VERIFICATION and SAMPLING ACTIVITIES for SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* **(STEC)** IN RAW BEEF

Based on FSIS Directive 10,010.1 FSIS Directive 10,010.2

Contents

ACRONYMS and ABREVIATIONS, Definitions

BB	Administrations Manager of the NVWA for an establishment, at slaughterhouses this is an official veterinarian ("Bedrijvenbeheerder")
HAV	Hazard Analysis Verification
HVT	HACCP Verification Task
NR	Non-compliance Record (Rapport van Bevindingen)
O&O	Department for evelopment & Support (Afdeling Ontwikkeling & Ondersteuning)
RTE	Products that are consumed raw
RvB	Non-compliance report ("Rapport van Bevindingen")
SIA	Senior Inspector Auditor
STEC	Shiga toxin-producing *E. coli* (STEC)—STEC may also be referred to as Verocytotoxin-producing *E. coli* (VTEC)
TL	Team leader(s)
VIC	Veterinarian(s) in charge

PREAMBLE

This instruction describes the current development proposal concerning STEC verification, including sampling, at veal/cattle slaughterhouses and beef processing facilities in the Netherlands, eligible for the export of raw veal/beef (intact and non-intact) to the USA. This instruction belongs only to activities concerning establishments with an export registration beef/veal to the USA. The instruction does not belong to establishments if all of the finished product groups are intended for RTE only.

CHAPTER I - GENERAL

I. PURPOSE

A. This document provides instructions in the frame of STEC-verification to VIC for collecting and submitting samples of raw beef products under the routine and follow-up sampling programs for Shiga toxin-producing *Escherichia coli* (STEC) for the export to the USA.

B. Instructions concerning STEC verification activities other than NVWA sampling are contained in Chapter VII of this document.

C. HEP: For the HEP criteria see RE-31 USA, requirements concerning establishments, Appendix 3 Key Points, point 6.

D. no longer applicable

E. VIC, responsible for collecting raw beef samples at establishments that produce raw beef products, are to be provided up to two hours of official regular time to read this instruction and also having a training (on-site/off-site, depending on the experience and needs of the VIC).

NOTE: For the purposes of this instruction, when the instruction references "raw beef" it includes veal and not-ready-to-eat (NRTE) beef; when the instruction references "establishments" it includes also establishments applying for a registration for the export of beef/veal products to the USA.

II. CANCELLATIONS

- NVWA Verification Activities for Escherichia coli O157:H7 in Raw Beef Products v 2014
- NVWA Verification Activities for STEC in Raw Beef Products
- Sampling Verification Activities for Shiga Toxin-producing Escherishia coli (STEC) in Raw Beef

III. BACKGROUND

A. NVWA considers all product, contaminated with STEC O157:H7 and the following 8 non-O157 STEC: O26, O45, O103, O104, O111, O121, O145 and O174 (Dutch top 9), and stx, and eae/aagR+aaiC genes present, to be ineligible for export to the USA.

B. Sampling verifies that an establishment's food safety procedures and controls adequately address STEC.

C. Establishments are required to hold or maintain control of raw beef products that NVWA has tested for STEC pending negative results.

D. STEC contamination is a food safety hazard during the slaughter and processing of raw intact and raw non-intact beef products. The establishment (with an export registration for beef/veal to the USA) may use a multi-hurdle approach and incorporate multiple controls and preventive measures to address the pathogen in its HACCP system. Thus, the establishment may control the pathogen through one or more CCP's in its HACCP plan or prevent the potential pathogen from becoming reasonably likely to occur through preventive measures in its SSOP's or through

other prerequisite programs, or a combination of these mechanisms. Nonetheless, establishments have to sample/test for STEC as detailed in instruction "RE-31 USA, requirements concerning establishments, Appendix 2"[1] (instruction about requirements concerning establishments eligible for the export of meat/beef to the USA).

E. BB's are to be aware that an establishment producing raw beef product needs to make sure that it effectively addresses the hazard.
An establishment may determine that its controls or preventive measures for E. coli O157:H7 effectively control or prevent non-O157 STEC. Interventions validated to control E. coli O157:H7 should be effective in controlling the non-O157 STECs when properly implemented as described in the establishment's supporting documentation unless data such as multiple non-O157 STEC sample results indicate otherwise. This has to be validated and is therefore only acceptable after a certain timeline where all relevant STEC types (E. coli O157:H7 and non-O157 STEC) are sampled.
See instruction RE-31, requirements concerning establishments, Appendix 2.

CHAPTER II – ELIGIBILITY CRITERIA FOR FSIS STEC SAMPLING

I. Sampling at establishments, eligible for the export of raw beef to the USA

A. VIC are to be aware that they have to sample and test eligible raw beef products produced under inspection, including inspected source materials that are subsequently used in retail operations conducted onsite.

B. Establishments that slaughter and further process raw beef product may be eligible for multiple raw beef products. These establishments may produce veal, organs, marrow bones, tenderized veal, ground product, beef manufacturing trimmings, bench trim, and other raw ground beef or beef patty components. These establishments may use purchased product (only from establishments with a registration, for the product concerned, for the export to the USA) to produce bench trim or raw non-intact products. Therefore, VIC may have to take samples for multiple sampling tasks.

C. In the event of a positive sample from any of the routine sampling programs, follow-up samples will be scheduled at the establishment. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC.

D. STEC sampling has to be part of Supervision 1 (team leader supervision) at least once a year.

[1] Detailed in Annex STEC sampling

II. SAMPLING FREQUENCIES FOR ROUTINE SAMPLING PROGRAMS

VIC have to sample each establishment that produces:

1. Raw ground beef products; and
2. Bench trim, other raw ground beef components, or beef manufacturing trimmings for each product.

Frequency: **at least** four times per calendar month. The verification has to be risk based; preferred is one sampling per week; at least it is to avoid piling up at the end of the month[2] .

One of the samplings has to be combined with a **HACCP Verification Task** (HVT) as portrayed in Chapter VIII.

III. INTENDED USE AND SAMPLING ELIGIBILITY

Veal/cattle slaughterhouses and beef processing facilities in the Netherlands, eligible for the export of raw veal/beef (intact and non-intact) to the USA, has to sample all batches irrespective of the product, related to the batch, is determined for the export to the USA.

