Comments received from the Competent Authority 17/5/2013

ANNEX I

UK COMMENTS ON THE DRAFT FVO AUDIT REPORT

Relevant paragraph of the draft inspection report	Comments
5.2.5.2 Second Site Visit The second site visited by the audit team was a fish processing unit for a PGI product. The CB provided the audit team with the inspection reports for 2010, 2011 and 2012. The CB stated that they never send the inspection reports to the CCA but always provide a written report to the FBO. The CB described their procedure if a non compliance was found. They allow a period of 28 days to rectify the matter. They would undertake a follow up visit, which could be unannounced to ensure the non compliance is rectified. In the event that it was not satisfactorily rectified the CB would have the authority to remove the PGI designation from the FBO. When questioned by the audit team if this procedure was written anywhere, the CB and CCA confirmed that it was not. A letter used by Defra to inform CBs that a product had successfully been granted a designation by the European Commission was reviewed by the audit team. The letter described the CBs' responsibilities and stated that Defra should be alerted about non compliances and any proposed changes to the product specification. However, the letter did not mention any requirement to submit all inspection reports to Defra. The CB clarified that they did not require any authority from Defra to remove the PGI designation from an FBO. The audit team asked the inspector from the CB to discuss how a measurable specification described in the PGI product specification was controlled. The inspector stated that this measurement was not undertaken during every inspection.	The findings do not accurately reflect the procedure for dealing with a non-compliance by stating "The CB would undertake a follow-up visit, which could be unannounced to ensure the non-compliance is rectified." The CB procedure for dealing with non-compliance is as follows: **<u>Initial Assessment</u>** - Where non-compliance is identified the participant is required to provide written confirmation of corrective action within 28 days of receipt of the inspection report. If the participant cannot provide appropriate written Corrective Action: - then approval is withheld and the reasons will be communicated in writing to the Applicant which will identify the corrective action that must be implemented before the application can be given further consideration. **<u>Surveillance Visit</u>** This will be carried out, on a risk basis, if it is identified that a participant has failed to implement those Corrective Actions which were identified at a previous inspection (either initial assessment or annual surveillance): - During the course of the inspection the inspector will check that corrective action has been implemented in respect of all non-

In all three reports provided to the audit team, this point was recorded as being checked. However, there were no written records available of any measurements being carried out by the inspector. The internal controls of this CB did not detect this. To date the inspection reports from the CB indicated that one non compliance in relation to the PGI designation was found in January 2010 and it related to the wording on the label not conforming with current legislation. Based on the documentation provided to the audit team, there was no unannounced follow up visit undertaken after 28 days, the normal procedure described by the CB. The next inspection took place in May 2010, the report of which stated under the 'Non Compliance' section: 'Confirmation of corrective action from the last audit'. The audit team requested the production manager at the processing site to illustrate how traceability of the PFN was controlled. The audit team was shown the electronic system which displayed the batches associated with the days production. The labelling associated with the boxes for the production carried the PGI symbol.	compliance reports raised during previous inspections and, if not, he will raise new non-compliance reports. Occasions where the CB may wish to undertake unannounced and short notice inspections include: - The certification body reserves the right to undertake unannounced and short notice inspections at the premises of approved producers in addition to the annual surveillance inspection. This may be carried out to ensure corrective action has been implemented where serious non-compliances have been identified.
5.2.5.3 Third Site Visit The inspector used a specific check list prepared by the CB which was developed to control this product including all requirements of the product specification. The check list consisted of detailed references to the FBO's own checks. In addition, the CB inspector took samples and sent these to an accredited laboratory for analysis*. However, the result of these analysis were sent to the CB's headquarters and never revealed to the inspector. This was a policy of the CB to guarantee the objectivity and impartiality of inspections. Linked to this the CB also said that it had a policy of *occasionally* rotating its inspectors so that the same inspector was not always visiting the same producer. The audit team undertook a traceability exercise and the result was satisfactory. The audit team reviewed a variety of the	* See following suggested word insertion: *'The auditor is required to report on their findings and the Control Body itself gathers the information; the Corrective Actions and Lab results and reviews these to reach a Certification decision. These practices are all in line with EN 45011 accreditation principles.'*

