Verification of Contaminants in Bee Products for Export

31 August 2015
TITLE
Animal Products RCS: Verification of Contaminants in Bee Products for Export

COMMENCEMENT
This Animal Products RCS comes into force on 31 August 2015.

REVOCATION
This Animal Products RCS revokes and replaces the Animal Products (Regulated Control Scheme – Verification of Contaminants in Bee Products for Export) Notice 2013.

ISSUING AUTHORITY
This Animal Products RCS is issued under section 40(1)(b) and 167(1)(f) of the Animal Products Act 1999.

Dated at Wellington this 24th day of August 2015

[signed]

Allan Kinsella
Director, Systems Audit, Assurance and Monitoring
Ministry for Primary Industries
(acting under delegated authority of the Director General)
A copy of the instrument of delegation may be inspected at the Director-General’s office.

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Introduction

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

Purpose

The prime purpose of this scheme is to enable MPI to verify the absence or presence, extent, and distribution of contaminants in bee products for export in order to ensure there is compliance with the OMARs.

Background

This notice imposes a regulated control scheme—

a) for the verification of contaminants in bee products for export by way of specifying certain sampling, testing, monitoring, and surveillance requirements; and

b) that is required to meet OMARs notified and made available under section 60A of the Act.

Who should read this Animal Products RCS?

This scheme should be read by persons specified in clause 1.1 of this notice.

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.

For the purposes of section 135(1)(c) of the Animal Products Act 1999, a failure to comply with this notice, without reasonable excuse, is an offence.
Part 1: Preliminary provisions

1.1 Application

This scheme applies to—

a) risk source operators including persons who hold a RMP for the processing of bee products intended for export, exporters of bee products, beekeepers who produce honey intended for export; and
b) recognised agencies; and

c) verifiers of an RMP; and

d) laboratories listed in schedule 2 of this scheme

1.2 Definitions

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

Act means the Animal Products Act 1999;

bee product means extracted honey, comb honey and royal jelly;

contaminant means in relation to a substance, the substance and all derivatives of the substance including conversion products, metabolites, reaction products and all associated impurities considered to be of toxicological significance;

contaminating agent in relation to a contaminant, means a thing (including an animal or a place) or person that, directly or indirectly,—

a) causes the contaminant to be, or to develop, in bee products for export; or
b) transfers the contaminant to bee products for export;

MPI database means the database used for the entry of sample information and the reporting of results;

recognised agency means an agency recognised under section 103 of the Act to carry out the functions and activities of a recognised agency under this scheme;

OMARs means overseas market access requirements notified under section 60A of the Act relating to bee products for export;

recognised laboratory means a laboratory recognised by the Director-General under the Animal Products Notice: Specifications for Laboratories;

risk source means a source of a contaminating agent and includes,—

a) a place where contamination of bee products for export may occur; and
b) a grouping of bees, hives or apiaries that may contain or may be exposed to a contaminating agent; and

c) a person in charge of bee products for export, or a place, that may contain or may be exposed to a contaminating agent;

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;
sampler means that person employed by a recognised agency for the purpose of taking samples under this scheme;

sampling coordinator means a person employed by a recognised agency to ensure that the part of the sampling plan assigned to that recognised agency is carried out;

sampling regime means that schedule of substances to be tested and the number of samples per test in a sampling year;

sampling plan means in accordance with the sampling regime in schedule 1 the confidential document supplied to sampling coordinators by the Director-General that is—

a) the schedule of samples to be taken from identified bee producers and processors of bee products for export within a specified time period; and
b) the tests to be performed on those samples; and
c) the recognised agencies that are to take the samples; and
d) the laboratories that are to perform those tests;

substance means —

a) any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, and includes any mixtures of those; and
b) any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which is a different substance from that element or compound; and
c) any mixtures or combinations of any of the above;

surveillance bee products for export means, as the case may require, a class of bee products for export—

a) originating from a risk source; and
b) that are specified as surveillance bee products for export in a surveillance list;

surveillance list means the list of risk sources under surveillance that is kept by the Director-General under clause 3.2 of this scheme; and
test means a test listed in the ‘Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm’.

