



## Comments on OIML/ TC6/ p5/ GCOP/ CD 1 dated 19 June 2014 – Guidance for the certification of prepackages

OIML TC 6

Due Date: 5 September 2014

Convener: South Africa

TC6\_p5\_N004

Member	Clause	Comment	Secretariat comment
Australia	General	Australia supports the guidance document detailing the establishment and maintenance of certification schemes for the control of quantity of product in prepackages and associated labelling. Such a system would promote international harmonisation of requirements concerning prepackages as well as benefit multinational companies engaged in international trade of prepackaged products by maintaining confidence and facilitating trade of such goods.	Noted
Denmark	General	Denmark notes that the aim of the document is to provide best practice guidance. We have no problems with that approach. However, we strongly believe that it is important that OIML does not spend resources on development and administration of a certification system on pre-packages. There is no sense in setting up new systems when existing systems can be used. This is not cost-effective and does not promote elimination of technical barriers to trade	OIML will not set up such systems, however, the hope is that as the result of the guidance packers will become certificated using such systems
Japan	Title (general)	Two different titles (see below) are shown on the cover page. Only one title shall be used for CD1.  1. Guidance for defining the system requirements for a certification system for prepackages. 2. Guidance for the certification of prepackages.	Amended the title suitably
Netherlands	General	A good overview on the consequences of the actual draft: OIML/TC6/p5/GCOP/CD1 is lacking while the draft contains too many open ends. Comment the draft in detail therefore is considered premature. The NL input will be delivered by the NL p-member delegate in the discussions on the draft during the meeting in Korea	Noted. Discussed at meeting. Any questions from NL on the understanding of the document will be handled as discussions progress.

Member	Clause	Comment	Secretariat comment
Sweden	General	Sweden notes that the aim of the document is to provide a best practice guidance. We have no problems with this approach. However, we strongly believe that it is important that OIML does not spend resources on development and administration of a certification system on pre-packages. There is no sense in setting up new systems when existing systems can be used. This is not cost-effective and does not promote elimination of technical barriers to trade. With reference to our international work on training in quality infrastructure and experience from ILAC and IAF many developing countries ask for fewer and harmonised systems to adapt to, in order to be able to enter international markets	Noted
Turkey	General	In our country, 76/211/EEC, 2007/45/EC and 75/107/EEC Directives were harmonized in 2002 and are still in force. In scope of these EU legislation which have classical approach principles, The Competent Departments have authority and responsibility about activities and controls of prepackaged products. Also, there isn't any determination about designated body procedures or certification process in these Directives for prepackaged products.	Noted
United States of America	General	The term "national legislation" is frequently used in this document. I believe that most of the details needed to implement these programs will be done not in national law but in regulations and/or policy and guidelines. I think national legislation is not needed to create this type of program. I suggest the term "national requirements" be substituted so that the reader understands that the enabling requirements can be provided through law or regulation or through administrative policy or guidelines.	Do not agree.
United States of America	General	I cannot find any mention that these programs can be established and maintained through a fee based system. It is more likely that countries would consider moving forward if they understood that the programs would be fee supported and that the costs of setting up the oversight and administration would fall on the participating packers and not the government. I recommend that a statement be added that these systems can be established and maintained using a fee system that is adopted as a component of the agreement. This will ensure that the anticipated costs and fees will be known to packers up front. Perhaps this can be placed in the Secretariat's introduction.	Noted. See C.2.2.3.
United States of America	Other General Information	Why not require the certificate to include a picture of the PDP and state the UPC code so that identification is easier to make?	Would not be able to include the barcode of each product.

Member	Clause	Comment	Secretariat comment
United States of America	Scope	I recommend that we be specific about the type of labelling requirements that a certification program can encompass under legal metrology. I recommend that you delete “associated” and insert labelling “related to the certification mark and the declaration of quantity, identity and responsibility (e.g., packer or distributor) name and address) for the product.”	Included in document.
Japan	Introduction	Not all OIML member countries are familiar with the ‘certification system for prepackages’. The introduction should include a comprehensive and easy explanation for this system.	Included in document.
Japan	3	Add a definition of ‘ <b>certification scheme</b> ’ which is frequently used in this document.	ISO terminology included.
United States of America	3	Add a statement that other terms and definitions may be included in a certification program agreement. This is simply to make it clear that if standards other than R87 or R79 are utilized in a program that it is permissible to incorporate appropriate definitions.	Included
United Kingdom	4.1	“The objectives of certification may be:” – should ‘may be’ replaced with ‘are’ or ‘include’?	Replaced with “include”
United States of America	4.1	I think these agreements will be based on national laws and regulations that may be similar to but not identical with OIML R87 and R79. I believe the intent of the group is to provide guidance to help establish bi-lateral agreements so we should make it clear that these agreements can be based on other standards related to quantity and labelling (I read in D.2.8.1 that both average and minimum systems may be used on certificates so perhaps a system open to other standards is acceptable) Harmonization with OIML Recommendations is an ongoing process and will take decades to achieve but that should not prevent countries from going ahead and experimenting with these programs using current national requirements. For example, in the U.S. NIST Handbook 133 “Checking the Net Contents of Packaged Goods” is adopted by most states and the U.S. Department of Agriculture. While HB 133 is not identical to the proposed requirements for R87 it may be appropriate for use (Note: like R87, HB 133 is not suitable for use as an in-plant statistical process control system) with this type of certification system. Perhaps this can be placed in the Secretariat’s introduction.	Noted

