



Regulated Control Scheme for Hormonal Growth Promotants

20 June 2017

TITLE

Animal Products Notice: Regulated Control Scheme for Hormonal Growth Promotants

COMMENCEMENT

This Animal Products Notice comes into force on 30 June 2017.

REVOCATION

This Notice revokes and replaces the *Animal Products RCS: Hormonal Growth Promotants*, which was issued on 29 June 2016.

ISSUING AUTHORITY

This Animal Products Notice is issued pursuant to section 40(1)(b) and 167(1)(f) of the Animal Products Act 1999.

Dated at Wellington this 22 day of June 2017.

[signed]

Allan Kinsella
Director, Systems Audit, Assurance and Monitoring
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the Notice but is intended to indicate its general effect.

Purpose

This Animal Products RCS is issued for the purpose of facilitating access to overseas markets in relation to the export of animal material and animal products derived from animals treated with Hormonal Growth Promotants (HGP).

Background

New Zealand exports animal material and animal products to overseas countries on a regular basis. Certain overseas markets place restrictions on the import of animal material and animal products that have originated from animals treated with Hormonal Growth Promotants.

This Notice creates a regulated control scheme for the use and management of HGPs implanted into animals, and for the handling and identification of HGP implanted animals and animal material and products derived from such animals.

The prime purpose of this regulated control scheme is to meet the requirements of certain overseas markets which require New Zealand to impose controls to ensure that animal material and product from HGP implanted animals is not exported to those markets.

Who should read this Notice?

This Notice should be read by any person to whom clause 1.1 of this Notice applies.

Why is this important?

Any failure to operate in accordance with this Notice may result in animal material or animal products not being eligible for export with an official assurance to HGP sensitive markets.

Operating other than in accordance with this Notice is an offence under section 135 of the Act.

Part 1: Preliminary provisions

1.1 Application

- (1) This Notice applies to:
- veterinarians who implant an HGP into an animal, train and supervise technicians to implant an HGP into an animal, or supervise the implantation of an HGP into an animal; and
 - competent persons; and
 - persons in charge of animals, including suppliers; and
 - primary processors of an HGP implanted animal; and
 - official assurance verifiers of primary processing of animal material or animal products; and
 - authorised users of the HGP database.

1.2 Definitions

- (1) In this Notice, unless the context otherwise requires:

Act means the Animal Products Act 1999;

animal identification means a NAIT device;

animal material and animal product have the same meaning as in the Act, but relate only to an animal to which this Notice applies;

animal status declaration or ASD means a completed and signed supplier statement regarding an animal presented for slaughter, as provided for in clause 11.4(1) of the Animal Products Notice: Specifications for Products Intended for Human Consumption, which was issued on 1 March 2016;

authorised user means a user of the HGP database who has been given database access rights by the Director-General;

competent person means a veterinarian or a technician;

directly supervise means the activity of a competent person being physically present and in direct control of the actions of the person that they are supervising;

employment means employment by the veterinarian or the veterinary practice with which the veterinarian is associated;

HGP means any veterinary medicine that contains either natural or synthetic hormones and is registered under the Agricultural Compounds and Veterinary Medicines Act 1997 for the purpose of increasing the muscle tone, growth rate, weight gain or feed efficiency of an animal;

HGP database means the database maintained by the Director-General under Part 9, into which specified information regarding HGP implanted animals is required to be entered under the supervision of a veterinarian;

HGP identification ear tag means an ear tag that is a two piece orange plastic rectangular ear tag, no smaller than 50 mm x 16 mm, that bears only the words "growth promotant" clearly printed, and that is used for identifying an HGP implanted animal;

HGP surveillance list means the list of suppliers or persons in charge under surveillance that is kept by the Director-General under Part 7 and, for the purposes of the European Union (EUN) Overseas Market Access Requirements;

HGP control system means all the activities described under Parts 2-9 of this Notice and includes the control of HGPs under the Agricultural Compounds and Veterinary Medicines Act 1997;

