

ISBN 0-478-07712-2

43 ACVM 11/02

New Zealand Food Safety Authority
Post Office Box 2835
Wellington, New Zealand



ACVM STANDARD FOR DISTRIBUTORS OF HORMONAL GROWTH PROMOTANTS

This document may be altered at any time. It was current as at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the ACVM Group of NZFSA or check its website (<http://www.nzfsa.govt.nz/acvm/>) to confirm that it is the current version.

Endorsement:

Date:

CONTENTS

- 1 INTRODUCTION
 - 1.1 Scope
 - 1.2 Definitions and abbreviations
 - 1.3 References

- 2 SPECIFICATIONS FOR DISTRIBUTORS OF HORMONAL GROWTH PROMOTANTS

APPENDICES

- A Conditions on Registration of Hormonal Growth Promotants

- B MAF document:
Legal requirements associated with the use of growth promotants (HGPs)
(November 2000)

- C Growth Promotant (HGP) Sale Record

- D Additional HGP Record – Cattle Identification Record

ACVM STANDARD FOR DISTRIBUTORS OF HORMONAL GROWTH PROMOTANTS

1 INTRODUCTION

Hormonal Growth Promotants (HGP) are a group of veterinary medicines that pose somewhat unique risks to New Zealand's trade in primary produce. Special conditions are placed on the registration of HGPs to minimise these risks (see Appendix A). These conditions are supported by use of contractual sales records, information sheets and tracking mechanisms for cattle from treatment through to slaughter.

The *ACVM Standard for Distributors of Hormonal Growth Promotants* supports the conditions on registration by providing the necessary controls and documentation to record and manage the storage and movement of HGP stocks by distributors to the point of transfer of these stocks to veterinarians.

This standard is not relevant to HGPs once stock has been transferred to the responsibility of the ordering veterinarian. However, a copy of the triplicate MAF/Industry Growth Promotant Sale Record is included (Appendix C) as well as an Additional HGP Record – Cattle Identification Record (Appendix D) as reference documents. These sales records form a supporting contract under the control of the prescribing veterinarian, with copies retained by the veterinarian, by the recipient farmer and by the NZFSA (Animal Products Group). Queries on the use of these forms or prescribing process should be directed to the New Zealand Veterinary Association or to the registrant of the HGP.

All distributors must be fully acquainted with all legislation, NZFSA standards and documentation that are relevant to the importation, management and use of HGPs in New Zealand; for example, the requirements of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, the Animal Products Act 1999, the Meat Act 1981 and their Regulations, in particular the Meat (Residues) Regulations 1996.

1.1 Scope

This standard defines the minimum specifications for acceptability of distributors of hormonal growth promotants, as an adjunct to the controls offered by the registration conditions.

This standard must be followed by all persons and organisations buying, selling, receiving, dispatching and/or storing registered hormonal growth promotants in New Zealand prior to receipt by the prescribing registered veterinarian.

1.2 Definitions and abbreviations

ACVM Act

The Agricultural Compounds and Veterinary Medicines Act 1997 and its Regulations.

ACVM Group

The Agricultural Compounds and Veterinary Medicines Group of NZFSA. This group has responsibility for issuing registrations, under the ACVM Act, that permit sale and use of all veterinary medicines (including HGPs) in New Zealand.

Note: The ACVM Group does not coordinate the register of HGP sales. This role is undertaken by NZFSA (Animal Products Group).

Controlled copy

A reference document to which responsibility for maintenance, updates and changes will be undertaken by a limited and defined group of people, and for which all changes and updates will be recorded in writing and maintained for audit.

Distributor

All persons and organisations buying, selling, receiving, dispatching and/or storing registered hormonal growth promotants in New Zealand, prior to receipt by the prescribing veterinarian.

Dose

The smallest single unit of an HGP that can be prescribed by a veterinarian.

Eartag

The MAF approved device for attachment to the ear of each HGP-treated cattle beast as a permanent identification of the animal's treatment status.

Hormonal growth promotant (HGP)

Any veterinary medicine that contains either natural or synthetic hormones and that will be sold for increasing the muscle tone, growth rate or ratio, weight gain or feed efficiency of animals.

Label

All information that accompanies any number of doses of an HGP at its time of sale or dispatch, including container information, supplied leaflets and/or advertising.

Recall

Compulsory return of faulty stock that has already been transported or sold to, veterinarians and/or distributors. A stock recall is usually directed and coordinated by the distributor, the registrant or by a regulatory authority.

Record form

The Growth Promotant (HGP) Sale Record (refer to Appendix C), and the Additional HGP Record – Cattle Identification Record (Appendix D).

Registrant

The person or organisation to whom registration of a HGP had been granted under the ACVM Act, and who is therefore responsible for ensuring compliance with legislative and industry requirements relevant to that HGP.

