NRA Special Review of

HORMONAL GROWTH PROMOTANTS

National Registration Authority
for Agricultural and Veterinary Chemicals

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FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals.

Under the NRA's Special Review Program, registered agricultural and veterinary chemicals are reviewed if concerns have been raised that they may pose an undue risk to people, the environment or Australia's trade with other countries.

In undertaking this review, the NRA worked in close cooperation with the State Departments of Agriculture and the NRA's Compliance and Enforcement Section.

The NRA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of evaluation documents for reviews is a part of that process.

The NRA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD *ad hoc* exchange program. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

For information on the NRA's Chemical Review Program contact Chemical Review on (02) 6272-3213, fax (02) 6272-3551, email: chemrev@nra.gov.au

1. INTRODUCTION

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has reviewed the existing label approvals for products defined as hormonal growth promotants under the Agvet Regulations, part of the Agvet Codes.

The following information provides a background to why the NRA conducted this review, the areas looked at in the review and the decisions and future actions relating to the labels of hormonal growth promotants.

1.1 Regulatory Information

Initiating a review

The NRA has statutory powers to reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers at any time. The basis for a reconsideration is an identified concern that the requirements prescribed by the regulations for continued approval are not being met. These requirements are that the NRA is satisfied that use of an active constituent or product, in accordance with the recommendations for its use would not:

- be an undue hazard to the safety of people exposed to its handling or people using anything containing its residues;
- be likely to have an effect that is harmful to human beings;
- be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- unduly prejudice trade or commerce between Australia and places outside Australia.

Obligations to submit data and other information on chemicals under review

On initiating a review, the NRA has to notify relevant approval holders and registrants of the matters it intends to reconsider and its reasons for doing so, and to invite them to make written submissions on those matters. These parties are also requested to submit all existing information and data (regardless of its age or confidentiality) on the chemical under review. The NRA also notifies the community of the review, inviting them to make submissions.

In addition to inviting public submissions, the NRA may consult with persons, organisations or government agencies with relevant knowledge or interests for the purposes of obtaining information or advice relating to the review.

Once a review is under way, the NRA may request additional information from approval holders and registrants. If such a request is denied, the NRA may suspend or cancel the relevant approval or registration.

Outcomes of review

There are three possible outcomes to a review:

1. The NRA is satisfied that the chemical under review continues to meet the prescribed requirements for the initial approval or registration and confirms the approval or registration.

2. The NRA is satisfied that the conditions to which the approval or registration is currently subject can be varied in such a way that the requirements for continued approval or registration will be complied with and varied the conditions of approval or registration.

3. The NRA is not satisfied that the conditions continue to be met and suspends or cancels the approval or registration.

The NRA must notify the approval holders, registrants and the community of the outcomes of reviews and in most cases provide them with the opportunity to comment on a draft set of recommendations.

2. Reasons for Review of Hormonal Growth Promotants

Hormonal Growth Promotants (HGPs) are defined by the AgVet Regulations as veterinary chemical products containing a substance that is, or a mixture of substances that are, responsible for oestrogenic, androgenic or gestagenic activity to enhance growth or production in bovines or bubalines. These products are widely used throughout Australia with the exception of Tasmania in cattle including calves, steers and heifers.

In 1995 a Monitoring and Control Scheme was developed with industry involvement, to regulate the supply of this class of products so as to ensure continued trade by Australian Meat and Meat Offal exporters with the EU. The EU has a strict trade directive that only permits HGP free meat and meat offal products to be imported into its member countries.

The NRA have experienced difficulties in recent times with respect to enforcing provisions relating to HGPs. These difficulties have the potential to impact severely on trade relations with the European Union (EU) with respect to HGP free meat export, significantly undermining confidence in Australia's ability to control and regulate the National HGP monitoring and control scheme.

The supply of HGPs is controlled by Division 2 of the Agricultural and Veterinary Chemicals Code Regulations (Agvet Regulations). These regulations underpin the necessary requirements to satisfy the EU directives with respect to support. These regulations require importers and suppliers to obtain a notification number from the NRA to allow them to supply from nominated premises as well as requiring a regime of record keeping. These records then enable all doses supplied to be accounted for.

Recent NRA Compliance action has identified a number of serious shortfalls within the HGP scheme specifically relating to labelling issues.

