Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Regulated Control Scheme – Monitoring of Specified Substances in Bee Products for Export

2 December 2019

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Regulated Control Scheme – Monitoring of Specified Substances in Bee Products for Export

COMMENCEMENT

This Animal Products Notice comes into force on 11 December 2019

REVOCATION

This Animal Products Notice: Regulated Control Scheme – Monitoring of Specified Substances in Bee Products for Export revokes and replaces the Animal Products Regulated Control Scheme: Monitoring of Specified Substances in Bee Products for Export, issued on 11 December 2018.

ISSUING AUTHORITY

This Animal Products Notice is issued under sections 38(2)(b), and 167(1) of the Animal Products Act 1999 imposing a regulated control scheme for the monitoring of specified substances in bee products for export in order to meet requirements of overseas markets that have been specified under section 60 of the Animal Products Act 1999.

Dated at Wellington, 2 December 2019

[signed]

Allan Kinsella
Director Assurance
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

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

Purpose

The purpose of this Scheme is to notify a sampling regime for specified substances monitoring of bee products.

Background

The Regulated Control Scheme – Monitoring of Specified Substances in Bee Products for Export is established under the Animal Products Act 1999 for official monitoring and surveillance of bee products. The primary objectives are –

a) to provide confidence to export markets about the quality, safety and integrity of New Zealand bee products in relation to dietary exposure and regulatory standards; and
b) to confirm whether the MPI system for the control of specified substances is working as designed.

The samples are tested for a wide range of specified substances at MPI recognised laboratories contracted to MPI for the provision of testing services.

The results of the Regulated Control Scheme – Monitoring of Specified Substances in Bee Products for Export are used to monitor and confirm that bee products produced for export for human consumption comply with New Zealand and importing country requirements.

Who should read this Animal Products Notice?

You should read this Scheme if you are –

a) supplying bee products intended for export; or
b) a laboratory recognised by MPI for the provision of testing services; or
c) a recognised agency; or
d) a verifier of an RMP.

Why is this important?

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

Failure to comply with this Scheme, without reasonable excuse, is an offence under section 135(1)(c) of the Animal Products Act 1999.

Part 1: Requirements

1.1 Regulated control scheme imposed

(1) This Notice imposes a regulated control scheme for the monitoring of specified substances in bee products for export by way of specifying certain sampling, testing, monitoring, and surveillance requirements that are required to meet export requirements set under the General Requirements for Export 08/035: Contaminant Requirements for Bee Products for Export, 19 December 2008 or specific country overseas market access requirements issued under section 60 of the Act.

1.2 Prime purpose of scheme

(1) The prime purpose of this Scheme is to enable the Director-General to monitor the absence or presence, extent, and distribution of specified substances in bee products for export in order to ensure there is compliance with the export requirements.

1.3 Definitions

(1) In the Scheme, unless the context otherwise requires,—

Act means the Animal Products Act 1999

bee product means extracted honey, comb honey and royal jelly

export requirements means the General Requirements for Export 08/035: Contaminant Requirements for Bee Products for Export, 19 December 2008 or specific country overseas market access requirements specified under section 60 of the Act relating to bee products for export

Scheme means the regulated control scheme imposed by this Notice

recognised agency means an agency recognised under section 101 of the Act to carry out the functions and activities of a recognised agency under this Scheme

recognised laboratory means a laboratory recognised under section 101 of the Act

risk source means a source of a specified substance and includes—

a) a place where specified substances of bee products for export may occur;
b) a grouping of bees, hives or apiaries that may contain or may be exposed to a specified substance; and
c) a person in charge of bee products for export, or a place, that may contain or may be exposed to a specified substance

risk source operator means—

a) the person in charge of a risk source; or
b) a person who is listed in a surveillance list as a risk source of the kind referred to in paragraph iii) of the definition of risk source

RMP means a registered risk management programme under Section 22 of the Act

specified substance means those substances or groups of substances, listed in the sampling regime set out in Schedule 1 of this Scheme to which a maximum permissible level applies, in accordance with the export requirements.

All terms or expressions that are defined in the Animal Products Act 1999 or regulations made under that Act and used, but not defined in this Notice, have the same meaning as in that Act or those regulations.

Part 2: Monitoring

2.1 Sampling regime

(1) The sampling regime for bee products for export set out in Schedule 1 sets out the number of samples to be tested for the existence of specified substances.

(2) The sampling regime applies from 1 July in any given year to 30 June of the following year.