HGP implanted animal means an animal into which an HGP has been implanted;

list of HGP ear tags means the list of ear tags from HGP implanted animals contained in the HGP database that are sent to the primary processor on a weekly basis. The list will consist of the RFID numbers and the visual identification numbers of the NAIT devices fitted to HGP implanted animals;

mob means animals of the same species presented for slaughter by a primary processor and slaughtered as a continuous line;

NAIT means the National Animal Identification and Tracing Act 2012;

NAIT device means an animal identification device that is an RFID manufactured or supplied in accordance with standards issued under section 14 or regulations made under the NAIT Act. Note that the standard will specify that device must be a tamperproof RFID which is an ISO coded transponder with a unique 16-digit identification number programmed into it;

official assurance verifier means a person recognised under section 103 of the Act to undertake the official assurance verification and employed by an agency recognised for the purposes of verifying export requirements;

person in charge means a person for the time being in charge of an animal at any point from the time an HGP is implanted into that animal until the time the HGP implanted animal is presented to a primary processor for processing;

primary processor means a primary processor of animals for an overseas market where an official assurance is required attesting to the absence of any animal material or products derived from an HGP implanted animal;

RFID means radio frequency identification device;

supervise as it applies to a veterinarian, means the activity of a veterinarian overseeing a technician implanting an HGP without that veterinarian necessarily being physically present;

supervising veterinarian means a person who supervises a technician implanting an HGP into an animal and, where the veterinarian implants the HGP, includes that veterinarian;

supplier means a person (not being a person solely engaged in facilitating the physical transfer of an animal or animal material, such as a transporter, purchasing agent or sale-yard operator) who presents an animal or animal material to a processor for processing;

technician means a person trained by a veterinarian to implant an HGP or to directly supervise implantation of an HGP by another person; and

veterinarian means a veterinarian who holds a current practising certificate issued by the Veterinary Council of New Zealand and who has been issued with a username and password to access the HGP database.

- (2) Unless the context otherwise requires, terms used in this Notice that are defined in the Act have the meanings so defined.

Part 2: General requirements and restrictions in relation to Hormonal Growth Promotants

2.1 Implanting an HGP

- (1) Only a competent person or a person in charge acting under the direct supervision of a competent person may implant an HGP into an animal.
- (2) A technician implanting an HGP into an animal, or directly supervising HGP implantation into an animal, must be acting under a supervising veterinarian.

2.2 Improper use of ear tags and an HGP

- (1) An HGP identification ear tag must not be used for any purpose other than identification of an HGP implanted animal in accordance with this Notice.
- (2) No person may remove an HGP or an HGP identification ear tag from any live animal.

Part 3: Obligations of supervising veterinarians

3.1 Application of this part

- (1) This Part applies only to supervising veterinarians.

3.2 Supervising veterinarians and competency records

- (1) A supervising veterinarian must use his or her best endeavours to ensure the technicians he or she supervises maintain ongoing compliance with this Notice.
- (2) For the purposes of this clause and section 144(1) of the Act a technician being supervised by a veterinarian is an agent of the veterinarian.
- (3) A supervising veterinarian must reassess the competency of each technician he or she supervises in relation to HGP implantation, at a frequency of at least once every 12 months.
- (4) A supervising veterinarian must keep a record of each technician supervised by that veterinarian, which must include:
 - a) the full name of the technician; and
 - b) the date of commencement of the technician's employment and the date the employment ceased; and
 - c) the dates when any HGP competency training took place and was completed; and
 - d) the name of the supervising veterinarian responsible for training the technician; and
 - e) the dates and results of the competency re-assessments of the technician carried out by the supervising veterinarian.
- (5) A supervising veterinarian must keep the records required by sub-clause (4) for a period of at least 4 years from when their employment of the technician ceases.
- (6) The records kept by a supervising veterinarian under sub-clause (4) must be kept in a readily accessible form and be made available on request to an official assurance verifier, animal product officer, or auditor of the HGP control system acting under an international agreement.

Part 4: Obligations of competent persons

4.1 Application of this part

- (1) This Part applies only to competent persons.

