



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Single Market for Goods
Internal Market and its International Dimension

EXPERT GROUP ON TOY SAFETY

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SUBJECT: Report of the Expert Group Meeting of 11 October 2013

ACTION Approved at the meeting on 18 February 2014.

EXPERT GROUP MEETING ON TOY SAFETY

**Approved Report of the Expert Group Meeting
on the implementation of Directive 2009/48/EC on the safety of toys**

Borschette Centre, rue Froissart 36, Brussels

11 October 2013 (09:30-13:00)

Chair: Head of Unit, DG Enterprise and Industry, Unit C.1

Participants:

- Competent authorities and market surveillance authorities under Directive 2009/48/EC
- EFTA States
- Stakeholders

1. Opening of the meeting

The Chair opened the meeting, welcoming all participants.

1.1 Approval of the draft agenda - EXP/2013/016 rev 1

On any other business to be added to the agenda, **SE** reminded having requested certain clarifications on the minutes of the Expert Group meeting held in September 2012. **TIE** requested that clarification on the practical consequences of the German government maintaining its national measures on the migration limits for certain chemical substances (antimony, arsenic, barium, lead and mercury) be provided, in light of the Commission Decision adopted on 7 October 2013. Finally, **DK** pointed out that at the last meeting it had sought clarification from COM on CEN's work item concerning exclusion of hard polymers from migration limits.

With these three issues to be discussed under any other business, the agenda was approved.

1.2 Adoption of the minutes of the last meeting - EXP/2013/015 rev 1

The minutes of the meeting of 3 May 2013 were approved.

2. Feedback on the Toy Safety Directive 2009/48/EC

2.1 Discussion on the explanatory guidance document - EXP/2013/020 and Annex, EXP/2013/021 and EXP/2013/025

COM introduced the changes included in the draft which had been distributed. Several changes had been agreed at the previous meeting, namely the modification of the wording regarding amusement toys in point 1.2.3 and the deletion of the reference to finger paints in point 11.3.10. In addition, in accordance with the discussion at the meeting of 3 May 2013, several additional modifications were suggested in relation to the proposed wording for language(s) of warnings in the case of online selling in point 3.2.6 and the clarification regarding the legal interpretation of Annex I and Article 2(1) in section 10.

Several adaptations had also been made to reflect the entry into application of the chemical requirements of Annex II Part III on 20 July 2013, by updating references to the Toy Safety Directive and to harmonised standards. Moreover, COM had identified further necessary updates (e.g., references to other Union legislation which had become obsolete, correction of references to exact wording of the Toy Safety Directive).

COM recalled that BE had submitted a written proposal for an alternative wording concerning the languages of warnings in the case of online selling in point 3.2.6. This wording was generally supported by the Expert Group.

SE had submitted an additional proposal concerning the CE marking on co-packs containing both toy and non-toy products, clarifying that when toys are co-packed with non-toy products, the non-toy products do not need to conform to the requirements of the Toy Safety Directive. LT welcomed the proposal made by SE and considered that further explanation might be added; it also asked to look into whether, for example, a baby walker with integrated toys should be CE marked. LT pointed out that for products with integrated toys, the CE marking referring to the toy part of the product was necessary. FR considered that a baby walker was a childcare article and the package should make clear that the CE marking only concerned the toy part of the product. COM agreed that the classification and need for CE marking for these articles could be looked into in the next Administrative Cooperation meeting. SE proposed to provide additional wording if this would be considered useful. It was agreed that the text proposed in writing by SE prior to the meeting would be included in the Explanatory Guidance Document and that additional explanations in this regard may be added at a later stage.

The picture included at the top of page 39 and its explanatory text indicating that warnings need to be placed on the toy itself and cannot be placed only on the counter display were discussed. It was generally considered that the text was not sufficiently clear. SE made a wording suggestion indicating that the warnings could not be placed only on the counter display; the warnings can also be placed on the counter display if the appropriate warnings have been correctly affixed on each toy. UK considered that this point should be reflected upon carefully, in particular, in view of the fact that in some cases it may not be possible to affix the warning on the toy itself, to which ES agreed. SE argued however that the explanatory text did not relate to the issue where on the toy the warning should be affixed, but rather to the issue if and how warnings may be placed on counter displays. COM recalled that the picture and the text should be considered together with the entire text in that section explaining where warnings should be placed on the toy itself (cf page 38). IE made an additional wording suggestion to further clarify the issue. SE and NL recalled that the warnings can only be put on the display if they are also correctly affixed on the toy itself. CEN suggested deleting the picture and the text. Several delegations asked for more time to look into the issue. **The Chair** concluded that

COM would distribute a new proposal for the wording and picture in this section and that deleting it would also be considered.

