

EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Veterinary and International affairs **Multilateral International relations**

Brussels, 28.05.2014 SANCO PL/BS/mpd (2014) 1644942

NOTE FOR THE FILE

Subject: Minutes of the Expert Group on Veterinary Checks – 28.03.2014

Present: All Member States except Croatia, Cyprus, Denmark, Estonia and

Malta

Iceland, Norway and Switzerland

Commission Personnel (COM): DG SANCO: Patricia Langhammer (G6), Bruno Saimour (G6), Izaskun El Busto Sanz (F5), Frank

Swartenbroux (E3), Jan Bloemendal (G7);

DG TAXUD: Valerie Enjolras, Pedro Martinez Martin (both B1)

Introduction

After the distribution of the Agenda, several points were added prior to the meeting – Agenda as attached. In addition COM reminded MS of the following:

COM raised the attention of the participants to imports of L-Cysteine from China, which is not listed in the Annex to Decision 2002/994/EC. COM clarified that ONLY the products listed in the Annex to that Decision can be exported from China, independent if they are pure or part of composite products. COM will work on a revision of that Annex, however, until the adoption of a revised Annex, the current version needs to be respected.

1. REVIEW OF LEGISLATION

COM informed that the first reading of the draft Official Control Regulation (OCR) in the Council's Joint Working Party of Veterinary Experts (Public Health) and Phytosanitary experts continued and will be finished in mid April (14 – 15.04.2014 next sessions). COM appreciated that MS provided their comments to the OCR well in time which enabled constructive discussions of the comments in the relevant Council's Joint Working Parties. COM started already to work with the Council Presidency and the Council Legal Service on a revised version of the document, which will then be presented for the second reading.

COM is working in parallel on the comments from the European Parliament (EP), in particular on the amendments voted on 20.01.2014 by the Environment Committee of the EP. The next step is the vote in the Plenary of the EP on 15.04.2014.

There were no comments from MS and COM concluded that the adoption of the OCR should be end of 2015.

2. COMPOSITE PRODUCTS

COM informed that the draft guidance document on composite products presented to the last working group had as well been presented to the working group for Food Hygiene on 24.01.2014 and to the Public Health section of the SCFCAH on 21.01.2014. In both meetings MS provided positive feedback. COM clarified several questions raised by MS and asked for comments in writing. Since then comments from four MS (DE, NL, PL, UK) were received and it seems that most MS are satisfied with the document.

As some written comments related to the requirement for an approved residue control plan for the third country of origin of any relevant ingredient of animal origin (processed or unprocessed), COM clarified in above meetings that this requirement emanates from the application of the Residue Directive (Directive 96/23/EC). That Directive is the legal basis for any relevant product of animal origin contained in a composite product to originate from a third country with an approved residue control plan for the relevant product type. When drafting the amended certificates for Regulation (EU) No 468/2012, the Legal Service has stated that there is no need to include in the health certificates a reference to Directive 96/23/EC as the obligation for animal products originating from third countries with an approved residue control plan is clear from that Directive.

Some other written comments were raised about the difference between food supplements and pharmaceutical/medicinal products. COM clarified that this difference depends on their production. If the composite products meet the conditions for medicinal products as defined in Article 1(2) of Directive 2001/83/EC, they do not need to be presented to BIPs. If they do not fulfil the requirements of Directive 2001/83/EC, they need to be presented to BIPs and could be considered as food supplements. In that latter case, the requirements of Regulation (EC) No 1924/2006 (nutrition and health claims on food) must be respected.

COM reminded that the composite products which are not subject to veterinary checks in BIPs have to be controlled regularly on the basis of the multi-annual national control plan as provided for by Article 15 of Regulation (EC) No 882/2004. MS should decide which competent authority should be responsible for such controls and at which stage of the distribution chain such controls are likely to produce the most meaningful result for composite products originating from third countries. Food business operators have the responsibility to guarantee the compliance of imported consignments and to provide the relevant documented evidence in case of control by the competent authorities in MS.

ES explained that a number of composite products were rejected in their BIPs because the ingredients of animal origin contained in the composite products were not produced in approved third countries. In such cases, ES wondered which document should be requested to prove the origin of the ingredients. COM answered it is the food business operator's responsibility to provide any relevant document. If there is any doubt about the authenticity/understanding/relevance of the documents, MS may ask the competent authorities of third countries for any additional information.

DE proposed to add several columns (reference of health certificate, type of commercial document, check or not in BIP) in the Annex providing some examples, so that it could be used as a decision support by the BIP. COM disagreed and explained that these examples are not rules but illustrations only. The Annex should remain as such as the evaluation to decide for a composite product or not is based on the individual product and its composition and should be based on a case by case decision.

