



+27 (0) 12 335 6994

+27 (0) 12 335 1059

+27 (0) 83 611 0467

www.wrsa.co.za

23073 GEZINA 0031

381 Booyesen Street/Booyesenstraat 381, ELOFFSDAL, 0084, Pretoria

Reg No: 2006/010722/08 VAT/BTW No.: 4200 228 098



2 May 2019

The Registrar: Fertilizers, Farm Feeds,
Agricultural Remedies and Stock Remedies Act
Private Bag X343
PRETORIA
0001
[MalutaM@daff.gov.za]

Dear Sirs,

PROPOSED REGULATIONS REGARDING STOCK REMEDIES

WRSA thank the department for the opportunity to comment on the proposed regulations regarding stock remedies in terms of the Fertilizers, Farm Feeds, Agricultural, Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

1. BACKGROUND: WILDLIFE RANCHING SOUTH AFRICA (WRSA):

1.1. WRSA is a registered, non-profit company with registration number 2006/010722/08.

1.2. WRSA is acknowledged by government and stakeholders as an organisation representing the national and international interests of the wildlife ranching industry. This relates to the sustainable breeding, conservation, production and marketing of wildlife in South Africa.

WRSA constitutes the largest collective of more than 2,000 commercial wildlife ranchers (land owners), businesses and individuals with an interest in commercial wildlife ranching, annually producing approximately 150,000 tons of red meat.

As an industry representative for commercial businesses, WRSA therefore has a real and direct interest in legislation pertaining to the wildlife industry's ability to produce much needed healthy protein.

2. BACKGROUND: Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

2.1. Stock remedies have been regulated successfully in South Africa since the promulgation of the above-mentioned Act.

2.2. The Act provides livestock owners with much needed access, at a reasonable price, to the necessary remedies to prevent and treat many serious diseases and parasites that threaten protein production in Southern Africa.

CEO/HUB: A Kitshoff-Botha,

President: T Mogashoa, **Adjunkpresident/Deputy President:** W vd Linde
Direkteure/Directors: NJ Adami, DJ Cunningham, ER Davey, A Douglas, M Geabo,
G Heyneke, Dr T Lesoli, J Malan, JL Pretorius, L van der Watt

2.3. However, because of the inefficient implementation of the Act, it has for instance led to the evaluation of a “normal” product, taking up to 5 years or more.
Although the Registrar was forced through a court order to improve the situation and negotiations took place between the Registrar and industry, no improvement on efficient implementation by the Registrar of Act 36/47 and his department has been forthcoming yet.

3. GENERAL COMMENTS REGARDING THE INTENDED REGULATIONS ON STOCK REMEDIES:

Further to item 2.3 above, WRSA fail to see how the practical implications of the proposed regulations will enable stock-owners in South Africa to grow and ensure food security and animal health in South Africa, nor create the 1 million jobs our President Ramaphosa has ear-maked for Agriculture.

3.1. Access and use:

In terms of the proposed regulations, only veterinarians and para-veterinarians will have access to and use of certain groups of stock remedies.

This will not only have a severe impact on producers of protein including the estimated 1-million small-scale stock owners, but also on consumers:

- 3.1.1.** Costs will drastically increase, by cutting out approximately 600 branches of agricultural co-operatives and retail stores;
- 3.1.2.** The severe shortage of veterinarians and para-veterinarians will have a definite negative effect on distribution, especially in the areas where most of the small-scale farmers are to be found;
- 3.1.3.** It can be expected that the above will lead to increasing prices to consumers on meat, milk and egg products.

3.2. Administrative process:

The intended regulations propose an unnecessary, double administrative process. Where a product was already exempted by the Scheduling Committee (DoH), the regulations propose for the decision-making process to be repeated.

This will not only increase costs, but also waste valuable time and add unnecessary administration to a system which already battles to be implemented efficiently.

- 3.2.1.** The Medicines Control Act (At 101 of 1965) determines the schedule for an active ingredient and therefore how it should be controlled in the market.
- 3.2.2.** Products are exempted from scheduling by The Scheduling Committee of the Medicine Control Council (DoH), where:
 - products are deemed to be safe, effective and in the public interest; and
 - where it is necessary for stock owners to have access for emergency treatment, as in the case of very acute tick-borne diseases such as red-water and heart-water.This enables the applicant to apply to Act 36/1947 (DAFF) for the product to be registered in accordance with Act 36/1947 and thereafter to be sold over the counter to stock owners, mainly via agricultural co-operatives.

4. SPECIFIC COMMENTS TO THE PROPOSED REGULATIONS:

4.1. REGISTRATION:

4.1.1. Clause 2(1): *An application ...must be submitted to the Registrar in duplicate form on form obtainable from the Registrars' office:*

WRSA proposes that an electronic system be introduced.

