

Notice of Direction under Section 81 of the Animal Products Act 1999 (Post Mortem Management of Animals with Injection Site Lesions or Unclear Treatment Status)

I issue the following direction pursuant to section 81 of the Animal Products Act 1999 (APA):

Post-mortem examiners, official assessors and animal product officers must comply with the following requirements as directed.

1 Purpose of the direction

- 1.1 This Direction is intended to expand and supplement the requirements of clause 70 (10) (b) of the Animal Products (Specifications for Products intended for Human Consumption) Notice, 2002 in respect of animals submitted where;
- (a) an injection site lesion (ISL) is detected at post-mortem inspection for which a veterinary treatment is suspected as the cause; and
 - (b) An unclear treatment status is determined by the post-mortem examiner, official assessor or animal product officer.

2 Background

- 2.1 Treatment of animals with parenteral veterinary medicines may result in a visible or palpable lesion detectable at post-mortem examination. No inferences about the residue status of the animal may be made merely on the detection of an ISL.
- 2.2 The detection of an ISL is the first step of a series of actions that may result in an animal being required to be tested for possible breach of the residue thresholds. The detection of an ISL is not a sufficient cause in itself for residue testing.
- 2.3 Current evidence from testing in New Zealand shows that nearly all ISLs detected at post-mortem examination are not associated with breaches of the residue thresholds; thus this Direction requires that a written case to support the need for testing in any instance is made. It must be complete and robust before approval for testing will be made.
- 2.4 Off-label use of veterinary medicines and non-adherence to label directions for veterinary treatments of animals may result in animal product with organoleptic properties or visible signs that cause the post-mortem examiner, official assessor or animal product officer to suspect a breach of the residue thresholds for that animal product.
- 2.5 Errors, omissions and inconsistencies on the ASD may give rise to an unclear treatment status.

DIRECTIONS

3 Removal of Lesions

- 3.1 Post-mortem examiners, official assessors or animal product officers must not excise a lesion until the carcass has been initially examined.
- 3.2 After the carcass has been initially examined at post-mortem inspection all injection site lesions must be removed from the carcass before it and associated offal may pass inspection as suitable for human consumption.
- 3.3 The requirements of this Direction must be followed for the meat and/or edible offal from a mob, line or animal from which an ISL is detected is to be passed as suitable for human consumption.

4 Risk Categories

- 4.1 Where evidence from the examination itself, the status of other animals in that line or mob, other documentation, or a trace-back to the supplier, causes the post-mortem examiner, official assessor, or animal product officer to determine that the lesion, presenting sign or symptom in any particular carcass or animal product is associated with the use of a registered veterinary medicine but is not associated with a residue risk then;
- (a) no samples of edible tissue (meat, fat and offals) nor the lesion itself shall be sampled for the purpose of residue testing under the requirements of any regulations or specifications under the APA.
 - (b) the animal, mob line of animals from which the injection site lesion 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).

- (c) the name of the person listed as the supplier on the Animal status Declaration (ASD) for the line or mob of which the animal was a member must not be entered onto the suspect list.
- (d) the samples must not be logged onto the residues database for any residue analysis..

4.2 Where evidence from the examination itself, from the status of other animals in that line or mob, other documentation, or a trace-back to the supplier gives the examiner cause to suspect an injection site lesion is associated with a residue risk from the use of a veterinary medicine then mortem examiner, official assessor or animal product officer must log the sample onto the residues database under the 'ISL option'. This database entry alone is not a sufficient cause for entering the primary producer or supplier of the animals onto the suspect list.