COM asked MS for comments by 04.04.2014 and explained that the draft guidance will be sent to the Legal Service for consultation. Then it will be a last time presented to SCFCAH and it is planned to be published before summer break.

3. RE-ENFORCED CHECKS IN TRACES

COM reported that incidents with importers are more and more frequent on the weight limit rule of consignments under REC. COM reminded MS that BIPs shall not provide information to importers concerning the weight of the consignment that triggered the REC. The rule of 10% was introduced in TRACES to avoid that importers can distort controls by sending underweight consignments so that a REC could be lifted faster. By providing operators with such confidential information, they are given the possibility to start such bad practices. MS are reminded that, even if the underweight consignments are not counted in the REC series, they may be sampled and tested according to Article 20 of Directive 97/78/EC, if the BIPs consider necessary.

COM emphasized the importance of the quality of data in TRACES, especially in relation with the REC procedure. In case of a RASFF notification following an unfavorable control result, it is important to input right data in the system so that the REC procedure can be launched properly. For example, Box 6 in the RASFF/Hazard tab shall be fulfilled with the nature of hazard which has to be tested during the REC. In case of laboratory test, the analysis result must match with the physical check result (an unsatisfactory laboratory result requires to change the physical check result to unsatisfactory in TRACES). Otherwise, the result in REC series is wrongly registered as "Satisfactory" and the following series are not launched.

4. TRANSIT/TRANSHIPMENT

COM thanked MS for replies related to the need of specially approved warehouses in the port of destination for non-conforming consignments awaiting the delivery to the ship (Article 13(2)(a) of 97/78/EC) and an empowerment provision has been included in the draft Official Control Regulation. This will allow drafting the necessary secondary legislation for customs warehouses.

COM informed that after the last working group no further contributions to amend the guidance for transit and transhipment have been received.

COM reported that they met on 10.02.2014 the US Command Region Europe and that public health staff working in US bases in the EU received training concerning the use of TRACES for non-compliant consignments arriving in the US bases. It was agreed to expand the system in place for transit consignments from the current 3 US bases in Germany to 12 other US bases located in Germany, Spain, Italy and Greece and to introduce the same monitoring and feedback mechanism in TRACES for these bases. It

was agreed to start with consignments of fresh meat and to continue then with other products of animal origin. COM will provide detailed information to the relevant BIPs as soon as the 12 US bases are included in TRACES and their staff is ready to carry out the controls on the non-conforming consignments.

While IT asked to add specific reference for collecting fees for transhipped consignments in the Guidance Document, COM replied that this should be solved on national level based on the costs of the controls carried out. IT asked when for mixed consignments CN code 9930 indicated in Chapter 5.3.4 of the Guidance could be used in TRACES and COM promised to provide further information on this.

After consultation with the TRACES team, COM confirmed that CN code 9930 is not yet in TRACES but will be introduced and available once TRACES-NT will be launched.

5. CHECKS OF INSECTS AT BIPS

COM informed that following point 6 d) on veterinary checks on Drosophila melanogaster for research on the Agenda of the last meeting of 11.12.2013, only one MS provided feedback and replied that there were no such imports during the last 3 years.

Therefore COM considered there is no problem with such consignments. However, COM provided further clarification to MS reminding them that the pre-notification requirement should be respected to ensure rapid veterinary checks. In addition, there are exemptions in the application of the identity and physical checks for certain categories of animals including bees and other insects. As such animals are presented in packages/containers, the identity check must at least consist of checks on the labels of a representative number of packages/containers and a visual check of the animal for verification of the species. Insects are not subjected to individual clinical examinations, especially if they have a specific health status for scientific purposes. As a conclusion, provided that no particular health risk is identified, sealed containers for research or scientific purposes do not need to be opened.

6. OVERVIEW OF BORDER CONTROLS AGAINST ASF

COM (FVO) presented the main findings and conclusions of a series of audits related to the specific controls against African Swine Fever at the borders of certain MS.

COM (FVO) reported on the unsatisfactory outcome of an audit to India regarding the residue control system for aquaculture products. The effectiveness of the Indian system relies mainly on pre-harvest and pre-export testing programmes in place. In spite of these programmes, RASFF notifications for residues of banned substances (nitrofurans) in farmed shrimp continue, albeit at a lower rate than in previous years. The fact that such notifications continue to occur is one of the reasons why the existing safeguard measure on Indian aquaculture products remains (Commission Decision 2010/381/EU). It is also the case that in India's national residue monitoring plan for aquaculture products, the violation rate is, at around 10%, significantly higher than the norm in EU Member States and indicates problems with improper use of veterinary medicinal products.