4.1.2. Clause 2(2):

WRSA supports the clause that *registration may only be made by a person who is resident in the Republic, or, in the case of a juristic person, who has a registered office in the Republic.*

4.1.3. Clause 2(3)(d): *An application shall be accompanied by all scientific documentation necessary for demonstrating the safety, quality and efficacy of the product.*

WRSA proposes:

a) This must be defined beforehand by the Registrar and his advisors.

b) Data generated overseas should be acceptable unless there is a compelling reason to do trials in South-Africa.

4.1.4. Clause 2(3)

WRSA proposes an additional sub-section 2(3)(i), specifying a maximum time that the registration approval/rejection should take, e.g. a maximum period of 12 months.

4.2. PERIOD OF VALIDITY OF RENEWAL OF REGISTRATION:

4.2.1. Clause 3(3)(a): *The application shall be made on a form obtainable from...*

WRSA proposes an electronic process.

4.2.2. Clause 3(3):

WRSA proposes an additional sub-section 3(3)(c), specifying that the process should be finalised within one (1) month.

4.3. APPLICATION FOR TRANSFER OF A REGISTRATION:

4.3.1. Clause 4(2)(a): *... application form...*

WRSA proposes and electronic application process.

4.3.2. Clause 4(2):

WRSA proposes and additional sub-section 4(2)(h), specifying that the process should be finalised within three (3) months.

4.4. CONTAINERS OF STOCK REMEDY

- 4.4.1. **Clause 6(4)(a):** *The container used is the same as the approved container in which the product is sold; and*
WRSA do not support this, as it will lead to counterfeit products, substandard and diluted product etc.

4.5. LABELLING OF CONTAINERS

- 4.5.1. **Clause 7(3)(c):** *Words on packaging”: Where applicable “Restricted used in terms of the Veterinary and Para-Veterinary Professions Act;*
WRSA proposes that this be deleted. Referring to ‘3.1’ above, this clause will lead to a longer chain to the end user and drastically increase the price.

4.6. APPROVAL OF ADVERTISEMENTS

- 4.6.1. **Clause 8(1):**
WRSA proposes an additional sub-section 8(1)(a), indicating that the process will not take longer than one (1) month.

4.7. PUBLICATION OR DISTRIBUTION OF FALSE OR MISLEADING ADVERTISEMENTS

- 4.7.1. **Clause 9(2):** *Stock remedies which fall within Group A and B may not be advertised to the public.*
WRSA proposes that this be deleted. Referring to 3.1 above, WRSA does not support these restrictions which will have a negative impact on producers and consumers.
- 4.7.2. **Clause 9(4):** *Any statement made in advertisements must be supported with scientific data which must be submitted to the Registrar.*
WRSA proposes to add the wording: ... where such data has not been used in the registration of the product.

4.8. PRODUCT CLASSES:

- 4.8.1. **Clause 10(1):** *... Classes of stock remedy...*
WRSA does not support this new additional classification.
Referring to 3.2 above, this is an unnecessary duplication of the already duplicated situation between Act101/65 and Act 36/47 about which objection was raised as early as 1983.
It will further complicate an already complicated and failing system by adding a second unnecessary bureaucratic administrative step. Refer to 2.3 above, regarding a court order addressing the inefficient implementation of the Act.

4.9. EXTRA-LABEL USE OF STOCK REMEDIES:

4.9.1. Clause 11(1)(c): *A stock remedy may only be used extra-label if there is no other stock remedy registered for that purpose.....*

WRSA proposes to include the word suitable: ... if there is no other suitable stock remedy....

WRSA comment: this extra-label use may only be acceptable if the veterinarian has followed the cascade approach recommended by the Food security and safety committee of the SAVC.

4.10. SUITABILITY OF ESTABLISHMENT:

4.10.1. Clause 13(1)(a): *An Establishment Have been inspected and issued with a Good Manufacturing Practice certificate; or*

WRSA comment: Who will undertake the inspection and issue the certificate?

5. WAY FORWARD

WRSA is concerned about the possible unintended consequences of the regulations and the effect it will have on time and expense for farmers to obtain the necessary drugs/chemicals to address specific disease conditions. It might be economically crippling, opening the door to yet more agricultural dumping from other parts of the world.

We would like to propose:

- 5.1.** Extensive engagement between your department and organisations representing stock-owners as producers of protein in our country, including but not limited to WRSA, Agri-SA, NAHF, AgBiz and others. The objective of such engagement should be to ensure a streamlined approach towards ensuring animal health, food security and affordability.
- 5.2.** The harmonization of the regulatory process in the SADC, for the benefit of all.

6. CLOSING

WRSA would appreciate an opportunity to meet with you and other officials from your department to discuss the proposed regulations in more detail.

In the meantime, please feel free to contact us, should you need any further information or clarification on our comments above.

Kind regards



Tebogo Mogashoa
President



Adri Kitshoff-Botha
Chief Executive Officer