CHAPTER III – Digital Sampling form

VIC are to use the "E-formulier monsterneming overige projecten Primaire fase, Secundaire fase, Export of Import" (E-form sampling other products for project in primary phase, secondary phase, export or import) . As detailed in instruction: "Werkvoorschrift digitaal monsterregistratieformulier" (Dutch only).

1. *Follow the procedure for packaging of the sample(s) and completing of the digital sample registration form as detailed in instruction "MON01-10 Werkvoorschrift digitaal monsterregistratieformulier".*

2. *Complete the digital sample registration form (see print screen next page):*
   *- indicate **2** "deelmonsters" (subsamples);*
   - matrix: "vlees" (meat/beef/veal);
   - kind of animal of origin: "kalf" (veal);
   - kind of analysis: STEC
   - kind of product in LV (labvantage): VYHHxx045[3], (= code of related project protocol)

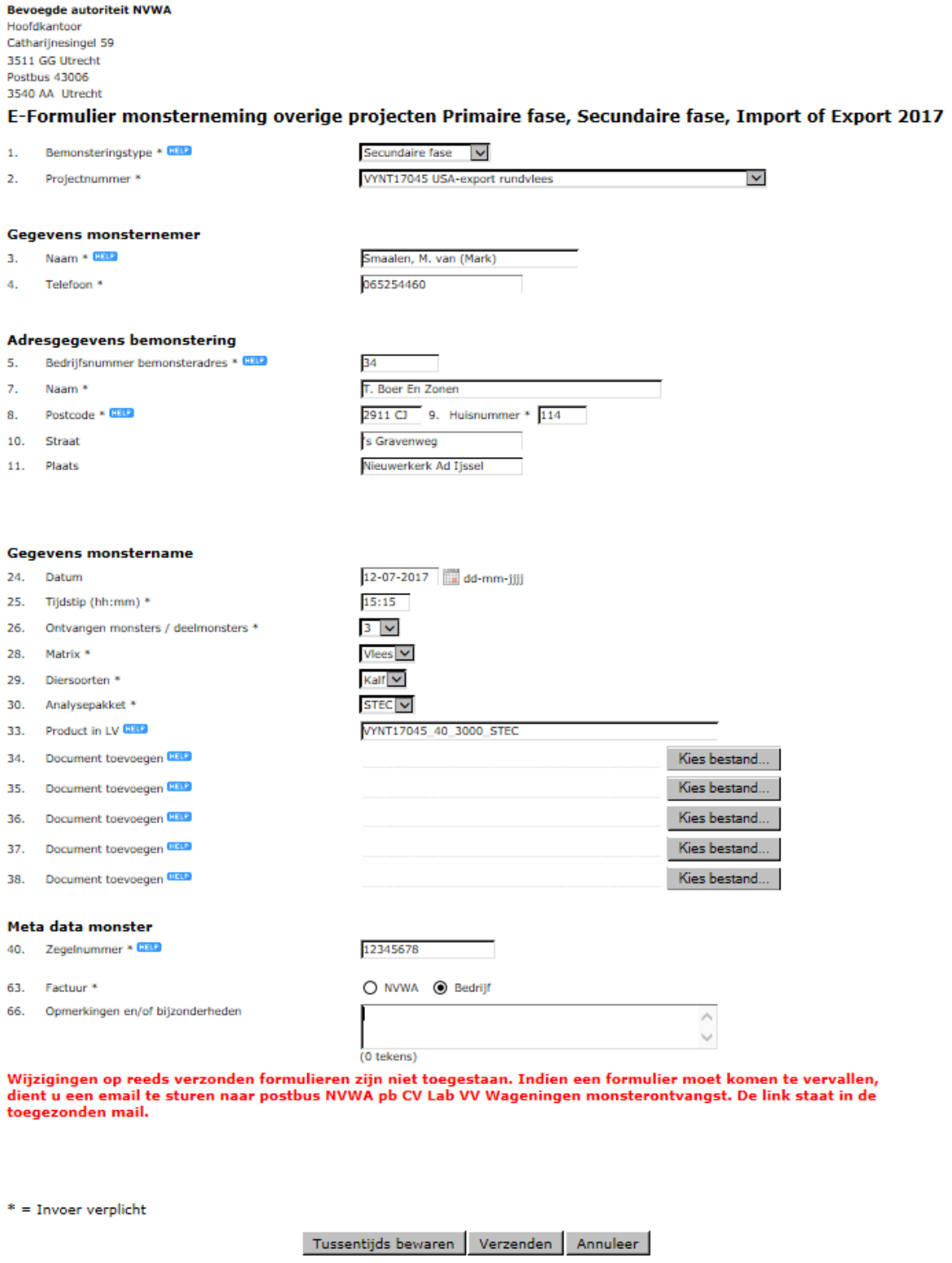
   META DATA
   - Zegelnummer (seal number):
   - Factuur (On account of): establishment

   Amendments to already sent forms are not allowed. If a form becomes void an email has to be sent to the sample-entrance of the NVWA laboratory.
3. *The sterile sampling bags containing the samples has to be kept cooled in a refrigerator.*

[2] It is always possible that something leads to refusal of the sample, no test result etc.; another sample has to be taken as soon as possible. Result must be at least four adequate samples per calendar month.

[3] Code changes every year; b.v. 20**19** VYHH**19**045

4. *The transport of the monsters has to take place at a temperature of max. +/- 5°C by cooled sampling transport of the NVWA-laboratory Wageningen.*



Bevoegde autoriteit NVWA
Hoofdkantoor
Catharijnesingel 59
3511 GG Utrecht
Postbus 43006
3540 AA Utrecht

E-Formulier monsterneming overige projecten Primaire fase, Secundaire fase, Import of Export 2017

1. Bemonsteringstype * HELP: Secundaire fase
2. Projectnummer *: VYNT17045 USA-export rundvlees

Gegevens monsternemer

3. Naam * HELP: Smaalen, M. van (Mark)
4. Telefoon *: 065254460

Adresgegevens bemonstering

5. Bedrijfsnummer bemonsteradres * HELP: 34
7. Naam *: T. Boer En Zonen
8. Postcode * HELP: 2911 CJ 9. Huisnummer *: 114
10. Straat: 's Gravenweg
11. Plaats: Nieuwerkerk Ad Ijssel

Gegevens monstername

24. Datum: 12-07-2017 dd-mm-jjjj
25. Tijdstip (hh:mm) *: 15:15
26. Ontvangen monsters / deelmonsters *: 3
28. Matrix *: Vlees
29. Diersoorten *: Kalf
30. Analysepakket *: STEC
33. Product in LV HELP: VYNT17045_40_3000_STEC
34. Document toevoegen HELP: Kies bestand...
35. Document toevoegen HELP: Kies bestand...
36. Document toevoegen HELP: Kies bestand...
37. Document toevoegen HELP: Kies bestand...
38. Document toevoegen HELP: Kies bestand...

