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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/2013/029
Date:	06/12/2013

SUBJECT: Adopted report of the Expert Group - Subgroup "Chemicals" meeting on 26 June 2013

SUMMARY:

ACTION: For information.

1 OPENING OF THE MEETING

COM welcomed participants and informed them about organisational aspects of this meeting.

1.1 Approval of the draft agenda

Several participants suggested items for "Any Other Business":

- TIE: Status of the situation in DE who requested to maintain their national limit values in toys for arsenic, antimony, barium, lead and mercury;
- FR: Status of di-iso-butyl phthalate (DIBP) appearing in Annex XIV REACH but not in Annex XVII REACH;
- DK: Preliminary work item on hard polymers work item in CEN. Views from this subgroup?

Agreement: With the above additions, the draft agenda was approved.

1.2 Approval of the minutes of the previous meeting

Agreement: Participants approved the minutes of the meeting on 20 March 2013.

2 DISCUSSION ITEMS

2.1 Information from the Commission

Chromium-VI – COM mandate to SCHER

COM presented the state of play.

DK suggested that a public consultation take place. ANEC supported this suggestion. COM agreed to propose this in the video conference with SCHER.

TIE presented the perspective of CEN: Good progress has been made on test methods for chromium VI for all materials, except finger paints. They are able to achieve the lowest limit value. If SCHER should propose to lower the limit values, TIE recommends also considering feasibility. It would be regrettable if CEN would not be able to develop a corresponding method. TIE therefore asked that SCHER liaise with CEN TC 52 WG 5.

DE (also chair of CEN TC 52 WG 5) confirmed that laboratories need to work on a method and see what is achievable. There is a good procedure for lower limits (except in the case of liquids) but EU laboratories need to see if they can follow up. The next meeting of CEN TC 52 WG 5 will be in October 2013. COM asked if the chair's contact details could be shared with SCHER; DE agreed.

UK drew attention to the need to take good care of the limits of detection and quantification (LOD, LOQ) for Cr VI.

Actions:

1. COM to suggest a public consultation on SCHER's Cr-VI draft Opinion;
2. COM to transmit the contact details of the chair of CEN TC 52 WG 5 to SCHER.

TCEP, TCPP, TDCP and bisphenol A – Limit values for Appendix C

COM gave an update on the state of play.

DE asked whether CEN methods had been considered. COM indicated that the draft for bisphenol A would refer to testing according to EN 71-10 and EN 71-11.

DK asked whether they would be presented as a single package and whether they would be submitted to a written vote or to a vote in a meeting; in the latter case what were the planned meeting dates? COM indicated that it was too early at this stage to foresee.

TIE pointed out that the TSD guidance document would need to be amended and that it would be useful to provide indications for testing according to the toy materials – for example, there is no sense in testing iron for the presence of bisphenol A. TIE suggested that the preparation of a guidance update be initiated, stressing that such guidance would be very helpful especially for SMEs and would ensure a measure of consistency across the EU. FR pointed out that the demand for tests was sometimes a commercial issue. TIE confirmed that small SMEs were sometimes faced with large distributors putting them in a difficult position by insisting on testing which made no sense. The guidance should cover all substances to be included in Appendix C and should preferably be elaborated by the subgroup.

In response to a comment from DK, TIE took the view that the guidance it was suggesting should not amount to an exemption from the obligation to perform a safety assessment. In the framework of a safety assessment for CMRs, it is sufficient to only compare them to the requirements from the CLP Regulation. But in case of lower limits like e.g. the case of phenol or formaldehyde, the assessment might be process-related. One might not be able to know if a certain substance is present or not, and in such a case one may choose to focus on materials and use input from the BOS/BOM – for example one should not test metals for TCEP.

DK agreed this was a promising idea, one could already look at a possible format. AT referred to EN 71-9 which already included a table on which chemical substances to test in which toy materials.

COM said that they would look into this and that the key word would be “focus” and “non-exhaustive”.

Action:

COM to place "Guidance on the testing of chemicals in toy materials" on the agenda of the next meeting.

PAHs

COM informed that the draft Regulation had received a favourable vote in the REACH Committee of 18-19 June 2013. A general limit of 1 mg/kg had been agreed, but for toys and childcare articles the limit was 0.5 mg/kg. A transition period of 2 years was foreseen, as well as a review clause after 4 years.

