



Part 2

Answers to the Commission's Recommendation to the Competent Authority content on the Inspection Mission's Draft Report carried out between February 18 and March 1, 2013 (reference number DG (SANCO) 2013/6865.

In relation with the recommendations given to the competent Authority (SAG) indicated on the draft report of the Inspection Mission, below you will find the actions already carried out and the ones to be carried out, including the time deadlines for the implementation of this measures.

Finally, you will find by the end of this document a Summary table with the action Plan to overcome the Mission's observations.

Recommendation N° 1

Through Circular N° 120 dated February 15, 2013 (attached), it was established the verification frequency of the habilitation requirements for holdings wanting to export to the EU and it was define the habilitation guideline for such market, as an instrument to carried the verifications out,

Since, the conditions of EU regulation compliance are certified at the moment of the export, it has been determined to carry out one annual verification, through the application of the current existing habilitation guideline. For establishments that have not been exporting during the last twelve (12) months, the guideline will be applied every four (4) months.

It has been planned the realization of training workshops aimed to Exports Regional Supervisors and to the Official Inspections Team Chief. These training courses will be carried out during the third and fourth trimester of 2013, what has been informed to some regions by Circular N° 278 dated May 16, 2013 (attached), and its scope in order to consider ungulates requirement, will be extended to the rest of the country during the month of June 2013.

Recommendation N° 2

It was carried out an improvement on SIPEC data base, with respect to the management of the ID/PABCO Agreement. This will let regional Authorities to manage (incorporate/eliminate) multiples RUP, of the same holder, associated to an ID/PABCO Agreement. This functionality is operative since the second week of May 2013.

Recommendation N° 3

The actions taken to give answer to this recommendation, are based fundamentally on regulatory changes, **establishing the obligation on the use of the SIPEC data base by the holders of the establishments belonging to the Bovine PABCO program level A, authorized to export to the EU**, not existing the possibility to generate movements of animals that have not been previously registered on each of the holdings.

On this sense the following action have been taken:



- The traceability regulation N° 3.423 of 2008, has been modified by Resolution N° 2927 of May 17, 2013 (Attached), on which definitions for Provider, Distributor and buyers of the identification rings, DIIO, are included, specifying for each of them, the obligations and responsibilities that they will have when entering the information on the SIPEC data base.
- In addition, the modalities for the verification of the DIIO application are define, measure that will ensure the correct and timely entry of the information to the System, avoiding traceability distortions of animals. The improvement within the System will be operative by May 31, 2013.
- A new PABCO Resolution has been elaborated, Resolution N° 2948 May 22, 2013 (attached) that establishes the obligation to the owner of a holding to register the traceability information on the SIPEC data base, such as, holding registration, animals identification, animals movements and the control on animal inventory. Additionally, by this same mean, changes or incorporation of a new Authorized Veterinary Doctor (MVA) must be informed, whether it's permanent or for a given period of time.
- In addition to the measures already mentioned above, measures for the verification and supervision of the EU requirements have been established on official documents such as:
 - Modification of the PABCO evaluation Guideline (Pauta F-PP-IT-050), that is applied by the MVA to the holding. The purpose of this modification is to strengthen the verification of traceability within the PABCO program, and the use of strictly veterinary medicines, based on practical exercises that the MVA will have to carry out during the supervision visits.
 - The elaboration of a new Supervision Guideline MVA (Pauta F-PP-IT-060), that is applied by the Official Veterinary Doctor (MVO), with the purpose of auditing and strengthening the verification carried out to Bovine PABCO holdings, level A. This guideline is based on the evaluation of 5 items where the fulfillments of the MVA obligations are valued and the correct application of the evaluation guidelines on aspects such as infrastructure, traceability, feed, cattle management and veterinary medicines. It also includes the sanctions for the infringement of the requested actions.

Recommendation N° 4

The measures taken to give answer to this recommendation are based on the addition of a column with the information of the safeguard periods at the animal consultation window within the SIPEC data base. This System is additionally supported by SAG's official information, showing registered or authorized medicines by SAG. These modifications allow warnings to different stake holders along the production chain, when animals had not fulfilled with the safeguard periods after the application of a treatment, furthermore, it does not allow the movement of animals when the destination is a slaughter facility.



Additionally, the modification to the PABCO Evaluation Guidelines (F-PP-IT-050 attached to this document) and the new MVA Supervision Guidelines (F-PP-IT-060, attached to this document), have an auditing character and will enable on field verification in greater detail, regarding the use of veterinary medicines relying on the registers of entry and the use of veterinary medicines that the holding possesses.

