

ANNEX 3:

COMMENTS ON THE DRAFT EU-FVO REPORT DG(SANCO)2013-6692 OF THE AUDIT CONDUCTED IN KENYA FROM 12TH TO 19TH NOVEMBER 2013.

No.	SPECIFIC AREA	COMMENT	JUSTIFICATION
1	In general, the report states “fresh peas and beans” as the targeted commodity	We request that this be changed to fresh beans and peas in pods	The change will reflect the specific commodities that are listed in Annex 1 of the EU Regulation 669.
2	In the objectives, the areas visited were included in a table format	We request the inclusion of [REDACTED] * [REDACTED] in the category of “Other” that were visited, and the number changed to 2	The EU-FVO audit team visited this additional stakeholder in the private sector.
3	In the “4 Background” there is need to give the correct information on the pesticides subject to the increased checks.	We propose the correct listing of the pesticides involved in the checks to include difenthiuron and indoxacarb – these have been omitted.	The list of compounds in the increased control list are seven (7) and not 5 as indicated in the report, since omethoate is included in the residue definition of dimethoate. The pesticides should therefore appear as they do in Annex 1 of Regulation 669.
4	Under 5.3 Official controls of Marketing and use of plant protection products, specifically under the Findings, specifically under 5.3.1 on Authorisation and marketing controls of Plant Protection Products.	We propose the inclusion of the word always in the third sentence to read: “ The published information does not <u>always</u> include details on the authorised uses, such as the pre-harvest interval (PHI). ”	This will reflect the true status as shown to the auditors.

No.	SPECIFIC AREA	COMMENT	JUSTIFICATION
5	Under 5.3 Official controls of Marketing and use of plant protection products, specifically under the Findings specifically under 5.3.1 on Authorization and marketing controls of Plant Protection Products, the statement included in this part is not true.	We propose to delete the statement “In 2012, the PCPB withdrew the authorisations for products containing dimethoate, but a Court annulled the decision due to lack of a legal basis” and replace with “In 2012, the private sector led by ██████* decided to carry out a campaign to impose a “self-ban” on the use of dimethoate produces on all vegetables and fruits. One of the dealers of dimethoate went to court and challenged this campaign; as a result the self-ban was halted” .	The statement included in the report is not factual and does not depict what truly happened, the proposed statement is the true representation of the facts as they stand.
6	Under 5.3 Official controls of Marketing and use of plant protection products, specifically under the Findings specifically under 5.3.1 on Authorization and marketing controls of Plant Protection Products, one statement in the first paragraph is misleading and does not represent the true information flow.	We propose that the sentence “In a meeting between PCPB and stakeholders in September 2013, it was agreed not to recommend foliar applications of products containing dimethoate, chlorpyrifos and omethoate” should come first then followed by “The PCPB commented that draft legislation is being discussed to provide a legal basis for the official withdrawal of authorizations”.	This is the true status on the findings as presented to the auditors.
7	Under 5.3 Official controls of Marketing and use of plant protection products, specifically under the Findings specifically under 5.3.1 on Authorization and marketing controls of Plant Protection Products, please provide clarity on the information stated.	Please provide specifics to the sentence “The label of a PPP seen by the audit team did not contain information about the PHI”	In order to provide clarity that can assist improvement, please give specifics on which label this was.

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8	Under 5.3 Official controls of Marketing and use of plant protection products, specifically under the section 5.3.2 Control of growers some information was not included	We propose the inclusion of the following statement "The Ministry of Agriculture has also provided training to 394 farmers".	The information could have been inadvertently left out.
9	Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.1 on Sampling Programmes for pesticide Residues, there is information missing to provide accuracy of the statement recorded.	We propose the last sentence in this paragraph to read "Until the time of the audit, 270 samples of beans and 187 samples of peas have been sampled within the extensive programme".	This is because other initiatives were ongoing and the signed program reflects the extensive program, as submitted to the commission and shown to the auditors.
10	Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.1 on Sampling Programmes for pesticide Residues, there is information missing to provide accuracy of the statement recorded.	We propose the inclusion of the following sentence in the first paragraph "This was proposed after [REDACTED] [REDACTED] [REDACTED] carried out an assessment of the industry in May 2013." This statement should be included just before the one that states "Risk factors are not included in the design of the programme".	This information was provided to the auditors and an elaborate explanation presented as to how the large sample size was derived.

No.	SPECIFIC AREA	COMMENT	JUSTIFICATION
11	Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.3 "Laboratory for Pesticide Residue Analysis" in particular on <i>Analytical spectrum and methods</i> some information that was presented is missing and should be included to provide accuracy of the statement recorded.	We propose the inclusion of GC-MS-MS in the first sentence so that it reads "The laboratory is equipped with GC-MS, GC-MS-MS and LC-MS/MS and also with GC classical detectors GC- ECD and GC-NPD, which are used for the multi-residue analysis of pesticides."	This range of equipments was shown to the auditors present and we feel that if this information is not included it is incomplete.
12	Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.3 "Laboratory for Pesticide Residue Analysis" in particular on <i>Analytical spectrum and methods</i> there is lack of specific clarity in the statement	There is need for clarity in the statement " <i>Some deficiencies</i> in the extraction procedure and quantification with the method applied were detected".	This would be useful to provide some information on the exact area so that improvement is targeted.