4.2 Implantation of an HGP

- (1) A competent person may only implant an HGP into an animal in accordance with:
 - a) this Notice; and
 - b) the conditions of registration of the HGP under the Agricultural Compounds and Veterinary Medicines Act 1997.
- (2) An HGP must not be implanted into:
 - a) a lactating dairy cow; or
 - b) a cow intended for the production of milk for human consumption; or
 - c) a bobby calf.
- (3) An HGP implanted animal must be fitted with:
 - a) a NAIT device; and
 - b) an HGP identification ear tag.
- (4) If an animal is implanted with an HGP a competent person must scan the NAIT device unique 16 digit identification number into the HGP database.
- (5) If an animal has an HGP identification ear tag fitted but is not implanted with an HGP a competent person must comply with sub-clause (3) as if the animal had been implanted with an HGP.

4.3 Custody of an HGP

- (1) A competent person must not transfer possession or custody of an HGP to any person other than a competent person, except where the transfer is to a person implanting or intending to implant an HGP into an animal under the supervision of a competent person.

4.4 Collection of information by competent person

- (1) Where for the purpose of the record required under clause 4.5, a competent person implanting an HGP into an animal collects personal information from a person in charge (including a supplier), the competent person must explain to the person in charge that:
 - a) the information is being collected for the purpose of the regulated control scheme under this Notice; and
 - b) the information will be entered into the HGP database as required under clause 4.5 and Part 9.

4.5 Veterinarians required to enter information on the HGP database and keep records of implantation of an HGP

- (1) 'Required information' for the purposes of this clause means the information required by sub-clause (3).

- (2) A record of HGP implantation in relation to every HGP implanted animal must be entered into the HGP database established under Part 9.
- (3) The required information to be entered into the HGP database is the:
 - a) name of the farm owner or person in charge at the time the HGP was implanted; and
 - b) physical address and phone number of the business operated by the person referred to in (a);
and
 - c) AHB or LIC herd identification number; and
 - d) date of HGP implantation of the animal; and
 - e) NAIT device unique 16 digit identification number; and
 - f) HGP product; and
 - g) animal class; and
 - h) veterinary practice details; and
 - i) competent person name.
- (4) The veterinarian shall only enter the FarmsOnLine number into the HGP database with the permission of the farm owner or person in charge at the time the HGP was implanted.
- (5) The supervising veterinarian in relation to an HGP implanted animal must ensure that the required information is entered into the HGP database:
 - a) within 10 working days of the HGP identification ear tag being fitted to that animal; and
 - b) prior to saving the final record to the HGP database and completing the approval requirement.
- (6) The supervising veterinarian must keep written information collected when an HGP is implanted into an animal that is later entered into the HGP database, for a period of at least 4 years from the date of HGP implantation of that animal.
- (7) The supervising veterinarian must give the person in charge a copy of the information that was entered into the HGP database within 20 working days of an animal being implanted with any HGP.

Part 5: Obligations of persons in charge

5.1 Application of this part

- (1) This Part only applies to persons in charge of animals including (but not limited to) suppliers.

5.2 Identification of animals

- (1) A person in charge of an HGP implanted animal must ensure that the animal has been, or is, correctly fitted with an HGP identification ear tag and a NAIT device immediately prior to the animal being implanted with an HGP.
- (2) An HGP implanted animal supplied for sale or slaughter must be identified by:
 - a) a NAIT device; and
 - b) an HGP identification ear tag; and
 - c) be accompanied by an animal status declaration form with the section relating to HGPs fully and correctly completed.
- (3) An HGP identification ear tag that is lost from an HGP implanted animal must be replaced by the person in charge of the animal before the animal is sold or supplied for processing.
- (4) Where the RFID is lost from an HGP implanted animal and a replacement RFID is fitted the person in charge of the animal must notify a competent person of the RFID unique number within 10 working days of replacing the RFID, for the purpose of updating the HGP database.

Part 6: Obligations of primary processors

6.1 Application of this part

- (1) This Part applies only to primary processors.

