EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Single Market for Goods
Internal Market and its International Dimension

EXPERT GROUP ON TOY SAFETY

SUBGROUP CHEMICALS

Document number:	ENTR/TOYS/EXP/WG/2013/023 rev 1
Date:	05/09/2013

Final report

SUBJECT: Final approved report
Expert Group subgroup chemicals meeting of 20 March 2013

SUMMARY:

ACTION:

(1) Welcome and adoption of the agenda

COM welcomes participants and asks if it is agreed that the BE delegation will chair this meeting on a single occasion?

Participants agree.

Participants agree to approve the agenda.

(2) Approval of the minutes of previous meeting

Participants agree to approve the minutes.

Discussion items

(3) Information from the Commission

Barium: the Regulation amending the TSD to lower the limits for barium has been uploaded on CircaBC – a written procedural vote is foreseen for which the deadline ends 28 March 2013. If the Regulation is approved, Council and EP have 3 months' time to oppose once forwarded by COM.

FR asks why it is a Regulation and not a Directive?

COM: in order to avoid time constraints for MS to transpose, a Regulation has been proposed as it does not need transposition and can be applied immediately. MS have the obligation to withdraw or repeal conflicting legislation.

TIE asks if the WTO was notified.

COM: WTO has been notified and a 60 days commenting period was given; no comments received.

Lead: COM will send out the formal invitation for attending the Committee (foreseen for 3 May). A discussion on lead, with a focus on especially the Impact Assessment, will be held.

FR asks if COM can confirm dates for the Expert meeting?

COM: 2 and 3 May 2013.

(4) Phenol

DK introduces documents EXP-WG-2013-019 and 020. TIE refers to their document 022.

DK asks to send the UK documents/opinions referred to in the TIE document in order to allow the DK experts to evaluate them.

As both DK and TIE say the value in part 9 of EN 71 is no longer appropriate, another limit value for the migration should be envisaged. The same principle for achieving the limit should be used as used for other chemicals by this group.

TIE indicates that the TDI value of 1,8 mg/kg bw/day is based on a controversial study (not performed according to GLP): a phenol solution has been used which was not pure. Therefor TIE does not consider it appropriate. TIE agrees that the same approach needs to be taken, but does not agree with the value from DK. TIE will send the documents as asked by DK by the 2nd of April.

DK refers to the EU RAR as it lists the critical NOAEL/LOAEL. So TIE is doubting this document? As soon as the info is received the experts will evaluate the info.

DE mentions that it is also interesting to consider the pH and what is the impact? Phenol is an acid and what does it mean for the final availability for the human body? When considering the determination (analytical) this pH and its impact need to be clarified.

BE questions if this is not addressed in the EU RAR?

TIE insists to identify the materials to be captured by the restriction and the conditions. Phenol is found in PVC materials. TIE will ask its members regarding the use of phenol in toys and its materials, and also on the impurities faced with.

DE informs that phenol can be used/found as monomer, preservative or additive. As preservative it is found in water based solutions but rather as impurity, so no additional use.

UK mentions that a study on EN 71-9 refers to certain uses, of which 2 limits are currently listed.

Conclusions:

- TIE will forward the UK documents to DK and will verify the use/impurity of phenol in toys.

- DK experts will evaluate the documents and come back by next meeting.

(5) Formaldehyde

SE collected information from the FR report sent to ECHA (will be uploaded on Circa). Apparently RAC agreed with changing the classification of formaldehyde to a carcinogen cat 1B and mutagen cat 2, entering into force in April 2015.

Formaldehyde is hazardous for inhalation. There is no information relating to a TDI.

Currently the TSD allows 1% based on current classification rules, but it will be 0,1% under the new classification rules.

SE proposes to use 0,1% as of 20 July for considering the limit under the CMR requirements in the TSD due to the opinion of RAC (change in classification).

Participants suggest adapting the technical guidance document with link to the RAC opinion and warning manufacturers about the upcoming change of classification.

DE informs that formaldehyde has also biocide/preservative action, which has not been evaluated sufficiently. So DE does not agree to have the link in the technical guide, but prefers rather to evaluate further.

AT says 0,1% is a total content, so safety for inhalation exposure cannot be ensured.

DK agree with DE and AT, but good idea to change the technical guide.

TIE notes that the classification is for certain exposure routes and not for all routes …. however other participants oppose.

Chair asks participants if they want to keep the limit for formaldehyde in Part 9 or Appendix C?

DE acknowledges that Appendix C is ok. DE questions assessing the whole area of biocides or only formaldehyde? Can more general rules be applied? Part 9 has a limit on preservatives and as monomer, but formaldehyde can also be an additive, for which no limit has been added in Part 9. So the strictest value should be used.

DK says that one limit is total content and the other is migration, so which one is more restrictive?

DE says that both are wrong.

AT refers to an additional value in part 3 of EN 717 (80 mg/kg).

DK asks why limits for formaldehyde were in Part 9, what was the toxicological reason? DE will check the toxicological data by May 2013.

DK states that one can go for content as it is a genotoxic carcinogen. These substances should not be present at all.

TIE will verify the use of formaldehyde by May and informs it is used in textile cfr EN 14184 part 1.

DK asks for the possibility to gather the information on limit values on formaldehyde in different standards/legislations …. and find the background for those values.