Registration certificate

Certificate issued by the ACVM Group of NZFSA at the time of granting an HGP registration. It documents the registrant and legal limitations associated with sale and use of the product in New Zealand.

Stock

The term 'stock' includes all doses of an HGP, fully packed and labelled for release to the market. It also includes the appropriate number of copies of the MAF leaflet and Growth Promotant (HGP) Sale Record forms (Appendices B, C and D)

Applicants should also note that the definitions given in section 2 of the ACVM Act 1997 apply.

1.3 References

Conditions on Registration of Hormonal Growth Promotants (Appendix A)

MAF leaflet for Hormonal Growth Promotants (Appendix B)

Growth Promotant (HGP) Sale Record (Appendix C)

Additional HGP Record – Cattle Identification Record (Appendix D)

2 SPECIFICATIONS FOR DISTRIBUTORS OF HORMONAL GROWTH PROMOTANTS

- 2.1 A registrant of a hormonal growth promotant (HGP), who is also the distributor of the HGP, must maintain a controlled copy of the current product registration certificate(s) and product label(s), and ensure that these reference documents are updated when changes occur. The registrant must ensure that all stock complies fully with the current reference documents prior to dispatch of the stock.
- 2.2 Distributors of HGPs must maintain controlled copies of the current MAF leaflets, Growth Promotant Sale Records* and HGP eartags, and ensure that these reference materials are updated when changes occur. The distributor must ensure that MAF information leaflets and eartags being provided with HGPs are the current version.
- 2.3 If the HGP is being imported by the distributor on behalf of the registrant, the distributor must retain a letter of authorisation from the registrant permitting this activity. If this authority is revoked, the registrant's letter of authorisation must be discarded immediately.
- 2.4 Distributors of HGPs may sell HGPs only to other approved distributors of HGPs or to veterinarians registered under the Veterinarians Act 1994. Where HGPs are sold to veterinarians, the distributor must maintain a written record of proof of the veterinarian's registration.
- 2.5 The distributor must maintain written records of all product receipt and dispatch, including that of damaged and expired stock. These records must include:
- the trade name of the HGP;
 - the quantity and package sizes of the HGP stock received and dispatched;
 - the dates of receipt and dispatch;
 - the source of origin of all HGPs received;
 - the company/person to whom the product order is dispatched;
 - batch numbers and dates of expiry of HGP received and dispatched.
- 2.6 The distributor must maintain written procedures for product stock recalls.

* HGP Sale Record documentation is provided by the New Zealand Veterinary Association, Post Office Box 11-212, Manners Street, Wellington.

- 2.7 The distributor must maintain full records of the transactions conducted (receipt and dispatch) during any stock recalls, which include:
- steps undertaken to recall product stock;
 - the reason for the product recall;
 - the trade name of the recalled HGP;
 - the quantity and package sizes of the HGP received and dispatched;
 - the dates of receipt and dispatch;
 - the source of origin of the HGP received;
 - the company/person to whom the product order is dispatched;
 - batch numbers and dates of expiry of the HGP received and dispatched;
 - details of untraceable product stock.
- 2.8 The distributors must maintain written procedures and records for regular reconciliation of stock received, distributed and on hand.
- 2.9 The distributor must retain sufficient copies of the current version of the MAF leaflet to accompany each dose ordered and dispatched.
- 2.10 The distributor must retain sufficient numbers of HGP eartags to accompany each HGP dose ordered, as well as a written procedure for the dispatch of initial and replacement eartags.
- 2.11 The distributor must maintain details of the procedures and standards for storage, processing, release and transportation of all HGPs.
- 2.12 The distributor's storage and transportation of HGPs must be secure, with stock movements, collection and receipt recorded under signature.

APPENDIX A:

CONDITIONS ON REGISTRATION OF HORMONAL GROWTH PROMOTANTS

The following conditions and labelling requirements will be applied to the registration of any hormonal growth promotant.

Conditions

- This product is a Prescription Animal Remedy (PAR) Class I.
 - Not to be sold to any person other than a veterinary surgeon or a distributor, or otherwise than pursuant to the prescription of a veterinary surgeon.
 - May be administered to an animal only by a veterinary surgeon; or under and in accordance with the authority or prescription of a veterinary surgeon.
 - Not to be sold, or prescribed or dispensed, except following a veterinary consultation.
- This product is registered for sale for use in cattle only.
- The registrant shall maintain comprehensive, reconcilable, and accurate stock records of all product imported or manufactured, stored, sold, gifted and/or returned by or to them. Such records shall include the date of the transaction, the number of doses involved, details of the other party, or parties, involved in the transaction, and any other relevant supporting documentation. The records, or copies of those records, shall be made available and/or supplied to MAF auditors on request.
- The registrant shall require and ensure all distributors it supplies maintain comprehensive, reconcilable, and accurate stock records of all product received, stored, sold, gifted and/or returned. Such records must include the date of the transaction, the number of doses involved, details of the other party, or parties, involved in the transaction, and any other relevant supporting documentation. The registrant shall also require and ensure those distributors make available and/or supply them with such records, or copies of such records, on request. The registrant shall ensure MAF auditors have access to these records, or copies of those records, when requested
- Registrants must ensure all product stocks held by themselves, distributors and veterinarians have the current versions of the MAF leaflet and sales documentation.
- The registrant shall ensure that sufficient copies of the current MAF approved leaflet, which describes end-user requirements, are made available to accompany every sale to an end-user.