Meta data monster

40. Zegelnummer * HELP: 12345678
63. Factuur *: NVWA Bedrijf
66. Opmerkingen en/of bijzonderheden
(0 tekens)

Wijzigingen op reeds verzonden formulieren zijn niet toegestaan. Indien een formulier moet komen te vervallen, dient u een email te sturen naar postbus NVWA pb CV Lab VV Wageningen monsterontvangst. De link staat in de toegezonden mail.

* = Invoer verplicht

Tussentijds bewaren | Verzenden | Annuleer

CHAPTER IV - SAMPLE COLLECTION PREPARATION

I. PREPARING TO COLLECT A SAMPLE OF RAW PRODUCT FOR STEC VERIFICATION TESTING

A. Verification sampling will takes place unannounced; VIC are to plan the sampling tasks (risk-) based on their knowledge of the establishment's practices.
Both batch size[4] and microbiological independence of the batch are defined in the companies STEC-sampling protocol. The USA, does not recognize "Clean-up to clean-up" alone as a supportable basis of distinguishing one portion of production from another portion of production.
VIC has to inform the establishment that it is required to hold or maintain control of the sampled recipient and their contents when NVWA collects samples for STEC until negative results become available; this in case further sampling (e.g. damaged sample) is needed. VIC has to inform the establishment that the sampled batch is not eligible for export to the USA until negative results become available.

B. VIC are to be aware that NVWA does not allow an establishment to deviate from it's own STEC sampling protocol without the approval of a SIA.

C. If VIC have questions concerning the establishment's definition of the sampled batch, they are to contact a SIA or O&O Import Export. If VIC have questions concerning the establishment's support for the sampled batch, they are to contact their team leader.

NOTE: When VIC are assigned to an unfamiliar establishment, they are to discuss sampling with the establishment and inform themselves about the establishment's STEC-sampling protocol during the entrance meeting.

II. SAMPLING SUPPLIES

VIC are to care for sufficient stock of N60 supply kits and additional supplies for N60 sampling, including packaging materials to be able to execute the sampling immediately at any time.
NVWA provides the sampling and packaging materials.

III. GENERAL SAMPLING INSTRUCTION FOR ROUTINE STEC SAMPLING

A. VIC are to notify establishment management about collecting samples. VIC are to inform the establishment of the reason they are collecting the sample (e.g., routine NVWA verification testing or follow-up sampling in response to an STEC positive from NVWA-testing).

B. VIC are to use a method for randomly selecting the production Batch for sampling. VIC are to randomly select a day, shift, and time. VIC are to collect samples from all shifts the establishment operates and include, where applicable Saturdays, even Sundays, in the random selection.
There needs to be an equal chance that sampling will occur during any particular shift.

[4] The establishment is not allowed to implement batches specifically designed for NVWA STEC-verification.

C. VIC may be assigned more than one sampling task in an establishment that produces raw ground beef product, beef manufacturing trimmings, other raw ground beef or beef patty components, and trim or raw non-intact product from purchased product.
1. VIC are not to collect a raw ground beef sample from the same Batch of source materials (i.e., beef manufacturing trimmings, bench trim, or other raw ground beef components) that already have been sampled by NVWA.
2. If an establishment produces 500 kg of product or less on a daily basis, or only on an intermittent basis, VIC are only to collect one sample.

D. VIC are to collect fresh and not frozen product for STEC sampling. VIC are only to collect a sample of frozen product if the establishment has a critical control point (CCP) for freezing in its HACCP plan, and freezing is an active process that achieves a reduction in STEC (e.g., a spiral freezer).

E. VIC are to collect the sample after the establishment has completed production of a batch (as defined by the establishment) and applied all antimicrobial treatments to the product to be sampled.
NOTE: Application of an antimicrobial treatment (other than a treatment that achieves a full-lethality) does not exempt the product from routine sampling.

F. If the product is to receive a full-lethality treatment, VIC are to verify that the establishment's hazard analysis and flow chart show that the product is intended for this use, and that the establishment has controls that ensure that the product is used as intended. VIC are to verify, through records review, that the establishment maintains sufficient documentation to support its assertion that product receives an intervention off-site. If so, VIC are not to sample the product.
EXAMPLE: The establishment receives letters of guarantee showing that all product receives a full-lethality treatment and maintains records documenting on-going communication with the receiving establishment to verify that all its product is being treated with the intervention.

G. VIC are to collect a sample even if an establishment has already tested the production batch for STEC.

I. If the establishment intends to test the product for any of the adulterant STEC before completing pre-shipment review, VIC are not to wait for the establishment to receive the test results before collecting the sample. Each time VIC collect samples tested for STEC, they are to verify that establishments are holding or maintaining control of the sampled recipient and their contents until negative results become available and that the sampled batch is not eligible for export to the USA until negative results become available.
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IV. ALTERNATIVE BATCHTING FOR RAW GROUND BEEF PRODUCT, BEEF MANUFACTURING TRIMMINGS, OTHER RAW GROUND BEEF COMPONENTS AND BENCH TRIM SAMPLING

Alternative batching is not allowed

V. GATHERING SUPPLIER INFORMATION

If the establishment processes source materials of other establishments they have to provide VIC, collecting raw ground beef or bench trim samples for STEC, the supplier and source material information upon request. This information enables NVWA to trace the raw material back to the original slaughter establishment. VIC can keep the actual label from empty packages.

In case of imported source materials, VIC are to record the Inspection certificate number and to verify the registration of the establishment of origin for the export of the source materials to the USA.

CHAPTER V – SAMPLE COLLECTION PROCEDURES

I. GENERAL

A. The establishment may be eligible for more than one sampling program. VIC are to sample beef components, beef manufacturing trimmings, and bench trim separately following the instructions provided in this Chapter. When the establishment produces multiple types of trim or components, VIC are to randomly select beef manufacturing trimmings, bench trim, and beef components. For a given sampling event, VIC are to collect only one type of trim or component type, whenever possible. The intent is that, through random selection, all eligible products the establishment produces that are subject to sampling will likely be selected over time.