6.2 Consignments of HGP implanted animals

- (1) A primary processor must have a documented HGP control system for identifying and separating animal material or animal product derived from an HGP implanted animal from animal material or animal product derived from a non-HGP implanted animal.
- (2) A primary processor must not supply any animal material or animal product for export, which is or may be derived from an HGP implanted animal, where an official assurance is required attesting to the absence of any animal material or products derived from an HGP implanted animal.
- (3) A primary processor may, for commercial reasons, declare an animal to be HGP implanted.
- (4) A primary processor must process an animal that is identified or declared by a processor as having been HGP implanted separately from a non-HGP implanted animal, and in accordance with this Notice.
- (5) Where an official assurance is required to establish HGP status, a primary processor must ensure that:
 - a) the NAIT device of every bovine animal is scanned or manually read into the system where it is compared to the tag information supplied on the list of HGP ear tags from the HGP database at the time of processing; and
 - b) the result of scanning indicates the animal could be HGP implanted; and
 - c) the animal is not declared as HGP implanted on the ASD or has an HGP identification ear tag; and
 - d) the official assurance verifier is informed of the above.
- (6) Despite sub-clause (5), if the NAIT device is not scannable, the visual identification on the NAIT device is compared to the visual identification details for the NAIT devices supplied on the list of HGP ear tags from the HGP database.
- (7) A primary processor must ensure that each carcass and edible offal from an HGP implanted animal can be identified as an HGP implanted animal at all stages of processing until post-mortem inspection is completed.
- (8) An animal must be identified or declared as an HGP implanted animal by the primary processor in any of the following circumstances:
 - a) the animal bears an HGP identification ear tag; or
 - b) scanning the animal's NAIT device shows that the animal identification is recorded on the HGP database; or
 - c) the visual identification from a NAIT device is on the list of HGP tags; or
 - d) the animal is declared as HGP implanted on the animal status declaration form on which that animal is listed; or
 - e) evidence of possible past use of an HGP is detected at post-mortem inspection;
 - f) laboratory testing confirms the presence of an HGP implant or the active ingredient of an HGP in the animal; or
 - g) if the animal has no HGP identification ear tag and is not on the HGP database but is present in a mob of HGP implanted animals from the same supplier and its freedom from HGP implantation cannot be independently confirmed; or
 - h) there is any other cause for the primary processor to suspect that an HGP has been implanted into the animal.

- (9) Where a non-compliance with the primary processor's HGP control system is identified, the primary processor must:
 - a) identify and record the reasons for the non-compliance; and
 - b) record the disposition of the animal material or product; and
 - c) ensure that the animal's HGP status is declared correctly in accordance with this Notice; and
 - d) ensure that corrective action measures are put in place at the primary processor's premises to prevent a recurrence of the non-compliance.
- (10) Where an HGP implanted animal is received for slaughter, the primary processor must inform the official assurance verifier if:
 - a) the HGP identification ear tag or the HGP declaration in the ASD are missing or incorrect, or
 - b) if the NAIT device is missing.

6.3 Records of primary processing

- (1) A primary processor must keep records in a readily accessible form relating to the processing of an HGP identified or declared animal, including an animal that is HGP non-compliant, for a period (in relation to each animal) of at least 4 years from the date of processing of that animal.
- (2) These records must be made available on written request to an official assurance verifier, animal products officer, or an auditor under an international agreement.

Part 7: Surveillance list

7.1 Surveillance list

- (1) The Director-General must keep and maintain an HGP surveillance list.
- (2) The purpose of the list is to identify a supplier or person in charge who has:
 - a) not kept records in accordance with this Notice; or
 - b) repeatedly presented an HGP implanted animal for slaughter where sub-clause 8.2(4) (a) and/or (b) have occurred.
- (3) The list may be kept in the manner and form determined by the Director-General including on the Ministry for Primary Industries' website.
- (4) The Director-General may enter a supplier or person in charge onto the HGP surveillance list if:
 - a) the record supplied by the supplier when the animal is presented for slaughter is not, or is suspected not to be, a record which complies with this Notice; or
 - b) the record supplied by a person in charge to the supplier of the animal presented for slaughter is not, or is suspected not to be, a record which complies with this Notice; or
 - c) by any act or omission, the supplier has breached a requirement of a Notice issued under section 60 of the Act ; or
 - d) a supplier or person in charge repeatedly presents an HGP implanted animal for slaughter where clause 8.2 (4) (a) and or (b) have occurred.
- (5) Every entry on the HGP surveillance list must identify the supplier or person in charge by name and business address.
- (6) The Director-General must notify a supplier or person in charge in writing (in accordance with section 165 of the Act) of any entry in relation to that supplier on the HGP surveillance list, and any subsequent amendments to the supplier's details.

