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UNICE TECHNICAL BARRIERS TO TRADE WORKING GROUP COMMENTS ON

PROPOSED ELEMENTS FOR EUROPEAN GUIDELINES ON INTERNATIONAL STANDARDISATION

UNICE has examined with interest the document entitled "Proposed elements for European guidelines on international standardisation" prepared by the Commission with a view to collecting input from stakeholders (document SOGS N381R2 of March 2001).

The Commission guidelines underline the importance of coherence for international standardisation and present the key principles for international standardisation, agreed upon in the triennial review of the Technical Barriers to Trade (TBT) Agreement in November 2000. The paper clearly stresses the importance of international standardisation in facilitating market access.

The Commission could be more clear about the intention of these guidelines. UNICE strongly supports the notion that the paper is intended to provide guidance for future Commission and member-state policy. The paper should not be seen as guidance for business actors. However, in discussing the stakeholders involved in standardisation, it is important to be clear that business is the largest stakeholder taking into account the large amount of resources it puts into the process – i.e. time and money.

Since the paper is meant to serve as European guidelines and contain key elements for international standards issues, we believe the paper should address more broadly the aspects of importance for the context of international standardisation. In this respect, it is not enough to have a common set of principles for elaborating the standards if the basic framework does not allow a uniform application of the standards. For instance, for developing international standards, the identification of *common regulatory objectives* is the starting point, and at the other end of the line, the procedure for *conformity assessment* is decisive for market access. The importance of harmonisation of regulatory requirements and mutual recognition of conformity assessment procedures and accreditation agreements should consequently also be stressed in the paper.

Please find below specific comments on the Commission draft and how it could be developed further.

Weakness in implementation of WTO-TBT

- Weakness in implementation of the WTO-TBT agreement. Under Point 2, which amongst other things discusses the main principles of the WTO-TBT Agreement, the Commission should comment on how the Agreement works in practice, i.e. that there is a

weakness in implementation of the agreement today, not only in developing countries but also in OECD countries. For example, there is currently weak enforcement of the Agreement's principles on using an international standard as first option and using the least trade-restrictive option for regulating. There has not been much international case law which could have contributed to a stronger implementation the Agreement. Again under point 9, the weak implementation is mentioned, but only briefly and with reference to developing countries.

Regulations-standards-conformity assessment

?? In order for the standard to be an efficient facilitator for trade and market access it needs to be placed in a wider context. The guidelines should therefore be more explicit on the link between standards, conformity assessment and regulations as instruments for facilitating trade (this is only mentioned briefly). Simply because, in many cases, harmonisation of all three components is necessary to ensure full market access. One example which the Commission might examine is the EU-US business approach put forward in TABD, Transatlantic Business Dialogue, on key regulatory instruments to be used for "Approved Once Accepted Everywhere". This is a general approach which business agrees on. It is then up to individual sectors to choose appropriate instruments:

Product Requirements
- Harmonisation of each other's regulations (including regulatory objectives) and standards.
- Mutual recognition of functional equivalence of regulations (including regulatory objectives) and standards.

Conformity Assessment
- Harmonisation of conformity assessment systems.
Mutual recognition of conformity assessment (e.g. EU/US MRA).
- Delegation of approval from governments to third party or supplier's laboratories (SDoC).

Reference can also be made to the components developed by the UN/ECE ad hoc team on Standards and Regulatory Techniques, START – "an international model for implementing good regulatory practice for the preparation, adoption ad application of technical regulations via the use of international standards".

?? Referring again to the above point on regulatory instruments, there is a weak link in the conformity assessment area. Currently the lack of coherence in this area is a weak link and tied to the standards issue. As is known, this link is weak both inside the EU, with many trade barriers in the conformity assessment area, and in other markets.

Different sector strategies

?? The guidelines need also to address and promote the global standards strategies of individual sectors, which are not tied to new approach but which also build on trying to harmonise standards globally. The only exception presented is the IT area with ETSI as an actor. In addition to this, "non new approach sectors" such as chemicals, pharmaceuticals, automotives and foodstuffs play a very large role in EU and global trade.

