AQIS Notice Number **MEAT 2001 / 13**		**Scheme for Corrective Action**
NSFS Ref 17		
J:\Food Exports\AMEATSEV\2006\Sam\meat_notices\Updated Individual\2001\2001_13 Scheme for corrective action.doc		Contact Officer: Stephen Tidswell
Date of Effect: 1 Aug 2001	Date of Expiry: Until Further Notice	Technical Services Branch Ph (02) 6272 4597 Fax (02) 6272 5442

Distribution Category	Last Notice this Category	Distribution Category	Last Notice this Category
☑ Central & Regional Office	98/33	☑ Managers, Export Meat Establishments	98/33
☑ OIC Inspection Staff Meat Establishments	98/33	☐ Licensed Meat Exporters	
☑Meat Inspection Staff	98/33	☐Managers, Export Slaughtering Establishments	

IMPLEMENTATION SCHEDULE (to be completed by the On Plant Supervisor on the AQIS file copy)

Date Received:_____ Date Discussed With Management:_____

Initial Implementation Date:_____ Date Completed:_____

Initials:_____

PURPOSE

This AQIS Meat Notice is to advise industry of amendments to the Scheme for Corrective Action. It replaces AQIS Meat Notice Meat 97/23 and 96/12 and complements the foreign country requirements identified in AQIS Meat Notice 98/33.

BACKGROUND

The Scheme was developed by the Australian meat industry and AQIS in early 1996 to provide a transparent framework for promotion of continuing compliance with minimum standards prescribed in the Export Meat Orders and, where applicable, in Export meat Manual Volume 2 - Essential Requirements. The Scheme, together with Meat Hygiene Assessment and the National Plant Management System (NPMS) formed key components of the Australian response package to concerns by US Authorities about production standards for export meat.

Formal implementation of the Scheme commenced on 13 May 1996 and the Scheme has been successful in providing a framework for assessment of meat export establishments.

Over recent years there has been minor amendments to the Scheme to provide clarity to the interpretation of the requirements in the SCA and re-affirmation of the implementation of foreign country requirements.

Over the past twelve months there has been an assessment of industry's implementation of MSQA and the AQIS on plant management systems. As a result of this assessment and to complement the future direction of the Meat Program the SCA has been amended.

SUMMARY OF CHANGES

A summary of the changes to the Scheme are identified below

1. Accumulation of SCA points will occur over a 6 month moving window instead of the current 12 month window
2. Points will accumulate below 4 points and cannot be removed by a voluntary CAP
3. A mandatory CAR will be issued to address the reason for the point allocation as a result of a rejection or marginal/unacceptable ATM audit
4. Points will be allocated when salmonella detection within the ESAM program is accompanied by an inadequate investigation and/or corrective action
5. Points below 4 points will drop off the SCA after 6 months provided the CAR issued for each point has been satisfactorily closed out
6. 4 points and above will result in a mandatory CAP, followed by a SCA audit
7. There is an increased emphasis on content and sustainability of the CAP
8. Point allocation and removal will be by AQIS Central Office
9. Point allocation will occur immediately and it will be management's responsibility to provide the required documentation to substantiate the removal of points where the point allocation is disputed eg. pipeline product.

The remainder of the Scheme is effectively unchanged.

This AQIS Notice will be effective immediately from the date of effect identified above and points currently allocated to an establishment under the current SCA will be carried over into the revised SCA. These points will drop off once the 6 month window is reached.

ATTACHMENTS

- The Scheme for Corrective Action (SCA)
- Attachment 1 - Accrual of points under the SCA
- Attachment 2 - Sanction Decision Tree

Steve Bailey
National Manager
Meat Inspection and Food Services Group

THE SCHEME FOR CORRECTIVE ACTION (SCA)

PURPOSE

1. This Scheme will ensure a standard approach is taken in the application of the Scheme to ensure sustained operational compliance occurs, underpinning food safety, and ensuring legislative and foreign country requirements are addressed in a comprehensive and timely manner.

SCOPE

2. The Scheme applies to all export registered meat establishments (including game and poultry) irrespective of the listing arrangements of an establishment with overseas country authorities. This document aims to set out the operating conditions and processes of the SCA.