- (a) the post-mortem examiner or official assessor must notify an animal product officer responsible for that primary processor of the finding as soon as is practicable and enter any details relating to the circumstances of the ISL of which the examiner or assessor is aware.
- (b) meat, kidney and liver must be sampled for the purpose of residue testing and sent to the destination laboratory for testing. Sampling, packing and dispatch of samples to the laboratory is independent of any decision by the residue programme co-ordinator to approve or not approve subsequent testing.
- (c) the animal product officer must conduct a review of the information entered on to the database record and, if considered necessary, interview the supplier and the supplier's clinical veterinarian by telephone. A summary of the findings must be entered into the residues database 'sample comments' section together with any recommendation the animal product officer may make regarding advisability of residue testing. This must be completed and entered without delay and the residue programme co-ordinator notified by e-mail of this action immediately upon completion of the report.
- (d) the animal product officer is responsible for completing and reviewing all the circumstances of the finding and entering a report onto the residues database. Expert opinion is a permissible component of the report.
- (e) elements of the report must include, but not be limited to; animal species and animal class, estimated age, number of animals in the line and number exhibiting an ISL, site of the ISL, estimated size of the ISL and age, other pathologic or diagnostic features, withholding period (WHP) compliance statements and veterinary medicines use as written on the ASD and the results of any enquiry back to primary producer by the animal product officer.
- (f) If the primary processor or supplier of the animals named on the ASD refuses to supply the information required by the animal product officer, the Director-General must be informed of that in writing as soon as practicable.

4.3 Where the post mortem examiner, official assessor or animal product officer has a reason other than the finding of an ISL to suspect a breach of the residue thresholds because of unclear treatment status then mortem examiner, official assessor or animal product officer must log the sample onto the residues database under the 'other reason to suspect' option. This database entry alone is not a sufficient cause for entering the primary producer or supplier of the animals onto the suspect list.

- (a) the post-mortem examiner or official assessor must notify an animal product officer responsible for that primary processor of the finding as soon as is practicable and enter any details relating to the event or circumstances which caused the 'reason to suspect'.
- (b) meat, kidney and liver and fat must be sampled for the purpose of residue testing and sent to the destination laboratory for testing. Sampling, packing and dispatch of samples to the laboratory is independent of any decision by the residue programme co-ordinator to approve or not approve subsequent testing.
- (c) the animal product officer must conduct a review of the information entered on to the database record and, if considered necessary, interview the supplier and the supplier's clinical veterinarian by telephone. A summary of the findings must be entered into the residues database 'sample comments' section together with any recommendation the animal product officer may make regarding advisability of residue testing. This must be completed and entered without delay and the residue

programme co-ordinator notified by e-mail of this action immediately upon completion of the report.

- (d) the animal product officer is responsible for completing and reviewing all the circumstances of the finding and entering a report onto the residues database. Expert opinion is a permissible component of the report.
- (e) elements of the report must include, but not be limited to; animal species and animal class, estimated age, number of animals in the line and number exhibiting the feature that gave rise to the suspicion, age, other pathologic or diagnostic features, withholding period (WHP) compliance statements and veterinary medicines use as written on the ASD and the results of any enquiry back to primary producer by the animal product officer.
- (f) If the primary processor or supplier of the animals named on the ASD refuses to supply the information required by the animal product officer, the Director-General must be informed of that in writing as soon as practicable.

5 Tissues Sampled

- 5.1 The following tissue samples must also be taken from the animal according to the direction in Clause 4.2(b) or 4.3(b):
 - (a) not less than 100 grams from one kidney except where the kidney is less than 100 grams when one whole kidney must be taken; and
 - (b) 200 grams of liver; and
 - (c) 100 grams of muscle from any place on the carcass located more than 10 centimetres distance from the excised lesion.
 - (d) 100 g of subcutaneous fat, or mesenteric fat or renal fat
- 5.2 The excised lesion or part thereof must not be sent for residue testing unless directed to do so by the residue program co-ordinator.

