Control Body response to the report recommendations received 11 August 2017

ANNEX

Response of the control body to the recommendations of report ref. DG(SANTE)/2017-6083-MR of the audit carried out from 09 May 2017 to 18 May 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised control body operating in Bolivia

N°	*Recommendation*	*Action Proposed by the control body*
1	Ensure that the CB selects inspectors who have sufficient experience and are competent to carry out effective inspections in line with points 5 and 5.2.3 of Section C of the CB quality and procedures manual. Recommendation is based on conclusion No 30 Associated finding: No 17	Because of the failures of the new inspectors on the operators inspections, we looked up for an strategy which is mentioned on the Procedures Manual of the Control Body*, we addend on: Section C, point 5 (5.2.4) to implement since the approval of this change. (Attached BOL-1A-BQPM). The new inspectors will still train on camp as it is mentioned on the added point.
2	Ensure that risk assessment applied by the CB serves as an adequate basis to determine the nature and frequency of controls and that for additional visits, operators are selected on a risk basis in line with points 1.6.4 and 1.6.6 of Section E of the CB quality and procedures manual. Recommendation is based on conclusion No 31 Associated finding: No 25	After the audit we added into the manual the following points: Section E, point 1.6.10 (subsection a-h) and 1.6-11 (a-c) Already knowing the flaws on the procedure of operators selection for additional visits, non-announced and special, since June we are working with the corrected procedures making sure to add all the modified points. Supporting documentation are filed in the Control Body* for anyone who asks for it.
3	Ensure that inspections are well prepared and carried out in the period of time when there is more risk of occurrence of irregularities as established in point 4.6 of Section D and points 1.3 and 1.4 and 1.6.7 of Section E of the CB quality and procedures manual. Recommendation is based on conclusion No 31 Associated findings: No 22 and 26	Inspections are always plannified when there is a greater chance of risk, but there are years where this dates change, during 2016 we changed this dates, so there is no doubt that it will be carried on this way we added a text inside point 1.6.4 of Section E. Now planning goes according to what has been added on the manual on section E, point 1.6.10 and 1.6.11 –BOL-1A-BQPM.
4	Ensure that the CB verifies the use of off-farm input in compliance with points 6.4.4, 6.5 and 6.5.1 of the CB organic standards. Recommendation is based on conclusion No 37 Associated finding: No 35	The inspector checks and inquires about the used inputs, the operator also records i ton the plan and also in supplement B parcels history, we are sorry that the new inspectors did not verify this point, during inspection we pointed out all this matters, we also added on the manual to remind all our control staff that has to be done necessarily. Section E, point 5(5.4.16) and points 2.6 and 4.3, it was also added to the inspection sheet point 1.7 so that the inspector does not miss this important matter BOL-1A-BQPM.
5	Ensure that sampling is carried out in the most appropriate time	A change has been made on the manual to exactly identify how the

ANNEX

Response of the control body to the recommendations of report ref. DG(SANTE)/2017-6083-MR of the audit carried out from 09 May 2017 to 18 May 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised control body operating in Bolivia

N°	*Recommendation*	*Action Proposed by the control body*
	in all stages of production, processing and commercialisation and that it is based on a risk assessment as established in points 4.1 and 4.8 of Section E of the CB quality and procedures manual. Recommendation is based on conclusion No 47 Associated findings:42 and 43	Control Body* is going to proceed in case of sampling, Section E, point 4.10 (a,b,c); point 4.11 (4.11.1-4.22.10), Since June all the operators that are selected for sampling will be done after analyzing the risk factors and classified ranks we will choose the operators which will be a priority for taking samples.
6	Ensure that the CB has a procedure in place for checking whether the analytical scope of the laboratory used for testing is adequate. Recommendation is based on conclusion No 48 Associated finding: 46	The documents which have been sent by GBA laboratory have been checked,and they do show the analytic reach to determine residue on the samples we sent. Now we checked all the documents available and started to work with a Laboratory*, this lab sent us all the methods they use and the analysis procedure for the products that are certified by the Control Body* (attached a Laboratory* documents)
7	Ensure that the list of organic operators subject to controls by the CB is regularly updated in line with point 6.8.3 of Section C of the quality and procedures manual and Article 12 of Regulation (EC) No 1235/2008 and, in particular, that the relevant information on the operator's certification status is readily made available as required by Article 11 of Regulation (EC) No 1235/2008. Recommendation is based in conclusion No 50 Associated finding: No 49	Immediately after the audit with the European Commission ended we updated the lists on our web-site a column was added where it shows the status of the certification of the operator, nowadays we have a list with all the changes that have been made until June of this year. (you can check * *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* certifications window and choose the EU one.
8	Ensure that inspections at operators are effective. In particular, ensure that all requirements of organic production are checked, all relevant premises are visited and that a proper verification of operator records are carried out by the inspectors in line with points 1.3, 1.4 and 5 of Section E of the CB quality and procedures manual. Recommendation is based in conclusion No 60 Associated findings: No 53, 54,55 and 59	The inspections that were done by the new inspectors had a lack of information that is why we re-inspected the operationsthat were assigned to new inspectors, before we re-inspected we communicated the operator about their flaws and also our inspectors failures, they were given a time to fix their weak points, once they fixed some issues they had they sent us a notification and we proceeded with the additional inspection as it says on Section E, point 1.6.6 on the manual BOL-1A-BQPM this re-inspection showed us that they improved on their Internal Control System, the new inspector entered with the guide inspector and with the new report of the inspector we then proceeded to continue with the renewal of the certification