FR requested that other language versions of the Explanatory Guidance Document be updated. **COM** acknowledged that the other language versions were not evolving with the same speed as the English version but recalled the limited resources and priorities of the translation services. **COM** had discussed with the translation services the update of the different language versions but this could not be completed before the end of the year. In addition, the translation into Croatian of the document would take more than one year, since a previously translated version of the document does not exist. It was concluded that once the new revision of the explanatory guidance document would be agreed, it would be sent to the translation services for update of the different language versions.

Concerning the new text proposed in Annex I, **SE** requested that either points 3 and 9 are added together with points 4 and 8 as items which should not be considered as toys without an assessment against the definition of Article 2.1 being necessary, or that only the first sentence would be kept and the additional text included be deleted. **COM** explained that the additional text intended to illustrate the argument but not to give an assessment on each of the elements of the list in Annex I and whether a margin of interpretation in each point was possible or not. **CEN** believed that the additional text was useful and would prefer it not to be deleted. It was therefore concluded that points 3 and 9 would be added to the text together with points 4 and 8.

The Chair concluded that a new proposal would be distributed following the discussion and it would be submitted for written approval.

2.2 Discussion on the technical documentation guidance document - EXP/2013/022 and 024 as well as their annexes, EXP/2013/025

COM introduced the changes proposed in the document distributed prior to the meeting. As agreed at the meeting of 3 May 2013, the reference to Commission Decision 2009/251/EC on DMF in Annex II had been deleted. In addition, as discussed at that meeting, the BOM/BOS template as suggested by TIE had been included, as well as the related letter and declaration of compliance, wording had been included regarding national provisions on formaldehyde – on the basis of information provided by FI and NO, and other changes updating references to the Toy Safety Directive and to

harmonised standards in order to reflect the entry into application of the chemical requirements of Annex II Part III on 20 July 2013.

Moreover, the Commission services identified further necessary updates (e.g., references to other Union legislation which have become obsolete). NO had provided additional information on national legislation. Finally, letterhead, footers and some small typographical errors were corrected.

COM recalled that BE had submitted written comments prior to the meeting. It suggested, as to the references to the harmonised standards (page 36), not to specify the year version of the standard and leave it as it was 20XX, so that the document would not need to be updated as soon as there is a new version of a standard. In addition, it suggested in page 62 to delete the references to the non-chemical standards. SE supported both suggestions.

CEN commented that the Norwegian national legislation on SCCPs may conflict with the EU POPs Regulation and questioned whether it was advisable under those circumstances to include a reference to the national legislation in the document.

The Chair concluded that both changes proposed by BE would be introduced and the document was approved.

3. Update of Activities from CEN - EXP/2013/023

CEN informed about activities, presenting on-going amendments, “fast track” amendments, new work items and formal vote results. CEN also presented on-going work on technical reports.

DE asked confirmation that its A-deviation on lower limits on nitrosamines and the particular test methods would be taken into account. DE asked CEN to address also the 24 hours migration time clearly in the A-deviation in EN 71-12:2013 annex C, because this is mandatory in Germany. CEN recalled that it was indeed aware of the derogation and the way it was worded, as well as the test methods.

4. Update of Activities from CENELEC

CENELEC informed about past and upcoming activities.

NL asked clarification as to what standard would cover toys containing lasers. CENELEC mentioned that electric toy standard EN 60825 and its annex would apply to

toys containing lasers. **LV** referred to toys with solar panels and asked whether standard EN 62115 covers such toys and whether these toys could present additional risks. **CENELEC** pointed out that it was not included so far in the scope of the standard since first all the safety assessment for these toys needs to be developed. **COM** confirmed that, since they are not covered by the standards, these toys would require EC-type examination.