B. VIC are to collect samples of a batch according to the establishment's batching practices.

C. See for sample collection procedures:

- **Beef manufacturing trimmings and bench trim** (N60 sample collection procedure): Annex 1
- **Raw ground beef product:** NVWA-instruction "MRNT 18109, Gehakt vlees en vleesbereidingen" (and also Directive 10,010.1, Attachment 4).
- **Other raw ground beef components:** Annex 1 ("Grap method")
- **Frozen components:** (Directive 10,010.1, Attachment 5).

II. FINAL PACKAGING

A. VIC are to collect beef products in their final package whenever possible. VIC are to collect the appropriate number of packaged products so that the sample equals two pounds (≥900 gram).

B. VIC are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies.

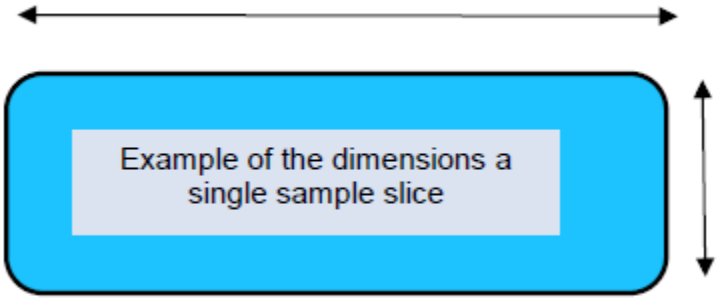
III. N60 SAMPLING METHOD

A. N60 sampling is the sample collection method VIC are to use when collecting samples of beef manufacturing trimmings and bench trim, provided the establishment produces beef manufacturing trimmings and bench trim in amounts that are large enough to be sampled using the N60 method. VIC assigned to establishments that produce beef manufacturing trimmings and bench trim of sufficient size to be sampled using the N60 method and trim too small to be sampled using the N60 method are to collect samples from the product that lends itself to N60 procedures. If the establishment commingles both types of trim, whenever possible, VIC are to collect samples from the product that lends itself to N60 procedures before commingling.
NOTE: If the establishment only produces beef manufacturing trimmings and bench trim that is too small to be sampled using the N60 method, VIC are to collect a sample by taking aseptic grab samples (see Section IV in this chapter (V)).

B. VIC are to not to use the N60 method when collecting other raw ground beef component samples. VIC are to collect other raw ground beef component samples by taking aseptic grab samples (see Section IV in this chapter).

C. N60 sampling involves collecting 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick (ca[5]. 7.6 x 2.5cm x 0.3 cm), as shown below. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. VIC are to collect only one sample slice from each of the 60 individual pieces of trim. VIC are not to take multiple samples from a single piece of beef manufacturing trimmings unless the production Batch consists of less than 60 individual pieces. Collecting thin slices from the external surface maximizes the amount of surface area sampled, which increases the likelihood of finding pathogens if they are present.

[5] Precisely: (7.62cm x 2.54cm x 0.32cm)



D. VIC are to use the 2 sterile sampling bags when collecting samples using N60 procedures. VIC are to place 30 pieces in each of two bags.
NOTE: When cut to the correct size, 30 sample slices should fill one sterile sampling bag.
-> 60 pieces

E. VIC has to take the verification samples from the same recipient/material as the establishment has done for their STEC-sampling; according to the establishments STEC-sampling protocol the sampled recipient is representative for the related batch

F. Some slaughter establishments may transfer beef manufacturing trimmings to another establishment with a different EG number that is in the same, complex and/or company as the slaughter establishment or separated from the slaughter facility by only a wall. VIC are to sample the beef manufacturing trimmings at the slaughter establishment, just as if an establishment would send this product to a more distant location.

G. VIC are to use the N60 method to collect samples from primal and subprimal cuts that are used to produce mechanically tenderized products before tenderization if VIC can safely do so.

H. If the establishment does not have the capability to temporarily shut off components for sampling activities (by example tenderizing components), or does not agree to do so, no product produced in/with this component is eligible for the export to the USA. Upon request a company has to show full cooperation to the NVWA according to 882/2004/EC (on official controls performed to ensure the verification of compliance with feed and food law,
animal health and animal welfare rules).

IV. ASEPTIC GRAB SAMPLING

A. VIC are to aseptically collect grab samples when collecting samples where the N60 method is not applicable/possible.

B. VIC are to aseptically collect grab samples when the products is not available in its final packaging, or the package is too large.

C. For aseptic grab samples, VIC are to collect a sufficient quantity of product to fill each of the two sterile sampling bags. For larger components, such as hearts, VIC are to collect one or more pieces or enough to fill each of the 2 bags.

V. PACKING THE SAMPLE

VIC are to use primarily the packaging materials provided by the NVWA.

VI. ACCESSING TEST RESULTS

A. VIC are to obtain sample results by accessing the dossier of the respective establishment at: T:\nvwa\lab wageningen\PROJECTEN_2018\VYHH18045 .The laboratories will report the results for all adulterant STECs (*E. coli* O157:H7 and non-O157 STEC) for each sample there.

B. "Not acceptable" positive test results for adulterant STEC are reported as soon as each analysis is completed and reviewed. If the sample confirms positive for STEC, NVWA laboratory Wageningen will display the specific STEC serogroups that are positive.

C. After receiving the STEC test results, VIC are to advise an establishment that is holding product that it does not need to continue to hold that product if it has tested negative for STEC.

D. Sample discard: if NVWA-Laboratory discards a sample submitted for STEC testing, VIC are to notify establishment management so that product may be released. BB/VIC are to take appropriate action, based on the reason for the sample discard when applicable. VIC are to review the reason for sample discard and make the necessary adjustments in how the samples are collected, sealed, packed and transported to ensure that the laboratory does not discard future samples because of improper handling or packaging.
NOTE: There may be reasons for sample discards that are beyond VIC control.

CHAPTER VI –FOLLOW-UP SAMPLING PROCEDURES

I. GENERAL

A. VIC are to collect follow-up samples in response to NVWA positives as soon as possible after the positive results were obtained. The purpose of follow-up sampling is to determine whether the establishment's process is effectively addressing STEC.