DEFINITIONS

3. ***Area Technical Manager (ATM):*** A supervising veterinary officer with responsibility for technical standards in a group of export meat establishments within a geographic area.

4. ***ATM Audit:*** a supervisory audit of operations at an export meat establishment conducted by an ATM each month or as programmed.

5. ***CEO Report:*** Report prepared for the company CEO every two months by the SCA Coordinator.

6. ***Corrective Action Request (CAR):*** A formal written request from AQIS to an establishment to correct non-conformities.

7. ***Corrective Action Plan (CAP):*** A comprehensive documented plan that ensures deficient activities are addressed in a sustainable manner and is agreed between the management of a meat establishment and AQIS. The plan must contain an investigation of cause, consideration of corrective and preventative measures, implementation of corrective action, monitoring, assessment and verification.

8. ***Delistment:*** Suspension of eligibility to export to a particular country, or group of countries, when operations at a meat establishment fail to comply with the certification requirements of those importing countries.

9. ***Deregistration:*** Revocation of registration at a meat establishment in respect to one or more export operations for which the establishment is registered. This may effectively stop production or processing of meat for both export and domestic markets.

10. ***Hazard Analysis Critical Control Point (HACCP):*** A systematic preventative approach recognised internationally for managing hazards in the food industry.

11. ***Lot Rejection:*** The rejection by an overseas country at the point of importation on a particular day, of an entire consignment of product with the same port mark and on the same health certificate, and related to food safety factors directly attributable to the establishment(s) of origin and including independent boning rooms ie. pathology, unsound condition, contamination including microbiological and chemical where there has been a failure to comply with on plant quality programs, and including processing defects as defined in Export Meat Manual Volume 1 Order 285 Appendix A.

12. ***Meat Hygiene Assessment (MHA):*** An objectively based system for the monitoring of processes and product, developed by AQIS in consultation with the meat processing industry.

13. ***Meat Program Manager (PM):*** The senior manager, based in Canberra, with overall responsibility for AQIS national inspection service delivery and standards.

14. ***National Plant Management System (NPMS):*** The AQIS verification and reporting system utilising check-lists and prompts to record company performance and track defects and corrective action on all export meat establishments.

15. ***On Plant Supervisor (OPS):*** The senior AQIS person at an export meat establishment.

16. ***Pipeline Product:*** That product produced by the company up to the end of a successful SCA audit.

17. ***SCA Audit:*** A comprehensive audit of all aspects of operations at a meat establishment for compliance with regulatory requirements. This audit pays particular attention to the implementation of the agreed CAP at the establishment. One or more senior AQIS technical officers conduct the SCA audit. The audit team must contain at least one senior AQIS technical officer who is not responsible for carrying out regular audits at the establishment.

18. ***Suspension of Registration:*** Suspension of eligibility to export to all countries [ie action in accordance with Section 48 of the Prescribed Goods (General) Orders].

19. ***Senior ATMs (SATM):*** A group of VO5s with responsibility for operational review.

20. ***US Rejection Details:*** Details of the product lots examined and rejected at US Import Inspection for specific reasons, provided each month to the SCA Coordinator by FSIS.

REFERENCES

21. AQIS Meat Notice 98/33 - Revised Scheme for Corrective Action and Sustained Operational Compliance

22. AQIS Meat Notice 95/32 - National Plant Management System

23. Export Control Act 1982, Prescribed Goods (General) Orders, Export Meat Manuals and AQIS Meat Notices

24. AQIS Meat Notice 00/09 – Carcase Microbiological Monitoring Program (ESAM).

25. AQIS Meat Notice 99/9 - Guidelines for microbiological testing of game meat in game meat establishments

METHODOLOGY

26. SCA point-scoring system

The point-scoring system is based on the accumulation of points within a **moving window over a 6-month period** as a result of poor audit ratings, individual lot rejections and salmonella testing performance with a point score allocated for certain incidents. The points score is **cumulative** during the 6 month period and allows for multiple incident / factors / triggers to contribute to the pathway and outcome. The accumulated points score will be adjusted to reflect monthly progress over the moving 6-month window period and Attachment 1 shows how points are accrued under the scheme for corrective action (SCA).

