Control Body's response to the report recommendations received 14 September 2018

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Response to the recommendations of report ref. DG(SANTE)/2018-6395-MR of the audit carried out from 13 April 2018 to 25 April 2018 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in Kenya

N°	***Recommendation***	***Action Proposed by the Control Body***
1	Ensure that inspectors carrying out controls on behalf of the CB are subject to adequate supervision and evaluation in order to guarantee that controls are effective, objective and free from any conflict of interest. Recommendation is based on conclusion No 33 Associated findings No 18, 19, 22, 77	**Comment**: We have reviewed the Inspection facilitation agreement, in particular, clause 4.7: *To ensure that the inspector is compliant with all requirements of the inspection declaration for each audit carried out under this agreement* To determine if it can be tightened up to better especially in the representation of the ISO requirement 5.2.1 (b): *any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent impartial provision of certification activities.* **Action**: Because we only sign agreements with accredited organisations, we have reassurance that their accreditor maintains oversight of their impartiality controls. In addition, the auditor signs a declaration before each audit assigned. We have updated this declaration to be explicit in terms of identification of any pressure from the auditor's employer: *"I confirm that the certifier/inspection body which employs me is not exerting any pressure in relation to the client and outcome of this audit"* {Evidence #01} The process of preparing for audits has also changed, with the process now including a meeting between the inspector and

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		certification staff ahead of audit to discuss, risk areas, key issues to focus on at audit as well as opportunity for the auditor to raise any issues or concern ahead of the inspection visit. {Evidence #12}
2	Ensure that CB controls and sampling are planned, and duly implemented, based on a duly documented risk assessment taking appropriately into potential non-compliances of the CB operators with the CB standards at all stages of production, preparation and distribution. Recommendation is based on conclusions Nos 34, 59 Associated findings No 24,25, 51	**No 24** **Root cause:** Lack of guidance in the EC organic regulation resulted in insufficient detail being recorded for risk assessments. **Action:** The COR + Non-EU operator risk assessment spreadsheet {Evidence # 15} has been reviewed and amended to include guidance for certification officers on how to decide level of risk, and evidence that each risk factor has been considered for each operator. See amended spreadsheet for details, this spreadsheet will be used for future risk assessments. The work instruction C406Wi {Evidence #02} has also been amended to take account of this. Staff training to be completed by end September 2018. **No 34 &59** **Comment**: We do not agree entirely with this finding. Out of 27 samples taken since April 2017, 11 have been of dried or harvested product, 16 have been from farm production. We do accept however, that in the case of the witness audit samples from growing crop have not been taken where it may have been appropriate to do so. **Root cause**: The international sampling spreadsheet grouped together licenses under companies, rather than each license having its own entry. It therefore lacked clarity in terms of whether samples should be taken from processor or the producer licenses. **Action**: The international sampling spreadsheet has now been

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		amended so that each licence has its own entry, so it is clear whether the sample should be taken from the producer or processor license. See example of amended international sampling plan 2018 spreadsheet. {Evidence # 03} An international sampling form has also been created to send to the inspector with sample request. This provides more clarity to the inspector. See International Sampling Form I1793Fm {Evidence # 04} **No 51** **Action**: In addition, the work instruction for taking and sending samples from outside the EU has also been amended so the technical manager must also check if the time of year the next inspection is scheduled is an appropriate time for sample taking. A column has been added to the international sampling plan spreadsheet to record this. {Evidence #04a}
3	Ensure that the CB standard for the granting of exemptions from production rules are correctly implemented, in particular that requirements under which parallel production can be temporarily allowed are respected. Recommendation is based on conclusion No 46 Associated finding No 44	**Comment:** This issue was raised as a non-compliance during a witnessed assessment from out 1235/2008 scope accreditation body in 2017. Since this issue was highlighted to us, we have completed a full assessment of our international licensees to assess where there is parallel production of organic and non-organic products **Root Cause:** *insufficient staff training and inconsistent application of this area of organic standard.* **Action:**

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		Operators: We have completed a full assessment of our international licensees to assess where there is parallel production of organic and non-organic products. This review highlighted two operators who both produce organic and non-organic tea. Both operators have been contacted and the EU rules have been clarified. Both operators have chosen to implement changes to their businesses to ensure complete separation of the organic and non-organic production units. This will include having a dedicated manager, separate production and harvesting equipment, and separate production and financial records. We are currently working with both operators to ensure these changes are implemented and will be verifying this through our inspection programme. Whilst these business changes are made the operators are complying with the requirements of ii-iv of Article 40 (EC 889/2008). **Staff**: Identified a lack of understanding of parallel production issues and the need to add to the training. Which all inspectors and certification officers undertook in 2017/18{Evidence 05 & 05a} Improvements will be made to monitoring processes to ensure allocated inspectors and certification officers have completed and understood the relevant training modules. Further training will be issued as an update to existing training module “Parallel Production” include to information on how to inspect and report non-organic aspects of parallel production. This