B. VIC are to collect follow-up samples from the same type of product that tested positive, if available. If the establishment is not producing the product requested, VIC are to collect follow-up samples from beef manufacturing trimmings if the establishment is producing them.

C. In the event that the establishment does not produce the product that tested positive or beef manufacturing trimmings, VIC are to collect follow-up samples from other raw ground beef components or bench trim, if available.

D. VIC are not to wait until the establishment takes corrective actions or has confidence that its corrective actions are effective to collect follow-up samples.

E. VIC are to continue collecting samples for a follow-up sampling task until the set is complete. Specifically, VIC are to continue collecting follow-up samples until the

applicable number of samples (16 or 8 consecutive negative samples, see Section II.C. of this chapter) have been collected for each follow-up sampling set triggered.

F. Follow-up sampling has to be done in response to each positive from NVWA's routine sampling programs at the establishment that received the positive result.

G. NVWA also schedules follow-up sampling sets at supplying slaughter establishments in response to a positive from raw ground beef sample from and a bench trim positive at an establishment sampled for off-site product.
Supplier follow-up sampling sets are discussed in more detail in Section II of this chapter.

H. NVWA may also schedule a follow-up sampling set outside these follow-up sampling projects, e.g., in response to an outbreak or recall.
I. Each positive result in a follow-up sampling set triggers another follow-up sampling set.

J. VIC are to contact NVWA-laboratory at Wageningen if they have questions concerning sampling.

K. VIC has to detail the intended follow-up sampling as required in this chapter in a written action plan (e.g. kind of product, frequency, activities concerning supplier/purchaser etc.). The team leader has to verify if VIC acted as required in this instruction, see also RE-36 Verenigde Staten, Toezicht NVWA op eisen VS, Bijlagen, 9.1 and 9.2 about "Teamleader Supervision".

II. FOLLOW-UP SAMPLING AT SUPPLIERS

A. If the originating slaughter establishments supplied more than one type of source material used in the positive ground beef or bench trim sample, NVWA has to generate sampling tasks for each type of source material.

B. VIC are to collect a single follow-up sample or multiple follow-up samples at supplier establishments as assigned. NVWA does not assign follow-up sampling tasks at establishments that only debone or fabricate beef primal or subprimal cuts but do not slaughter.

C. If NVWA determines that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had previously been identified within approximately 4 months (or 120 days) of the current raw ground product or bench trim positive result, NVWA assigns 16 (or 8 in response to an establishment produces less than 500 kg per day of the product that tested positive) follow-up sampling tasks for the originating slaughter establishments. The follow-up samples has to be identified for each component used in the positive raw ground beef or bench trim product.

NOTE: Follow-up samples of raw ground beef product are to be collected from the grinders that used purchased source materials.

III. SPECIAL INSTRUCTIONS FOR FOLLOW-UP SAMPLING OF INTACT BEEF COMPONENTS THAT WERE NOT INTENDED FOR USE IN RAW NON-INTACT PRODUCT

Not applicable; all product has to be seen as possible non-intact

CHAPTER VII – BB's RESPONSIBILITIES RELATED TO POSITIVE STEC SAMPLE RESULTS

I. BB's RESPONSIBILITIES WHEN AN ESTABLISHMENT RECEIVES A POSITIVE STEC SAMPLE RESULT FROM NVWA

A. Verify the corrective action requirements:

1. VIC are to verify that products that tested positive for STEC from NVWA or establishment testing received are considered unfit for the export to the USA and to be properly canalised in according to the establishment's own STEC-sampling protocol.
   NOTE: establishments has to hold or maintain control of product that NVWA tests for adulterants pending receipt of acceptable test results.

B. Consider the implications of any noncompliance based on the positive NVWA result:

1. VIC has to document a report of findings ("Rapport van Bevindingen" (RvB)) in light of art. 14 of 178/2002/EC for the confirmed positive result from NVWA testing, if the corrective actions as laid down in chapter III.I.1.A are not met. VIC is to ensure, if applicable, recall and proper treatment of the respective batch.

2. If NVWA finds the product to be positive for non-O157 STEC or *E. coli* O157:H7, and the establishment also tested the product, VIC is to check establishment test results to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7 or non-O157 STEC.

3. "If a batch is sampled by both, establishment and NVWA, and the NVWA sample is positive, the batch will be declared positive, irrespective the result of the establishment's sample result." Furthermore, VIC is to issue an extra HAV with a SIA because the establishment's HACCP system was inadequate resulting in adulterated product being produced.
   The VIC has to verify that the establishment has subsequently evaluated their STEC-sampling procedure and testing method concerning the underlying reasons for missing the adulterant (steps 3, 5 and 7, checklist chapter VIII). To ensure that the establishment has regained control over the pathogen respectively the sampling and test method has regained a sufficient performance standard to find STEC, VIC has to increase the sampling frequency. To lower the sampling frequency the test results of establishment and NVWA has to be conform; return to normal test frequency is only possible with the accord of the NVWA team leader.

However if In case multiple follow-up samples of the NVWA remains positive VIC has to issue an extra HAV with the SIA.

4. If VIC has concerns about the adequacy of the HACCP system, they are to discuss their concerns with their supervisors.

II. BB's RESPONSIBILITIES WHEN AN ESTABLISHMENT HAS A POSITIVE STEC SAMPLE RESULT FROM ITS OWN TESTING

A. When performing the HACCP verification task (step 3 in checklist, chapter VIII), VIC is to review the records associated with any STEC testing conducted by an establishment (see table, chapter VIII). If VIC find presumptive positive or confirmed positive STEC results in the testing records, they are to verify that the establishment is implementing corrective actions (step 5 in checklist) according to the establishment's STEC-sampling protocol. When an establishment tests product, a presumptive positive or positive result alone does not warrant a NR (RvB). VIC is only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions in accordance with its HACCP system and STEC-sampling protocol to meet the requirements.

B. VIC is to verify that the establishment addresses the product as if it had tested positive, if an establishment is only performing screening tests (e.g., a presumptive positive) and does not follow up with additional testing to determine whether STEC is isolated from the product.

C. When performing a HACCP verification task, VIC is to verify that establishment employees conducting sampling for STEC do not sample sterile product that could not be contaminated with STEC (e.g., product taken from the interior of a carcass). If VIC observe such sampling, they are to document noncompliance.

