sector; a healthy food system, and a food secure future for all South Africans. Forever.

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Executive Summary

The draft regulations reflect positive advancements to both the 2021 draft regulations and the 2023 update which have been recognised and acknowledged by the UnPoison Network. However, fundamental issues persist, with key deficiencies rooted in poor definitions; exploitable vagueness and lack of enforceability; lack of provisions for public participation and access to information regarding the pesticide registration and renewal processes; no provisions to publish the national agrochemical database perpetuating a lack of transparency; a registration process that is not suited to biologicals limiting the accessibility of safer products and the advancement of a biologicals sector; and the regulations incorporate a risk based approach which is entirely inappropriate given the inherently toxic nature of pesticides.

1. **Precautionary Principle over Risk-Based Approach**

In response to the proposed updates to Act 36 of 1947, we advocate for a precautionary approach rather than a risk-based framework to protect South Africa's people and ecosystems from pesticide-related harm. Under Section 24 of the South African Constitution, every citizen has the right to an environment that is safe, non-harmful, and protected for the benefit of present and future generations. In line with this, the National Environmental Management Act (NEMA) of 1998 emphasises the precautionary principle, mandating the prevention of environmental degradation where scientific evidence indicates potential harm.

The 2010 South African Pesticide Management Policy also reflects this approach by advocating for robust risk mitigation measures to reduce pesticide exposure for vulnerable groups, including children, pregnant women, women farm workers, residents of areas surrounding agricultural and forestry spraying, and marginalised communities - both urban and rural.

By adopting a precautionary framework, Act 36 would shift toward a "first, do no harm" ethos, allowing the restriction or phase-out of substances that pose potential risks without needing conclusive scientific proof of harm. The 2017 amendment to NEMA reinforces this by mandating that regulatory decisions account for irreversible impacts on biodiversity and human health.

International best practices underscore the efficacy of precautionary regulation. For example, the European Union employs this model to prevent the entry of high-risk pesticides, focusing on sustainable alternatives and safer application practices. Similarly, Canada's Pest Control

Products Act includes precautionary provisions that limit pesticide approvals if potential risks are not fully understood, prioritising public health over mere economic considerations.

To support a sustainable regulatory model, Act 36 should prioritise precautionary measures to reflect South Africa's constitutional and environmental obligations. Adopting these standards aligns with the polluter-pays principle and establishes a strong legal foundation for preserving the country's public health, biodiversity, and ecological balance for future generations.

2. **Public Participation for Registrations and Renewals and the National Database Access**

Since 2019, we have consistently called for a public participation process in the registration and renewal of pesticides, aligned with South African legal frameworks on access to information and public involvement in environmental governance. This change is a long-overdue imperative. Currently, public input is limited to derogation applications for restricted or banned substances, but the registration and renewal of pesticides directly impacts public interests, health, externalised economic burdens, and our environmental integrity.

The Promotion of Access to Information Act (PAIA) of 2000 enshrines the public's right to access information that impacts them. This is further strengthened by Section 32 of the Constitution, which guarantees the right to information held by the state when needed for the exercise or protection of any rights. Without transparency in pesticide registration and renewal processes, stakeholders—including community members, environmental groups, and affected individuals—are effectively denied their right to meaningful participation, as recognized in Section 33 of the National Environmental Management Act (NEMA). Section 2(4)(f) of NEMA mandates public involvement in decisions impacting the environment and health, reflecting the Aarhus Convention's principles on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters. This international standard emphasises the public's right to participate early in decision-making, particularly in areas with potential harm.

To align Act 36 with these constitutional, legal, and international standards, a structured, transparent public participation process must be established for pesticide registrations and renewals. Such participation would enhance regulatory accountability, ensure decisions reflect broad societal values, and strengthen public trust in pesticide governance.