5. Update of Activities from Notified Bodies - EXP/02013/018

Notified Bodies informed about their activities since the last Expert Group meeting and that the next meeting would take place in October 2013.

FR recalled that, as it mentioned in the previous meeting, the hot water bottles in plush material should not be considered as a separate item but should be examined as being part of the toy.

6. Discussion and approval of Recommendation No 1 (Format EC-type examination certificate) rev3 - EXP/02013/017

Notified Bodies reported on the work on the revision of Recommendation No 1 which had been discussed at the previous Expert Group Meeting. The new version distributed incorporated the changes agreed at the meeting and Notified Bodies requested the approval of the document.

TIE pointed out that in the Annex including the list of references to the technical documentation provided to the Notified Body for the EC-type examination and the list of technical documentation to be maintained by the manufacturer, it should be clarified for point e) that whilst the address of the place of storage was not relevant for the EC-type certificate, the address of the manufacturer was. **TIE** suggested splitting the point into two items. **TIE** also suggested that point h) would be divided into three items. **Notified Bodies** agreed to make both changes.

PL mentioned that it would welcome the possibility to discuss the document with its notified bodies and indicated that it would provide any comments it may have within two weeks. **Notified Bodies** reminded however that the Polish Notified Bodies participated in the Notified Bodies meeting and had an opportunity to raise any issues on the document at that stage.

The Chair concluded that subject to these changes the document was agreed.

7. Discussion on the working paper on the amendment of Appendix A of Annex II of Directive 2009/48/EC as regards nickel – EXP/2013/019

COM presented the proposal for the inclusion of an additional exempted use for nickel in Appendix A of Annex II to Directive 2009/48/EC. Appendix A is entitled "List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III". It currently contains the substance nickel for which a use is permitted in stainless steel. The working document proposes an additional exemption for the use of nickel in parts of toys allowing the correct electric function of toys. The document was presented as taking the form of a Directive with 18 months transition period.

TIE expressed its concerns about this amendment being in the form of a Directive which would require implementation by Member States with an 18 months transition period. **TIE** would welcome that the amendment took the form of a Regulation which would require a reduced transition period, also in view of the fact that the industry did not need any adaptations to comply with this amendment.

SE and **DK** supported the **COM** proposal to introduce this exemption. **FR** requested additional time to look into the scope of the exemption and the implications of Article 1. **FR** pointed out that Appendix A concerns all toys and wondered if the wording proposed was not too broad or if the exception should be dependent on whether the nickel parts were accessible and on the age group the toy would target. It also requested clarification from **COM** as to the procedure how this amendment was expected to be voted, whether a written voting procedure may be launched or if it may be discussed and voted at a subsequent meeting. **TIE** recalled that the exemption for nickel in stainless steel and the **SCHER** opinion concerned all toys and were not dependent on age grade or accessibility. **FR** indicated that the explanation on the accessibility could be added in a recital. **DE** referred to recital 7 and pointed out that it should be explained that the nickel migration limits remain valid if prolonged contact with the skin is possible.

SE, DK, FR, DE, PL, EE and **UK** supported that this amendment would take the form of a Regulation. **SE** and **FR** argued that the industry would not need to adapt in order to comply. **COM** pointed out that introducing amendments to the Directive via Regulations would risk leading to inconsistencies at national level, since the Directive would have been transposed into national law but not its amendments via Regulation. At the question from the Chair it was concluded that a number of delegations were neutral but there was important support for adopting a Regulation.

The Chair concluded that recital 7 would be adapted as suggested by DE and a recital on accessibility would be added as requested by FR. The Chair asked FR to inform in writing of any remaining comments on the document. The proposal would be discussed at the next Committee meeting.

8. Information from the Commission

8.1 Update on chemicals

Chromium VI: COM indicated that it had requested an opinion to SCHER on Chromium VI in toys since it has shown to be highly toxic and possibly have carcinogenic properties. It was foreseen that the draft opinion would be adopted in spring 2014, followed by a two-month public consultation after which the final opinion of SCHER would be adopted.

Under REACH, a restriction of Chromium VI in leather articles and articles containing leather parts (limit value 3 mg/kg) is ready for a vote in the REACH committee and is expected to be adopted soon thereafter.