D. If establishment records show testing of trim and other raw ground beef components for STEC, but the establishment never finds any positives, VIC has to notify the O&O specialist. In addition, if establishment records show multiple positives for STEC in its own testing, evidencing a potential systemic problem, VIC has to issue an extraordinary audit by a SIA and OO specialist to review the establishment's trim and other raw ground beef components sampling and testing methods for trim for STEC.

III. ESTABLISHMENTS CONDUCTING PRE-SHIPMENT REVIEW, AWAITING STEC ANALYSIS, FOR PRODUCT THAT IS NOT AT THE PRODUCING ESTABLISHMENT

When performing a HACCP verification task BB's are to be aware that some establishments analyse samples for STEC while they are moving the product, but the product has still to be under the establishment's control. BB's are to be aware that NVWA provides establishments the flexibility to move their product before export certification when the establishment is conducting testing for STEC and maintains control of the product (e.g., through NVWA provenance documents ("geleidebiljetten")). Export to the USA is not possible until the negative sample result is affirmed.

Chapter VIII HACCP Verification Task

Deze checklist is bedoeld om te gebruiken bij de maandelijkse STEC HACCP verificatie en is een extra hulpmiddel voor HVT.

Deze lijst moet altijd gecombineerd worden met een NVWA verificatie monster van het betreffende product. Let op!: het dient hier wel om de bemonstering te gaan die het bedrijf gebruikt om een uitspraak te doen over dit product. De uitslag van de NVWA moet dus naast die van het bedrijf te leggen zijn. **Deze ingevulde lijst dient, tezamen met alle STEC uitslagen van die maand van zowel het bedrijf als de NVWA, in pdf-formaat digitaal verstuurd te worden naar export@nvwa.nl (in de onderwerpregel vermelden: USA STEC uitslagen) voor de 10de van de eerstvolgende maand.**

Stap 1	Selecteer een product
Uitleg	Bekijk de lijst met de naar USA te exporteren producten en zorg er voor dat alle producten minimaal 1x door de NVWA geverifieerd zijn in de loop der tijd. Kies een product en ga in de volgende stappen te werk met als uitgangspunt het gekozen product.
Product	
Stap 2	Verifieer de monitoring
Uitleg	Indien er in het productie proces een CCP is ingericht specifiek voor het beheersen van STEC (Fecale bezoedeling, antimicrobiële behandeling of additieven) dan dien je te verifiëren of de monitoring plaatsvindt volgens de vastgelegde procedures.
Bevind.	
Stap 3	Verifieer de STEC verificaties
Uitleg	De bedrijvenbeheerder controleert of de door het bedrijf vastgelegde procedures voor monstername ook zo als beschreven uitgevoerd worden. Dus, meekijken met een monstername van het bedrijf. Beoordeel tevens de testuitslagen en kijk of bij afwijkingen de door het bedrijf vastgelegde corrigerende maatregelen ook zijn uitgevoerd.
Bevind.	
Stap 4	Verifieer de STEC registraties?
Uitleg	Beoordeel alle STEC uitslagen. Kijk hierbij ook of wel alle monsternames hebben plaatsgevonden volgens het STEC monstername plan van het bedrijf. Juiste frequenties en producten.
Antw.	

Stap 5	Verifieer de corrigerende acties?
Uitleg	Controleer of in geval van afwijkende resultaten van het bedrijf en/of NVWA de juiste corrigerende maatregelen zijn genomen zoals deze zijn vastgelegd in de procedures van het bedrijf en de NVWA
Bevind.	
Stap 6	Verifieer de pre-shipments
Uitleg	Controleer of de pre-shipments allemaal uitgevoerd zijn en controleer ook of er geen claims of instructies (bijv. "zorgvuldig verhitten", "niet rauw consumeren", "voor consumptie behandelen", etc.) meegestuurd worden waarmee het bedrijf zich denkt vrij te waren van verantwoordelijkheid.
Bevind.	
Stap 7	Handhaving bij non-conformiteit
Uitleg	In een geval van een non-conformiteit (overtreding/niet voldoen) dient afdeling export op de hoogte gebracht te worden middels export@nvwa.nl (Betref: USA STEC verificatie). Indien er een overtreding heeft plaatsgevonden op basis van Europese wetgeving dient er tevens een rapport van bevindingen opgemaakt te worden. Deel in alle gevallen de bevindingen met het bedrijf
Bevind.	

Datum:	Handtekening:

Annex 1: SAMPLE COLLECTION PROCEDURES

I. N-60 methode

Bij de N-60 methode wordt bemonsterd door het afsnijden van reepjes oppervlakte vlees van 1 bij 3 inch en 1/8 inch dik (25,4 x 76.2 mm en 3 mm dik)

Deze methode is geschikt voor:

•Beef components te vertalen met: vleesdelen

•Beef manufacturing trimmings te vertalen met: uitgesneden vlees

•Bench trim te vertalen met: afsnijdsels*

* *De USA heeft dus een andere definitie van wat onder "trimmings" wordt verstaan.*
Indien de te bemonsteren partij te kleine stukken omvat moet de zg. "grab" methode gebruikt te worden.

Benodigdheden

- Transportbakje
- Sprayfles met alcohol
- Mes
- Aanzetstaal
- Vleeshaak
- Steriele handschoenen
- 2 whirlpack zakjes

En aanbevolen:
Monsterzakhouder

Voorbereiding:

1. Neem kennis van het N-60 bemonsteringsschema van het bedrijf en plan je verificatie monstername in, minimaal te reserveren tijd 30-60 minuten afhankelijk van de partij en je eigen ervaring.
2. Controleer of je monstername set compleet is.
3. Controleer of er die dag een koerier beschikbaar is die de monsters dezelfde dag kan afleveren op het lab.
4. Maak van te voren afspraken met het bedrijf voor goede omstandigheden voor de monstername, een ter beschikking van de NVWA staande snijplank/tafel is wel het minimum.
5. Uitzondering hierop kan zijn bemonstering rechtstreeks uit Dolav's, zolang maar hygiënisch gewerkt kan worden[6].
6. Meld je op de werkvloer bij degene van het bedrijf die de bedrijfsmonsters neemt.
7. Spreek duidelijk af welke partij/batch bemonsterd gaat worden.
8. Registreer in eigen administratie welke partij/batch bemonsterd wordt (dit in verband met controle op de blokkering).