Details of the SCA Scoring Process

Accrual / Removal of points

a. Points will be accumulated for all non-conformities over a 6-month rolling window as per Attachment1. Non conformities (marginal / unacceptable audit ratings, inadequate salmonella investigations and /or corrective action and rejections) are to be addressed through the CAR protocol (see also sections 28 & 29).

b. Points can be deleted in two ways:

- If an establishment accumulates less than four points during a 6 month rolling window, the relevant point/s will be deleted at the start of the 7th month after the point was allocated - provided that there was effective corrective action implemented in response to the CARs.

- If 4 or more points are accumulated, points will be removed after a mandatory CAP and successful SCA audit.

c. A new rolling window will commence from the point of the successful SCA audit i.e. if the successful SCA audit occurs in January then the new window will commence in January. Points for non-conformities are then applied as normal (refer Attachment 1) i.e. first rejection scores 1 point, second rejection

scores 2 more points etc. A CAR is generated for every non-conformity and the company carries out the normal investigation and institutes appropriate corrective action.

- There will be no consideration by AQIS of 'pipeline product' as a reason to remove points, unless the Company can conclusively prove the product is 'pipeline product'. This information should be provided to the ATM.

d. After the completion of a successful CAP and SCA audit, performance of the CAP will be monitored to ensure the CAP is being sustained. The establishment's continued effective implementation of the CAP will be deemed not to be maintained if there is
   a) a marginal or unacceptable ATM audit rating in the 2 months period after the SCA audit, or
   b) a rejection, for the same reason that the CAP was issued, in product produced during the 2 month period immediately after a successful SCA audit.

- It will be the company's responsibility to prove conclusively that the rejections in the months following the conclusion of a successful SCA audit are NOT due to product produced during the 2 month period after the audit. This information should be provided to the ATM.

e. Where the CAP is deemed not to be sustained the PM may require further action which may include:

- a further audit of the establishment
- an increase in the MHA monitoring
- an increase in AQIS Check the Checker
- suspension of the MSQA
- suspension of an operation
- delisting from an overseas market

f. Seasonal establishments will carry over points from the 6-month rolling window at closure.

- The points accumulated up to the point of closure will be re-applied at re-commencement of the establishments operations.

27. Lot Rejections

All rejected lots are to be subjected to investigation by the management of the producing establishment to determine the cause and to subsequently implement corrective action. In order to initiate the investigation the OPS will generate a CAR for each lot rejected. The documented outcome of the investigation will be used to close out the relevant CAR and is to be held on file by both AQIS and management for audit and future information.

Where an establishment receives multiple rejections (more than 1) in a single month, and where port marks are clearly different (between the rejected lots), points incurred for the rejections will be applied in the normal manner (refer Attachment 1).

Rejections related to unsound condition and pathological defects will initially attract points on a presumptive basis. It will be the responsibility of the company to conclusively prove that they were not at fault. If found not to be directly attributable to the performance of the establishment of origin by a thorough and documented investigation using the CAR protocol and upon recommendation from the ATM, points for such rejections will be removed from the system.

Rejections related to labelling defects, (including port marks), transport damage and miscellaneous are not to be considered as triggers for routinely incurring points. Rejections related to carton damage need to be the subject of a documented investigation by the management. Although such rejections do not routinely attract points in the SCA, if excessive or repeated rejections are found to be attributable to the establishment of origin, points may be allocated at the discretion of the PM.

28. Corrective Action "Trigger" point scores

Based on the cumulative point score the following action is required.