- Registrants shall ensure all product stocks held by themselves, distributors, and veterinarians have the old MAF leaflet(s), or representation of its contents, removed and replaced by the current MAF leaflet within 28 days of receiving written notice from the Animal Remedies Board of a change.
- The registrant shall ensure that sufficient numbers of a means of identification, as approved and required by the Director General of MAF pursuant to Regulation 6 of the Meat (Residues) Regulations 1996, are provided to end-users to ensure that each and every treated animal can be identified from time of implantation and for the remainder of that animal's life.
- The registrant shall ensure distributors of this product and veterinarians are supplied with sufficient copies of the current MAF approved veterinary and farmer sale record sheets to ensure these can be completed and supplied with each transaction within 28 days of the Animal Remedies Board supplying these, or modifications of previous editions.
- This product is licensed subject to the Animal Remedies Board being provided with ongoing credible assurances that the sale and use of this product, or this class of products, is not unduly adversely impacting on the sale of animals, meat and/or meat products.

Labelling requirements

In addition to the standard labelling requirements, the registrant shall ensure that each of the following compulsory label statements are prominently displayed in the accompanying package insert, and/or other packaging:

- “Use of this product in species other than cattle is strictly prohibited.”
- “For food safety reasons, cattle must be implanted only under the skin of their ears.”
- “Treated cattle must be identified at the time of implantation, and remain so identified for the rest of their lives with the MAF sanctioned means of identification.”
- “Removal of this identification is strictly prohibited.”
- “Use of this means of identification for any other purpose is strictly prohibited.”
- “Subsequent purchasers of stock must be informed of the above requirements.”
- “Failure to abide by any conditions outlined in the packaging, package insert or accompanying MAF approved leaflet could result in prosecution and fines of up to \$100,000 and could expose the export and domestic food industry to unnecessary trade risks.”

The registrant shall ensure that the following compulsory label statement is prominently displayed on all outer packaging that represents the smallest saleable unit:

- “All users must read and abide by their obligations in the accompanying MAF leaflet.”

APPENDIX B: MAF DOCUMENT: LEGAL REQUIREMENTS ASSOCIATED WITH THE USE OF GROWTH PROMOTANTS (HGPs) (NOVEMBER 2000)



REQUIREMENTS ASSOCIATED WITH THE USE OF HORMONAL GROWTH PROMOTANTS (HGPs)

FROM 30 NOVEMBER 2000

To enable New Zealand farmers to benefit from the use of hormone based growth promotants (HGPs), while ensuring their use does not affect the credibility of NZ's international and domestic assurances, HGPs are required by law to be used in accordance with the following conditions:

1. HGPs may be used in cattle only. The use in other species is strictly prohibited.
2. HGPs must only be administered by a veterinarian, a trained technician employed or contracted by a veterinarian or under the direct supervision of a veterinarian or trained technician.
3. HGPs must only be implanted under the skin of the cattle's ear.
4. All treated cattle must be identified either prior to, or immediately after the HGP implantation:
 - with the MAF approved HGP ear tag (orange tag) supplied with the HGP doses, and
 - with a primary tag and a secondary tag used under the Animal Health Board (AHB) and the MINDA identification systems. These tags should be purchased prior to HGP implantation by the owner or person in charge of the cattle if the animals are not already identified with the appropriate tags.
5. Cattle which lose any of these tags must be retagged in accordance with point 4 and the AHB and MINDA identification systems.
6. The MAF approved HGP ear tag (orange tag) must not be used for any purpose other than for identifying HGP treated cattle.

The above conditions are contained in the Overseas Market Access Requirements 00/137 entitled "Hormonal Growth Promotants" and its subsequent amendments available at <http://www.maf.govt.nz>

**It is an offence under the Animal Products Act 1999 to fail to comply with these requirements.
Fines up to \$ 20 000 for individuals and \$ 100 000 for farms run as companies are applicable.**

Additionally:

- a) Auditable records must be maintained by owners or persons in charge of HGP treated cattle and veterinarians or trained technicians for at least 5 years of:
- the HGP product administered to the cattle (product trade name, doses) and date of implantation,
 - the name of the owner or person in charge of the cattle and the name of the veterinarian or trained technician who administered or supervised the HGP implantation,
 - the identification numbers (AHB herd number or LIC participant code and individual animal number) of each HGP treated cattle,
- and where appropriate:
- the number of HGP treated cattle on the property,
 - the number of HGP treated cattle disposed of the property (sold, died, slaughtered, etc)
- b) Subsequent purchasers of HGP treated cattle should be informed by the vendor that the cattle have been treated.