Additionally, the national pesticide database must not only be updated quarterly by the Registrar, but must also be published for public access on the same schedule. Quarterly publication would ensure timely access to information that directly impacts public health and environmental oversight, reinforcing the right to informed participation as mandated by PAIA, the Constitution, and NEMA. Integrating this measure would significantly advance the Act's commitment to public transparency, accountability, and regulatory integrity.

3. Co-formulants Must be Regulated in the Same Manner as Active Ingredients

It is our firm position that co-formulants must be regulated in the same manner as active ingredients in all pesticide-related provisions. This recommendation is grounded in the imperative to protect the right to an environment that is not harmful to health or well-being, as enshrined in Section 24 of the Constitution.

Co-formulants, though often categorised as inactive, can play a significant role in determining the overall toxicity, environmental impact, and efficacy of pesticide products. Scientific evidence increasingly demonstrates that certain co-formulants may enhance the toxicity of active ingredients or independently exert harmful effects on human health and the environment. Failure to regulate these substances on par with active ingredients could lead to violations of constitutional rights, particularly the right to a healthy environment and the principle of public health protection, which are key obligations under the Bill of Rights.

Furthermore, Act 36 of 1947, in its preamble and purpose, aims to regulate substances used in agricultural practices to safeguard human, animal, and environmental health. To omit co-formulants from rigorous oversight would contradict the purpose of the Act and undermine the regulatory framework's intent. Additionally, international best practices, including those informed by the principles of the Stockholm Convention on Persistent Organic Pollutants, call for the comprehensive regulation of all substances contributing to pesticide formulations.

We therefore request that the Registrar amend the draft regulations to explicitly include the "and co-formulant(s)" to every instance where active ingredients are referred to. This will align South African pesticide regulation to its constitutional obligations and international best practices.

4. The Registration of Biological Solutions

The outdated framework of Act 36 of 1947, originally intended for agrichemicals, presents significant barriers to the registration and effective regulation of biopesticides, biostimulants, and biofertilizers. This structure inadequately serves these biological solutions, which differ fundamentally from conventional chemical pesticides in their mechanisms, impacts, and environmental interactions.

NEMA's precautionary principle (Section 2(4)(a)) mandates that when there is a risk of serious environmental harm, regulatory measures must be tailored to prevent such harm. Applying this principle requires a framework for biological products that is distinct from that used for agrichemicals, aligning regulatory scrutiny with the potential impacts and benefits of each category of product.

Globally, countries such as Canada, the United States, and members of the European Union have established dedicated regulatory processes for biological solutions. The United States' EPA, for instance, maintains a separate Office of Pesticide Programs division to expedite biopesticide registrations under specific criteria, ensuring these products undergo an evaluation process that acknowledges their unique characteristics and lower-risk profiles. Similarly, the

EU's 2009 Plant Protection Regulation (Regulation (EC) No 1107/2009) provides a streamlined path for low-risk biological products, creating incentives for their development and adoption while ensuring human and environmental safety.

A distinct regulatory pathway in South Africa for biopesticides, biostimulants, and biofertilizers would enable alignment with best practices internationally and foster innovation in safer, sustainable pest and crop management solutions. This approach would not only meet the demand for low-impact alternatives but also uphold South Africa's constitutional and legislative commitments to environmental health and public well-being.

5. **Reference to HCA Act of 2021**

We submit that referencing the Regulations for Hazardous Chemical Agents, 2021 (HCA 2021) within the current draft update of Act 36 of 1947 is legally premature and potentially problematic. As the HCA regulations are presently undergoing an update, any reference to the HCA 2021 in the draft regulations of Act 36 may quickly become outdated or inconsistent with the new regulatory standards once they are promulgated.

Including such references risks creating regulatory ambiguity and instability for both industry stakeholders and regulatory bodies. Specifically, referencing outdated regulations introduces potential conflicts with forthcoming requirements and compliance criteria, creating uncertainty for entities subject to the regulations. Additionally, prematurely linking Act 36 to HCA 2021 may hinder swift adaptation to improved standards that the updated HCA regulations will bring.