7.2 Prohibition on exporting animals, material and products from sources on the HGP surveillance list

- (1) No person may export animal material or animal products to any overseas market to which this Notice applies, which are sourced from a supplier or person in charge who is on the HGP surveillance list at the time official assurance for export is sought.
- (2) No supplier or person in charge on the HGP surveillance list may supply any animal material or animal products to any person for export to any overseas market to which this Notice applies.

7.3 Amendment of incorrect entry on the HGP surveillance list

- (1) A supplier or person in charge whose name is entered onto the HGP surveillance list may apply in writing to the Director-General to request that an entry relating to that supplier is amended because it is incorrect.
- (2) Following an application made under sub-clause (1) the Director-General must amend the entry within 5 working days of receipt of the application unless the Director-General is satisfied that the entry is correct.
- (3) If, after receiving and considering an application under sub-clause (1), the Director-General decides not to amend the entry, the Director-General must provide written reasons to the applicant within 5 working days of the Director-General's decision.

7.4 Amendment or revocation of entry on the HGP surveillance list if risk under control or eliminated

- (1) The Director-General may revoke or amend an entry on the surveillance list if the Director-General is provided with written information that shows there were insufficient grounds for the entry to be made, or that the risk associated with the entry has been eliminated or brought under control.
- (2) A supplier or person in charge whose name is entered onto the HGP surveillance list may apply in writing to the Director-General and supply such information as is necessary to demonstrate to the satisfaction of the Director-General that there were insufficient grounds for the entry or (as the case may be) that the risk associated with the entry has been eliminated or brought under control.
- (3) If, after receiving and considering an application under sub-clause (2), the Director-General decides not to revoke or amend the entry, the Director-General must provide written reasons to the applicant within 5 working days of the Director-General's decision.

7.5 Surveillance notice

- (1) The Director-General must provide a surveillance notice in writing to the affected supplier or person in charge as soon as practicable but not later than 7 working days after making a new entry or revoking or amending an existing entry on the surveillance list.
- (2) A surveillance notice under sub-clause (1) must be notified in accordance with section 164(2) to (4) of the Act and must specify:
 - a) the date on and from which the notice takes effect; and
 - b) the part or parts of this regulated control scheme that have not been complied with; and
 - c) if applicable, any other lawful reason that the Director-General has for placing the supplier on the surveillance list; and
 - d) other administrative matters as the Director-General considers appropriate.

Part 8: Obligations of official assurance verifiers

8.1 Application of this part

- (1) This Part applies to official assurance verifiers who are responsible for verifying that:
 - a) the requirements of any notice issued under section 60 of the Act or other overseas market access requirements in relation to an HGP implanted animal have been met, for the purposes of an official assurance; and
 - b) the control of HGP implanted animals by primary processors is in accordance with this Notice.

8.2 Verification procedures

- (1) A recognised agency employing an official assurance verifier to whom this Part applies must implement and maintain documented procedures for verifying the compliance with this Notice of any primary processor to whom that agency provides verification services.
- (2) At least once in each calendar month an official assurance verifier must audit the documented system implemented by the primary processor (under clause 6.2(1)) for the control of HGP identified or declared animals.
- (3) Any non-compliance by a primary processor detected by an official assurance verifier acting under this Part must be fully documented by the official assurance verifier and may be used as a basis for determining whether an official assurance can be issued for a consignment of animal material from an HGP implanted animal.
- (4) The primary processor must inform the official assurance verifier under clause 6.2 if an HGP implanted animal is received for slaughter and:
 - a) the HGP identification ear tag or the HGP declaration in the ASD are missing or incorrect, or
 - b) if the NAIT device is missing; or,
 - c) the results of scanning indicate the animal could be HGP implanted, and the animal is not declared as HGP implanted on the ASD and does not have an HGP identification ear tag.
- (5) The Director-General may place a person in charge or a supplier to be in charge on the surveillance list if that person or supplier repeatedly supplies an animal where the events under sub clause (4) have occurred.