labels used by this FBO and found a number of examples of names being used which was not the name used in the official register. This was not detected by the CB inspector. In addition stocks of labels with the old colours of the PDO symbol were found in the label storage room of the FBO.	
5.2.5.4 Fourth Site Visit The fourth site visited was another producer of the same PDO cheese product which is controlled by the same CB. The FBO stated that 85% of raw materials used was for the production of the PDO product. The FBO stated that due to the continuous shortage of the raw milk supply since Summer 2012, 40% of the raw materials has been sourced from outside the geographical area mentioned in the product specification which is permitted in special circumstances. The audit team noted that some products were not adequately labelled to indicate the date of production. In addition the audit found some batches of PDO product without any identification. This CB inspector took samples of finished product and sent them to an accredited laboratory for analysis as described for the previous site. The analytical results were sent to the CB head office. When the FBO required additional raw material and these were delivered by another establishment, there was no information provided about the geographical origin of the raw material as required in the product specification* . The audit team reviewed a selection of labels used by the FBO and a number of examples were seen in which the name on the labels differed from the registered name. Two labels contained the registered name without using the symbol or the wording 'Protected Designation of Origin'. The FBO explained, these were used when the product was exported outside the EU. This problem had not been detected by the CB inspector. In both producers visited for this PFN, all staff met had considerable knowledge of their obligations relating to the product specifications. The obligations were clearly illustrated and well documented. The audit team was provided with a copy of the	There is no reference in the product specification that requires the raw materials' geographical origin, when drawn from outside the geographical area, to be identified. The CB will ensure future audits record these details.

Good Labelling Practice for the PFN which had been prepared by the producer organisation.	
5.2.5.8 Eighth Site Visit The eight site visit was to a producer of a TSG product of animal origin. The CB provided inspection reports for 2009, 2010 and 2011. A number of non compliances were detected in 2011. However, the follow up was based on documentary evidence and did not include a follow up inspection as foreseen in the operating procedures of the CB. The audit team reviewed examples of the packaging and noted that neither the symbol nor the registered name was used. On further discussion it was revealed that the FBO was not producing any product according to the specification of the registered name. An amendment of the product specification was in progress and at the time of the audit the amendment had not been approved.	Two of the three non compliances were closed with very substantial corrective evidence and the third was about tracing the young animals – therefore not appropriate to revisit. The corrective action details in relation to this third element stated that they would insist on traceability to the premises of origin being available for the next batch. In the 2012 report, the control body received a comprehensive corrective action report.
5.2.7 Enforcement Measures Findings If a non compliance is detected at producer level, an opportunity is given to rectify the situation within a given time frame. Where a CB identifies a non-compliance with the registered specification of a PDO/PGI/TSG product it must be brought to the attention of the CCA. The CCA informs the producer concerned that their right to use the registered name is being withdrawn until corrective action is verified by the CB and the non-compliance is rectified”	One of the CBs operates an online system of reporting, with each participant having access to their own site audit report, normally within 10 working days of the audit. It is often the case that the CB’s auditors upload the report on the day of the audit. The report can then be reviewed and an email message sent to the client confirming the non-compliance and the requirement to provide Corrective Action. This email is in addition to the on-site notification at the time of the audit. The client has the facility to upload any written, photographic or video, evidence of Corrective Action for approval. If approved, the report will then be closed. This could take as little as a few hours from the report being reviewed by the CB and the email message being sent. In the above scenario, the non-compliance would possibly be closed before the client had received notification from DEFRA that

	their certificate had been withdrawn. . The CB would then have to notify DEFRA of receipt of appropriate evidence of Corrective Action, and DEFRA would then have to notify the participant of their re-instatement. The CB would therefore suggest that it is more appropriate if they were to only notify DEFRA where appropriate evidence of Corrective Action had not been received and certification had been withheld or withdrawn by the CB.