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N°	*Recommendation*	*Action Proposed by the Control Body*
		will be completed by the end of October 2018 The work instruction "Opening and Closing Meeting Crib Sheet C224Wi has been updated to emphasize the requirement for full access to all areas of the site including non-organic and to ensure that all buildings/room will be accessible during the site visit (i.e. keys for locked areas taken on the site visit). {Evidence 06).
4	Ensure that the validity of testing results of organic samples are reliable, and that, for this purpose, in particular sampling procedures are duly respected samples are appropriately stored, transported and swiftly delivered to the laboratories and that scope of testing by laboratory is performed as requested / recommended by the CB inspector and that accredited methods are used Recommendation is based on conclusion No 60 Associated findings No 52, 53, 54, 55, 56	**No 60 & 54** **Comment:** If an inspector is taking a sample because they are concerned about contamination from neighbouring fields then they record that on the form (tick box Neighbouring Farm and then complete Additional information section). **Action:** The Sample Collection Form has been amended to include information on where and at what point in the process the sample had been collected. See amended Sample Collection Form C139Fm{Evidence 07}. Inspectors have already been issued with the documents and there will be training in Autumn 2018 **No 55** **Action:** Inspectors will be issued with cool bags and icepacks for the transport of perishable items fresh produce samples. Not all samples require refrigeration (reference Codex sampling guidelines CAC/GL 33-1999 section 3.6 and (EU) No 691/2013 section 7). Our sample taking work instruction has been updated to make clear which product samples require refrigeration. Inspectors will be trained on 26th September 2018 Regarding delay in sending sample to lab – the work instruction Receiving & Sending Samples has been amended – target is now 5 working days of sample taken. See amended Receiving &

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		Sending Samples. {Evidence #08} **No 56** **Regarding different analysis carried out than that requested by the inspector –** **Comment:** In general the technical team have more specialist knowledge regarding testing than inspectors, and where decisions are made to send a sample for a different test this is done on the basis of this knowledge and normally after speaking to the inspector. **Root cause:** We accept that the decision-making process has not always been documented in the sample record. **CB Action:** We have amended the work instruction Receiving & Sending Samples C342Wi {Evidence 08}. If we consider a different test is more appropriate, we will check with the inspector why they had asked for the test, if decided a different test is more appropriate we record in the sample record details of why a change has been made. Staff will be trained on this amendment by end Sept 2018. **Regarding the accreditation of sampling methods –** **Comment:** We do request an accredited test to be carried out by accredited labs, this requirement is included in a contract with each lab we use. In this instance neither the lab or ourselves identified that the particular test was not accredited. **Root Cause**: Human error **Action:** Work instruction has been amended {Evidence 11 & 11a}and staff reminded of importance of checking test is accredited. The use of **please note that it has been necessary to*

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N°	*Recommendation*	*Action Proposed by the Control Body*
		delete this text in order to respect the provisions of Article 339 of the Lisbon Treaty as regards confidentiality has been reduced to a very small number of tests which we have confirmed are accredited. **No 52** **Comment:** There appears to have been a misunderstanding of one of our procedures by the auditors. We assume this finding is based on wording in work instruction C057Wi {Evidence 11} regarding formal and informal samples, which says: 'We are likely to require formal samples in the following situations: • Where contamination has previously been identified following informal sampling, and this sample is to confirm the result. • If the result of the testing is likely to lead to termination of the licence. • Where fraud is suspected.' This does not mean that inspectors are instructed to only take formal samples in the 3 scenarios described in the work instruction. In the vast majority of sampling formal samples are taken. All inspector training is based on them taking formal samples that follow statistical methods based on CODEX guidelines and described in the work instruction C057Wi {Evidence 11}. **CB Action:** We have amended the wording in the work instruction to make it clearer that formal sampling (meeting Codex requirements) is required whenever possible.