Cumulative points		**Action**
Score 1, 2 and 3	CARs issued as result of Marginal rating at routine ATM monthly audit, for each lot rejected, and for failure of an effective response to excessive positive Salmonella results in the testing program for that slaughter species ie failure of Salmonella sampling windows that are not adequately investigated.	Issues addressed through CAR.
Score 4 or > 4	CAR issued requiring development of CAP	Mandatory CAP & SCA audit
Any score	PM discretion	CAP/ SCA audit

Penalties are imposed where corrective or preventative measures have failed to consistently maintain compliance with regulatory standards. Sanctions initially result in cumulative scores under the SCA and progress to include SCA audits (involving more than one auditor), suspension of an operation or a MSQA arrangement, the possibility of increased AQIS presence or MHA checks,

delistment from selected markets until control is re-established and in extreme cases, deregistration. Attachment 2 identifies schematically the sort of process that could be implemented from continued failure by an establishment, within the SCA system.

Corrective Action Plans (CAPs)

The CAP is pivotal in the SCA. A key objective of a CAP is to address the fundamental cause of non-conformities at the establishment and prevent recurrence of deficiencies.

To initiate the CAP development process after 4 or more points have been accumulated, either the OPS or the ATM will generate a Corrective Action Request (CAR), that requires the company to develop a draft CAP. Development of the draft CAP must occur within 10 working days of the CAR being issued.

To enable the development of a CAP the senior management of the establishment will appoint an **investigative team** who, with the involvement of the AQIS OPS, are to:

- address any immediate corrective action relating to food safety issues
- undertake an immediate comprehensive assessment of all operations at the establishment
  - this may take the form of a series of internal audits.
- re-examine establishment HACCP & QA programs in the context of the findings of the assessment
- develop, agree on and sign (management & OPS) a draft CAP within 10 working days of the generation of the CAR.

[**NB: <u>CAP Structure</u> – (1)** the investigation must determine the "underlying cause" for the accumulation of deficiencies that has led to the activation of the trigger point. Previous CARs can be collated and used in the investigation process. **(2)** Corrective action to be implemented must be of a "preventative" nature and be effective and sustainable. Corrective action should include consideration of the need for recall and re-work of product within the export system, and still in Australia. **(3)** The CAP must also outline how each element will be monitored to ensure effective implementation and how management will subsequently verify it. **(4)** CAPs without comprehensive supporting documentation will not be accepted.]

After the OPS and establishment management have agreed to and signed the draft CAP,

- It is to be forwarded to the ATM who will carry out a desk-audit of the document.

- If acceptable, the ATM approves the CAP.
- The CAP is to be implemented within 4 weeks (20 working days) of the date on which the OPS and establishment management agreed to and signed the draft CAP.
- The ATM will verify the CAP implementation at the next monthly audit.

29. SCA Audits

As a general principle, the SCA audit is to be conducted within six weeks (30 working days) of a CAP (draft) being agreed and signed by OPS and management. It is necessary for the ATM to have verified the CAP during an on-site audit prior to the SCA audit.

At the discretion of the Program Manager, a SCA audit that is already scheduled will still proceed following an ATM audit where the ATM has been unable to verify the CAP has been effectively implemented. In certain circumstances, the Program Manager may agree to delay a SCA audit eg: if seasonal nature of production of a particular species precludes effective implementation of all aspects of the CAP.

Two AQIS technical auditors, one being the usual ATM and the other an ATM not responsible for the regular auditing of the establishment, will conduct the SCA audit – this latter officer will usually be the lead auditor.

The SCA audit will be a comprehensive audit of all relevant aspects of the establishment's operations with particular attention paid to the implementation and maintenance of the corrective action elements outlined in the CAP. To assist this process, checklists, including a checklist drawn up from the CAP will be used.

There will be only two possible outcomes from the SCA audit – acceptable or unacceptable.

The SCA audit will in most instances substitute for the routine monthly audit within the month in which it is conducted. The audit may take one or more days depending on the size and complexity of the establishment. The normal audit protocols will be followed. AQIS fee–for-service charges will be applied for both auditors for the full time of the SCA audit.

Outcomes from Unsuccessful SCA Audits

Where an establishment has been rated Unacceptable at a SCA audit, then sanctions will be applied following consultation with the PM and in line with the sanction decision tree in Attachment 2. An unacceptable outcome may attract operational sanctions at the establishment, such as suspension of an operation or delisting from an overseas market.