6 Sampling and Retention of Animals

- 6.1 Where animals from the same line are detected with an ISL then only animal carcasses with the ISL and their associated offals must be retained pending analytical results. Animals not showing ISLs but which are part of the line or mob in which animals with ISLs are detected need not be retained awaiting residue results from the tested animal product.
- 6.2 Where the unclear treatment status manifests as an overt physical sign or characteristic then those carcasses or product not showing that sign or characteristic need not be retained awaiting residues results from the tested animal product.
- 6.3 Where the unclear treatment status arises from examination of the ASD then all animals in that line or mob must be retained.
- 6.4 All animal carcasses and associated offals for which approval is sought for residue testing that is initiated by the finding of an ISL or other reason to suspect a breach of the residue thresholds must be retained until disposition is determined and notified to the post-mortem examiner, official assessor or animal product officer by the residue programme co-ordinator.
- 6.5 Samples from one retained animal only from a line of affected animals must be taken for testing. This animal must be selected by any method chosen by the post-mortem examiner, official assessor or animal product officer.

7 Sampling procedures

- 7.1 Every sampler must ensure that the equipment and sampling procedures used during sampling do not contaminate or cross-contaminate samples in a manner that may affect test results.
- 7.2 Every sampler must identify, package, and store the samples as required in clauses 8, 9 and 10:
 - (a) without delay after the sample has been taken; and
 - (b) in such a manner that the validity of test results will not be compromised.
- 7.3 Every sampler who becomes aware that an unsuitable sample has been dispatched to a laboratory must immediately notify the residue programme co-ordinator by e-mail.

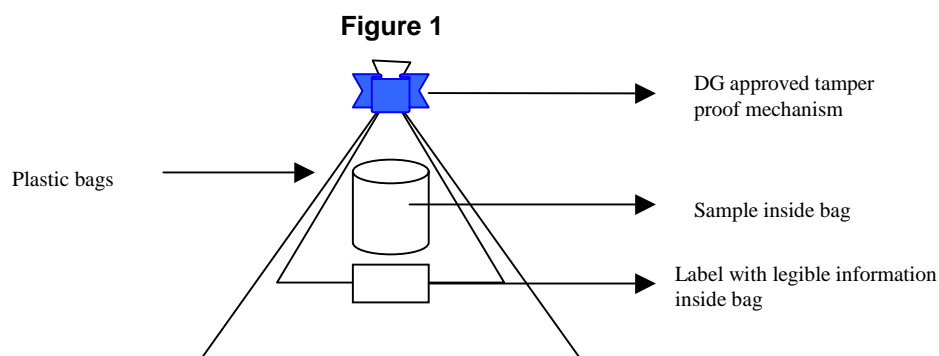
8 Identifying samples

- 8.1 Every sampler must mark or clearly identify the sample package at the time of sampling in a manner that —
 - (a) maintains the identity of the sample in a durable and legible manner; and
 - (b) allows clear and correct matching to any relevant records; and
 - (c) shows the sample number as allocated by the computer.

9 Packaging

9.1 Every sampler must:

- (a) individually pack each sample in packaging so that the sample does not contaminate any other sample or packaging material in a manner that may affect test results, and to prevent any error in identification of the sample; and
- (b) pack a sample using packaging material that is durable, leak proof, and free from contaminants; and
- (c) fix a tamper-proof mechanism, that is approved by the Director-General, —
 - (i) to the packaged sample immediately after the packaging is in place; and
 - (ii) to the outer dispatch packaging of the sample, before dispatch to the destination laboratory; and
- (d) store all approved tamper-proof mechanisms in a secure place when not in use; and
- (e) remove any previously applied tape, tamper-proof mechanism or other device from the outer dispatch packaging before re-using that packaging; and
- (f) place the packaged sample in plastic bags as shown in Figure 1 or in any other manner approved by the Director-General.



- 9.2 Each sample must be labelled and the label must clearly identify the sample to which it relates, and must state the unique sample number, as allocated by the computer programme.