Member	Clause	Comment	Secretariat comment
Japan	4.3	We recommend sorting the items a) to v) by dividing into several categories on the basis of contents. Or, this whole clause may be split into several sub clauses.	Secretariat will undertake to categorise these possible paragraphs in the future if required.
United Kingdom	4.3	Does not refer to Annex E, add to the end of k) “(see Annex E)”	Agree and included.
United Kingdom	A.2.3	So that there is evidence that rejects are not marketed add “e) disposal of non-conforming prepackages”	Agree and included.
United States of America	4.2.4	All of the requirements, procedures and fees currently implemented by most legal metrology programs are public information. For this section delete “publicly available” before procedures since it is unnecessary to state the obvious.	Clarified at the meeting that certifiers should be used that is open and transparent with their requirements.
Japan	4.4 Table 1, 4.5 Examples of schemes (gen)	The schemes A-N in Table 1 are practically explained in Clause 4.5. We recommend moving this table to Clause 4.5.	Added clarification under 4.4.
Japan	4.4	The difference between Clauses 4.3 and 4.4 is not clear. We consider that Clause 4.4 mentions not ‘elements’ but ‘procedures’. Title should be changed to <b><i>‘Procedures for a certification scheme for prepackages’</i></b> .	Suitably amended 4.4.
Japan	4.4.1	This clause seems to mention items to be evaluated in the assessment. If so, all items should be expressed using bullet points for clarification.	Comment withdrawn.
United States of America	4.4.3	If this system is to be respected and to gain acceptance it should not include a statement based on something as unscientific as “subsequent production items conform to the specified requirements” based on past inspections or oversight. I don’t think that is what the system is attempting to achieve anyway. I recommend that this section be revised to read that the packer may only declare that prepackages were filled and labeled under the requirements of a system which conformed to the (name of the system) certificate system.	Discussed at meeting and suitably addressed
Japan	4.5	It is not clear whether this clause provides <b>explanations</b> or <b>examples</b> for the schemes A-N in Table 1. If this clause merely provides examples, the entire clause should be moved to an informative annex accompanied with Table 1.	Included new Annexure B.

Member	Clause	Comment	Secretariat comment
United States of America	4.5.1 Example of scheme A	<p>This example illustrates a potential weakness in the guidance document. A weakness exists if small or speciality packers are allowed access to the certificate system without being required to meet the all of the requirements larger packers meet and if they are not subject to unannounced inspections:</p> <p><i>“ A farmer has a small production of preserves which he sells prepacked in glass jars on the local market. The jars are labeled with the name of the product, the name of the farmer, the place where the farmer is located and the nominal quantity. The farmer’s production process ensures that all jars are overfilled (i.e. this is similar to a minimum system). The designated body assesses the farmer’s production system and issues a certificate. The certificate mentions that if the farmer changes his production process, he has to inform the designated body. In this case it would not be necessary for the designated body to do surveillance on the production system.”</i></p> <p>I do not think the integrity of the system can be maintained if different rules are made for any segment (even the little back road farmer or “boutique” shop or “mom and pop” store). Regardless of size of production or annual export sales these entities must be required to meet traceability and production record requirements to permit even minimal oversight. I would think that a packer who volunteers for a system would expect to take on additional responsibilities for the privilege of participation and to obtain the benefits of the system. I think the integrity of the system can only be maintained if there is the understanding by all that there will be ongoing or periodic oversight (i.e., unannounced inspections with satisfactory results are critical in helping build of trust) of all packers who receive certificates. Otherwise, the certificate must inform the user that the packer is not subject to verification. As the Russia proverb reads "doveryai no proveryai (“trust, but verify”) which is good advice in a competitive business environment.</p>	Do not agree.
Japan	5	This clause merely provides a list of annexes and it seems unnecessary. It should be deleted.	Leave in.