2.2 Sampling plan

(1) The Director-General may at any time, while the sampling regime set out in Schedule 1 applies, provide to any recognised agency a confidential sampling plan. The specified sampling plan will set out any number of specified substances to be tested for and any number of samples be tested.

(2) The Director-General must ensure that while the sampling regime set out in Schedule 1 applies, the overall number of samples to be tested as set out in the sampling plans provided must meet the number of samples to be taken as set in the sampling regime set out in Schedule 1.

(3) A sampling plan must set out—

a) the operator processing bee products for export subject to the sampling plan
b) the location at which the sampling will take place;
c) the recognised agency that is required to take samples;
d) the assay number for each test;
e) the recognised laboratory to which samples must be sent; and
f) any other matters relevant to the implementation of the sampling plan.

2.3 Operator obligations

(1) Any operator processing bee products for export, identified in a sampling plan, must allow access to a recognised agency and comply with requests by the recognised agency to sample bee product in accordance with the sampling plan.

2.4 Recognised agency obligations

(1) The recognised agency identified in the sampling plan must take all samples for this Scheme.

(2) The recognised agency must take all samples within the time that the sampling regime applies.

(3) Whenever samples are taken, as far as practical, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week.

(4) The recognised agency must ensure samples are packaged, and transported to the recognised laboratory, identified in the sampling plan, within 10 working days of the sample being taken. However, if it is impractical for any reason for the samples to be sent to the recognised laboratory within 10 working days the Director-General may approve a different time frame.

(5) A sample must be labelled with—

a) the sample number provided by MPI;
b) the date of sampling; and
c) the assay number for the tests as set out in the sampling plan.

(6) Each sample must weigh at least 500 grams.

(7) Samples must be identified and securely stored (with a tamper-evident mechanism) from the time of sampling and suitably packaged before being couriered to a recognised laboratory.

(8) Samples must be collected in suitable containers to maintain sample integrity and traceability. In particular, containers must prevent substitution, cross-contamination and degradation.

(9) The recognised agency must enter all required information relating to the taking of a sample into a database provided by the Director-General for the purpose (the MPI database) within 10 working days of a sample being taken.

(10) The recognised agency must notify the Director-General, within 10 working days, if it becomes aware any part of a sampling plan cannot be carried out.

Part 3: Surveillance

3.1 Application of risk management measures

(1) The Director-General may apply the risk management measures set out in sub-clause (2) to a risk source if he or she has reasonable grounds to suspect that a specified substance is present in bee products for export from the risk source having regard to the following matters:

a) available evidence of the possible presence and distribution of the specified substance;
b) the availability and known pattern of use of the specified substance and its potential for abuse or misuse;
c) the nature, likely persistence and potential for transfer of the specified substance;
d) the potential harm to human or animal health from the specified substance;
e) the potential risk to trade;
f) the limit set for the specified substance;
g) the availability of effective and reliable sampling and testing methods; or
h) any other administrative matters the Director-General considers relevant.

(2) The risk management measures that may be applied are—

a) making an entry on the surveillance list in accordance with clause 3.2 Surveillance list;
b) identifying of the bee product for export in the particular manner specified by the Director-General;
c) applying conditions in relation to the supply of the bee product for export from the risk source;
d) requiring an animal product officer to take responsibility for investigating and reporting on the risk source and potential for wider contamination;
e) requiring an animal product officer to verify whether the person in charge of the risk source is complying with the risk management measures that apply to the risk source; and
f) any other measure for managing risk provided for by the Act.

3.2 Surveillance list

(1) The Director-General must keep and maintain a surveillance list of risk sources. The purpose of the list is—

a) to enable bee products for export to be identified, isolated, dealt with, and disposed of in accordance with directions of the Director-General; and
b) to enable measures to be applied to risk sources.

(2) The list may be kept in the manner and form determined by the Director-General, including on the MPI website.

(3) The Director-General may enter any risk sources onto the surveillance list if the Director-General considers it appropriate to enable measures to be applied to the risk sources, and also may remove or amend entries on the list.

(4) The Director-General must advise any risk source operator in writing within 5 working days of any test result in relation to a specified substance that indicates that the bee product does not meet export requirements.

(5) Each entry must, to the extent practicable—

a) identify the risk source, for example by name, type or location;
b) identify the risk source operator;
c) specify the bee product for export; and
d) identify the specified substance in relation to the bee products for export that is associated with the risk source.