Part 9: Hormonal Growth Promotants Database

9.1 Application of this part

- (1) This Part applies to:
 - a) authorised users; and
 - b) eligible persons wishing to become authorised users.

9.2 HGP database

- (1) The Director-General must maintain a database containing the information about every HGP implanted animal required to be entered under clause 4.5(3).
- (2) The HGP database must be accessible only to authorised users, and the Director-General must ensure that sufficient measures are in place at all times to protect the HGP database from being accessed and used by unauthorised persons.
- (3) The required information for the HGP database must be entered accurately and within the periods required by this Notice.
- (4) The Director-General shall provide the lists of HGP ear tags to primary processors on a weekly basis.

9.3 Authorised users

- (1) A person who accesses or enters information into the HGP database must, at the time of accessing the database, be an authorised user, and have a user name and password issued to them by the Director-General.
- (2) Any of the following persons may apply to be authorised users of the HGP database:
 - a) veterinarians and supervising veterinarians; or
 - b) technicians; or
 - c) data entry personnel who input required HGP information; or
 - d) official assurance verifiers; or
 - e) employees of the Ministry for Primary Industries.
- (3) In conferring authorised user status on any person the Director-General may grant the authorised user a level of access to the HGP database that is commensurate with the functions of the authorised user under this Notice or (in the case of a person referred to in sub-clause (2) (c) or (e)), as required to perform that person's functions in relation to HGP information.
- (4) An authorised user must not disclose the following information to any other person, except as reasonably required to enable the authorised user to perform his or her functions under this Notice or (in the case of a person referred to in sub-clause (2) (c) or (e)), as required to perform that person's functions in relation to HGP information:
 - a) his or her HGP database username or password; or
 - b) any information contained on the HGP database.
- (5) The Director-General may at any time, and without Notice (if the seriousness of the situation requires), suspend or withdraw authorised user status from any authorised user of the HGP database, if the Director-General becomes aware on reasonable grounds that the authorised user:
 - a) is no longer eligible to be an authorised user of the HGP database (under sub-clause (2)); or
 - b) has failed to comply with this Notice; or
 - c) has disclosed his or her username or password to the HGP database to any other person (except as provided in sub-clause (4)); or

- d) has disclosed any information from the HGP database to any other person (except as provided in sub-clause (4)); or
 - e) has otherwise misused his or her access rights or privileges to the database in any way.
- (6) In the event that the Director-General suspends access to the HGP database in respect of any user, he or she must notify the user of the expected duration of the suspension and any steps required to be taken by the user to enable the user's access to be restored.

Part 10: Transitional Provisions

10.1 Application of this part

- (1) The following transitional provisions will end 30 June 2018.

10.2 Transitional provisions

- (1) For the purposes of this part, barcoded tag means the barcoded ear tag with a pre-printed individual animal identifier included in the barcode, and includes replacement barcoded tags.
- (2) When an official assurance is required to establish HGP status and the NAIT device is not present, the primary processor may scan or manually read the barcoded tag or replacement barcoded tag into the system and compare it to the tag information supplied on the lists of HGP ear tags from the HGP database at the time of processing.
- (3) The primary processor must declare the animal a HGP implanted animal if the scanning in (2) shows that the animal identification is recorded on the HGP database.
- (4) The primary processor must inform the official assurance verifier when an animal is declared as HGP treated under (3) and the HGP identification ear tag or the HGP declaration in the ASD are missing or incorrect.
- (5) For clarity, the animal is eligible for HGP sensitive markets if the animal is not in the HGP database and there is no other evidence identifying it as a possible HGP treated animal.