ANEC expressed dissatisfaction with the outcome. DK reported on a definition issue discussed in the REACH Committee: the definition of "childcare articles" might not necessarily be the same for the PAH restriction as for the phthalates restriction, as the relevant exposure in the case of phthalates was through mouthing, but in the case of PAHs was through dermal contact. This would be addressed in guidance. AT expressed surprise at the use of the same term in different meanings; TIE was concerned about the confusion this might cause. DE also agreed on the need for clear definitions. UK asked what the definition of exposure was – i.e. how long – and expressed much interested in upcoming guidance.

COM proposed that anyone with information on the progress made should keep the subgroup updated.

Kathone

ANEC reminded that in previous discussions it had been concluded that action would be undertaken on kathone and invited COM to make progress by the next meeting of the subgroup.

Action:
COM to inform the subgroup at its next meeting about the progress on kathone.

2.2 Phenol

DK reported that their experts had agreed to follow TIE's approach to set the TDI at 0.5 mg/kg bw/day. However, exposure considerations should be consistent with those for bisphenol A. Thus their experts proposed a limit value of 5 mg/l, thus decreasing the 15 mg/l limit value given in EN 71-9 for monomer migration.

TIE considered that the current limit value in EN 71-9 provides a sufficient safety level. With bisphenol A the margin of exposure (MoE) was 20,000, which was high compared to the usual MoE of 100 considered to ensure safety.

DK and UK insisted that a consistent approach should be used to set the limit for phenol. TIE replied that bisphenol A should not be used as a precedent. The model used to agree on bisphenol A is not a validated approach and should not be presented as one. Scientific evidence is very important. The practical approach taken in one case should not become the new standard approach.

ANEC recalled that a 3 hour exposure time had been used by CSTEE regarding children's exposure to phthalates; this was indeed a worst-case assumption, but not totally unrealistic, at least for a certain age range. ANEC further recalled that the RIVM

approach[1] was the basis for policy-making, and that very good reasons would be needed if one were to deviate from this approach.

UK noted that later on, the exposure time of 3 hours had subsequently been deemed not representative and 1.5 h had been deemed more representative. ANEC challenged this statement. UK pointed to coming CEN mouthing studies which might prove all of us wrong. COM asked if one should wait for the CEN study. DK said no: in protecting children one should use the highest exposure through worst case assumptions.

DE said they could live with both limits, either 15 or 5 mg/l, as they are actually not so far away from each other. TIE considered that the current limit of 15 mg/l was valid from a toxicological viewpoint and questioned the proposed decrease to 5 mg/l. DK insisted that, since the TDI had been lowered by a factor of 3, the limit value should follow-up consequently.

NL reported that in a 2004 investigation of 60 bath toys, phenol had not been detectable and the phenol limit had not been exceeded. The related report would be made available to the group.

TIE confirmed, on request of COM, that a 5 mg/l limit value would not necessarily pose problems. TIE reported that phenol was mainly present in soft PVC; this should be placed into a guidance document.

On balance, the group recommended that the limit value for phenol as a monomer should be put at 5 mg/l, as a new entry in Appendix C of the TSD. TIE added that it could not agree as it is not based on toxicological approach but would not oppose to the decision taken by the members of this group; it reserved the right to come back with comments as this did not appear to make toxicological sense.

Agreements:

1. TDI for phenol: 0.5 mg/kg bw/day;
2. Limit value for phenol as a monomer: 5 mg/l when determined according to EN 71-10 and 71-11.

Actions:

1. COM to consider inclusion of the recommended phenol limit 5 mg/l into Appendix C of the Toy Safety Directive;
2. COM to consider guidance that phenol is mainly present in soft PVC.
3. NL to make available their 2004 Report on phenol in 60 bathing toys. (see EXP-WG-2013-031)

2.3 Formaldehyde

DE reported that it was looking at the (old) data underlying EN 71-9 and had identified analytical problems. A common view was needed on limits, but this would still leave the

[1] See RIVM Report "Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements". http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

analytical problems to be solved. If a solution was found for formamide, the solution for formaldehyde would be similar. DE clarified that it had not been involved in COM's request for the background to the limits in the standard.

COM undertook to upload in CircaBC the data from CEN when received, so that they could be discussed at the next meeting.

NL asked if it would be helpful if they sent their own data. DE stated that this really depended on the method, so when sending data the method should be included.

ANEC did not believe it was sufficient to ask CEN to provide data: someone would be needed to interpret the data.