Uitvoering

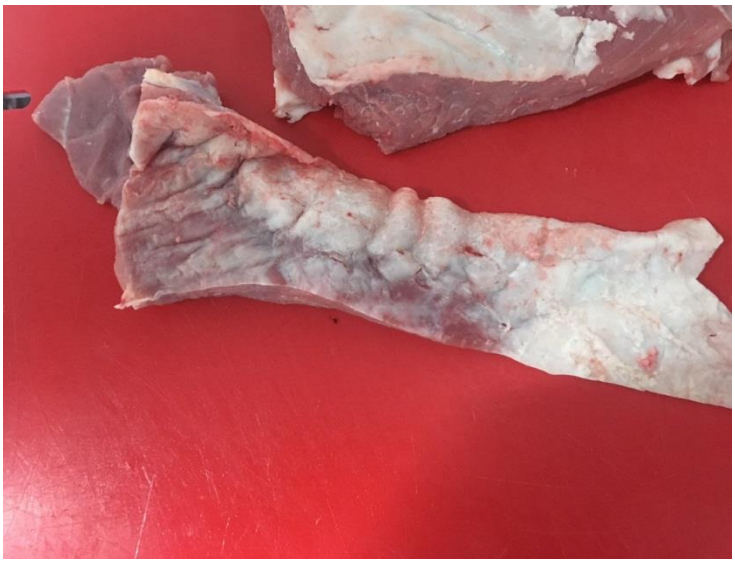
Principe van een verificatie onderzoek is dat niet alleen dezelfde partij wordt bemonsterd maar dat de monstername gelijktijdig met het bedrijf plaats vindt teneinde ook de correcte uitvoering door het bedrijf te verifiëren. (dus geen monstername op een tafel nat van de alcohol bv.)

Start met het ontsmetten van de eigen werkplek, gebruik hiervoor de alcohol spray en laat het oppervlak drogen of maak dit droog met daarvoor geschikte middelen. Ontsmet de te gebruiken gereedschappen met alcohol.

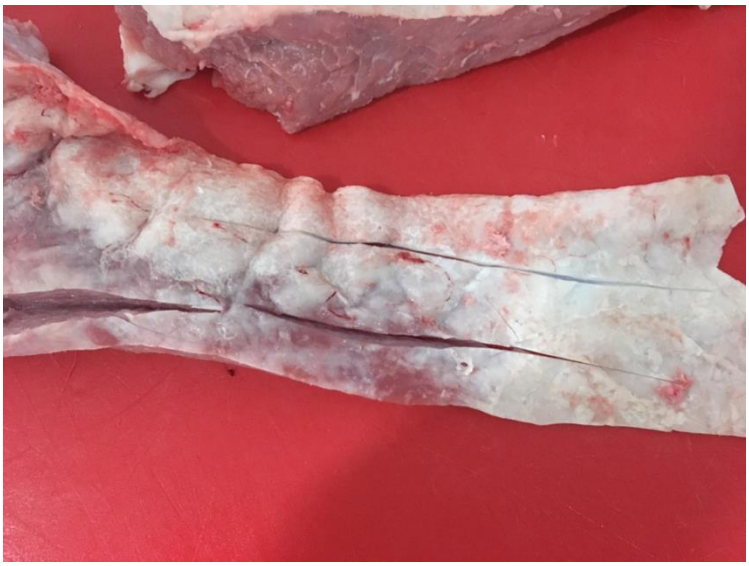
[6] *Met de huidige bedrijfsprotocollen niet waarschijnlijk*

Plaats een monsterzak in de houder en houdt de tweede zak gereed.
Doe nu de steriele handschoenen aan en droog zo nodig nog de gereedschappen.
Vergeet ook niet het aanzetstaal te desinfecteren! Dit zal je zeker nodig hebben tijdens de monstername, een goed scherp mes is een absolute noodzaak om goed te kunnen werken.

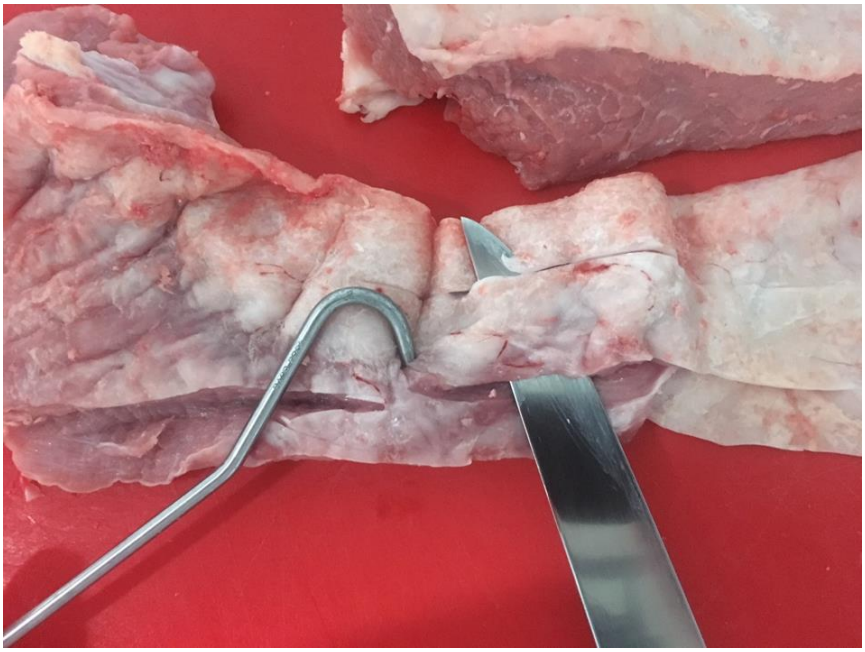
Pak, bij voorkeur met gebruik van de vleeshaak een vleesdeel uit de bak en leg dit met het uitwendige oppervlak op tafel