PAHs: A REACH restriction has been elaborated and voted in the REACH Committee; the scrutiny by the European Parliament ended on 12 October 2013. It is foreseen that the PAH restriction is published in the Official Journal before the end of 2013 and that the transition period for the applicability of the restriction would be of 2 years. The restriction will establish two limits for PAHs: 0.5 mg/kg in toys and childcare articles and 1 mg/kg for all other consumer articles.

UK asked about the input the Expert Group had on the PAH discussion. COM mentioned that the restriction has been discussed extensively between the different COM services. The proposal initially had a single limit value for all articles but following discussion with Member States, a lower limit was set for toys and childcare articles. AT requested clarification as to which PAHs would be included. COM pointed out that the 8 PAHs already covered by REACH would be concerned by this restriction.

8.2 Update on the work of the chemicals subgroup

COM reported that the subgroup agreed to start a discussion on the testing of toy materials - which materials should be tested for which chemicals. It decided on a toxicological limit value (Tolerable Daily Intake TDI) for phenol of 5 mg/kg bw/day and on a limit value for phenol of 5 mg/l when determined in accordance with EN 71-9, -10

and -11 (same principle as for bisphenol A). It also agreed to continue the discussion on formaldehyde in toys (presence, analytical methods and possible future limit value) and to reorganise the priorities for non-threshold carcinogens in view of future discussions. It was concluded that formamide should be tested in the following foam materials: EVA (polyethylene-vinylacetate), PE (polyethylene) and PU (polyurethane); discussions on the analytical method for formaldehyde may be coming to a close soon in that group. The presence of biocides in toys would be discussed at the next meeting.

8.3 Reporting obligation under Article 48 of the Toy Safety Directive

COM explained that according to Article 48 of the Toy Safety Directive there is an obligation for Member States to report every 5 years on the application of the Directive. The first report is due by 20 July 2014 and COM is then to make a summary of the Member State reports. Article 48 prescribes what the reports must contain: an evaluation of the situation concerning the safety of toys, an evaluation of the effectiveness of the Directive and a presentation of market surveillance activities performed. This is not limitative and other information may be considered useful and included in the report. COM indicated that a format for reporting would be prepared in the coming weeks/months. COM asked for input from the different delegations on the information the report may contain. Comments from participants were welcome within 6 weeks from the meeting, i.e. 22 November.

SE pointed out that it may be easier to make suggestions after a first draft for the format was made available by COM. It also asked about the language requirements for reporting. **FR** suggested commenting on the setting up of the Directive, since it will be the first report after its entry into force and the difficulties encountered as well as the most relevant actions undertaken in each Member State. COM indicated that the report can be submitted in any official language; receiving the report in English would however facilitate the task for the COM services.

<p>The Chair asked delegations to provide suggestions on the information to be included in the report or on the format by 22 November 2013. COM will propose a first draft format on that basis in the coming months.</p>

10. Any Other Business

10.1 Amendments of the minutes of the Expert Group meeting on September 2012

SE pointed out that at the last meeting the COM agreed to insert a note in the minutes of the meeting on 11 September 2012. COM had inserted such a note in the minutes. SE asked for further clarification and indicated that it would look into the explanations provided by the COM and may come back on this issue at a later stage. **COM** explained the clarifications which concerned CE marking and the internet webpages as well as the applicability of Article 17 of the Directive to online selling. These clarifications were made on the form of a note from the meeting secretariat included in the minutes of the 11 September 2012 meeting in such a way as not to give the impression that these had been actually discussed at that meeting.

10.2 DK request for further clarification on hard polymers

DK asked the COM at the last meeting on the discussions on the possibility for CEN to exclude hard polymers from standard EN 71-3 corresponding to the migration limits, and requested further feedback from COM. **COM** indicated that this had been discussed at the last meeting of the subgroup on chemicals and recalled that CEN had informed that the first meeting to assess this issue would take place in November. **DK** requested an opinion from the COM on this issue before starting the analysis on the subgroup. **COM** however recalled that for scientific evidence it relies on the opinion of the subgroup before expressing a view. It appeared more appropriate to discuss at the chemicals subgroup and subsequently at the Expert Group. **DE** considered that the COM should however look into whether it was possible at all to exclude such materials according to the Directive.