(6) Where a surveillance notice under clause 3.5 has been provided to a risk source operator, the Director-General must notify any identified bee producer or processor of bee products for export associated with the risk source operator (if different) and the verifier in writing (in accordance with the manner set out in section 165 of the Act) of any entry to the surveillance list and amendments to those details.

3.3 Amendment of incorrect or unreasonable entry on surveillance list

(1) A risk source operator may apply in writing to the Director-General to request that an entry relating to the risk source operator on the surveillance list be amended because it is unreasonable or incorrect.

(2) 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 and reasonable.

(3) The Director-General must provide written reasons to the risk source operator within 5 working days if the Director-General decides to not amend the entry.

3.4 Amendment or revocation of entry on surveillance list if risk eliminated or brought under control

(1) The Director-General may remove or amend an entry on the surveillance list if the Director-General is provided with written information that shows to the satisfaction of the Director-General the risk associated with a particular entry is eliminated or brought under control.

(2) A risk source operator 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 the risk has been eliminated or brought under control.

(3) The Director-General must provide written reasons to the risk source operator within 5 working days of an application being received by the Director-General if the Director-General decides to not amend or remove the entry.

3.5 Surveillance notices

(1) The Director-General must provide a surveillance notice in writing to the affected risk source operator as soon as practicable but not later than 7 working days after making a new entry or removing or amending an existing entry in the surveillance list.

(2) A surveillance notice must be notified (in accordance with section 165 of the Act) and must specify—

a) the date on and from which the notice takes effect;
b) details of the specified substance in relation to the risk source;
c) any requirements on or conditions applying to the risk source operator (which may include controls under section 81B of the Act);
d) any relevant risk management measures under clause 3.1(2)); and
e) any other administrative matters as the Director-General considers appropriate.

3.6 Amendment or revocation of surveillance condition

(1) A risk source operator may apply in writing to the Director-General to request that a condition specified in a surveillance notice be amended or revoked because the specified substance in relation to the risk source can be contained.

(2) The Director-General must amend or revoke the condition if the risk source operator satisfies the Director-General that, respectively, the risk specified substance can be contained by either applying the condition as amended or without applying the condition.

(3) The Director-General must provide written reasons to the risk source operator within 5 working days of the application being received by the Director-General if the Director-General decides to not amend or revoke the condition.

3.7 Application for retest

(1) A risk source operator may apply in writing to the Director-General for a sample to be retested.

(2) The Director-General must agree to a retest if—

a) in the opinion of the Director-General it is practicable; and
b) the risk source operator meets the cost of the retesting.

3.8 Certain obligations relating to surveillance of bee products for export

(1) A risk source operator who has been entered onto the surveillance list must comply with the requirements or conditions of the relevant surveillance notice.

(2) A risk source operator may not dispose, by way of sale to any person, any batches or lots of bee products that are on the surveillance list, unless the risk source operator has the approval of the Director-General.

(3) A risk source operator, who receives bee product for export that is on the surveillance list, must ensure that the verifier for its operation is notified as soon as practicable after receipt.

Part 4: Surveys

(1) The Director-General may carry out surveys, research, investigations or other work if the Director-General considers that it is desirable in order to—

a) determine how best to achieve the purpose of this Scheme in relation to any monitoring programme including developing or testing, legislative, administrative or other measures that may be used or applied in connection with or for the purpose of a monitoring programme;
b) investigate or confirm the absence, presence, extent or distribution of a substance in bee products for export; or
c) investigate or confirm the risk posed by a substance or thing to bee products for export.

Part 5: Testing by recognised laboratories

(1) A recognised laboratory must only test samples of bee products where the integrity of the sample and packaging has been maintained throughout transport to the laboratory.

(2) A recognised laboratory must only use a test method that that is covered in the scope of its ISO/IEC 17025 accreditation, and is suitable for the intended sample matrix.

Schedule 1 – Sampling regime

Honey

Specified substance or class of substances	Number of samples tested
Chloramphenicol	9 samples
Nitrofurans	9 samples
Antibacterial substances	42 samples
Carbamates and pyrethroids	60 samples
Organophosphorus compounds	[60] samples
Organochlorine compounds	[60] samples
Other agricultural compounds	[60] samples
Chemical elements	18 samples
Amitraz	30 samples
Tutin	[30] samples
Nitroimidazoles	[18] samples

Square brackets indicate specified substances or class of substances tested on the same sample.