No.	SPECIFIC AREA	COMMENT	JUSTIFICATION
13	<p>Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.3 “Laboratory for Pesticide Residue Analysis” in particular on <i>Quality Assurance procedures</i> some information that was presented is alarmingly negative and did not take cognizance of the information that was provided to the auditors.</p>	<p>We propose that the statements in the second last paragraph should read “However, there is a lack of additional quality control checks based on internal standards and the estimation of uncertainty was not clearly defined, evaluated and reported although a procedure on estimation of uncertainty was in place. A substantial number of certified standards are available. Although monitoring of standards is carried out, the preparation of new standards and working solution procedures presented some deficiencies.</p>	<p>This would provide the true accurate status of the documentation that was provided – the procedure was provided to the auditors to review as well as that for monitoring of standards. Further, the alarmingly negative language used makes the reader perceive that although improvements have been noted, there are deficiencies that affect the reliability of results as reported in the conclusion.</p>
14	<p>Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under 5.4.3 “Laboratory for Pesticide Residue Analysis”, in particular on <i>Quality Assurance procedures</i> some information that was presented is alarmingly negative and did not take cognizance of the information that was provided to the auditors.</p>	<p>We propose that the sentence in the second last paragraph should read as follows: “The laboratory participated in a 2012 proficiency test for pesticide residues provided by the National Measurement Institute of Australia with unsatisfactory results. Only one compound obtained a z-score below 2”.</p>	<p>During the audit several reports of proficiency testing results were presented, however it was only the results of 2012 PT that were poor. We request that the nomenclature used internationally to describe the performance be used to replace the “very poor” statement used, which depicts alarming status.</p>

No.	SPECIFIC AREA	COMMENT	JUSTIFICATION
15	Under 5.3 Official controls of pesticide residues in food of plant origin, specifically under the Findings that are specifically under Conclusions we propose the re-wording of some statements.	<p>We propose the inclusion of the word “substantially in the sentence “Since the last audit, the quality control procedures have substantially improved”.</p> <p>The sentence after this one i.e. “<i>However, the current limited scope and deficiencies in the some critical quality control aspects for routine analysis mean that the results do not provide reliable data</i>” presents a conflicting scenario which implies that the work currently ongoing in the monitoring plan cannot be relied upon at present. This statement should be reworded.</p> <p>The paragraph that reads”..... <i>A comprehensive monitoring programme for peas and beans in pods had started shortly before the audit. Sampling procedures are in line with the CODEX Guideline, but the lack of risk analysis reduces the effectiveness of the programme. The shortcomings in the KEPHIS laboratory used for analysis affect the reliability of results obtained</i>” poses great concern and should be clarified and reworded.</p>	<p>This was the statement presented by the auditors during the audit.</p> <p>The conflicting statement presents a dilemma in that the current enhanced monitoring plan might not provide reliable results for decision making.</p> <p>The statement used is of great concern to the Kenyan Competent authority (CA). In the findings, the audit team noted that there was an extensive monitoring program in place. In providing a conclusion that there is a lack of risk analysis which reduces the effectiveness of the program, means that the program could be a waste of resources. This statement should be strongly justified especially since this is the first extensive program Kenya has undertaken due to the increased controls, after the assistance of an EU consultant.</p> <p>Further, in noting that some deficiencies in the laboratory affect the reliability of results obtained implies that the program should not proceed under the current arrangement. This should be reworded to provide the necessary direction.</p>

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16	In the part 5.5 on private controls on peas and beans in pods exported to the EU in particular the <i>Conclusion</i> the of this part, the statement included seems to imply use of alternative laboratories to that proposed by the Kenyan CA	The statements: <i>“Analysis is performed in the KEPHIS laboratory or by accredited private laboratories in the EU with an analytical scope with over 200 pesticides”</i> is of concern and should be re-worded.	Making reference to the comments above in 14, the draft report currently states that <i>“The shortcomings in the KEPHIS laboratory used for analysis affect the reliability of results obtained”</i> . When this statement is read making reference to the paragraph reference to in the Conclusion of Part 5.5, it is read to imply that European Private laboratories that provide analytical scope of over 200 pesticides should be used instead of what the Kenyan CA has proposed. This seems to be a hided technical barrier to trade and in particular the acceptance of results from the extensive monitoring program. Please clarify this point.

*Please note that it has been necessary to delete this text in order to respect the provisions of Article 339 of the Lisbon Treaty as regards confidentiality.