(2) 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: Contaminant monitoring

2.1 Sampling regime

(1) The sampling regime sets out (for a specified period) the number of samples to be tested for the existence of a specified substance or class of substances.

(2) The sampling regime for bee products for export is set out in schedule 1.

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

2.2 Sampling plan

(1) The Director-General may distribute to any sampling coordinator a sampling plan for the specified sampling regime set out in schedule 1.

(2) The Director-General may amend any sampling plan issued under sub-clause (6)

(3) A sampling plan must set out—
   a) the identified bee producer or processor of bee products for export at which sampling under the sampling plan will take place; and
   b) which recognised agency is required to take samples; and
   c) the assay number for each test; and
   d) the laboratory to which samples must be sent; and
   e) any other matters relevant to the implementation of the sampling plan.

(4) The sampling coordinator must notify the Director-General within 10 working days if any part of a sampling plan cannot be carried out.

(5) By way of explanation, certain additional requirements and obligations relating to functions to be undertaken by recognised agencies in connection with this scheme are set out in the notice that recognises the relevant recognised agencies (as issued by the Director-General under section 103 of the Act).

2.3 Sample collection and despatch

(1) Samples taken for this scheme may only be taken by—
   a) a sampler; or
   b) a person directly supervised by a sampler.

(2) Samples of honey (excluding comb honey) must not be taken from containers of less than 10 kg where by doing so would destroy the integrity of the pack without the prior approval of the Director General.

(3) Where the sample is the entire pack and is less than 10 kg the entire sample may be taken if the identified bee producer or processor of bee products for export is in agreement.

(4) Samples must be collected, packaged, and sent to the laboratory identified in the sampling plan within 10 working days of the sample being taken and in a manner that accords with—
   a) the requirements of the sampling plan; and
   b) procedures documented by the recognised agency.

(5) A sample must be labelled with—
   a) the MPI database generated sample number; and
b) the date of sampling; and

c) the assay number for the tests as set out in the sampling plan.

(6) The sample must not be labelled with —

a) any information other than the information listed in sub-clause (5); and

b) the name or address of the identified bee producer or processor of bee products for export from which it was taken.

(7) Each sample must not be less than 200 grams.

(8) If two or more samples are required from the same identified bee producer or processor of bee products they must be taken at the time of sampling, packaged separately and sent to the laboratory (s) advised in the sampling plan.

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

(10) A sampler must take a sample during a normal verification visit to the premises from which the sample is being taken.

(11) If a sample is not taken during a normal verification visit, approval to take a resample from the identified bee producer or processor of bee products for export must be obtained from the Director General.

(12) A sampler must enter all required information relating to the taking of a sample into, and complete all mandatory fields in, the MPI database within 10 working days of a sample being taken.

(13) By way of explanation, certain additional requirements and obligations relating to functions to be undertaken by samplers in connection with this scheme are set out in the notice that recognises the relevant RCS recognised agencies (as issued by the Director-General under section 103 of the Act).
Part 3: Contaminant 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 there is a source of contamination, of bee products for export at the risk source having regard to the following matters:
   a) available evidence of the possible presence and distribution of the contaminant; or
   b) the availability and known pattern of use of the contaminant and its potential for abuse or misuse; or
   c) the nature, likely persistence and potential for transfer of the contaminant; or
   d) the potential harm to human or animal health from the contaminant; or
   e) the potential risk to trade; or
   f) the limit set for the contaminant; or
   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; and
   b) identification of the bee product for export in the manner specified by the Director-General; and
   c) applying conditions in relation to the supply of the bee product for export from the risk source; and
   d) any other relevant risk management measure determined by the Director-General.

3.2 Surveillance list

(1) The Director-General must keep and maintain a surveillance list. 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 revoke or amend entries on the list.

(4) The Director-General must advise any risk source operator in writing within 5 working days of the entry of any test result to the database that does not meet any Overseas Market Access Requirement that they have been entered onto the surveillance list and the risk management measures applicable to that entry.