?? The Commission clearly needs to be a facilitator and set global strategies for standards harmonisation also in this area even they do not fit into the CEN/CENELEC - ISO/IEC concept. UNICE's experts aware that the standards in these more regulated sectors in many cases are mandatory and have a strong regulatory interface. Many of these business sectors are nevertheless involved, working with the regulators to achieve global harmonisation.

Principles for international standards

?? Consensus and efficiency, discussed under point 6, should be elaborated on rather more. It should be acknowledged that setting up international standards based on consensus might not be as simple as suggested, e.g. due to the fact that there are different regulatory objectives as well as different structures for conformity assessment. Therefore the sentence in the last paragraph of section 5 is very important: "… provide information on existing regulations and standards in order to explore commonalties".

?? When it comes to efficiency and accountability, it should be made clear that application of the consensus principle needs the consensus of the relevant economic actors, i.e. those who later buy and use the standard.

?? It may not only be, as the paper states, in cases where we have fast-moving technology, that efficiency needs to be prioritised. *There are also cases where there are no or minor health and security aspects involved in standardising and where efficiency may be more important than consensus.*

?? Regarding the coherence discussion under point 4, business strongly agrees that coherence in many cases is important and a key to trade facilitation. The whole chapter under point 4 is, however, somewhat *oversimplified* – e.g. it cannot be categorically stated that the "balance of interests" would be disturbed, as stated under point 4, if we had simultaneously produced standards.

Again, the *effects of a non-coherent system strongly depend on the sector*. Regulatory requirements and standards in areas such as foodstuffs and pharmaceuticals stem not only from different regulatory objectives but also from the fact that there are different structures for conformity assessment. Referring to the discussion above on key regulatory instruments, the recipe is not necessarily "one" international standard. What is needed is to achieve global market access is a mix of regulatory instruments depending on different sectors. This does not mean that EU business wants to weaken the definition and promotion of international standards in the WTO-TBT Agreement. But in guidelines like this the picture should not be unduly oversimplified.

?? Other comments on principles stated under point 4. In previous WTO-TBT papers, it is mentioned that the international standards development process should ensure that *global market competition is not distorted*. This principle should still be valid. *Quality* is not mentioned as a principle. Quality must not be forgotten in the objective of effectiveness and consensus. Quality should be ensured by the active participation of all stakeholders - each expert within their field - from the very beginning of the process. Thus early participation of regulators is important in order to have the final standard accepted and referred to by regulators.

National – European-international standardisation

?? The national position to build international consensus, as discussed under point 3, should be elaborated on rather more. As a contrast to what is said under this point it should be pointed out that some stakeholders, among them global business, clearly find the national platform for standardisation and assuring national consensus ever less relevant. *There is an increased reluctance to allocate resources to parallel national, regional and international levels of standardisation.*

It should however also be pointed out that safeguarding the national level in standardisation may be important to ensure that all stakeholders have access to active participation in standardisation, i.e. for SMEs, consumers and other NGOs which in many cases have too few resources to participate at the European or international level. Thus, national participation in international standards bodies should not only be seen as a way to build consensus, but also to *ensure wider participation of stakeholders*.

When safeguarding national standardisation it is, however, important to maintain the principle of *withdrawing conflicting national standards* when regional or international standards are available. National particularities should be considered when the international standard is developed and addressed in the international standard if they are judged to be of general interest. National deviations should be accepted only if justified through *de facto* different national conditions in essential areas, such as health, safety and environment.

?? In the discussion under point 8 on synergies offered by international standardisation, the paper should mention the *Vienna and Dresden Agreements* tied to CEN and CENELEC, which have been created for the purpose of avoiding overlaps and duplication and strengthening the alignment with international standards. This mechanism is of utmost importance to industry. The Commission position that "…there is in most cases no need for a single European position for the elaboration and adoption of an international standard" contradicts much of the Commission's harmonisation policy in this area.

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