Conclusions:

- Participants agree to have a reference/insertion in the technical guide.
- The aim is to combine all possible amendments into one and focus on the agreed substances. Afterwards the subgroup can look at the general rule on biocides.
- COM will send a request to CEN to ask the limit values in standards and the toxicological/scientific background.
- DE will check the toxicological data (of EN 71 part 9) by May 2013.
- TIE will verify the use of formaldehyde by May 2013.
- Next meeting the received data will be evaluated and a proposal might be made.

(6) Formamide

UK introduces documents EXP-WG-2013-011 and TIE refers to document 013.

UK analysed the different reports regarding formamide and concluded that inhalation exposure is indeed the problem. The ≤ 20µg/m^3 after 3 days or 28 days in combination with the parameters for testing as specified on page 7 of document 011 is suggested.

BE does not agree with the 1 m^2 and refers to the TIE document 013: puzzle mats have less area, so another surface area should be used in order to cover the EVA puzzle mats.

DE also has comments regarding the air change rate of 0,5. DE is in favour of using a small chamber, as a consequence the conditions in order to test part and not the whole toy need to be re-evaluated. DE is not in favour of using the big chamber in case of dispute. DE also has a problem with the preconditioning as formamide may disappear while preconditioning. DE asks to investigate the 3 days …. and proposes using even 1 day.

IT has a problem with the chamber dimension and suggests a minimum of 200 l is needed. IT informs that they developed a new method, which will be sent in 2 weeks. IT never used the whole toy for testing. FR replies that no repeatability is guaranteed in that case. IT refers to the fact that robustness is guaranteed by the method using adequate loading. DE asks why such a low loading is maintained?

UK informs that the method is proportionate! The method comes from the construction area covering carpets to mats … Having looked at the variation data, the loading was split in 3 different loadings, but toys would reflect a low loading only due to the small size (compared to carpets). The argument for the preconditioning is trying to cover the long term exposure.

SE and DK agree with DE to have no precondition requirement.

DE would like to have more data in order to accept the preconditioning. DE will verify with a DE test house and will try to find out what the impact is of preconditioning.

SE states that the preconditioning is not the problem but rather the unpackaging.

IT prefers no note a) in the table, and to bring a reference to the 200 l chamber in the table.

UK says precondition can be taken out; it is not a requirement; it is a testing parameter. The method is rather all about reference material and repeatability. b, c and d can be deleted in the notes. UK suggests 0,5 m^2 as minimum size for the samples.

TIE will send a proposal in writing concerning the sentence to have 20 µg in less than 28 days.

IT questions if all the toy needs to be tested, how can all parameters be assured, as the production is not assured either?

DK supports the UK proposal.

Conclusion:

- Participants will reflect on the following proposal:

- Ethylene vinyl acetate (EVA) foam material used individually or combined with an overall accessible surface area greater than 0,5 m^2,

- The maximum emission for formamide from the EVA foam material shall be ≤20µg/m^3 after maximum of 28 days from commencement of testing,
- The methods should be specified to demonstrate compliance shall use ISO 16000-6 and ISO 16000-9 with the following conditions:

Conditions	
Temperature: 23°C	Chamber size at least 200 l
Humidity: 50%	Duration **3 or 28** day(s)
Air change rate: 0.5h^{-1}	Loading **0.04** m^2/ m^3
Air velocity: 0.1-0.3 m/s	
Note Selection of samples tested shall be representative of whole toy For the validation and use of different chamber sizes it is advised that FprCEN/TS 16516* Construction products - Assessment of release of dangerous substances - Determination of emissions into indoor air is used to validate testing and the use of reference materials where available.	

- Participants will reflect on the materials for the amendment: only EVA or also PE?

- IT will send their new developed method by mid-April.

- DE will verify with test house the impact of preconditioning.

- TIE will reflect on the sentence regarding the 20 µg in 28 days and send a new proposal in writing.

(7) Non threshold substances

DE presents a table with the 1st attempt to set the limit of quantification (LOQ) for these substances.

SE informs that in the last CARACAL meeting a discussion (inquiry) was held on CMRs cat 1A and 1B. The project undertaken under REACH may provide input for the discussion in this group.

Conclusion:

- Participants will add their limit of quantification for the next meeting.

- AT will verify the list for completeness and correctness by mid-April.

- Participants will collect information on the use of the substances.

- COM will verify with REACH unit the extent of the question on classification asked from Member States and when the results will be obtained.

(8) Any Other Business

FR introduces documents EXP-WG-2013-009 and 010 regarding chromium VI. 2 l water intake is proposed in the study, however we only took 400 mg liquid intake in the TSD, meaning the 400 mg intake of liquid results in an overestimation of the limit in TSD.

Conclusion:

- COM will send a request to SCHER to evaluate the TDI for Chromium VI, saying RIVM refers to this study and adding the study to the request.

SE seeks clarification regarding the CE marking in the TSD in relation to a chemical non-compliance under REACH: in the latter case, can the manufacturer affix the CE marking? As the chemical requirements in the TSD mention that the manufacturer has to comply with relevant chemical legislation (REACH in this case), he can only affix the CE marking if he complies with all requirements. So the toy also needs to comply with other legislation in order to have the CE marking affixed by the manufacturer.

Conclusion:

- COM will upload the document regarding passing the limit of 0,1% on phthalates vs serious risk.

COM closes the meeting and thanks participants. Next meeting is scheduled for 19 June 2013.