COM invited NL to provide the data it had referred to as well as the related method, and invited all to examine and provide feedback.

DE pointed out that the standards were related to different materials: on the one hand textiles, on the other hand wood and different types of wood. The release had to be examined very carefully in view of different materials. This triggered the question from the UK whether it is possible to have a single limit value.

TIE stated that the document it had provided contained useful information, e.g. on differences of manufactured wood compared to raw wood. COM undertook to upload this document into Circa BC.

DK recalled the follow-up which had been decided last time, i.e. that the technical documentation guidance document was to be updated once the reclassification of formaldehyde was published in the Official Journal, perhaps around April 2015.

COM undertook to monitor the reclassification of formaldehyde.

Actions:

1. COM to request from CEN documents on formaldehyde analysis;
2. COM to upload those documents on CIRCABC [see EXP-WG-2013-035];
3. NL to provide their own data and methods on formaldehyde analysis;
4. COM to upload those documents on CIRCABC [see EXP-WG-2013-036];
5. COM to upload TIE's document on formaldehyde on CIRCABC [see EXP-WG-2013-037];
6. ALL to examine the data and methods and provide feedback;
7. COM to monitor the re-classification of formaldehyde.

2.4 Non-threshold CMRs

NO provided explanations on the table proposed by NO, DK and SE. Substances highlighted "in red" are already covered somewhere, e.g. benzene in REACH. The substances "in orange" are primarily associated with azodyes, it appears that they should not be prioritised as REACH already has a ban on azodyes and EN 71-7 (finger paints) also covers them. Are there other relevant materials? The substances "in yellow" are monomers and for them limit setting is difficult, so the approach needs to be discussed in principle. In conclusion, it is proposed to start with the substances highlighted "in green".

COM asked if the group agreed to delete the substances "in red" for the time being.

DE asked if benzene should be reconsidered under REACH. NL commented that there had been recent RAPEX notifications for benzene in felt-tip pens and believed that the 5 mg/kg limit was rather high. COM asked for evidence backing the latter statement.

DK wondered if a lower limit should be included in Appendix C for toys for children under 36 months or intended to be placed in the mouth. DK would like to avoid the REACH process but felt a discussion of principle was necessary. AT took the view that felt-tip pens were not normally for children under 36 months and did not believe Appendix C was the right way forward. UK reminded of the origin of the REACH restriction which was linked to balloon blowing kits; such kits are also not for children under 36 months. NL pointed out benzene might be found in adhesives which in theory could be for young children but acknowledged this was perhaps rather theoretical.

In view of the above, participants agreed to leave the REACH limits for benzene unchanged. Also for the remaining substances "in red", it was agreed to leave them aside.

DE asked why aniline was not among the substances "in orange" (azodyes). NO replied that it was also a rubber and polyurethane processing chemical.

DK took the view that the substances "in yellow" (monomers) were not less important and should be discussed, and suggested assigning priorities.

TIE recalled the origin of the list: These were substances which had originally been identified for possible discussion under EN 71-9. TIE was concerned that the approach which was now being taken would miss an important preliminary step: Are these substances used in toys? The example of ethylene oxide which is a gas at room temperature and which is very reactive was given. Why would this substance be present in toy materials? TIE had inquired about the listed substances and found that some of their interlocutors did not know what the substances were used for. Test laboratories approached by TIE had only identified benzene, formaldehyde, azodyes as relevant for consumer products, and acknowledged that they had never detected some of the others.

ANEC recalled previous discussions on this issue and called for an in-depth investigation whether substances were used in toys or not. DK agreed an investigation would be needed before banning substances "in green" at detection limits. Respective possible approaches should be discussed in this group.

AT recalled that 4 substances had been found in toys according to UBA – three "green" substances (aniline, trichloroethylene and formaldehyde) and one "orange" substance (4-Chloro-o-toluidine). TIE took the view that it was not sufficient that substances "had been found in toys" (some of them might be highly volatile) but that uses needed to be identified.

UK noted that EN 71-9 addressed a number of these substances. The question was whether the toys concerned were intended to be mouthed and what the relation of a restriction would be to the standard: e.g., if aniline would be restricted, would this be done in Appendix C or under EN 71-9? EN 71-9 had been based on a study of toy manufacturers' information on chemicals used in toys.