The current definition of hormonal growth promotants is found at Clause 3 of the AgVet Regulations. Legal advice has indicated that if a HGP was supplied for use in an animal other than a bovine or bubaline the requirements of Division 2 do not apply. Essentially what this means is that if HGPs are supplied for use on bovines or bubalines the supplier is required to

make the necessary records to ensure accountability of every dose. If they are supplied for use, for example in a horse, they are no longer regarded as HGPs and therefore the record keeping requirements are not applicable and therefore not legally enforceable.

Labels in their current format do no state as a matter of law, that the products can only be used in bovines or bubalines. The comments on the labels such that *"this product must not be implanted in any other site or any other site or any other species of animal"* are not considered to be 'instructions' according to our current legal advice. These comments are considered to be 'restraints' but as there is no species of animal specified to which the restraint applies, the restraint statement cannot be relied upon for enforcement purposes.

All product labels for HGPs need to contain the necessary wording to enable instructions to be enforceable.

3. Assessment of HGP Labels

Taking into consideration the above, the current HGP labels do not meet the needs of the NRA in regard to enforceability of the HGP control scheme.

Where instructions on the approved label do not make it clear that the product is to used only in a particular way(s), it is not an offence to use the product (or claim that it can be used) in a different way. It is therefore possible under the current labels to embellish or exaggerate label instructions without contravening s.84(1)(of the Agvet Codes eg. If the approved labels states "to be used on horses" then a person might be perfectly entitled to say that is can also be used on dogs, cats and goats.

In order to restrict the use of a product, the label instructions must clearly indicate the way(s) in which it can and cannot be used. A simple way of achieving this is to include the work 'only' when appropriate eg, 'to be used on horses only'. It would then be inconsistent with the label instructions to claim that the product can also be used on dogs, cats or goats. This is because the word 'only' has a restrictive effect in that it limits the use of the product to horses.

The NRA has developed revised statements for labels with these principles in mind. The label instructions will precisely and accurately restrict the use of the product as intended.

In addition to this consideration is to be given to the addition of a label statement to the effect that the product can only be supplied in accordance with Division 2 of the AgVet Regulations. This would also aid in preventing the products being supplied in some other circumstance outside the provisions of the HGP scheme.

4. Review recommendations

All labels for current HGP products have been reviewed to determine their suitability in meeting the needs of the HGP program in regard to supply. The following revisions to the current labels are required and these will also be translated into Appendix 6 of the Labelling Code for Veterinary Chemical Products.

(a) Supply Statements

In light of the above information the following statement must appear on all labels (refer to the Vet labelling code, Appendix 6 labelling requirements for HGPs for the positioning of this statement):

This product must only be supplied in accordance with Division 2 part 4 of the AgVet Regulations (Supply of Hormonal Growth Promotants).

(b) Use Statements

The statements appearing in the far right hand column of the table below are to be included on product labels. As can be seen these are product specific. The label statement is to appear as the first statement following the 'restraints' heading.

Table 1: Label statements for use

NCRIS No	Product Name	Registrant	Label statement for use
49956	Synovex S Steer Growth and Finishing Implants	Fort Dodge Australia Limited	FOR USE ONLY in steers
49620	Synovex With Trenbolone Acetate Growth and Finishing Implants for Steers and Heifers	Fort Dodge Australia Limited	FOR USE ONLY in steers and heifers
49955	Synovex H Heifer Growth and Finishing Implants	Fort Dodge Australia Limited	FOR USE ONLY in heifers
49954	Synovex C Calf Growth Promotant	Fort Dodge Australia Limited	FOR USE ONLY in calves
46111	Revalor S Steer Growth Promotant and Finishing Implants	Intervet Rural Co Pty Ltd	FOR USE ONLY in steers
47248	Revalor H Heifer Growth Promotant and Finishing Implants	Intervet Rural Co Pty Ltd	FOR USE ONLY in heifers
48945	Revalor G Growth Promotant For Grass Fed Heifers and Steers	Intervet Rural Co Pty Ltd	FOR USE ONLY in heifers and steers
47311	Coopers Ralgro Cattle Growth Promotor	Schering Plough Pty Ltd	FOR USE ONLY in steers
50068	Progro S Growth and Finishing Implants For Steers	Pro Beef Australia Pty Limited	FOR USE ONLY in steers
50912	Progro TE-S Growth and Finishing Implants For Steers	Pro Beef Australia Pty Limited	FOR USE ONLY in steers
50055	Progro H Growth and Finishing Implants For Heifers	Pro Beef Australia Pty Limited	FOR USE ONLY in heifers
51467	Progro T-S Growth and Finishing Implants For Steers	Pro Beef Australia Pty Limited	FOR USE ONLY in steers