The Chair concluded that this point would be discussed at the next Expert Group.
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10.3 Clarifications on the migration limits applicable in Germany

DE referred to the Commission decision of 7 October 2012. **DE** pointed out that this decision should not have any impact on market surveillance since it confirmed the already existing situation. **TIE** requested further clarification from the DE authorities as to whether the former values of the standard EN 71-3 which reflected the requirements of the previous Toy Safety Directive would remain in force in Germany. The new Directive

makes a distinction between different types of materials which was not present in the former Directive. Industry recalled the importance of understanding from a technical perspective the real limit values which would apply to each material and how the products should be assessed. **DE** pointed out that until the judgement on the case will be delivered by the General Court, the DE limit values will remain in force. Therefore, from a technical perspective, for the five substances concerned the values in the former versions of EN 71-3 and EN 71-7 should apply.

TIE indicated that it would send a document with further questions they had and requesting additional clarifications.

The Chair informed the Expert Group that the document sent by TIE would be distributed to all participants.

10.4 Prosafe project for toys – Joint Action with China

DK asked the COM for clarification as to how DG Enterprise and Industry is involved in the work of the Joint Action (JA) with China undertaken by Prosafe. **COM** indicated that the DG is involved in the work and would participate in the meetings of the related JA working group.

11. Closing of the Expert Meeting

The Chair closed the meeting, thanking all participants.

Annex

List of Participants
Expert Group on Toy Safety

11 October 2013

Country	Organisation	Present
Austria	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES) Institut für Lebensmittelsicherheit	X
Croatia	Ministry of Health	X
Cyprus	Ministry of Commerce, Industry & Tourism	X
Czech Republic	Czech Office for Standards Metrology and Testing (COSMT)	X
Denmark	Danish EPA	X
Denmark	DSTA	X
Estonia	Ministry of Economic Affairs & Communications	X
Estonia	Health Board	X
Finland	Ministry of Employment and Economy	X
Finland	Finnish Safety & Chemicals Agency (Tukes)	X
France	Ministère de l'économie et des finances Direction Générale des douanes et droits indirects (DGDDI)	X
France	Ministère de l'économie et des finances – Direction Générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF)	X
France	Ministère du redressement productif (DGCIS), SQUALPI	X
France	SCL Laboratoire de Marseille	X
Germany	BMELV	X
Germany	Federal Institute for Risk Assessment	X
Germany	Landesamt für Gesundheit und Lebensmittelsicherheit	X

Country	Organisation	Present
Ireland	National Consumer Agency	X
Italy	ICQ global	X
Latvia	Consumer Right Protection Centre	X
Lithuania	State Non Food Products Inspectorate	X
Lithuania	Ministry of Economy	X
Luxembourg	ILNAS Surveillance du marché	X
Malta	Regulatory Affairs Directorate, Standards Authority	X
Netherlands	Food & Consumer Product Safety Authority	X
Netherlands	Consumer products & services – Netherlands Standardisation Institute	X
Netherlands	Ministry of Health	X
Poland	Ministry of Economy	X
Poland	Monitoring of the Market Surveillance Office of Competition & Consumer Protection	X
Portugal	Autoridade de Segurança Alimentar e Económica	X
Romania	Permanent Representation	X
Slovenia	Ministry of Health	X
Slovenia	Institute of Public Health	X
Spain	Instituto Nacional del Consumo	X
Spain	Ministerio de Economía	X
Sweden	Swedish Chemicals Agency	X
Sweden	Swedish Consumer Agency	X
United Kingdom	Consumer & Competition Policy Directorate	X
United Kingdom	Department for Business Innovation & Skills	X
Norway	Norwegian Environment Agency	X
Norway	Directorate for Civil Protection & Emergency Planning	X

Country	Organisation	Present
Switzerland	Swiss Federal Office of Public Health	X
Turkey	Ministry of Economy	X
Turkey	Ministry of Customs and Trade	X
	NB-TOYS	X
	CEN	X
	CENELEC	X
	TIE	X
	European Commission, DG ENTR	X