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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods
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PACKAGINGS

Notes on the Conference on Quality Assurance programmes for the Manufacture of Dangerous Goods Packaging – National Implementation and Enforcement held in Geneva on 2003-07-04

Transmitted by the International Organization for Standardization (ISO)

On invitation by ISO, a conference was held on the implementation and enforcement of one of the clauses of the UN Recommendations on the Transport of Dangerous Goods (Model Regulations), which requires that

> *a quality assurance programme shall be applied for the manufacture of dangerous goods packagings, which satisfies the competent authority* (UN 6.1.1.4, 6.5.1.6.1 and 6.6.1.2).

The United Nations Subcommittee of Experts on the Transport of Dangerous Goods was addressed by the ISO- representative (Abram) during its 23. Session on this behalf, supported by information paper UN/SCETDG/23/INF 8 together with an information copy of the working draft of the standard

> *EN ISO 16106 "Packaging – Transport packages for dangerous goods – Dangerous goods packagings, intermediate bulk containers (IBC's) and large packagings. Guidelines for the application of EN ISO 9001".*

20 experts from 9 countries and 4 NGOs took part in the conference, which was opened by M. Abram in the name of the Director of ISO, Mr. M.A. Smith.

As a member of the joint CEN/ISO working group[1] in charge of preparing this standard Mr. K. Wieser (DIN/BAM, Germany) highlighted the background of the UN requirement as part of the UN design type testing and marking scheme and the incentives for the establishment of this standardizing project. He gave his views on a possible role of this standard in context with the UN Model Regulation, i.e. reference to the standard as one option to comply with UN.
Mr. M. Castle (BS/PIRA, United Kingdom) as the secretary of the joint CEN/ISO working group provided information on the status of the draft: By an ISO inquiry ending February 5, 2003, this work item has been re-established on the work programme of ISO and the associated draft has been approved as DIS. With CEN its also on the work programme and is ready for parallel inquiry[2]

The agenda of the conference was deemed to highlight the role of quality assurance programmes for the user of packagings and the implementation of the UN requirement in some countries. Representatives of United Kingdom,United States of America, Canada and Germany gave descriptions of their national schemes.

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[1] *ISO/TC 122/SC3 /WG8 – CEN/TC 261/SC5/WG 16 „Dangerous Goods Packaging"*
[2] *Parallel CEN/ISO has been started on August 18, 2003 with a time to react of two month.*

Packaging user's view

Mr. Krampe (CEFIC, Beiersdorf AG) described the advantages that users of packagings would expect from an international standard on the quality management of the manufacture of dangerous goods packagings:

- Packagings of a design type may be supplied from various manufacturers in different countries. To avoid shipments with empty packagings, they are supplied locally. Worldwide operating customers need the same product quality obtainable everywhere.Many of the specifications of „typical" packagings for dangerous goods (e.g. drums) used by the (European) chemical industry are standardized (CEN/ISO). But there is no international standard for a quality assurance programme for the manufacturing of dangerous goods packagings.
- From an users viewpoint this leads to difficulties within his own quality assurance system for producing goods for his customers. Different local standards would require many individual quality contracts between users and suppliers. Therefore a standard quality assurance programme for manufacturing packagings for dangerous goods would be helpful to decrease of the number of tests and of individual audits at the supplier's plants.

United Kingdom's view

Mr. Castle (United Kingdom, PIRA) summarized the main instruments to control packaging quality in the United Kingdom:

- Design Type testing and type approval
  - Test labs/houses have to be approved by the United Kingdom accreditation service;
  - Type approvals are given only by PIRA under uniform rules (at present about 2500 approvals, about 50% hold by manufacturers and 50% by users);
  - Approval holders are declared responsible for the realisation of a quality assurance programme;
  - An annual fee has to be paid for each type approval.
- Enforcement/ Monitoring the quality of packagings
  - Random call-ins (repetition of design type testing) are executed by PIRA, which are focussing on specific types of packagings each year. In addition call-ins are also started following (competitors) information on expected non-compliances. In this case quite high failure rates occur (about 50%).
  - The annual fee for an approval covers the cost for call-ins.
  - In case of detected failures costs have to paid by the approval holder.
  - The reconditioning industry is subjected inspections once a year. As a specific quality assurance element a guide on the performance of leak tests has been agreed with industry.
  - For combination packagings the assignment of responsibility for the manufacture is considered as a specifically difficult obstacle for the application of quality assurance programmes.
- Appraisal of introducing the standard
  - United Kingdom manufacturers don't want the standard. The competent authority has no indication that there is a safety-related need for this standard in the United Kingdom.