NCRIS No	Product Name	Registrant	Label statement for use
49511*	Elanco AH 0336 Component-S Growth and Finishing Implants For Steers	Elanco Animal Health	FOR USE ONLY in steers
50230*	Elanco AH 0361 Component TE-S Growth and Finishing Implants For Steers	Elanco Animal Health	FOR USE ONLY in steers
49510*	Elanco Ah0337 Component H Growth and Finishing Implants For Heifers	Elanco Animal Health	FOR USE ONLY in heifers
50238*	Elanco AH0362 Component TS Growth and Finishing Implants For Steers	Elanco Animal Health	FOR USE ONLY in steers
46230	Elanco AH 0351 Oestradiol Compudose 100	Elanco Animal Health	FOR USE ONLY in steers, spayed heifers and vealer heifers
36789	Elanco AH 0323 Oestradiol Compudose 200	Elanco Animal Health	FOR USE ONLY in steers, spayed heifers and vealer heifers
36799	Elanco AH 0343 Oestradiol Compudose 400	Elanco Animal Health	FOR USE ONLY in steers, spayed heifers and vealer heifers

* registration stopped on 30 June 2001 as part of the NRA renewal process.

For all future products the following statement is to be added:

FOR USE ONLY in *{species for which the product is registered}*

(c) Cancellation of product labels

To ensure that all labels in the marketplace comply with the new labelling requirements for HGPs all labels approved prior to **{date of decision}** will be cancelled.

Each approved label to be cancelled is noted below in Table 2. The phase out period for these labels will be as follows:

Cancellation of labels: 12th October 2001
Cease retail supply: 30 April 2003
Cease use: expiry date of products

For any product remaining on the retail shelf after 30 April 2003, registrants will be required to undertake a compulsory recall at their own expense.

Table 2: Label approvals to be cancelled

Product	Product Name	Label approval no	Date of label approval
49956	Synovex S Steer Growth and Finishing Implants	49956/01	19/8/1997
		49956/0400	6/4/2000
49620	Synovex with Trenbolone Acetate Growth and Finishing Implants For Steers and Heifers	49620/0400	6/4/2000
		49620/0798	28/7/1998
		49620/1297	6/1/1998
49955	Synovex H Heifer Growth and Finishing Implants	49955/01	19/8/1997
		49955/0400	6/4/2000

Product	Product Name	Label approval no	Date of label approval
49954	Synovex C Calf Growth Promotant	49954/01	19/8/1997
		49954/0201	20/2/2001
		49954/0400	6/4/2000
46111	Revalor S Steer Growth Promotant and Finishing Implants	46111/01	30/1/1997
47248	Revalor H Heifer Growth Promotant and Finishing Implants	47248/01	31/1/1997
48945	Revalor G Growth Promotant For Grass Fed Heifers and Steers	48945/1097	20/10/1997
47311	Coopers Ralgro Cattle Growth Promotor	47311/0298	5/2/1997
		47311/0800	15/8/2000
50068	Progro S Growth and Finishing Implants For Steers	50068/0897	20/8/1999
50912	Progro TE-S Growth and Finishing Implants For Steers	50912/0199	19/1/1999
		50912/1198	3/11/1998
50055	Progro H Growth and Finishing Implants for Heifers	50055/0897	20/8/1997
51467	Progro T-S Growth And Finishing Implants for Steers	51467/1298	2/12/1998
49511*	Elanco AH 0336 Component-S Growth and Finishing Implants For Steers	49511/01	15/4/1997
50230*	Elanco AH 0361 Component TE-S Growth and Finishing Implants for Steers	50230/0598	25/5/1998
49510*	Elanco AH0337 Component H Growth and Finishing Implants for Heifers	49510/01	15/4/1997
50238*	Elanco AH0362 Component TS Growth And Finishing Implants For Steers	50238/0898	27/8/1998
46230	Elanco AH 0351 Oestradiol Compudose 100	46230/01	5/6/1997
		46230/1199	16/11/1999
		46230/1200	4/1/2001
36789	Elanco AH 0323 Oestradiol Compudose 200	36789/01	5/6/1997
		36789/1199	16/11/1999
		36789/1200	3/1/2001
36799	Elanco AH 0343 Oestradiol Compudose 400	36799/01	5/6/1997
		36799/1199	16/11/1999
		36799/1200	3/1/2001

* registration stopped on 30 June 2001 as part of NRA renewal process