EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Internal Market for the Free Movement of Goods
Internal Market and its International Dimension

EXPERT GROUP ON TOY SAFETY

SUB GROUP CHEMICALS

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Final report

SUBJECT: Final approved report
Expert Group subgroup chemicals meeting of 16 January 2013

SUMMARY:

ACTION:

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: B-100 04/020. Telephone: direct line (32-2) 2966252 - Fax: (32-2) 2921301

(1) Welcome and adoption of the agenda

Participants asked to discuss Kathone and lead under AoB. COM informed that this WG made a proposal already to the Expert group regarding Kathone and that further discussion is needed in the latter. Lead will be discussed under information from the Commission – update of amendments.

A paper on Formaldehyde will be introduced in AoB

Participants agreed to adopt the agenda including the above mentioned requests under AoB

(2) Approval of the minutes of previous meeting

By lack of comments by end January 2013, participants agreed to adopt the minutes

Discussion items

(3) Information from the Commission

DG ENTR REACH unit introduced the discussion regarding the COM PAH restriction proposal. The aim was to discuss technical aspects of the proposal. Currently the proposal is under comitology procedure, therefore there will be no disclosure of details of the proposal. However technical details of the scope need to be dealt with before adoption of the text and therefore COM sought input from this group.

Discussion points:

a. limit value,
b. inclusion of coatings in scope,
c. direct and prolonged skin contact,
d. normal and reasonably foreseeable use.

Participants asked clarification about the limit value.

FR asks clarification on the limit values of PAH, COM replied that the limits apply to each of the individual PAH

DK forwarded already an opinion under the REACH committee. According to DK 1 ppm is too high, because the file from DE indicates that there is still a risk present at this level. Furthermore DK points out that the DE file did not take into account all exposure routes. No evidence to support that PAH are not found in coatings, but if found, they should be restricted as well. DK proposes to take lower limits for toys and child care articles. Regarding prolonged skin contact: comments were sent in written via the REACH Committee. DK found the 2nd proposal to be much better and improved compared to the earlier proposal.

Anec: it is clear from the DE report that the limit proposed is not sufficient. Take the ALARA limit. The scope is also problematic: extend to the products that are used by consumers.

COM indicates that only the discussion items will be dealt with. Other elements of the proposal are under discussion in the REACH Committee and are not subject to this meeting..

UK: prolonged skin contact is indeed an issue. Other aspects of concern: content or migration limits to be used? COM replies that the limits proposed are content. UK questions what the limit should be if migration is the aspect to be looked at from a hazard point of view and was used in the DE report. Depending on the solvent used for extractions different results can be obtained. Regarding coatings: if it is content limit, it does not matter to have coatings. Accessible is also under discussion as pedals and tires of bicycles are not easily mouthed, but perhaps they should be captured by the restriction.

TIE: direct skin contact is difficult to define. Exposure scenarios are taken into account in the proposal which is positive. Annoying is the total content principle as migration is causing the hazard not the content, so lowering the limits is not justified. Total content is easier for surveillance, but setting these limits should be done carefully as they are not based on migration approach. It is however a good compromise proposal. No need to specify toys and child care articles separately, all consumers need to be protected the same way.

COM: direct and prolonged contact is obviously not a precise concept. It is a terminology adopted in several restrictions. The general concept is however understandable and useful to enforcers based on their own discretion to distinguish short or intermittent exposure from more prolonged contact. COM has asked ECHA an opinion regarding the application of this criterion to skin contact with Nickel, however PAHs are carcinogenic substances. ECHA is working to define a technical position (time, frequency) regarding nickel only, these could be different for a different substance having a different type of effect. Do the participants have a general view how this concept can be applied with carcinogenic substances as in this case there is rather dermal exposure than oral exposure? COM acknowledges the problems with measuring migration limits and clarifies that the German dossier establishes a link between content and migration, although based on limited data. However, COM looked at the correlation established in the DE report between migration and content and proposed limits based on its overall evaluation of the evidence provided in the risk assessment.

DE: there is a method available on migration, but further discussions are needed to stabilize the method. Prolonged skin contact has to be looked at in relation to the limit; therefore DE considers that the limit of 1 mg/kg should be applied to the sum of the PAHs and not to each individual substance. DE will distribute the migration method based on dynamic migration/methanol for determination of PAHS.