10 Sample submission form

- 10.1 Every sampler must complete the appropriate sample submission on the residues database
- (a) as soon as practicable after taking the sample; and
 - (b) before dispatching the sample to the laboratory.
- 10.2 The sample submission form must be completed fully and accurately
- 10.3 The sample submission form must be in the form set out on the Ministry website <http://residues.maf.govt.nz/residues>. The electronic form once completed must be saved to the residues database.
- 10.4 If the post-mortem examiner, official assessor or animal product officer is unable to enter the required information onto the residues database that person must contact the residue programme co-ordinator for directions and must comply with those directions.
- 10.5 If the post-mortem examiner, official assessor or animal product officer becomes aware of any error in connection with a sample database entry, then the sampler must correct the error as soon as practicable after becoming aware of the error
- 10.6 The post-mortem examiner, official assessor or animal product officer advise must the destination laboratory and the residue programme co-ordinator by e-mail of the error and any actions taken to correct the entry.

11 Storage of samples

- Every post-mortem examiner, official assessor or animal product officer involved in the storage or handling of samples must ensure that;
- (a) the temperature in sample freezers and chillers is regularly monitored and recorded; and
 - (b) samples are stored in such a way that no cross contamination that may affect test results occurs; and
 - (c) sample identity and security is maintained; and
 - (d) samples are chilled at a temperature of -4°C or colder immediately after being taken, and frozen, to a temperature of -12°C or colder, as soon as practicable thereafter, and in any case, within 8 hours after the sample is taken; and

12 Dispatching samples

- 12.1 The post-mortem examiner, official assessor or animal product officer must dispatch the sample to the destination laboratory specified in this Direction as practicable, and in any case within 1 working day of taking the sample.
- 12.2 The post-mortem examiner, official assessor or animal product officer must take all reasonable steps to ensure that;
- (a) samples for dispatch are held secure at all times and maintained in a suitable condition until reception at the laboratory; and
 - (b) if samples are required to be frozen, they arrive at the laboratory at a temperature of 0°C or colder (frozen).
- 12.3 The requirements in subclause (12.2) include, but are not limited to, ensuring that individual transporters are made aware of their responsibilities that include;
- (a) delivering the samples in a manner that ensures that sample suitability and security is maintained during transportation; and
 - (b) delivering each sample to the destination laboratory on a normal working day and within working hours; and
 - (c) delivering the samples promptly and within scheduled deadlines.

13 Retention and Disposition of Animals

- 13.1 Where the results of analysis show the sample(s) taken meet the residue thresholds then the whole line can be accepted as fit for human consumption.
- 13.2 Where the sample taken and analysed does not comply with the residue thresholds, that animal, its associated offal, and all the retained carcasses and their associated offals shall be declared as 'not fit for human consumption'.
- 13.3 If results of analysis from the sample taken as directed show the residue thresholds are breached the primary processor may elect to test the appropriate residue marker tissue(s) of all or a proportion of the retained but untested animals as determined by the residue programme co-ordinator. This will enable residue conformance for each or a sufficient number of retained animal(s) and their associated offals to be individually determined. Such samples must be treated according to the requirements of this Direction
- 13.4 Such animals that fall within the provision of 13.2 and 13.3 must be identified and securely held at that primary processor until a decision on disposition of the animals. Removal to another storage facility at a different site by the primary processor may only be made with the written approval of the animal product officer responsible for the site where detection and storage occurred.
- 13.5 Where testing shows a breach of the residue thresholds, the supplier of the animal must be placed on the suspect list.