MONITORING

30. ATMs will monitor that CARs are issued to the company to ensure issues that accumulate points under the Scheme are addressed by the company and CAPs are prepared in a timely fashion.

31. OPS monitor that the CARs and CAPs address the issues, which resulted in point accumulation under the Scheme.

RESPONSIBILITY

32. Companies shall
    - ensure the response to both CARs and CAPs address the issues as required in this AQIS notice,
    - ensure that they meet the time parameters outlined in this notice, and
    - discuss the reasons for possible non-compliance within the timeframes identified in this notice with both the OPS and ATM.

33. AQIS shall
    - ensure that the company's documented response meets both the time parameters and the issues required to be addressed in this notice, and
    - follow the requirements outlined in the SCA-SOP under the Meat Inspection Quality Assurance program.

RECORDS

34. ESAM and other carcase/product microbiological testing reports

35. CAPs.

36. CARs

37. US rejection details

38. CEO reports

39. SCA Audit outcomes.

CORRECTIVE ACTION

40. Where a company with an approved quality arrangement fails to comply with the above requirement they will be considered to have failed to comply with a CAR and Order 459.5 under Part 32 of the Export Meat Orders shall be invoked. This order states
    - If an authorised officer has reasonable grounds to believe that animals or prescribed goods may have been affected by a failure to comply with the arrangement or a failure of the kind referred to in suborder 459.1, the officer may do any of the following:

- Cancel a certification given for the goods under Order 73 of the Prescribed Goods (General) Orders;
- Suspend or revoke an export permit that has been granted in respect of the goods under order 75 of the Prescribed Goods (General) Orders

41. Where a company without an approved quality arrangement fails to comply with a CAR then in respect of the goods under Order 75 of the Prescribed Goods (General) Orders the authorised officer does have grounds to believe that Orders that apply to the goods have not been complied with.

42. Under these circumstances
    - export permits should not be signed, dated and/or sealed for the product, and
    - Documentation Section should be notified

VERIFICATION

43. The SCA Coordinator, in Canberra, will monitor the effective application of this Scheme by tracking SCA timeframe parameters and reporting outcomes to either the ATM Coordinator or the PM.

44. Internal audit of the Meat Inspection Quality Assurance program SOP-SCA. The Program Manager will conduct the internal audit or identify an auditor to conduct it on his behalf. The internal audit will be conducted at least once a year.

45. Foreign official system audits outcome / comments as they occur from time to time.

46. Desk audit of CAP standards and SCA audit outcomes undertaken by the ATM Coordinator. This will occur at least twice a year to enable feedback to the Meat Program Conference.

Attachment 1
Accrual of Points under the SCA

1. Monthly AQIS Audits

- A marginal (M) rating from a monthly ATM audit
- An unacceptable (U) rating from a monthly ATM audit

Incident/Factors Trigger	**Points allocated**
First ATM marginal audit (M)	1
Second ATM marginal audit (M)	2
Third and subsequent ATM marginal audit (M)	3
Any Unacceptable ATM audit (U)	4

2. Notification of rejections from markets for food safety issues that relate directly to the establishment(s) of origin:

- Contamination
- Processing defects
- Unsound Condition
- Pathological defects

Incident/Factors Trigger	**Point Allocated**
First lot rejection	1
Second lot rejection	2
Third and Subsequent lot rejection	3

Note: Any rejection may be rated at the discretion of the PM.

3. Failure of Salmonella testing window coupled with unsatisfactory investigation / corrective action. (AQIS Meat Notice 00/09).

