

DIRECTIONS ISSUED PURSUANT TO SECTION 81 OF THE ANIMAL PRODUCTS ACT 1999 UNDER DELEGATED AUTHORITY OF THE DIRECTOR-GENERAL

The following directions are issued to:

Name: Post-mortem examiners, official assessors (referred to as 'Examiners' in this Notice) and animal product officers

PURPOSE

The following directions are issued for the post-mortem management of an animal with an injection site lesion (ISL).

These directions are intended to expand and supplement the requirements of clause 11 (3) of the Animal Products Notice: Specifications for Products Intended for Human Consumption in respect of an animal submitted where an injection site lesion is detected at post-mortem inspection for which a veterinary treatment is suspected as the cause.

BACKGROUND

Treatment of an animal with injectable veterinary medicines may result in a visible or palpable lesion that is detectable at post-mortem examination. No inferences about the residue status of the animal may be made, merely on the detection of an ISL.

The detection of an ISL is not a sufficient cause in itself for residue testing. These directions describe the process to be followed to determine if an animal is required to be tested for possible breach of the residue limits.

Evidence from testing in New Zealand shows that nearly all ISLs detected at post-mortem examination are not associated with breaches of the residue limits. These directions require that a written case is presented to an identified animal products officer (referred to as 'residue programme co-ordinators' in this Notice) upon which a decision to submit tissues for testing will be made.

DIRECTIONS

Removal of an ISL

1. No person may excise an ISL until the carcass has been initially examined.
2. After the carcass has been initially examined at post-mortem inspection, all ISLs must be removed from the carcass before the remaining material may be considered as fit for intended purpose.

Risk categories: No risk

3. If evidence causes the examiner or animal product officer to determine that the lesion is *not* associated with a residue risk then:
- a) no samples, nor the lesion itself, shall be taken for the purpose of residue testing under the requirements of any regulations or specifications under the APA; and
 - b) the animal and the line of animals from which the ISL was taken must not be retained for any longer than is required for the examiner to be satisfied as to the residue status of the animal(s).

Risk categories: Risk associated with use of a veterinary medicine

4. Where evidence from the examination itself, from the status of other animals in that line, other documentation, or a trace-back to the supplier causes the examiner cause to suspect an ISL is associated with a residue risk from the use of a veterinary medicine:
- a) the examiner must notify an animal product officer responsible for that primary processor of the finding as soon as is practicable and record any details relating to the circumstances of the ISL of which the examiner or assessor is aware; and
 - b) the following meat, kidney, liver and fat samples must be taken and held.

| Matrix | Sample type | Sample size |
|------------|--|-------------|
| Animal fat | Solid fat – kidney or omental only | 100 grams |
| Liver | Whole or part liver | 200 grams |
| Kidney | Single kidney (large animal) or Two kidneys (small animal e.g. sheep, pigs, bobby calves) | |
| Muscle | Diaphragm muscle | 100 grams |

5. Where animals from the same line are detected with an ISL, then only animal carcasses with an ISL and their associated offals must be retained. Animals from the same line not showing ISLs need not be retained.
6. Samples must be taken for testing from one of the retained animals. This animal must be selected by any method chosen by the examiner or animal product officer.
7. The animal product officer must:
- a) review the information notified by the examiner and if considered necessary, contact the supplier and the supplier's veterinarian; and
 - b) document the findings of the review and email the findings to a residue programme coordinator at residues@mpi.govt.nz as soon as practicable.
8. The documented findings of the animal product officer must include:
- a) details of the animal(s) and number in the line; and
 - b) the number of animal(s) having an ISL, description and location of the ISL(s); and
 - c) withholding period compliance statements as written on the ASD; and
 - d) the findings of any enquiry back to the supplier or veterinarian by the animal product officer.

9. The residue programme coordinator must review the findings and notify the animal product officer whether the samples should be submitted for analysis and which test assay numbers should be requested.
10. If the primary processor or supplier refuses to supply any information required by the animal product officer, the animal product officer must inform the residue programme coordinator in writing as soon as practicable.
11. Samples must only be submitted to the laboratory when agreement to do so is provided by a residue programme co-ordinator.
12. Where samples are approved for sending to the laboratory for testing, the animal product officer must enter all required information relating to the taking of a sample into the MPI database as a 'surveillance sample' and select ISL as the reason for sampling. A residue programme co-ordinator will determine whether any animal material must be retained.
13. Where samples are not approved for testing, a residue programme co-ordinator will direct all associated retained products be released and the samples disposed of.

DEFINITIONS

Terms used in this Notice that are defined in the Animal Products Act 1999 or the Agricultural Compounds and Veterinary Medicines Act 1997 have the meanings so defined

The following definitions and meanings apply for the purposes of this Direction:

Evidence means the:

- a) post-mortem examiner, official assessor, or animal product officer's observations of the ISL;
- b) status of other animals in that line;
- c) other documentation; or
- d) a trace-back to the supplier

Residue threshold means the maximum level specified for an agricultural compound for a specified animal material or product as listed in the Animal Products Notice: Contaminant Specifications, the Food Notice: Maximum Residue Levels for Agricultural Compounds, or the acceptable level of any substance in relation to any type or class of animal product made in any specification issued under Part 1 regulation 6 (2) of the Animal Products Regulations 2000

Residue programme co-ordinator means a person who has responsibility to carry out functions in the National Chemical Residue Programme.

DURATION

These directions remain in force until revoked in writing by the Director-General or under delegated authority of the Director-General.

Dated at Wellington on this 25th day of July 2018.

[signed]
Allan Kinsella
Director, Assurance
Regulation and Assurance Branch

INFORMATION

Failure to comply with this direction, without reasonable excuse, may constitute an offence under section 135 of the Animal Products Act 1999. The penalty under section 135(3)(a) of the Act is a fine not exceeding \$20,000.