Farmers and veterinarians are advised that MAF regularly conducts audits on farm, at veterinary practices and at slaughter premises to verify that all of the requirements of use are met.

HELP US TO PROTECT NEW ZEALAND MEAT TRADE.

Issue: 20 November 2000

APPENDIX C: GROWTH PROMOTANT (HGP) SALE RECORD

This is a triplicate form that consists of the MAF Register Copy, the Veterinary Practice Copy and the Farmer Copy.



Growth Promotant (HGP) Sale Record – Register Copy

- 1 I will ensure the product is only used on cattle, and will only be administered under the skin of cattle ears.
- 2 I will ensure all treated cattle are identified with MAF approved tags at the time of implantation, and that they will remain so identified while they are under my control. I will replace lost tags.
- 3 I will not use surplus Growth Promotant tags for any other purpose.
- 4 I will keep available records on farm, for 5 years, which account for all doses purchased as per the record sheet laid out below.

I understand it is an offence under the Meat Act (1981), its amendments or any successive legislation, to fail to comply with these requirements detailed in Points 1, 2 and 3 above.
 (Note: Fines of up to \$20,000 for individuals and \$100,000 for farms run as companies are applicable when offences are committed.)

Growth Promotant Sale Record – (TO BE KEPT FOR FIVE YEARS)

Date.....	Product Name	Number of Doses	Name and Signature(s) of Authorising Veterinarian (and Salesperson if Applicable)
Name of Purchaser or Purchaser's Agent.....			
Signature (Agreeing to abide by points 1-4 above)			
Farm Location (Physical Address).....			Salesperson's Name Signature
Phone No. (0).....			
Name of Veterinary Practice.....			Veterinarian's Name Signature

THIS COPY IS TO BE POSTED, WITHIN SEVEN DAYS, TO:

**The MAF Regulatory Authority
 HGP Register
 P.O. Box 2526
 WELLINGTON**



Growth Promotant (HGP) Sale Record – Veterinary Practice Copy

- 1 I will ensure the product is only used on cattle, and will only be administered under the skin of cattle ears.
- 2 I will ensure all treated cattle are identified with MAF approved tags at the time of implantation, and that they will remain so identified while they are under my control. I will replace lost tags.
- 3 I will not use surplus Growth Promotant tags for any other purpose.
- 4 I will keep available records on farm, for 5 years, which account for all doses purchased as per the record sheet laid out below.

I understand it is an offence under the Meat Act (1 981), its amendments or any successive legislation, to fail to comply with these requirements detailed in Points 1, 2 and 3 above.

(Note: Fines of up to \$20,000 for individuals and \$100,000 for farms run as companies are applicable when offences are committed.)

Growth Promotant Sale Record – (TO BE KEPT FOR FIVE YEARS)

Date..... Name of Purchaser or Purchaser's Agent..... Signature (Agreeing to abide by points 1-4 above) Farm Location (Physical Address)..... Phone No. (0)..... Name of Veterinary Practice	Product Name	Number of Doses	Name and Signature(s) of Authorising Veterinarian (and Salesperson if Applicable)
		 Salesperson's Name Signature
		 Veterinarian's Name Signature



Growth Promotant (HGP) Sale Record – Farmer Copy

- 1 I will ensure the product is only used on cattle, and will only be administered under the skin of cattle ears.
- 2 I will ensure all treated cattle are identified with MAF approved tags at the time of implantation, and that they will remain so identified while they are under my control. I will replace lost tags.
- 3 I will not use surplus Growth Promotant tags for any other purpose.
- 4 I will keep available records on farm, for 5 years, which account for all doses purchased as per the record sheet laid out below.

I understand it is an offence under the Meat Act (1 981), its amendments or any successive legislation, to fail to comply with these requirements detailed in Points 1, 2 and 3 above.

(Note: Fines of up to \$20,000 for individuals and \$100,000 for farms run as companies are applicable when offences are committed.)

Growth Promotant Sale Record – (TO BE KEPT FOR FIVE YEARS)

Date.....	Product Name	Number of Doses	Name and Signature(s) of Authorising Veterinarian (and Salesperson if Applicable)	
Name of Purchaser or Purchaser's Agent.....				
Signature				
(Agreeing to abide by points 1-4 above)			
Farm Location (Physical Address).....			Salesperson's Name	Signature
.....			
Phone No. (0).....		Veterinarian's Name	Signature
Name of Veterinary Practice.....			