Member	Clause	Comment	Secretariat comment
United Kingdom	A.5	A.5.1 leaves it to the packer to decide on the retention period but A.5.2 requires them to be kept for at least 2 years. A.5.2 is not clear Suggest: “A.5.1 Records to should maintained for a sufficient period decided by the packer with a minimum period of 2 years A.5.2 Records that are produced while controlling prepackages should be traceable to: a) the prepackages concerned, b) the person responsible for the control, and c) the measuring instrument used”	A.5.1 to be changed to 2 years. Combined A.5.1 and A.5.2.
United Kingdom	A.7.1	Clarify by adding: “ the same product” in the same production run and are brought together for storage & distribution.”	Agree
United Kingdom	A.7.5	Clarify to read: “A.7.5 Quantities to be packed a) Labelled (nominal) quantity b) Target quantity c) Action control limits d) Where used, warning control limits or other control rules (e.g. rule of 5)”	Agree
United Kingdom	A8.2 NOTE 2	Observation: In UK legal metrology when an instrument is verified (to comply with statutory requirements) it is not a requirement t calculate nor state an uncertainty of measurement. Is this going to be a problem for the UK?	Note 2 amended
United Kingdom	A.8.3	Suggest add: “NOTE 1: records of calibration should always state ‘as found’ errors to demonstrate the instrument was maintained to the required accuracy. NOTE 2: When an instrument is found outside the required accuracy the non-conforming products procedure must be implemented.”	Agree and included.

Member	Clause	Comment	Secretariat comment
United Kingdom	A.8.4	Suggest adding: “NOTE 1: A daily pre-use check on weighing instruments for level, zero and span (and for automatic instruments standard deviation & rejection mechanism set points) is recommended to demonstrate the instrument is working correctly. NOTE 2: A daily pre-use check with distilled water can demonstrate that density measuring instruments are operating correctly.”	Agree and included.
United Kingdom	A.9.2	Clarify by inserting to read “..taken of the standard deviation <u>and filling rate</u> of the filling process. NOTE: A low sampling rate will require the target quantity to be higher than the nominal quantity to ensure the 3 quantity requirements in OIML R87 are met.”	Agree, note included
United States of America	Annex A; A.9.2	Delete “manual” before adjustment. Many packaging systems utilize automated adjustment mechanisms that operate on feedback from verification devices in the packaging line. When troubleshooting to find the source of unreasonable variations samples should be taken to verify the performance of systems that make adjustments automatically.	Agreed to leave unchanged.
United Kingdom	A.10.3	Clarify by inserting to read “... cause and actions undertaken, <u>including how the rejected prepackages have been disposed</u> , should be kept ...”	Include note
United Kingdom	A.10.5	Suggest add new paragraph: A.10.5 Where checks and calibration of instruments indicate that they are outside the required accuracy, the impact on the quantity of the prepackages produced should be assessed and A.10.1 implemented when necessary.	Include and check duplication with Note 2.
United States of America	C.2.1.5	This section provides a bright line rule about a threat to impartiality and then gives an option about whether or not certification is to be provided. In the last sentence change “should” to “must” because “should” allows the user to define right or wrong by not providing a bright line rule which can then be an enforceable requirement. A similar problem is found in C.2.1.10, 11, 12 and many other sections in this Annex. The integrity of these systems will rest primarily on trust and that can only be assured if there are clearly stated rules that can be enforced by the parties.	Discussed at meeting

Member	Clause	Comment	Secretariat comment
United States of America	C.2.1.6.	I think requiring the designated bodies to provide their ethics rules on prohibited financial and professional working relationships as well. For example, packers should be prohibited from providing unauthorized compensation or other perks directly to auditors or inspectors of the designated body during audits. This may be covered by C.2.2.3 but saying there “should” not be undue financial or other conditions will not help ensure integrity.	The Netherlands to provide wording in general to indicate that CAB suitably take care of requirements in C.
United Kingdom	C2.1.10	The requirement for certification and consultancy to remain separate might make it difficult for the designated body to give advice	Discussed and agreed to leave unchanged.
United States of America	C.6.	In b) replace “repeated” with “Two or more...”to be specific. In c) delete “major” since it is subjective. Just say “Any noncompliance” and that gives the designated body the authority to act without getting involved in an argument over the ambiguity caused by the term “major.”	Agree
United States of America	Annex D	Again the use of “should” <u>must</u> be avoided. Use “must” instead.	Noted
Japan	Annex D, D.2.8.1	It mentions that “ <i>include a reference .... average system, <u>minimum system</u>...</i> ”. However, OIML R 87, on which this guide document is based, does not seem to cover the minimum system. It is not clear whether this guide document as well as R 87 cover other inspection systems. If these documents are only based on ‘average system’, reference to minimum system should be deleted.  For our memorandum, TC 6 agreed to include the minimum system to R 87 at the meeting in Pretoria in 2009 (Resolution 1). However, an explicit note to minimum system was deleted at the next meeting in Pretoria in 2010 (Resolution 1), and at the same time, TC 6 agreed that all packaging systems might be included inexplicitly in R 87.	Clarified what is meant in a note
ISO		Mention is made that the CB can be accredited for ISO/IEC 17065 amongst other things. It would be good if in addition to being accredited as a minimum they are required to operate in accordance with ISO/IEC 17065. This would allow them to pick from “self-declaration” (SDoC) to 3 <sup>rd</sup> party (accreditation) depending on the need and risk involved in non-conformity. If the obligation is for them to comply with ISO/IEC 17065 it will definitely raise the standard of the process.	Agree to see comment from USA C.2.1.6.