ANNEX

Response of the control body to the recommendations of report ref. DG(SANTE)/2017-6083-MR of the audit carried out from 09 May 2017 to 18 May 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised control body operating in Bolivia

N°	*Recommendation*	*Action Proposed by the control body*
		according to the non-compliances found and the SCI evaluation.
9	Ensure that the assessment by the CB of controls carried out by PGs is adequate in order to guarantee the effectiveness of such controls, and in particular that: Controls carries out by the ICS cover all requirements of the CB's standards, PGs' inspectors effectively verify these requirements and The CB inspectors are able to evaluate the effectiveness of the ICS in line with point 6 of Section E of the CB quality and procedures manual. Recommendation is based on conclusion No 61 Associated findings: No 56 and 57	We evaluate the Internal Control System inside and after an inspection, we also do a follow up on the internal inspector to see how the inspection goes but it is not enough and demands more information that is why we set ourselves parameters of evaluation of the internal control system and we will proceed as the manual shows Section E, point 6 (6.1) of the (a-g) underlined text, point 8 (a-i) of the manual BOL-1A-BQPM
10	Ensure that physical checks based on risk assessment are carried out on exported consignments as is required in Article 13.4 of Regulation (EC) No 1235/2008. Recommendation is based on conclusion No 66 Associated finding: No 65	We checked the standard 1135/2008 and also the modification of it 1842/2016 to see the requirements and since April we already use the format and we showed the auditors during the audit right now we are accomplishing what it states on article 13 point , we attach the first certify issued on April and the last one on July, We also added to the manual where it states the inspection of the container depending on the risk factors that the operator shows. Section E, point 1 6 9 of BOL-1A-BQPM
11	Ensure that measures in case of suspicion of infringements and irregularities are taken and are adequate to prevent the fraudulent use of the organic indications in line with point 4.17 of Section E of the CB quality and procedures manual. In particular, ensure that adequate actions are taken in all cases when analytical results show the presence of a substance not authorised PPPs in organic production. Recommendation is based on conclusion No 73 Associated finding: No 69	For this we modified the manual Section E, point 5 (1-12) added, this for us to keep in mind the procedure of inspection in case that we detect results of prohibited substances on the product. Manual BOL-1A-BQPM.
12	Ensure that the CB takes appropriate enforcement measures towards PGs as a whole, in particular in case of severe	On this particular cases we proceeded to penalize the producer when we found the use of prohibited substances, being organic, transitions went down

ANNEX

Response of the control body to the recommendations of report ref. DG(SANTE)/2017-6083-MR of the audit carried out from 09 May 2017 to 18 May 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised control body operating in Bolivia

N°	*Recommendation*	*Action Proposed by the control body*
	irregularities in line with point 5 of Section L of the CB quality and procedures manual. Recommendation is based on conclusion No 74 Associated finding: No 70	to start again the transition T1, now we will evaluate the Internal Control System to see its effectiveness and penalize as stated on the catalog of sanctions of the manual point 5 and 6, this sanction goes to the SCI, depending of their evaluation as it shows on point 6.1 (a-g) of section E also modified. BOL-1A-BQPM.

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