Recommendation N° 5

With the aim to correct the deficiencies detected and to improve the Control Systems of SAG, by Circular N° 278 May 16, 2013, it has been communicated, on a first stage to some Regional Offices, that in order to consider the unguulates specifications there will be guidance workshops for Regional Supervisors and Team Chiefs, regarding the interpretation and application of the “Hygiene Package”. This will be extended to the rest of the Regions of the country by the month of June 2013. The workshops that will be developed during the indicated period will focus specially on the following subjects:

1. Regulation (EC) n° 853/2004 laying down specific hygiene rules for food of animal origin.
2. Regulation (EC) n° 852/2004, on the hygiene of foodstuffs
3. Traceability
4. HACCP evaluation
5. Issuance of noncompliance notifications (criteria)

Latter to the Workshops, follow up visits will be carried out to the Regions and holdings.

Additionally, an auditing team at the central level has been formed to follow up the results of the regional audits to bovine meat export slaughter holdings, authorized to export to the EU. This working group will developed its activities during the month of May to end up during the first week of June 2013.

The control System efficacy, will be verified periodically through the Supervision of the Official Integrated Inspection System (SIO)

Response to the FVO assessment of the action plan presented by the Chilean Competent Authority on May 30 in response to Report ref. DG (SANCO) / 2013 – 6865-MR on the audit carried out between February 18 and March 1, 2013 to evaluate controls on the production of fresh bovine, ovine and pig meat, meat products and tripe for export to the EU and associated certification procedures.

We have made the following adjustments to previously implemented steps in order to ensure full compliance with the recommendations.

Recommendation No. 2

On improving the PABCO (Animal Herds Under Official Certification) system for ovine holdings and animals and ensuring that all exports have only one PABCO ID/agreement number and that all animal movements are accompanied by a movement document in accordance with the requirements set out in the legislation by the national authority to comply with traceability requirements in the PABCO Program and European Union Regulation (EU) No. 206/2010, and to be able to certify all the specifications of the OVI certificate that is established in Regulation 206/2016.

- A. This process does not require additional time to associate every RUP (Livestock Identification Numbers) with each ID/agreement. This information is already on the system, although it is kept separately (there is an ID/agreement number for each RUP that is recorded when the herd owner makes the application), therefore, an IT process is only needed to associate the information (of each RUP to its corresponding ID/agreement) as required.

Information shall be updated at the Central Level to ensure that all PABCO ID/agreements are associated with the RUP that belong to them.

In addition to associating RUP numbers, this process also included corroborating suspension and deletion dates and associating the Assessments that the Authorized Veterinarian (MVA) has carried out of herds (Guideline F-PP-IT-050) with the corresponding ID/agreement number, which will allow all the Assessments carried out by the MVA in any of his or her RUP's to be reviewed by any associated MVA:

On the other hand, while the information for reconciling animals in regions is updated, the information held that is held regarding the PABCO ID/agreements will be reviewed and checked with the back-up documentation that is kept in each SAG office in order to guarantee that the information on each establishment in the PABCO agreement is up to date.

- B. Regarding the control of sheep movements, Law No. 20,596 of 2012, which "Improves supervision to prevent livestock theft" establishes that all animal movements or shipments, including sheep shipments, must be accompanied by the official SAG Animal Movement Form, and that the driver of the means of transport or the person responsible for the cargo shall be obliged to carry this form throughout

transport and to hand it over to the recipient of the shipment when transport is complete.

This document shall be distributed as set out in the regulations regarding the Official Animal Traceability Program and shall be kept among the PABCO herd's records as a back-up document.

Recommendation No. 3

On urgently improving official controls of the PABCO A System to ensure that all the deficiencies regarding animal identification, animal movement and notification of events on the SIPEC database are detected, properly corrected and monitored by authorized and official veterinarians, in order to ensure that all cattle that is slaughtered for export to the European Union can certify compliance with all the requisites and specifications outlined in the BOV certificate that is established in Regulation 206/2010.

- A. An annex establishing sample sizes has been added to the PABCO Assessment Guideline (Guideline F-PP-IT-050) to be used by the MVA when assessing herds.

The sample shall be verified using a table with a critical prevalence of 5% and a confidence interval of 95%. This allows us to infer that if at least one animal of those selected for verification using the table does not coincide with those registered on the SIPEC website; the failure rate for that establishment's Official Individual Identification Devices (OIID) is at least 5%. Consequently, in this case, the non-compliance would be recorded in the corresponding section of the guideline. Otherwise, if differences are not detected in the sample verification, we may infer with a confidence level of 95% that the OIID record failure rate, if such a record exists, will be less than 5%.

In this way, a minimum number of animals shall be selected at random from the total animal population present on the (RUP) holding for verification with the records held on SIPECweb, in accordance with the following table:

Minimum sample size adjusted for RUP animal population in order to detect at least one animal that is not registered on SIPECweb.