USA's view

Mr. Richard (USA) gave the following view on the situation in theUnited States of America

- Design Type testing and type approval/allocation of UN-marks
- Design type tests including the allocation of the UN-mark are performed by DOT approved test labs, test labs registered with DOT and by shippers according to a self certifying program. There are currently about 30 DOT approved test labs. All of the test labs and self certifiers are subject to the oversight and inspection by DOT-RSPA and other DOT enforcement personnel.
- Retesting (full design type test program) of all approved packaging design types is required; for single packagings every year and for combination packagings every second year.
- Enforcement / Monitoring the quality of packagings
  - In charge of DOT-RSPA packaging are bought from the market and tested by an independent test lab. The selection of packaging is based on an expert valuation of suspected non-

compliances. Consequently, a rather high failure rate is detected (up to 70%)
- About 500 testings are performed any year
- Detected non-compliances are fined with up to 50,000 $ and approval holder including the penalty are published in the Internet.
- An incident reporting system lists any reported leakage and the incidents and accidents are analysed.

- Appraisal of introducing the standard
  - The data interpretation of the reporting system shows the subordinate role of the containment function of packagings. The percentage of failing packaging capabilities amounts in spillage records with ranges below 1/1000. Even then misuse e.g. wrong closing of packages is more relevant than bad quality of the packagings. Better instruction of users is deemed therefore more relevant than more detailed requirements on quality assurance programmes;
  - Such a standard as an obligatory rule would be much too rigid for theUnited States of America.
  - The responsible care process also sustains the quality of packagings.

Germany's view

Mr. Nitsche (BAM) gave a presentation of the German quality control system, the main elements of which are:

- Design type testing and type approval
  - Design types are tested by BAM or test labs/houses (41 at present) accredited and supervised by BAM.
  - Design type approvals (unlimited validity) denoting approval holder and manufacturing facility are issued by BAM (only); certificates including necessary information for users are published under www.tes.bam.de.
  - Presupposition for a type approval is a quality assurance programme (QAP), valid for the manufacturing facility(ies) which is valuated and approved by BAM. Enforcement / Monitoring the quality of packagings
- Enforcement / Monitoring the quality of packagings
  - Implementation and application of the approved quality assurance programme is monitored and checked every year (check of quality records and testing of packagings at random) by BAM or independent inspection bodies, recognised by BAM.
  - In the case of serious non-compliances, design types are retested and the manufacturing facility will be audited and checked unscheduled.
- Appraisal of introducing the standard
  - The application of EN ISO 16101 could help to deregulate the enforcement and monitoring.
  - The standard would allow for a bonus for companies which are applying a ISO 9001 quality management system.
  - The application of EN ISO 16101 could support the comparability of packaging qualities and of an internationally balanced competitive situation;
  - It could support compliance with the performance criteria

Canada's view

Mr. Lewycky (Transport Canada) explained the Canadian system and highlighted the following characteristics:

- Design type testing and type approval
  - Anyone can do design type tests as long as they are done right
  - Many manufacturer do there own testing
  - Test report must be filed with Transport Canada
  - Designs registered with the competent authority, Transport Canada by the manufacturer (UN IBC's, UN Packagings: drums, jerricans and composite packagings); other UN codes are not registered.

  - Concerning registered UN types the manufacturer must provide a QA system meeting ISO9001 or 9002, registered by SCC accredited register. Other UN codes have to be produced concerning the QA system ISO 9003.
  - are subject to audit & revocation of Transport Canada
- Enforcement / Monitoring the quality of packagings
  - Registered facilities are subject to audit & revocation of Certificate
- Appraisal of introducing the standard
  - Canada has already endorsed a stringent ISO 9000 regime, which works to the satisfaction of the competent authority. The application of EN ISO 16106 could lead to unnecessary adaptations and restrictions.
  - Canada wants to keep the flexibility within its national QA regime.
  - The experience to influence the standardising efforts by the CEN/ISO working group on dangerous goods packagings are negative and agreement with this standard project is not to be expected.

Conclusion/summary

In summarizing these views and considering the differences of the five highlighted national situations, it was realised that the standard has different importance in these countries and that it would certainly not be adequate to make it a general or even binding rule in context with the application of the UN Model regulations.

However, this should not hinder its role as an optional interpretation of the UN requirement and the voluntary application among those parties or countries with similar national schemes, as a basis for bilateral agreements or contracts between users and manufacturers of packagings.

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