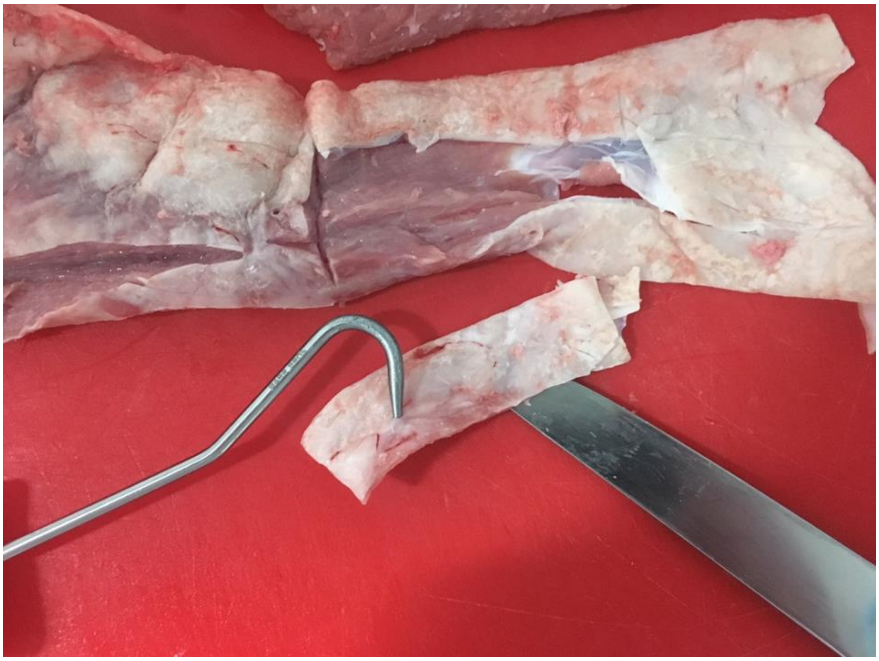
Maak 2 evenwijdige insnijdingen in het oppervlak met 2,5 cm tussenruimte. Maak de insnijdingen wat langer dan het benodigde deel.



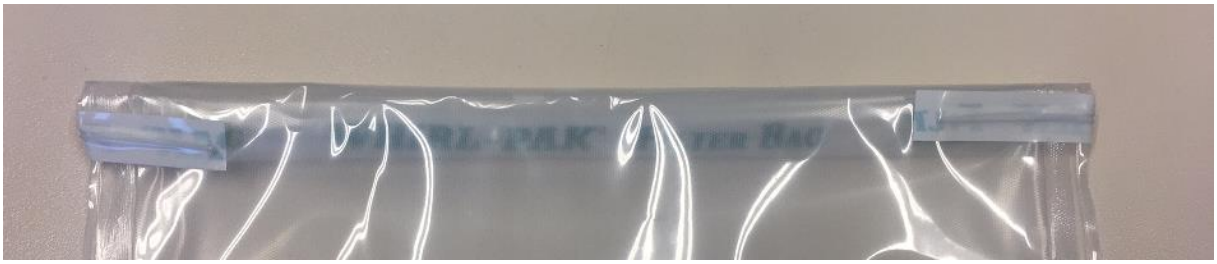
Plaats de vleeshaak links tussen het begin van de insnijdingen (rechts voor linkshandigen) en steek de punt van het mes 3 mm onder het oppervlak door het vlees heen vanuit de ene naar de andere snede.



Houdt het vlees met de vleeshaak onder spanning en snijdt met het mes een 3 mm dik plakje oppervlak los. Hierbij is het essentieel dat het mes goed scherp is.



Snijdt uiteindelijk het losgesneden deel op lengte en plaats het in de monsterzak.
Verzamel op deze wijze 2 x 30 monsters in de monsterzakken.
Na het vullen van de monsterzakken de lucht zoveel mogelijk uit de zak drukken en de zakken sluiten door de bovenzijde 4-5 keer om te slaan en de beide uiteinden om te buigen.



Na de monstername

1. Blokkeer de bemonsterde bakken met snippers en laat deze in de BO cel opslaan totdat de uitslag bekend is.

2. Voer de monstername in in Labvantage:

(E-formulier: Projectnummer geldig voor 2018, dit wisselt per jaar)

3. Gebruik voor verzending van de monsters een omzak van het juiste type en vermeld het nummer hiervan op het inzendformulier.

4. Plaats de monsters in de koelkast in afwachting van de koerier.

II. Grab methode

Een "grab sample" is gedefinieerd als een monsternametechniek waarbij een enkele monstername of meting wordt gedaan op een specifiek moment en tijd.
Voor de STEC verificatie wordt dit toegepast op partijen of batches die bestaan uit delen te klein voor de N-60 methode of voor producten waarbij de N-60 methode niet uitvoerbaar is zoals bijv. bij organen.

Benodigdheden Grab Methode

- Steriele handschoenen
- 2 whirlpack zakken

Voor grote organen:

- Mes
- Ontsmettingsdoekjes o.i.d.

Voor de verzending dient ook hier gebruik gemaakt te worden van een omverpakking met verzegelings-nummer, in een door het lab voorgeschreven model.

Voorbereiding Grab Methode

Deze is verder geheel gelijk aan de voorbereiding bij de N-60 methode.
Enige verschil is dat de Grab methode over het algemeen aanzienlijk minder tijd zal kosten.

Uitvoering Grab Methode

Vlees snippers:
Open een whirlpack zak en neem met de andere hand voorzien van steriele handschoen meerdere snippers van verschillende plaatsen, zoveel als mogelijk van externe delen (dus oppervlakkige delen) en vul hiermee de whirlpack zak tot halverwege. Eventueel kan gebruik worden gemaakt van een vlees haak, deze moet dan wel ontsmet kunnen worden.

Vul de tweede zak op gelijke wijze.

Organen:
Gebruik wederom steriele handschoenen en vul de zak met één of meer organen om de zak tot halverwege te vullen.
Bij grote organen zoals een lever, snijdt met steriel mes een voldoende groot stuk af om de whirlpack zak tot minimaal halverwege te vullen.
Vul wederom de tweede zak op gelijke wijze.

Afhandeling Grab Methode

De verdere afhandeling van de beide Grab monster zakken is gelijk aan de N-60 methode.
Ook het invullen van het inzendformulier is identiek, matrix blijft gewoon “vlees”.

III. Blokkeren van de bemonsterde batch/partij

Volgt

Annex 2: DIVERSE

I. Important Information and Material for training purposes

See the FSIS film: STEC Sampling of Domestic Raw Beef Products

II. Background information/Achtergrondinformatie

FSIS Directive 10,010.1 FSIS Directive 10,010.2