Total population on a holding (RUP)	No. of animals to be selected for the sample
1– 50	31
51– 100	45
101– 150	46
151– 200	51
201– 250	51
251– 300	53
301– 350	53
351– 400	55
401– 450	55
451– 500	56
501– 600	56
601– 700	56
701– 800	57
801– 900	57
901– 1.000	57
1,001–2,000	58
2.001 – 3.000	58
3,001 – 4,000	58
4,001 – 5,000	59
5,001 – 6,000	59
6,001 – 7,000	59
7,001 – 8,000	59
8,001 – 9,000	59
9,001 – 10,000	59

For those establishments (RUP) with more than one group of animals, which may be geographically distant from each other due to the size of the holding, each group shall be separately listed and identified with its corresponding animal numbers, in order to determine each group's percentage of the total herd on the holding in order to verify a sample taken in a representative way.

In order to decide how many animals to select from each group in the RUP, the percentage of each group shall be multiplied by the sample size given in the table above. Each group's sample shall be randomly selected.

Finally, the total number of animals selected shall coincide with the sample size for the RUP's total animal population (table).

As stated in Technical Instruction I-PP-IT-015 of the PABCO Program for cattle, the verifications shall be carried out by the MVA with a frequency of at least three times (visits) per calendar year, to take place every four months, and to be delayed for no more than one month.

In the case of the Magallanes and Aysén regions, because of their climate and geographical conditions due to the fact that they are extreme regions, these verifications may be spread throughout the year as appropriate for the livestock activities that are carried out in the region. Therefore, physical verification of animals in these regions shall take place once a year, using the same sample size and verifying the total number of animals set out in the table above, either during a single visit or in partial samples, which shall be outlined in each of the Assessment guidelines to be applied.

- B. The same steps have been included in the MVA Supervision Guideline (Guideline F-PP-IT-060) that is applied by the Official Medical Veterinarian to audit and boost verification of A level PABCO bovine herds.
- C. All producers shall have passwords for the SIPECweb. In accordance with the provisions of Resolution No. 2,948 of May 22, 2013, all producers that participate in the PABCO program must request a username and password so that they can enter the system and do the following:
 - a. Register and update information on the establishment.
 - b. Carry out and register the Animal Stock Statement
 - c. Register the OIIDs that are applied in the establishment, and related removals and changes
 - d. Register animal movements in the establishment and confirm entry movements, if applicable
 - e. Register incorporations and changes to the herd made by the Authorized Veterinarian (MVA).
- D. The SIPEC database has a range of IT validation tools for to detect data entry errors or data entry after deadlines, thereby ensuring that all obligations and/or restrictions set out in the regulations for the Traceability and PABCO Programs are enforced in the IT system.

Messages inform the user of the aforementioned validations. An error message appears if a user is not allowed to carry out an action, and a warning appears if an

action is allowed but entails a consequence, for example, the loss of a condition, and the user will then use his or her discretion to make the decision.

Furthermore, in order to further improve the quality of the data entered into the SIPEC database and to encourage trust among users, a new function has been created to lock RUPs that consists of disabling the ability to carry out actions on a locked establishment's data. This ensures that any action regarding a locked RUP's data may only be carried out by the said establishment's Owner.

It should be noted that SAG may only see a locked establishment's data and may not carry out any action to alter the said establishment's data.

For this reason, as of June 1, only establishment owners may carry out the following actions to add, delete or modify data on their locked RUP.

- Establishment data: Background information (Name, Address, Location and others), data on associated people (Owners, MVA, Contacts and others), Classification data (Type of holding, species and others) and other information.
- Animal data: OIID purchase/sale records, OIID removals made without application, Official Individual Identification Form (OIIF) records (applications, changes and removal of animals with OIIDs), and data on animals with OIIDs.
- Animal movements: movements of animals with OIIDs or group movements groups to or from a locked RUP, Movement reversals, Movement deletion or editing by group, documentary verification of movements, Pending receptions.
- Animal Stock Declarations (DEA): Entry of new DEAs, Deletion or Editing of Current DEAs.

E. A level PABCO bovine establishments authorized to export to the EU.

A new TEMPORARY "VALID FOR THE EU" STATUS has been created in the Livestock Information System, SIPECweb for the A level PABCO Bovine Program that shall incorporate all establishments currently able to provide animals for the EU market.

The establishments that acquire this STATUS shall be all those that participate in the A level Bovine PABCO program and that have fully addressed their non-compliances and updated their information in the SIPECweb system.

Finally, we can state that 169 A level bovine PABCO holdings are eligible to export to the EU from the current total of 1,429.