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		No 53 **Comment:** This is not standard practice, we were facing difficulties in using plastic bags in Kenya, due to a ban on their use and had been unable to secure permission from the Kenyan authorities to use plastic bags in time for the audit. Paper envelopes were provided to the inspector to use instead of plastic. All other samples taken always use the described sampling equipment as described in our procedures, this was a recent issue only affecting Kenya. **CB Action:** We have applied to the Kenyan authorities for use of plastic bags so that these can be used for future samples taken in Kenya. Additional information in the Taking and sending samples from outside the EU {Evidence 4b}
5	Ensure that inspections at operators are sufficiently effective to guarantee that all elements of the CB standard are appropriately implemented, and in particular that the OMP is updated to allow inspectors to adequately prepare the inspection, inspectors use checklists and guidelines during controls at operators, areas and premises under organic and non-organic management are visited, relevant records and documents including those on which the calculation of the balance of input and output is based are verified in a meaningful manner, and that Recommendation is based on conclusions No 39, 82 Associated findings No 37, 67-77, 80, 81, 85	**Root Cause:** Insufficient planning and preparation for the inspection was identified. **Action:** Larger or more extensive operations will have 2 inspectors allocated in future where appropriate, and an independent interpreter will be used if required Allocation of International Inspections CO99Pd has been updated{Evidence #12}. Pre-inspection meetings will be undertaken with relevant CO, Technical staff and the inspector. This meeting may generate specific issues to be covered at inspection, to be included in the pre-inspection information zip file. to clarify the areas to be covered and recorded on the report and any potential sampling requirements identified prior to inspection Allocation of

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		International Inspections CO99Pd to be updated to cover this. {Evidence 12}(As per No 3) The work instruction 'Opening and closing meeting crib sheet C224Wi has been updated to include emphasis on requirement for full access to all areas of the site including non-organic and to ensure that all buildings/room will be accessible during the site visit. (i.e. keys for locked areas taken on the site visit) [Evidence #06} A new training module will be issued through * on "Appropriate Audits to use at producer inspections" which will cover use of PPPs on organic and non-organic areas, including appropriateness of quantities used, Yield to sales of organic production and non-organic production. The new training module will be completed by the end of October 2018 – current guidance is attached.{Evidence 16} There will also be an update to the current parallel production guidance (as per No.3){Evidence #05}
6	Ensure that inspection reports and supporting documents contain sufficient information to enable the CB HQ to adequately perform its certification, enforcement and evaluation tasks in line with the CB quality manual. Recommendation is based on conclusion No 82 Associated finding No 77	**Root Cause:** Lack of objective evidence identified in some inspector's reports. In this case, not sufficient questions were completed in the inspection report. Lack of objective evidence in the inspection report had been identified as an issue at the previous recent internal witnessed inspection of this particular inspector. **Action:** Mandatory completion of all questions in the inspection report are not required at spot inspections, but in future the appropriate questions to be completed will be identified at pre-inspection meeting (as per No.5) See International Inspection planning

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		meeting checklist {Evidence # 14} Guidance to be given to inspectors at national training (September 2018) as a reminder on the inclusion and appropriate use of objective evidence in reports.
7	Ensure that all requirements of Article 13 of Regulation (EC) No 1235/2008 are respected, to avoid undue issuing of CoIs for consignments deemed for EU export, and in particular that risk based physical checks are carried out on consignments deemed for EU export before issuing a CoI, and that maximum quantities available for EU export per operator are correctly calculated. Recommendation is based on conclusion No 88 Associated findings No 83, 85	**No 88 & 83** **Root Cause:** There was no documented guidance to carry out a risk assessment for products requiring a COI and nowhere to document any assessment done to determine where a physical check is required. **CB Action:** The COR + Non-EU operator risk assessment spreadsheet has been reviewed and amended to include an assessment of risk for COIs and work instruction amended {Evidence# 17}. See amended spreadsheet for details, this spreadsheet will be used for future risk assessments. The work instruction C406Wi {Evidence # 02} has also been amended to take account of this. Staff training will be carried out for all relevant staff**.** **Action:** The COR and Non-EU operator risk assessment spreadsheet has been reviewed and amended to include an assessment of risk for COIs and work instruction amended. this spreadsheet will be used for future risk assessments. The work instruction has also been amended to take account of this. Staff training will be carried out for all relevant staff.

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8	Ensure that enforcement measures are effective to guarantee that the CB standard is adequately implemented, and in particular that the root cause of any presence of unauthorised substances in organic products is investigated to either confirm or disregard a suspected non-compliance with the CB standard. Recommendation is based on conclusion No 94 Associated finding No 92	**No 94 & 92** **Root cause:** Procedures did not sufficiently document the investigation requirements for all quantifiable detections, in particular in the case of the presence of traces of unauthorised substances. Our procedures did not take into account sufficiently the risks around comingling when considering dehydration/concentration factors. **Action:** Procedures and work instructions are being reviewed and updated to document investigation requirements for all quantifiable detections. We are reviewing how we handle low level residue detections on products where processing factors are considered, this will now include additional steps for verifying the risks of comingling products which may lead to traces of residues of prohibited substances.

**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*