(5) Each entry must, to the extent practicable,—
   a) identify the risk source, for example by name, type or location; and
   b) identify the risk source operator; and
   c) specify the bee product that is the surveillance material; and
   d) specify the class or description of identified contaminant that is the risk contaminant in connection with the surveillance bee products for export.

(6) The Director-General may determine, for each listed risk source, the sampling rate at which bee products for export must be sampled for specified contaminants.
(7) The Director-General must notify the risk source operator and identified bee producer or processor of bee products for export (if different) and 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 a 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 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 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 revoke 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 revoking or amending an existing entry in the surveillance list.

(2) A surveillance notice 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) details of the contaminant under surveillance; and
   c) any requirements on or conditions applying to the risk source operator (which may include controls under section 81B of the Act); and
   d) any relevant risk management measures under clause (25); 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 of a surveillance notice be amended or revoked because the risk contaminant can be contained either by applying the condition as amended or without applying the condition.
(2) The Director-General must amend or revoke the condition if the risk source operator satisfies the Director-General that the risk contaminant 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 processor of bee products for export must notify the Director-General of any information required by the scheme in relation to any surveillance of bee products for export.

(2) A processor of bee products for export, including any person notified by any means that they are entered onto the surveillance list must comply with the requirements or conditions of the relevant surveillance listing.

(3) When processing surveillance bee products for export received from a risk source whether directly or indirectly, a processor must ensure that the bee product is identified, held, processed or disposed of according to requirements of this scheme.

(4) A processor of bee products for export may not dispose, by way of sale to any person, any batches or lots of bee products from which a non-compliant sample was taken and tested, unless the operator has the approval of the Director-General.

(5) A processor of bee products for export who receives surveillance bee product must ensure that the verifier for their operation is notified as soon as practicable after receipt.
Part 4: Surveys

4.1 Purpose of surveys

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 or surveillance measure 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 or surveillance measure; or

b) investigate or confirm the absence, presence, extent or distribution of a substance or thing 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: Laboratories

5.1 Test methods

Recognised laboratories conducting tests for contaminant monitoring and surveillance must only use test methods agreed in writing between the Director-General and the relevant laboratory.
Part 6: Transitional provisions

(1) This Part applies to laboratories that are not recognised under the Animal Products Notice: Specifications for Laboratories.

(2) For the period 31 August 2015 to 31 August 2017 the terms in the column in Table 1 below headed ‘new terms’ as used in this Notice are to be read to include the equivalent terms in the column in the table below headed ‘previous terms’

Table 1:

<table>
<thead>
<tr>
<th>New terms</th>
<th>Previous terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognised laboratory</td>
<td>Approved laboratory</td>
</tr>
</tbody>
</table>

(3) For the period 31 August 2015 to 31 August 2017 the definitions in Table 2 below apply to the previous terms used in Table 1.

Table 2:

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved laboratory</td>
<td>means a laboratory approved under the Laboratory Approval Scheme</td>
</tr>
<tr>
<td>Laboratory Approval Scheme</td>
<td>means Laboratory Approval Scheme recognised by the Director-General under the Animal Products (Recognised Agencies and Persons Specifications) Notice 2011</td>
</tr>
</tbody>
</table>
Schedule 1 – Sampling regime

1 Honey and comb honey

<table>
<thead>
<tr>
<th>Contaminant, compound or class</th>
<th>Number of samples tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol</td>
<td>8 samples</td>
</tr>
<tr>
<td>Nitrofurans</td>
<td>8 samples</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>80 samples</td>
</tr>
<tr>
<td>Carbamates</td>
<td>25 samples</td>
</tr>
<tr>
<td>Synthetic pyrethroids</td>
<td>[25] samples</td>
</tr>
<tr>
<td>Organophosphates</td>
<td>[25] samples</td>
</tr>
<tr>
<td>Organochlorines</td>
<td>[25] samples</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>16 samples</td>
</tr>
<tr>
<td>Amitraz</td>
<td>20 samples</td>
</tr>
</tbody>
</table>