14 Responsibilities of the Accredited Person Responsible for Co-ordination of the Residues Programme

- The residue programme co-ordinator is responsible for:
- 14.1 Reviewing the report by the animal product officer and ensuring the report is complete as soon as practicable after notification.
- 14.2 Correcting any deficiencies in the report that need enquiry to the post-mortem examiner, official assessor or animal product officer without delay.
- 14.3 Any further enquiries to the person named on the ASD as the supplier of the animals. These must be made without delay. If the supplier of the animals named on the ASD refuses to supply the information required by the residue programme co-ordinator, the Director-General must be informed as soon as soon as practicable.
- 14.4 Confirming that any animals retained pending analysis comply with any Specifications or Directions made under the APA.
- 14.5 Approving residue testing or not as the case may be, specifying the tissues to be tested, the residues or class of compounds to be analysed and notifying the relevant parties by e-mail immediately.
- 14.6 Reviewing the results of analyses and any other relevant information and make a decision on disposition of the tested animal and any other retained animals.
- 14.7 Notifying the affected parties of the decision on disposition by e-mail immediately.
- 14.8 Granting permission for less than 100% of any other retained animals to be tested, if the primary processor elects to do that, and which tissues must be tested. This decision must be notified to the primary producer and the animal product officer within 1 day of any request.

- 14.9 Advising the animal product officer of the expected date of the analytical results from the laboratory.
- 14.10 Informing the Director General by e-mail within 1 day of being informed that a breach of the residue threshold has occurred.
- 14.11 All necessary actions as required under the APA for entry onto the suspect list if a breach of the residue thresholds has occurred.

15 Definitions

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

- 15.1 Residue risk; means breaching a residue threshold caused by the use of;
- (a) a registered veterinary medicine in a manner that does not comply with the label directions for the WHP for that product; or
 - (b) any other approved veterinary medicine preparations scheduled as 'pharmacy only prescription only or restricted medicines' under the Medicines Act 1981 used as veterinary medicines in a manner that does not comply with the prescribing veterinarians direction; or
 - (c) an unregistered veterinary medicine.
- A residue risk is not caused by;
- a lesion resulting from the use of a registered vaccine or a registered parenteral nutritional/electrolyte product
 - a lesion resulting from the use of a registered veterinary medicine where the animals have been submitted for slaughter and declared outside the WHP for that veterinary medicine
- 15.1 ACVM Regulations means the Agricultural and Veterinary Medicines Regulations 2001, Schedule 2.
- 15.2 Animal product officer means a person appointed under section 78 of the APA.
- 15.3 Marker Residue Tissue is, of the tissues taken for analysis, the one(s) determined by the residue programme co-ordinator to give sufficient information for the disposition of the carcass and associated offals to be made.
- 15.4 Official assessor means a person appointed under section 79 of the APA.
- 15.5 Post-mortem examiner means a person accredited under section 103 of the APA to perform post-mortem examinations.
- 15.6 Registered; means registered under the Agricultural Compounds and Veterinary Medicines Act 1997.
- 15.7 Residue threshold means the number specified for an agricultural compound for a specified animal material or product as listed in the maximum permissible levels in the Meat (Residues) Regulations 1996 (and any subsequent amendments) in the Table Maximum Residue Limits for Agricultural Compounds (MRLs) issued under the Food Regulations (1984) 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 r6 (2) of the Animal Products Regulations 2000.
- 15.8 Residue programme co-ordinator means a person accredited under section 103 of the Act to be responsible for co-ordination and verification activities of the residue programme including but not limited to sampling plans, investigations, suspect list and laboratories.
- 15.9 Residue has the same meaning as 'contaminant'.
- 15.10 Supplier is the person named in the ASD as submitting the animals to the primary processor for slaughter and human consumption.

16 Residue Programme Co-ordinator

The Residue Programme Co-ordinators are:

Jayne Roiri roirij@maf.govt.nz (027 491 6806) and
Susan Morris morriss@maf.govt.nz (025 223 1893)

The destination laboratory is

Agriquality New Zealand
1b Bell Road
Lower Hutt
Tel 04 570 8800

Signed at Wellington this 24th day of December 2003.

(Signed)

Tony Zohrab
Director (Animal Products)
New Zealand Food Safety Authority
(Acting under delegated authority)

Although not part of the Notice of Direction affected parties are advised that this direction issued under the Animal Products Act (1999) replaces TD 01/173 Post Mortem Inspection of Injection Site Lesions (ISLs) and replaces the product disposition instructions of TD 00/76 sect 8.1 and 8.2 for animals with injection site lesions at post mortem examination.