COM suggested that the list from NO be cross-checked with EN 71-9 and that those substances appearing on both lists should be kept. AT and DE supported this. UK

agreed to do the cross-checking but wondered if they were used in toys for children under 36 months, as this is the scope of Appendix C.

COM concluded that UK would draw up a priority list by end of July.

DE asked if, for monomers, EN 71-9 should be examined and the limits be taken over for them, too? DE also wondered whether the substances "in orange", especially aromatic amines, should be discussed.

On aromatic amines, DE further pointed out that they are on the one hand governed by REACH when in textiles, and on the other hand in EN 71-7 when in fingerpaints. Other participants considered that they might occur in dyes, paints for use on e.g. windows and in modelling clay of the play-doh type. Aromatic amines generally are CMR substances.

Participants asked which limit values would prevail, the CMR limits as stipulated in Annex II of the TSD or the limits in EN 71-7. TIE took the view that no notified body would challenge the values of EN 71-7 when performing conformity assessment. It was in this context generally understood that compliance with the CMR limits in CLP is not proof of safety, as the limits are hazard-based, not risk-based. AT pointed out that toys could be found on the market with chemical content below the CMR limits but above the limits of EN 71-7.

FR asked whether these substances were registered under REACH. COM pointed out that there was no need to contact ECHA to obtain lists of registered substances, as they are published on the ECHA website. NL under took to look into the information on the ECHA website.

On monomers, DK and NO pointed out that the monomers "in yellow" in the table are genotoxic carcinogens. The categorisation in the table reflected a real prioritisation exercise and DK and NO urged not to add more substances to the "yellow" group. NO proposed a step-wise approach to deal with them: (1) first check the content at detection limit or LOQ, (2) then, if found, test for migration. This was supported by TIE in principle, as it is risk-based. TIE also indicated that the proposal to look first at total content is certainly proposed because market surveillance authorities feels it is quicker and cheaper than migration which indeed is not often the case. FR also indicated a total digestion can also breakdown polymers to monomers which may lead to false positive detection.COM asked if it was agreed to put the 3 substances in the middle of the "yellow" group (ethylene-oxide, 1.2-propylene-oxide, ethylene-imine) into the "red" category. This met with general agreement from participants. COM undertook to upload the document into Circa BC and acknowledged that it was a document in progress anyway. COM also undertook to check with ENTR's REACH Unit if their document (Cefic presentation on CMRs and REACH Article 68(2)) could be uploaded into Circa BC.

Agreement:

Priorities for the further discussion of non-threshold carcinogens:

1. The substances underlaid with green,

2. The substances underlaid with yellow,

3. The substances underlaid with orange;

Substances underlaid with red, including benzene, will be left aside for the time being because they are regulated already.

Actions:

1. UK to cross-check the list from NO, DK and SE with the substances in EN 71-9 by the end of July 2013;
2. COM to consider which CMR limit values prevail: Those in EN 71-7 over those in the Toy Safety Directive, or vice-versa?
3. NL to check whether the substances on the non-threshold CMRs list are registered under REACH (see EXP-WG-2013-033-rev1);
4. COM to move ethylene oxide, 1,2-propylene oxide, ethylene imine into the "red" category, and upload on CIRCABC;
5. COM to check with ENTR's REACH Unit whether the Cefic presentation on CMRs and REACH Article 68(2) could be uploaded on CIRCABC for this subgroup. (see EXP-WG-2013-034)

2.5 Formamide

UK recalled the background to the table displaying the testing conditions for formamide in foam mats which had been agreed as a basis for further reflection in the last subgroup meeting. DK agreed with UK that it made sense to lay down test conditions. DE recalled that pre-conditioning, which had been raised on an earlier occasion, should last 3 hours at least, according to a test laboratory. FR reported that ANSES had conducted migration tests some 3 years ago, and that formamide may decompose within 3 hours. DK considered that mats should be tested immediately, because they were used immediately.

TIE suggested to include the sentence proposed by TIE and to delete the reference to 3 days. In response to a request from COM, TIE agreed to make a proposal in writing which COM undertook to circulate.

FR reported that formamide had been found in polyethylene (PE) foams. DE concluded that limits were perhaps not only necessary for EVA and PE, but possibly also for polyurethane (PU). The group agreed.

TIE pointed at the importance of identifying the materials concerned – for example, no formamide is used in in rubber foam, which could be used as an alternative to EVA foam.