COM indicated that the limit is for each individual PAH although given that 8 PAHs are restricted it is implicit that in a worst case situation, the maximum concentration tolerated would be slightly below 8 mg/kg the restricted PAHs, each of them contributing slightly below 1 mg/kg. COM will distribute the report from ECHA regarding skin contact of nickel when finalized.

TIE: Care should be taken not to extend ECHA’s opinion on the meaning of direct and prolonged contact with the skin for Nickel release, to other restrictions (i.e. Azodyes, PAH). The exposure to Nickel leading to sensitization is different than it is for the other substances which are carcinogenic ones. For azodyes, there is a need to have enzymatic reaction with the colorants at the surface of the skin, so that they are potentially “broken”

into aromatic amines which are further absorbed through the skin. The potential release of PAHs from plastics which are quite inert materials would also require a significant exposure time. Therefore the concept of "direct and prolonged contact with the skin" should be significantly different (with higher time exposure values) than it would be for Nickel release.

(4) State of play

Barium:

- the draft was send to TBT committee (60 days for comments)

- the draft will be submitted to MS for voting via written procedure (around March). No changes as regard the proposal presented back in October.

TCEP:

- FR opposed to the written procedure

- FR wants further discussion on the limit values for the substitutes

- the draft will be on the agenda of the next committee (date tbc)

Lead:

- IA finalised, it will accompany a proposal for lowering the limits foreseen for the first quarter of 2013.

- the IA does not make any choice on the option, so the decision as regards a total or partial revision is not yet made

Nickel:

- SCHER opinion is adopted and will be made available on the public website

- a proposal is to be made for the next committee (date tbc)

(5) Anec Letter

COM questioned the intention of the letter and underlined that the subgroup on chemicals worked well. The group consists of chemical experts which facilitates the discussion compared to discussion with Expert group/committee. It was never the aim of the group to change the TSD, however it was made clear from the beginning that the work to be done by the group had to be elaborated within the legal framework of the TSD. The proposals made by the group have all been filed to the Expert group and committee and amendments based on these proposals have been drafted. It is correct that it takes time, but this is due to the procedures at COM. COM asks if participants want to end the functioning of this group or if members feel the group is not functioning as it should and if they want to stop participating?

ANEC says the interpretation from COM is not correct. ANEC and BEUC published a position paper to criticize the chemical requirements of the TSD, not the group. COM

replies that the title of the refers to a critical review of the subgroup and not to the requirements of the TSD.

DE understands that Anec has problems with the outcome of some proposals. DE can also not understand the title of the paper. This group made good proposals which are transferred to other groups who decide. Their decision is outside the responsibility of this group.

UK agrees with DE. The alternative is the Expert working group which is not a good forum due to lack of expertise and time to discuss items.

DK agrees with DE. It takes time to get results and acknowledges it is sometimes the fault of this group not having papers in time. We need to seek consensus and work in between meetings.

AT agrees with previous speakers. We do not want to cancel this group

COM concludes that the aim of the group is clear and that the group will be kept.

(6) BPA

SE introduces the document EXP-WG-2013-004

COM asks participants how to introduce BPA in appendix C? Do participants require a reference to the testmethod?

DK supports the proposal. As there is no correlation between content and migration, the migration limit and the content limit should both apply. In the recitals reflection should be made to the discussion on low dose effect of BPA and make a new assessment when new scientific data becomes available.

ANEC questions if this limit is the appropriate one? Anec questioned the limit in EN 1400 and proposed 0,002 mg/l. 0,002 mg/l is the quantification limit (method AGES)

AT described the situation in AT regarding soothers and teethers: AT regulation bans the use of BpA. Guidance documents specifies a limit of 1 mg/kg (total content).

UK has concerns about the content vs migration. The measurement issues worries UK.

ANEC informs that the endocrine society expressed disappointment for neglecting BPA.

TIE supports the proposal. Accessibility of materials should be considered. Is appendix C taking accessibility into account? Clarification regarding this is sought.

FR refers to the FR law: a full ban has been decided.

DK asks to refer to endocrine disruptors in the recitals as well. The TDI of BPA did not change, so we have to wait until the TDI changes in order to set lower limits.

