Barretos - SP, 26th October, 2016.

LOT CONTROL PROTOCOL FOR EXPORT

OF TRIMMINGS AND CUTS INTENDED FOR GRINDING TO USA

1. Objective:

After the recognition of equivalence of the brazilian Sanitary Inspection System by the United States Department of Agriculture - USDA, national establishments must meet specific requirements established by the Ministry of Agriculture, Livestock and Supply (MAPA) to export fresh beef to the US.

One of the requirements is the monitoring of the presence of Shiga Toxin-Producing *Escherichia coli* (STEC), serogroups O157:H7, 026, 045, 0103, 0111, 0121 and 0145 and *Salmonella spp.* in 100% of lots of trimmings and cuts for grinding intended for export to this country.

2. Definitions:

2.1 Fresh beef likely to export to the US:

Meat obtained from pieces of boneless beef carcasses that has been kept attached to the carcasses during chilling, removed during deboning, ie boneless cuts and trimmings, excluding the hump.

Industrial meat (meat obtained from the slaughter room as head meat, cheek, bleeding meat and esophagus), offals and bone-in beef also are excluded from this definition.

2.2 Shipping Mark:

Sequence of numbers or letters, or combination of both which identify the products of a single loading by the exporting establishment. This unique brand is used to relate the product to the international health certificate to which it belongs.

2.3 Microbiological independence

According to the established by FSIS (67 FR 62325, October 7, 2002) when one lot of trimmings results positive, the batches composed from the same raw material source would likely be implicated. Thus, it is expected that the establishment has a scientific basis which justify the reason that any product derived from such raw materials should not be considered adulterated.

One way to avoid the results for one lot implicating another is to ensure that the lots are microbiologically independent.

In order to establish independence between lots, establishments could meet the following requirements:

- Preventing cross-contamination between carcasses by application of sanitation procedures during operation and handling of these.
- As the sampling plan established by the Memorandum 63/2016/CGCOA/DIPOA/SDA/GM/MAPA is very restrictive, since it provides sampling (N = 60) every hour, covering all production lines, a high confidence level of detection of positive results is given when the STEC and/or *Salmonella spp.* are present in a lot.
- Ensuring that the product or rework of a given production period is limited to this period, in order to prevent that possible contamination could be carried to another production period (lot) and so, that different lots are implicated in the case of a positive result.
- Conducting Sanitation Standard Operating Procedures in production intervals as a control measure to prevent the spread of STEC / *Salmonella spp*. cross-contamination of a production period (lot) to another.

2.4 Lot:

According to the Memorandum 63/2016, the lot is representative of a defined production unit, clearly identified and distinguished from other units. It is produced in a given period without flow interruption or changes that may lead to a part of the lot differ significantly from other. The lot is complete, includes reworks, is available for inspection and testing and is traceable from origin to distribution.

Lots is defined so that if a positive result is found from one lot, the product in other lots is microbiologically independent and is not implicated.

Considering the above requirements for Brazilian establishments authorized to export to the US, the lot is defined as all the boxes or packages of trimmings or cuts intended for grinding produced by the establishment in a given production period separated from other periods by interventions.

Intervention means the treatment required to establish microbiological independence of a specific period production with respect to another. Examples are sanitation operating procedures performed in the production breaks for lunch, dinner and shifts exchange.

2.5 Lot identification in the products

All boxes of products that compose a lot should be clearly labeled with a unique identification, which is capable of distinguishing this lot from others.

The products are identified on the label with a code composed by: Lot number to which they belong, the product code number and production date.

3. Key points:

Requirements of a lot:

- It should provide a unique identification;

- It could be divided into different shipping marks;

- It could be shipped in different containers.

One shipping mark could be composed of one or more lots (in the same container). However, each individual lot should be tested negative, according to the sampling plan established by the Memorandum 63/2016.

4. Sampling Plan to trimming / cuts intended for grinding:

All products lots intended to US are sampled (N=60) for STEC, serogroups O157: H7, 026, 045, 0103, 0111, 0121 and 0145 and *Salmonella spp*.

It should be collected at least one sample every hour, to cover all production lines, according to Memorandum 63/2016/CGCOA/DIPOA/SDA/GM/MAPA.

Samples should be taken from the product surface (parts more exposed to contamination), avoiding excess of fat.

Each sample should be of a size 3 cm wide, 8 cm length and 0.5 cm thick, weighing about 5 to 10 grams, a total of 60 pieces, with a final weight of 325 grams minimum.

Tests for STEC comprise three steps:

a) first stage - consists of "PCR Screening Test" to detect potentially positive result;

In the case of a negative result in this first step, analysis procedures will be completed and therefore the products of this lot will be released.

In case of a positive result in this first step samples are considered potentially positive and additional tests will be required for confirmation. If the company chooses to use only the Screening Test, without performing the confirmation, the result is considered positive and a second Screening Test (retesting) could not be performed in the product, because it is not a conclusive test.

In this situation, the trimmings and cuts intended for grinding with the same lot should be submitted to a treatment that inactivate STEC. The heat treatment should be sufficient to ensure complete destruction of pathogens (*Salmonella* reduction of 6.5D or more severe, since this pathogen has comparable thermal resistance of STEC). Another possible option is the destination of products to rendering.

If the establishment opts for confirmation of the potentially positive result in PCR Screening Test, this analysis should be performed in an accredited laboratory by MAPA, where the second and third stages will be carried out as detailed below:

b) second stage – consists in the isolation and reaction with antigen to detect the presumably positive;

c) third stage - consists of serologic or genetic determination for detection of the confirmed positive serogroup.

The analyses for *Salmonella spp.* comprise a single step, which consists of "PCR Screening Test" to detect positive.

Only lots with negative results in tests for STEC and *Salmonella spp.* could be destined to the US. The results of these analyses will be presented routinely to the Federal Inspection Service (SIF) present in the establishment as supporting documentation to international health certification.

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