It is clear that the pre-harvest and pre-export testing programmes have mitigated to some extent the long-standing deficiencies in official controls on farms, and in particular, the almost total absence of official controls on the use of veterinary medicinal products on farms. However, the programmes are relatively narrow in the scope of testing, focussing on a small range of antibiotics.

The recent FVO audit (the report of which is in preparation) has concluded that any relaxation of the current safeguard measure would not be warranted at this stage. Given that many Member States are now using multi-analytes methodology for antibiotic testing, it would be appropriate for Member States to consider, even for a restricted period, expanding the range of substances tested for in imported consignments of aquaculture products from India (over and above the list in Commission Decision 2010/381/EU). This means that MS should apply the 10 % sampling rate referred to in Article 3 of the aforementioned Decision and use multi-analytes tests for all the substances referred to in the same Article and not only carry out laboratory tests for one of the substances.

The results of such an exercise would be useful in shaping the EU's policy response to the issue of chemical residues in Indian aquaculture products and help gauge the extent of human exposure to residues which are not currently covered by the Indian pre-harvest and pre-export testing programmes.

While FR reported on very high results in shrimps from China, DE confirmed to use the multi-resdidues method, but, RPAs and MRLs for more substances are needed to ensure uniform application. On request of BE, COM clarified that it is necessary to continue testing horse meat from Mexico to ensure that a high level of control is maintained.

7. TAXUD ISSUES (DG TAXUD)

a) Update on Single Window-CVED project

COM (TAXUD) presented the state of play of the Single Window-CVED (SW-CVED) project and reported that 9 MS will participate in a pilot with conformance tests starting in the end of 2014. A SW-CVED working group consisting of official MS-representatives and traders will start from May 2014, which will deal with the implementation options of an EU Single Window.

In reply to BE, COM clarified that the SW-CVED is to be considered as an EU interface between TRACES and national customs systems. This should not be confused with national Single Windows or the One Stop Shop approach, which are initiatives addressed to the traders.

In reply to IT, COM clarified that a call for nominations for the SW-CVED working group has been sent to MS and all – even those that are not participating in the SW-CVED project – can apply. As this project group will not only deal with the CVED, the participants should have a "customs profile"; however DG SANCO will be closely involved in the discussion as it has already been the case in the past.

b) Questionnaire on enforcement of SPS requirements

COM (TAXUD) introduced the Study on the enforcement by Customs of provisions on sanitary and phytosanitary requirements. It is an internal study to identify the difficulties and room for improvement on controls on sanitary and phytosanitary goods by customs. In order to get an overall picture of the issues to be addressed, TAXUD asked representatives of the working group to reply to the two following questions by the end of April:

- 1. How do Customs and Veterinary authorities cooperate and communicate to carry out controls on live animals and POAO entering the EU customs territory?
 - Do you identify weaknesses?
 - Do you have recommendations to improve collaboration?
- 2. What are the challenges on the enforcement of provisions on sanitary requirements by customs?
 - Are the tasks between customs and veterinary authorities clearly distributed?
 - Do you have recommendations to improve the efficiency of the controls by customs?

In reply to BE and FR, COM (TAXUD) clarified that they will communicate the main conclusions of the study to the veterinary expert group once the replies will be analyzed. In reply to DE, COM (SANCO) clarified that the outcome of the study could feed into the development of the secondary legislation, which will start once the draft OCR, which is currently under discussion in the Council and the European Parliament has been adopted. COM encouraged MS to reply to the questions to give their colleagues in DG TAXUD as much input as possible.

8. MISCELLANEOUS

a) Guidance documents recently published

COM presented the recently published guidance documents:

Guidance on samples for horses for the implementation of the risk assessment referred to in Decision 2014/92/EU available on:

http://ec.europa.eu/food/animal/bips/guidelines_en.htm

Guidance (SANCO/1446/2005 Rev.2014) on non-harmonised products available on: http://ec.europa.eu/food/international/trade/docs/interpretation_imports.pdf

b) Draft legislation (Mayotte, straw pellets)

COM informed that during the next SCFCAH in April, the following two documents will be presented for vote.

Mayotte: SANCO/10476/2014

This draft Decision amends Implementing Decision 2012/44/EU on the rules applicable to veterinary checks to be carried out on live animals and products of animal origin

entering certain French overseas departments from third country. Due to the change of status of Mayotte, which has become a French oversea department, the entry point at the major port of Mayotte has to be included in Decision 2012/44/EU.