Until the updated HCA regulations are formally promulgated and effective, it is advisable for Act 36 to avoid specific references to the 2021 HCA regulations. Instead, we recommend using language that provides flexibility, such as referencing "the most current regulations governing hazardous chemical agents as promulgated by the Department of Employment and Labour" This approach will ensure that Act 36 aligns with the latest, legally binding standards and minimises potential inconsistencies.

6. **Definitions in Annexure A**

While we welcome the classification of "low risk products", "substances of concern" and "restricted agricultural remedies" in the 2023 update, the definitions are problematic and create scope for misclassification and misuse that can, and has already resulted in serious harm.

The definitions in Annexure A are an imperative protection mechanism that when defined and applied correctly in the registration process will provide robust protections to the South African people, the environment, and the farming sector, yet if poorly defined as they currently are, pose significant danger and risk.

Low Risk Products

A “low risk” designation requires clear criteria to prevent potential misuse and ensure public safety. However, as currently written, the criteria are vague, allow for substances to be misclassified with impunity, and fail to align with international standards.

Criterion (ii) – “Active substances for which it is not possible to differentiate between the exposure associated with its use as an agricultural remedy with its environmentally relevant exposure levels or other uses in the food chain” - this wording is vague and risks allowing substances into the “low risk” category that may have significant, unassessed environmental or human health impacts. Allowing substances without sufficient differentiation of exposure levels contradicts the regulatory objective of protecting public and environmental health.

Criterion (iii) – “Active substances for which no consumer exposure linked to the mode of application is foreseen” – is problematic because it does not define “foreseen,” nor does it specify under what conditions exposure might occur inadvertently.

To ensure public and environmental protection, and to form the regulatory foundation upon which a robust biological inputs sector can be built, these definitions must employ the precautionary approach and remove all potential risk for misclassification. The definition of Low Risk Products should be modelled on the *Commission Regulation (EU) 2017/1432 of 7 August 2017* by the European Union that defines low risk products.

Restricted Agricultural Remedy

Neither the definition in the definitions list, nor in Annexure A define’s what the restrictions are, which licence is required to be able to sell, distribute, buy or apply restricted agricultural remedies. This must be specified to ensure enforceability and prevent restricted remedies from finding their way into households for domestic use.

We also note that restricted Agricultural Products need to be specified wherever Substances of Concern are mentioned in the regulations by adding “and restricted agrichemical remedies” as currently the regulations specify limitations and stringent oversight to “substances of concern” yet omit the same for “restricted agrichemical products”.

Grouping of Substances of Concern and Restricted Agricultural Remedies

There is also seeming inconsistency with how pesticides are grouped in Substances of Concern and Restricted Agricultural Remedies. Recommendations have been made inline in our comments table.

7. **Penalties**

UnPoison notes that penalties are only referred to with regard to labelling and no other misdemeanour has been defined with accompanying penalties.

Definitions:

- **Add: Agricultural remedy -** as this is an outdated South African term that misrepresents agrochemicals and pesticides. There is a need to provide a definition indicating this refers to pesticides and plant protection products as they are more commonly referred to globally.
- **Add: Exposure Assessment For Children** - these must be in line with child-specific exposure assessments in risk evaluations at various stages of a child's development, as developed by the Organisation for Economic Co-operation and Development (OECD).
- **"Restricted Ag Remedy** - change "or" to "and"....and qualifications of person….
- **Add: Highly Hazardous Pesticides** refers to pesticides that are acknowledged to have high levels of acute or chronic toxicity, or hazards to health or environment, according to internationally accepted classification systems such as WHO or Global Harmonized System (GHS) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous. [Source: FAO/WHO Guidelines on Highly Hazardous Pesticides]
- **Add: Pesticides** means any substance, or mixture of substances of chemical or biological ingredient intended for repelling, destroying, or controlling any pest, or regulating plant growth.
- **Add: Phase-out period** is a limited time by which a cancellation of a pesticide registration is implemented.
- **Restricted Agricultural Remedy - needs a clear definition and clear guidelines in Annex A**
- **Add: Risk Communication** is an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
- **Vulnerable group** - this includes children, pregnant women, women in agriculture, residents of agricultural areas where spraying occurs, and both rural and urban low income communities.