TIE indicates that the second paragraph under table 1 (page 2) of the document EXP-WG-2013 004 should be corrected to replace “CMR” by “BPA” in the second sentence. TIE asks to refer in the technical guide the information regarding which toy materials would be covered by the BPA restriction.

COM concludes that the participants propose to restrict BPA at 0.1 mg/l (migration) in appendix C referring to test according to the test method of EN 71 part 10 en 11 and referring in the recitals to endocrine disruptors, new scientific data,…

(7) phenol

DK introduces the document EXP-WG-2013-006

DE will ask the Bavarian Authority on Food Safety to transfer their data into mg/l instead of mg/kg in order to be able to compare.

Based on the information from DK, the limit of EN 71-9 should be lowered to 0,18 mg/l as migration limit based on test method EN 71-10 and 11.

CZ highlights that the NOEL mentioned in a 2012 report from EFSA, however dating from 2001 is 70 mg/kg/bw/day.

AT pointed out, that within another EFSA opinion (2008) dealing with food additives, a LOAEL of 1,8 mg/kg bw/day is used for calculations. The data are confusing, therefore it must be clarified which one are the correct ones.

TIE has additional data, arriving not to change the limit from the EN 71-9

Participants agreed to verify if there is new scientific data and check with the finish authorities if they have data regarding their recommendation and send around by 15 February. Com concludes to postpone the discussion until further information is received.

(8) Formamide

DE introduces the test method from TUV and questions if we need to proceed with the chamber test? According to DE, only if the effect of chamber sizes can be calculated and allows also the use different chambers, e.g. 1 m^3 and 20l

FR reitinerates that they want to keep the total content instead of emission.

COM refers to previous discussions and agreements made. We will not go back to the discussion on total content.

UK agreed to reduce the chamber from 30 to 1 m3. The correlation factor needed to be looked at, beside the temperature and humidity will be part of a paper to be elaborated by mid February.

DE says the 1 m3 is not often found in labs.

FR points out the sampling will be an issue because all the studies give huge variations between mats of the same color in a same toy

Regarding the IT publications as mentioned by TIE, IT will be able to reply by the end of January.

DE refers to FR and IT analysis: do other materials then EVA , e.g. PU mats need to be looked at?

FR says that also foamed PE is found to contain formamide. In EVA mats less and less formamide is found, however manufacturers may change to the use of other foaming agents as substitutes some of them could lead to more dangerous by-products.

All participants reflected on the scope of the possible amendment. TIE will make a proposal of scope by mid February.

COM concluded that the discussion will be continued at the next meeting.

(9) Formaldehyde

Formaldehyde is found in wooden toys, textiles and in preservatives.

DE introduces the method developed by the BfR and highlights that each material may react differently for formaldehyde. Different times used in the method (from 3 to 24h) make a huge difference in results. Preparing an equivalent method for formaldehyde is possible with a special chamber test. There have been major assumptions made: formal data have been given to the project partner. Bfr proposes to use the 0,005 ppm as safe limit with a 5% assumption in stead of 10% for toys. Advantage of this method is that no more cutting of the toys is needed. Preconditioning of the materials is important (humidity) and the bottle neck method is possible. The BfR value with 10% should be used, arriving at 0,01 ppm. DE will ask BfR feedback on the formaldehyde during the EFRA sitzung prior to the fair.

COM will ask the EN version of the method

DE/UK will look into the background of EN 71 part 9 regarding formaldehyde.

SE mentions it is classified as 1A (as of 2016). SE will verify the TDI/NOAEL for formaldehyde.

AT says the TDI is 150 µg/kg bw/day according to the WHO set for drinking water in 2003.

COM concludes to discuss further at the next meeting when all relevant information is gathered

(10) AoB

DK asks how to continue with CMR substances? Participants should reflect for the next meeting.

In FR press a statement was made that France pushes for a ban of Endocrine disruptors in toys. FR will verify and provide further information.

SE introduces the information they spread to industry colorful leaflets with useful information.

Participants agreed to verify the detection limit for the 22 non treshhold substances for the next meeting.

The next meeting will be scheduled for 20 March 2013.

Participants expressed the wish to have the Expert and ADCO meeting on 16-17 April 2013. The NB toys meeting is scheduled for 18 April 2013.

The meeting is closed.