FR asked to add footnote (1) to HC products for the entry point in Mayotte and COM agreed to do so.

Straw pellets: SANCO/10487/2014

During the last SCFCAH in the beginning of March, a draft Implementing Decision adding Serbia to the third countries list in Annex V to Regulation (EC) No 136/2004 for the export of hay and straw to the EU has been voted. Based on a request from Ukraine to export straw pellets for energetic combustion and based on concerns from some Member States on the animal health situation in Belarus, further changes to that Annex have to be considered. Due to the changed animal health status in Belarus exports of hay and straw are restricted to straw pellets used for energetic combustion and Ukraine was added for the same product in Annex V to the above Regulation.

Monitoring procedures have been put in place to ensure that the straw pellets do not deviate to animal feed and reach the combustion plant. Several MS commented and outlined that treatment of the straw pellets should be under the responsibility of the third country concerned and minimum temperature requirements as well as a model health certificate should be laid down. COM replied that the pressure treatment of the straw pellets causes a certain raise of temperature. However, as the straw cannot be considered as safe, further channelling procedures are necessary. COM explained how TRACES should be used for the channelling.

c) Update of BIP list

COM informed that the last update to the BIP list has been voted during SCFCAH on 04.03.2014 and the draft Decision is currently under adoption procedure.

COM informed that the next update to the BIP list can be prepared and reminded MS of the need to use the attached template to assist in transferring correctly any changes to the list of BIPs and of the e-mail addresses, to which any requests can be submitted: sanco-consult-G6@ec.europa.eu or sanco-G6-imports@ec.europa.eu



COM asked MS to provide any requests for amendments to the list of BIPs or TRACES units by the end of April 2014.

d) Controls of honey

COM informed that SANCO was represented at the beekeeping advisory group organised by AGRI on 25.02.2014. The advisory group was particularly concerned about how checks of the requirements laid down in Directive 2001/110/EC are implemented by Member States for honey originating from third countries.

Therefore COM decided to launch a questionnaire to MS asking them if and how BIPs check the requirements laid down in the above mentioned Directive. The questionnaire will be sent soon by the FVO to MS¹ and COM invited MS to co-ordinate internally with all relevant authorities involved and to reply to the questionnaire.

COM gave a presentation on residues of veterinary medicinal products (VMPs) in honey. A clear distinction should be made between residues of allowed substances (listed in table 1 of the annex to Regulation (EC) No 37/2010) and the non-allowed substances (all substances not listed in Table 1 of Regulation 37/2010, hormones for growth promotion, bovine somatotropin).

As allowed substances have been evaluated with favourable outcome by the European Medicines Agency for at least one other food producing species, detected levels of these substances or their residues, in absence of a specific MRL for the matrix under consideration (e.g. honey), a risk assessment according to the principles laid down in Article 6 of Regulation (EC) No 470/2009 (ADI-approach) should determine the level of residues that would make the food commodity unsafe and justify its removal from the food chain / distribution chain. A zerotolerance approach would only be justified for substances that have been effectively evaluated as unsafe (listed in Table 2 "prohibited substances" of the annex to R 37/2010 and the banned uses such as hormones for growth promotion and bovine somatotropin). In case such a risk assessment would lead to different conclusions in different Member States, arrangements have been made with the European Medicines Agency to compare these evaluations and advice the Commission within a short time frame. As a consequence; when confronted to residues of allowed substances in non-target tissues of target animals or tissues of non-target animals containing residues (e.g. antibiotics in honey), no rejection or withdrawal should occur in absence of such a risk assessment.

e) Transhipment of fishery products in third countries

IS reported problems regarding transhipments of fishery products in third countries, in particular in obtaining the health certificates for import into the EU/EEA from Canadian authorities for fishery products unloaded from EU vessels and reloaded into container after a storage in Canadian EU-approved warehouses.

COM clarified that in such case the third country of dispatch (Canada) is responsible to issue health certificates for export to the EU/EEA, at least to provide guarantees about the identification of the vessel in the EU lists and the hygiene of subsequent handling and storage. COM informed that they are currently in discussion with Canada regarding the required procedure to issue such a certificate.

On the other hand, COM reminded the MS that detailed rules on transhipment procedure and relevant certification are laid down in Chapter 3.4 of the Guidance Document for veterinary controls on consignments of fishery products originating from third countries².

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The questionnaire was sent on 14.04.2014 to MS.