Part I - Application for Registration		
	2.2	Many offshore companies hold registrations in SA - this should be applied retrospectively

	3.c	"~~Where relevant~~, all necessary scientific information as indicated on the application form…." Should be: "All scientific documentation…." We cannot have vagueness in the regs that allows for applicant discretion and interpretation.
	3.f	Sub regulation 14.a.3 of HCA act does not have sufficient SDS GHS info requirements and is deficient. UnPoison advises waiting until HCA act has been published OR including UnPoison's comment on 14.3.a in HCA draft regs: "*(3) Where the need for medical surveillance has been determined as necessary by the occupational medicine practitioner, as contemplated in sub regulation (2), the occupational medicine practitioner must specify requirements for medical screening including-* ***(a)*** *an evaluation of the employee's medical, occupational and exposure history;* ***(b)*** *the appropriate clinical examination and medical tests;* ***(c)*** *the intervals at which medical screening must be conducted, appropriate to the health risks and health status of the employee."*
	3.h	"~~Where relevant~~, all scientific documentation…." Should be: "All scientific documentation…." We cannot have vagueness in the regs that allows for applicant discretion and interpretation.
	3.h	~~"…. as set out in the guidelines issued by the registrar's office."~~ All documents must be supplied. We are concerned that the specific guidelines have not been referred to, may be at the Registrar's discretion, and may change from time to time. This again creates grey areas and exploitable loopholes. Which guidelines are these? Have they been published? We cannot refer to something that is not gazetted.
	3.h.vi	This is not applicable to biologicals. Should say "…. with the exception of biological remedies"
	3.h.vii	co-formulants must be included - "… of the active ingredient, **the co-formulants** and the agricultural remedy in accordance with…."
	3.h.x	" …of its active ingredients **and co-formulant(s)** in the environment…"

	3.h.viii	Exposure assessment for children - must refer to definition.
	3.h.xii	Must align to codex - the work has been done by FAO under the Code as Alimentarius section.
	3.h.xiii	The specific SACNASP qualification category must be defined - not any SACNASP scientist, that allows a loophole for incorrectly qualified people to do the work. Should say: ".... local trials need to be generated under the supervision of a person registered as a professional scientist with SACNASP **under category ecotoxicology**;
	3.h.xiv	The specific SACNASP qualification category must be defined - not any SACNASP scientist, that allows a loophole for incorrectly qualified people to do the work. Should say: "... a person registered as a professional scientist with SACNASP **under the category of ecologist;**"
	3.h.xv	"... registered as **a natural research scientist** with SACNASP;"
	3.h.xvii	"In the case of an aerial application, a risk assessment report……in comparison with other spraying methods; ~~or an explanation as to why an aerial application is essential in that scenario.~~" An explanation cannot suffice. A risk assessment report must be done to justify aerial spraying. Nothing else.
	3.h.viii	Must refer to the same requirements as 10.3.i
	7	".... alternative solutions for **restricted substances and** substances of concern **managed and maintained by his office**." What process or resource does the Registrar have to identify suitable alternatives? Alternatives must be approved independently, and not
	8.1	"The Registrar ~~must~~ **may** grant the registration if satisfied with the following: The word "must" undermines the Registrar's right of refusal. We suggest reframing 8.1 to place onus on industry to comply, **"No approval will be given unless the following conditions are met:"**