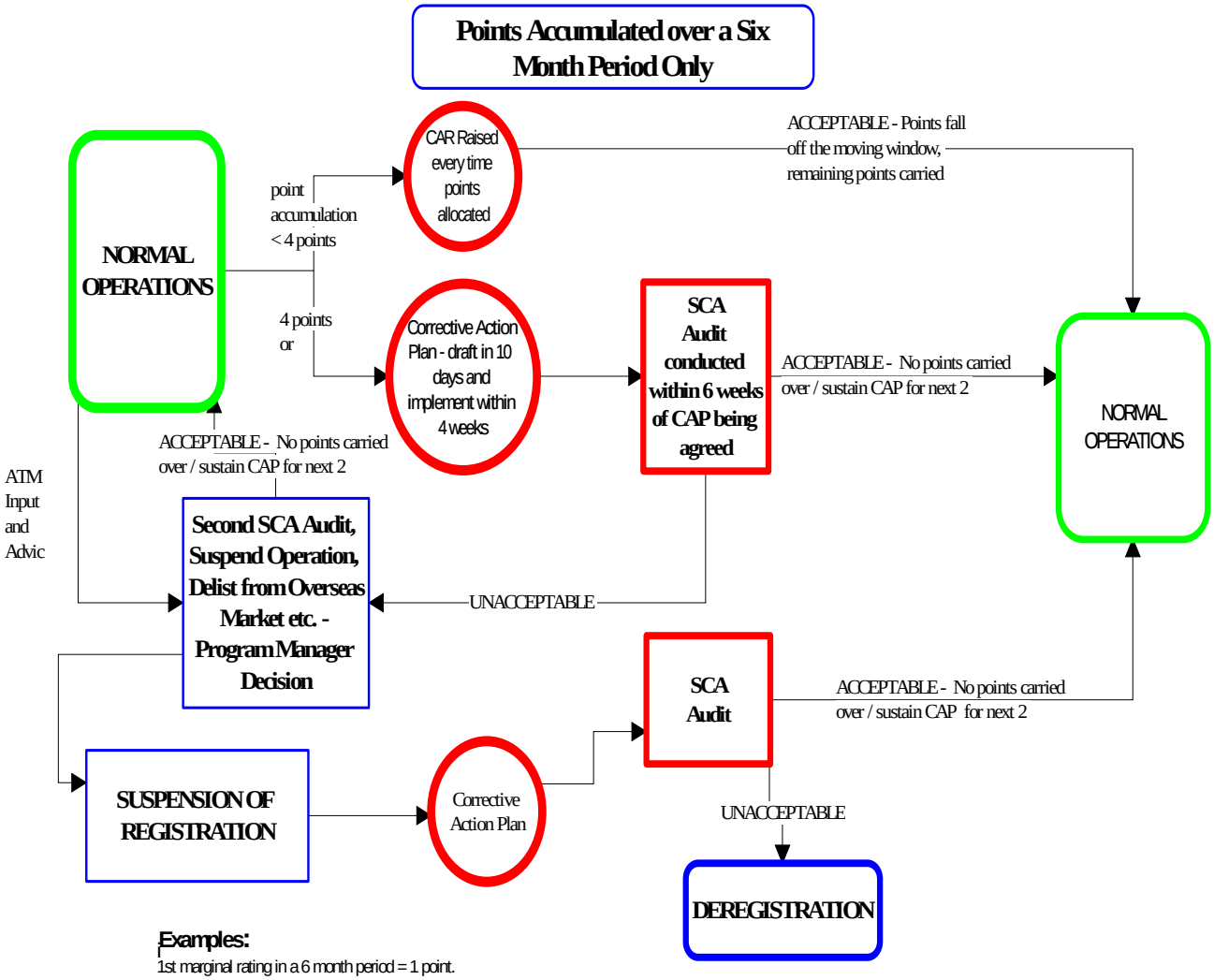
- failure of 1st sample window + unsatisfactory investigation / corrective action. 1 points

- failure of 2nd sample window + unsatisfactory investigation / corrective action. 2 points

- failure of 3rd sample window + unsatisfactory
- investigation / corrective action. 4 points.

Attachment 2

Sanction Decision Tree



Examples:

1st marginal rating in a 6 month period = 1 point.
CAR mandatory

2nd marginal ratings in a 6 month period = 3 points.
(ie 1+2) and 2 CARs mandatory

1 marginal rating + 1 rejection = 2 points.
2 CARs mandatory

1 marginal + 2 rejections = 4 points.
(ie 1+1+2) and 3 CARs mandatory plus
CAP followed by SCA Audit

3 marginal ratings in a 6 month period = 6 points.
(ie 1+2+3) and 3 CARs mandatory
plus CAP followed by SCA Audit