COM concluded that three materials where formamide should be checked (namely: EVA, PE and polyurethane foams) would be included in an indicative list.

Agreement:

Foam materials to be tested for formamide include EVA, PE, PU.

Actions:

1. TIE to make a proposal to include their proposed sentence and to delete the reference to 3 days when analysing the maximum emission of formamide from EVA foam material;
2. COM to upload the proposal on CIRCABC. (see EXP-WG-2013-046 and -047)

3 ANY OTHER BUSINESS

3.1 Status of the situation in Germany (DE) who requested to maintain their national limit values in toys for arsenic, antimony, barium, lead and mercury

DE referred to the Order of the President of the General Court of 15 May 2013. The legal services in Germany are to develop a clear view and a regulation how to handle the issue of the German limit values after the Order and as of 21.7.2013, including for market surveillance. A special regulation is reportedly in the making, but no further information can be given at this stage.

3.2 Status of di-iso-butyl phthalate (DIBP)

This substance is toxic for reproduction category 1B and has been included in Annex XIV of REACH, entry 7. The latest application date for authorisations is 21 August 2013. DIBP is also included in Annex XVII of REACH, Appendix 6. It was said that, according to a REACH person, a REACH Annex XV dossier would have to be prepared if DIBP should be restricted. COM confirmed that for finger paints the general CMR provisions of REACH apply, for toys which are considered an "article" under REACH the TSD's CMR provisions apply.

3.3 Hard polymers work item in CEN. Views from this subgroup?

DK recalled that at the last Expert Meeting on 3 May 2013, CEN had informed of a new work item: CEN was examining a possible exemption of hard polymers from EN 71-3. DK wished to hear the views of the subgroup on this.

DE (who is also chair of CEN TC 52 WG 5) clarified that the idea behind the work item was to treat hard polymers in the same way as glass, which has been excluded for historical reasons. The reasoning behind the exclusion would be that chemicals are not expected to migrate beyond the limits stipulated in the TSD. The work item first aims to collect data, and if the data confirm that chemicals are not expected to migrate beyond TSD limits, then a proposal may be put forward. The first question that will be tackled under the work item is the definition of hard polymer. It will also be examined to what extent the test specimen, which are normally flat with a certain thickness, are representative of final products with different shape and thickness, and to what extent standard tests applied to non-samples will generate the same results. In other words, a lot of questions are to be answered and examinations to be made before a decision on a possible exclusion of hard polymers from EN 71-3 can be taken.

NL took the view that polymers in the glass-like state are very hard and hardly anything migrates out of them. However, this does not apply when they are above the glass transition state. Accordingly, an exemption for hard polymers makes sense but they key lies in the definition of "hard polymers".

DK took the view that assessing whether chemicals will migrate or not is part of the safety assessment. Materials should not be excluded from the requirements just because they are hard polymers. Instead, each safety assessment should conclude that migration does not occur. Exemptions from the provisions of a Directive cannot be laid down in standards, a committee procedure would be necessary.

DE pointed out that the work item was not being undertaken in the framework of a mandate from COM and that therefore it was by no means certain at this stage that a reference to it would be published rendering it a harmonised standard. TIE added that CEN was at this stage merely examining, but had not yet taken a decision. The outcome from the work item could be useful for the purposes of safety assessment if an exemption turned out not to be the way forward.

DK recalled that operators need to demonstrate in their safety assessment that there is no need to test.

COM concluded that there was a question of principle and that at this stage all possibilities should be considered.

3.4 Additional item raised by SE: Exclusion of toys from the new Biocides Regulation

SE raised a concern regarding the exclusion of toys from the new Biocides Regulation. They volunteered to bring a biocides expert to the next meeting of the chemicals subgroup in order to discuss the concerns. COM asked for clarification as to the purpose of such discussion, reminding that the chemicals subgroup's mission is to advise the Commission in the preparation of legislative proposals and policy initiatives with regards to chemical substances which may be used in toys.

DE welcomed any information coming. If there was a problem, this should be addressed.

SE undertook to prepare a written document to be communicated in advance of the next meeting and to bring a biocides expert to the next meeting.

Actions:

1. SE to provide information on the presence of biocides in toys to COM;
2. COM to upload the info on CIRCABC.

4 CLOSING OF THE MEETING

The Chair indicated that one further meeting of this expert group could be financed in 2013. It was agreed to seek a meeting date in November.

There being no further business, COM thanked participants and adjourned the meeting.