	~~8.1.b~~	Remove 8.1.a - this is a vague loophole open to interpretation and exploitable. It is effectively covered by 8.1.e “Widespread and commonly recognised practice” is undefined, vague and open to interpretation. “Unreasonable adverse effects”. Undefined, this cannot be measured. Vague and open to interpretation and exploitation.
	~~8.1.d~~	The agricultural remedy does not contain a substance of concern (highly hazardous pesticides); an active ingredient, **or a co formulant** banned in the Republic of South Africa or in any other country. How does he ensure he doesn’t approve these?
	8.1.f	“.... that such residues are in accordance with **CODEX** and with the Foodstuffs, Cosmetics and Disinfectants Act…”
	8.1.g	**ADD: “The application to register or renew a pesticide is gazetted and opened for public comment for 90 days.”**
	8.3.a	Must specify how much data must be submitted from the registration, whether this is a full registration or one third
	8.3.b	Must specify how much data must be submitted from the registration, whether this is a full registration or one third
	8.5	Define exceptional circumstances? This cannot be vague. A specified set of circumstances needs to be listed. 24 months is too long. Spraying emergency registrations for more than 12 months will be disastrous. This must be limited to 12 months.
	8.6.a	This is indefinable - define “realistic worst case conditions of use” and “negligible”
	8.6.c	Must include: “**Substantive evidence is provided and gazetted as part of the public participation process** that shows not approving the agricultural remedy….”
	8.6.d	**ADD”** the application for derogation has followed the public participation process defined by the Guideline For The Application For A Derogation For An Agricultural Remedy Identified As A Substance Of Concern published by the Registrar in April 2024.

	8.7	We need a maximum specified period - and an address for where public comment needs to go
	9.1.a	**ADD:** The agricultural remedy does not include HHPs as co formulant(s).
	9.1.b	**ADD:** In the case of a biological registration, no synthetic ingredients are added, and no co formulants that can be classified as HHPs.
	9. (2)	**ADD:** The Registrar has the authority to regulate, restrict or prohibit the manufacture, import, export, distribution, sale, possession, and application of agricultural remedies, require a manufacturer recall, and the authority to confiscate or destroy prohibited or unregistered pesticides.
Part II - Approval for Registration		
	10.1	What happens after the renewal period?
	10.2.f	**Remove "to the best of the applicant's knowledge".** There can be no loopholes or grey areas. It is the duty of the applicant to be certain.
	10.3.e	Who makes the declaration? Must add: ".... and validated by the Registrar." Someone needs to be accountable for the validity of the declaration, in case of a public health risk. Declaration needs to be a manufacturer's confirmation letter dated and signed, listing all the ingredients in the formulation, accompanied by tests and data etc.
	10.3.g	**Remove "where relevant,"**
	10.3.i	**Remove "where relevant,"**
	10.4	**Remove**
Part III - Labelling and Container		
	15.1	"...shall be in accordance with the GHS **Classification of Labelling of Chemicals** and…."
	15.2	"No agricultural remedy shall be distributed or sold without a **GHS compliant** label or package leaflet **approved by the Registrar**."

	16	**Rewrite** to read as: “All labels and package leaflets shall be in English and contain a QR code linked to labels online that are in all official South African languages.”
	18.1.l	“… hazard statement(s), ~~and a minimum of two precautionary statement(s)~~, giving precedence to the most important/ severe hazards. ” There CANNOT be a minimum. Several HHPs present many risks that are as severe as each other and precautionary statements cannot be prioritised in this regard. There is no recognised grading to determine hazard severity, so this cannot be left to open interpretation.
	18.1m	This must only refer to the Poisons Information Helpline 0861-555-777. Griffon Poison Centre is run by a senior Croplife member/employee and this is a conflict of interest. This service must be independent, and there must be only one national database.
	18.1.p	**Directions For Use must not be removed.** If Restricted Uses are required on the label, move the directions to the secondary panel or leaflet and say Refer to Directions For Use in (Leaflet) etc.
	19.1.a	This is the most important info on the label - **MUST** be on the main panel
	19.1.d	“ ….this agricultural remedy is to be used ~~only~~ **strictly** in accordance with the instructions on the label.”
	21	“....information referred to in regulation 18 sub paragraphs (a)(b)(c)(d)**(e)**(f)(g)....” 18.1.e must be included here.
	24.2.a	“Is in ~~good condition~~ **tact** and legibly labelled;” - “good condition” is too vague
	24.2.b	“It is ~~sufficiently~~ durable..” “sufficiently” is too vague and not definable
	24.2.d	“It must be closed **in a childproof container in line with ISO 13127 standards for child resistant packaging** and sealed in a manner that…” America introduced the Poison Prevention Packaging Act in 1970 and this should be domesticated for South Africa.
	24.2.g	“.... to prevent spillage when ~~pouring out~~ **decanting** the contents…”