Published on: http://ec.europa.eu/food/animal/bips/docs/guidance_fish_rev1_19042012_en.pdf

ES informed that they do not agree with COM's interpretation and following the last FVO audit on fishery products they intend to prepare an action plan detailing their understanding of the situation.

COM replied that the Hygiene Regulations are clear in relation to direct landings and such triangular trade cannot be considered as direct landings. COM concluded that they will wait for the action plan from Spain and monitor FVOs decisions on this issue. In addition, COM asked MS with similar problems to contribute in writing.

f) Controls on bulk consignment of fishery products

ES presented their problems with the implementation of veterinary controls on consignments of frozen tuna arriving in bulk. Therefore they would like to apply the derogation provided for in Article 19(2) of Directive 97/78/EC, so that the tuna could be unloaded and transported directly to the processing industry where the veterinary checks will be carried out.

COM replied that the above derogation applies only to frozen and deep-frozen tuna, which is landed directly by the fishing/freezer vessel. The derogation cannot be applied for consignments arriving in containers. There is a legal procedure foreseen for such derogations and up to now, no MS has applied for that.

COM explained that each consignment of fishery products coming from a third country needs to undergo veterinary checks in an approved BIP. Even if the consignments consist of thousand or more tonnes, the veterinary checks – identity and physical checks including sampling - have to be finalised before the second part of the CVED can be issued and before the consignment can be released by the BIP and delivered to industry for further processing. This is applicable for standard controls whilst for re-enforced control the consignment must be detained by the BIP until results of the laboratory checks are available. If there are no warehouses in the port to detain such consignments, they need to be detained on the vessel of arrival or different solutions have to be found.

g) Controls of zoo ungulates

FR asked if any MS has already communicated a list of approved bodies in the third countries which can export zoo ungulates into the Union.

CH explained the economical constraints of visiting the approved bodies in third countries before their approval. IT and DE in support of CH stated that they do not have any list of approved bodies in third countries.

COM reminded the MS that, according to Regulation (EU) No 780/2013 amending Regulation (EU) No 206/2010, they shall inform the SCFCAH of any authorisation granted for the introduction of ungulates destined to an approved body and they shall communicate the list of origin bodies they have approved in the third countries. These rules are in place since September 2013 and COM has received no communication yet.

ES raised problems with import controls of non-harmonised animals when the consignments are presented to a BIP located in another MS than the one of destination. They outlined concerns that the relevant MS of entry would not carry out controls against

national import requirements of the MS of destination. COM replied that if the BIP of entry carries out veterinary checks on behalf of the MS of destination, it needs to ensure that the animal health requirements of the MS of destination are respected (Article 8 (A) (1) of Directive 91/496/EEC) and asked ES to provide some examples to detail the problem in writing.

(signed)
G6 – Import Controls

Encl: Agenda

List of distributed documents

Cc: Experts in 28 MS, Norway, Iceland, Switzerland, Faroe Islands + ESA, B. Van Goethem, E. Poudelet, M. Scannell, B. Gautrais, M. Valletta, T. Gumbel, C. Garau, L. Terzi, A. Laddomada, K. Van Dyck, K. De Smet, E. Strickland, R. Tascon, G. Maréchal, N. Guth, A. Dionisi, J. Bloemendal, S. Andre, D. Carton, K. Kroon, P. Bernorio, H. Klein, A.E. Füssel, B. Logar, M. Klemencic, J. Baele, S. Curzon, G. Balkamos, L. Battistini, I. El Busto Sainz, R. Matejcik, M. Dodic, M. Cronin, T. Theoharis, J. Maciulyte, F. Swartenbroux, A. Berends, V. Enjolras, P. Martinez Martin, M. Wils, G. Jennes, Unit G6.

EXPERT GROUP ON VETERINARY IMPORT CONTROLS LEGISLATION "VETERINARY CHECKS"

28 March 2014

- AGENDA -

- 1) Review of legislation
- 2) Composite products
- 3) Re-enforced checks in TRACES
- 4) Transit/transhipment
- 5) Checks of insects at BIPs
- 6) Overview of border controls against ASF (FVO)
- 7) TAXUD issues
 - a) Update on Single Window-CVED project
 - b) Questionnaire on enforcement of SPS requirements
- 8) Miscellaneous
 - a) Guidance documents recently published
 - b) Draft legislation (Mayotte, straw pellets)
 - c) Update of BIP list
 - d) Controls of honey
 - e) Transhipment of fishery products in third countries
 - f) Controls on bulk consignments of fishery products
 - g) Controls of zoo ungulates