	24.3	**Add: Household, Garden and Veterinary Agricultural Remedies** (a) GHS compliant labels on all agricultural remedies sold for household, garden and veterinary (domestic pets) use shall: (i) indicate in words and with a pictogram that non-permeable gloves must be worn when using this product; (ii) Include the Poison Information Helpline number - 0861 555 777; (iii) Include clear disposal instructions and details of manufacturer drop-off centres for empty containers. (iv) Include QR codes to more detailed labels and in the official South African languages.
Part IV - Importation Of An Agricultural Remedy Into The Republic		
	25.3	**This clause is unconstitutional and must be removed. It cannot be for the Registrar's discretion to override his own regulations governing the importation of agricultural remedies. What reason could there ever be?**
	25.3	**ADD:** No agricultural remedy shall be imported that is banned in another country. Requests to import banned agricultural remedies require substantive evidence that no viable alternatives exist, (excluding cost as a viable factor) and detailed plans on how exposures will be mitigated, including that any required PPE is available and affordable. a. Prohibited substances ○ (i) Agricultural remedies or active ingredients explicitly banned or restricted in South Africa, shall not be imported under any circumstances, except where authorised by the relevant authority for restricted scientific research or testing purposes only. ○ (ii) Any violation of this provision shall result in the immediate seizure of the imported remedy and applicable legal penalties.
	25.4	**ADD:** Compliance with the Rotterdam Convention and Prior Informed Consent (PIC) Procedure: a. no agricultural remedy listed in Annex III of the Rotterdam Convention may be imported into South Africa without adherence to the Prior Informed Consent Procedure as

		outlined by The Regulations to Domesticate The Requirements of The Rotterdam Convention as published under. Government Notice R.413 October 2024 b. Such consent shall only be granted if the applicant provides: ○ (i) a comprehensive risk assessment report consistent with the criteria set forth in the Rotterdam Convention, ○ (ii) documentation verifying adherence to international standards for safety, handling, and environmental impact, and ○ (iii) evidence of registration and legal use in the country of origin. c. Transparency and Public Disclosure ○ (i)The Registrar must maintain a publicly accessible register of all agricultural remedies subject to prior informed consent and provide a quarterly update on applications, imports, and approvals under this section. d. The Registrar must also notify the exporting country of any changes in importation policies regarding the listed agricultural remedies.
	26.c	"…. of the active ingredient **and co-formulant** of the agricultural remedy…"
	26.i	"~~where relevant,~~ the registration number…" The registration number is always relevant.
	26.j	"where relevant, the batch number;"
	26.l	**Define who the relevant authority is?**
	27.1.a	"The agricultural remedy does not contain active ingredients and/or co-formulants regarded **as restricted agricultural remedies or** substances of concern or the remedy…
	27.1.b	"Impost is for experimentation, laboratory analysis, ~~relabeling~~ or some other purpose…" **Relabeling is illegal.**
Part V- Manufacturing Establishments		
	29.1	An establishment where an agricultural remedy is manufactured, controlled, stored, packed or labelled, **must be in compliance with the OHS Act on building and storage.**
	29.1.3	".... of an agricultural remedy shall be ~~adequate~~ **in line with the**

		OSH Act for the proper carrying out of that function." "Adequate" is open for interpretation.
	30.1.a	**HAC 2021 is being updated**
	30.1.c	"....to ensure quality is in accordance with **GAP or OECD** for registration of the agricultural remedy." Sub reg must comply with existing standards.
	30.1.e.i	"Maintained for five years from the time it is ~~made~~ **manufactured**; "
PART VI - Advertising of An Agricultural Remedy		
	31.7	"...unless ~~definite~~ **scientific** evidence to substantiate those claims is available."
	31.9.a	"...unless this can be substantiated **with scientific** data that has been approved by the Registrar;"
	32.1.c	"The applicable GHS signal word, hazard statement **and pictogram."**
	33.4	"...a restricted agricultural remedy to be supplied to a person who **is not a qualified PCO** to use the agricultural remedy…"
	33.5	"...or any manner of application other than those stated ~~by~~ **on** the label…"
	33.6	"..... on safety instructions for human health and the environment **according to their GHS labelling categorization.**"
Part VIII- Disposal of Containers and Agricultural Remedy		
	34.1	No person shall dispose of agricultural remedies and their empty containers or parts **unless via the Extended Producer Responsibility scheme.**
	34.2	"~~Where applicable~~, all containers must be recycled as a waste management measure…" Should be "All **restricted remedies and substances of concern containers** must be recycled as a management measure…"
	34.4.a	Specify who must keep the records, is it the end user or the EPR scheme?

	34.4.b	Made available by whom? End user or the ERP scheme?
	ADD	Manufacturers and importers of agricultural remedies shall emboss their logo into all agricultural hard containers and shall provide a "buy-back" scheme for end-users to return empty containers.
Part IX - Records and Returns to be Furnished		
	35.2	**ADD:** (f) quantity of agricultural remedy imported
	35.3	"...shall be submitted on or before the 31st May of the **following** year ~~following the calendar year~~ covered by…"
	35.5	**ADD:** All sales data will be aggregated and published annually by the Registrar in a report as public information.
	36	**If the Registrar makes these reports available then other entities can also verify validity.**
	37	**ADD a process for end users and members of the public to report adverse reactions.**
	38	If during the registration process or at any time after the registration of an agricultural remedy, the registration holder, **an end user or member of the public** has factual or scientific evidence of any adverse effect…"
	39	"The Registrar shall maintain **and publicly publish** a quarterly updated list of registered agricultural remedies."
	40	**ADD:** Based on the volumes of agricultural remedies imported, the Registrar will charge a pro-rata fee to be increased annually. This fee will cover costs related to the management of agricultural remedies and risk mitigation (e.g. maintaining a publicly accessible register of registered agricultural remedies, enforcement costs, monitoring and surveillance costs, funding the national Poison Information Helpline located within the Department of Health).
Part X - Sampling and Permissible Deviations		
	40.1.b	There is no 15.3.c in this document to which this sub reg refers.
	40.1.c	There is no 15.3.c in this document to which this sub reg refers.
	40.3	There is no 15.4.b in this document to which this sub reg refers.

Part XII - General		
	44	Section 18 deals only with the main panel of the label - what about all the other possible offences?
	45.3	"Monies paid in terms of these regulations, ~~except in terms of Section 6 of the Act,~~ are not refundable." Why are derogations refundable? This is an unacceptable incentive to circumvent restrictions and bans. There must be no discounts for attempts to perpetuate the legal availability of hazardous substances.
	47.c	If this is being repealed, please make clear that the amended PCO regs of 18 February 2011 are being maintained.
	48.3	"Regulation 8.1.d and regulation 10.3.e shall come into effect ~~on 01 September 2024~~ **immediately.**
	48.4	**Remove:** ~~"Regulations 3.h.vi and xii and xv and regulation 39 shall come into effect 12 months from the date of publication on publication.~~ 12 months from publication is unacceptable as this was published in the 2023 regulations. Manufacturers and the Registrar have already had 12 months since the regs were published to comply.
	48.5	"Regulation 3.h.vi and xvii shall come into effect ~~24~~ **6** months from the date of publication." Unacceptable. Applicants will have had 24 months since the 2023 regs were published if a period of no more than 6 months is granted. We cannot afford an additional 2 years.
Part XII	**Add**	**Phase-Out Periods** 49. (1) When a notice has been given under this Act to withdraw an agricultural remedy from the market, the following shall apply for the provision of a limited time period to sell and use the agricultural remedy in question: (a) No phase-out period will be allowed for agricultural remedies classified as a highly hazardous pesticide, classified as a WHO 1a or 1b pesticide, or classified as a GHS 1a or 1b. This will constitute an immediate withdrawal and the registration holder must immediately withdraw the agricultural remedy from the market and dispose of it at its own expense. (b) For agricultural remedies not falling into 49 (1a), a phase out period may be deemed necessary by the Registrar, the selling, distribution and use will continue for a period not

		exceeding 12 months. After which, the registration holder must withdraw the pesticide from the market and dispose of it at its own expense according to legal requirements on waste management. (c) Manufacturers shall submit a risk communication plan to the registrar within one week of notification to phase-out an agricultural remedy outlining how the risks of exposures will be communicated to all end-users and mitigated. (2) Manufacturers shall recall agricultural remedies notified for immediate withdrawal due to severe health and/or environmental effects and dispose of these in accordance with the National Environmental Management Waste Act (Act 59 2008). Recall by manufacturers of an agricultural remedy for disposal will be necessary if the risks of the agricultural remedy cannot be effectively managed or mitigated and has already been supplied to the users. (3) Gazetted notifications of a phase-out period for banned agricultural remedy shall be shared extensively to potential end-users to minimise exposure during the phase-out period. Information shall be shared through the following: • an Official Gazette, • published in newspapers, or displayed on a webpage, • clinics, public health or agriculture extension SMS services, and, • formally to, o worker and farmer unions/associations, o retailers, o retailers of pesticides, especially in farming/vector control intensive (and remote) communities, o consumer associations/groups, o NGOs/civil societies prominent and active in the country in relation to agriculture and public health, o relevant inspectorates (e.g., agriculture, environmental health, labour, environment, customs).
Annexure A - Criteria for Low Risk Products, Substances of Concern, and Restricted Remedies		
Low risk	1.i	Active substances without significant hazardous properties ~~identified~~. “Identified” creates an exploitable loophole. It is the manufacturers duty to ensure all hazardous properties are identified, so that they are liable if the product causes harm.

	1.ii	**Remove.** Confusing and vague wording, which risks allowing substances into the "low risk" category that may have significant, unassessed environmental or human health impacts.
	1.iii	"Active substance for which there is no consumer exposure linked to the ~~mode~~ **manner** of application ~~is foreseen~~;" "...is foreseen" must be removed, this adds a loophole of exploitable vagueness. It is the duty of the applicant to be certain. Typo? Should be "mode of action" or "manner of application". But, see below!!
	1.iii	**Remove.** ~~"Active substance for which no consumer exposure linked to the **manner** of application is foreseen;"~~ **All pesticides have MRL's - there will always be consumer exposure.**
Substance of Concern		What is the process for registrar granting a registration with substance of concern - 8.1.d
	2.iv	According to their toxicity and effect, these pesticides should be regrouped into the Restricted Agricultural Remedy classification.
	2.v	According to their toxicity and effect, these pesticides should be regrouped into the Restricted Agricultural Remedy classification.
Restricted Agricultural Remedies	3.ii	Agricultural remedy formulations of this class are more appropriately grouped in Substances of Concern.
	3.iv	According to their toxicity and effect, agricultural remedies in this class are more appropriately grouped in Substances of Concerm
Annexure B - Application Form		
	5	**Toxicology and GHS Formulated Product -** must include: Toxicity to aquatic organisms
		Minimum Label Requirements: must include the Poison Information Helpline number.

These comments were made on behalf of the UnPoison Network via a collaborative input process in faith that our comments will assist the process of legislative reform so necessary to effectively govern the registration, distribution, use of, and exposure to agrochemicals. We trust that our comments will receive your attention and be included in the coming amendments.

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