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Directorate-General for Health & Consumers

Scientific Committee on Health and Environmental Risks

SCHER

RISK FROM ORGANIC CMR SUBSTANCES IN TOYS

Scientific Committees
on consumer safety
on emerging and newly identified health risks
on health and environmental risks

SCHER adopted this opinion at its 7th plenary on 18 May 2010

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1. BACKGROUND

The recently revised Toys Safety Directive (TSD) limits the presence of most carcinogenic, mutagenic, and reprotoxic (CMR) substances (categories 1A, 1B and 2) in toys to a maximum concentration equal to the individual concentration limits established for the classification as CMR in mixtures. Member States and the European Parliament accepted to establish migration limits only for certain metals and for a few specific CMR substances, namely nitrosamines (in rubber), for which migration limits were set at the levels recommended by the Scientific Committee for Consumer Protection (SCCP) in its opinion of December 2007. The presence of CMR substances in concentrations greater than the above-mentioned limits is permitted only for inaccessible parts of toys, or after a positive opinion of the Scientific Committee.

2. TERMS OF REFERENCE

DG Enterprise would like to establish a sound scientific basis for setting safe limits for the presence of organic CMR substances in toys, in particular for toys for children under 36 months of age or for other toys intended to be put in the mouth, either through the assessment that concludes that food contact grade materials are suitable for use in toys, or through the development of more appropriate criteria. However, to minimize the amount of additional testing, DG Enterprise would prefer, as far as this is compatible with the scientific data, to make full or partial use of existing legislative limits, such as those used for the classification and labelling of dangerous substances, or for food contact materials (FCM).

DG Enterprise recognizes that in earlier opinions on safe limits for organic substances in toys, the committee favoured an approach based on migration testing, but found that the implementation of migration testing as proposed by the European Standardisation Organisation (CEN) in its draft standards EN71-9, 71-10 and 71-11 was not fully satisfactory. If the Committee is of the opinion that the development of additional standardized testing procedures is necessary to obtain reliable migration data, DG Enterprise would like the present opinion to provide sufficient guidance to ensure that a suitable specification can be provided to CEN.

DG Enterprise would therefore like an opinion on the following questions:

1. The limits for most organic CMRs in toys are set at the individual concentration limits established for the classification of CMR substances in mixtures. By comparison, would migration limits for CMR substances set at, for example, 10% of the above limits (i.e. release of 10% of the maximum allowed content during migration testing), in combination with an assumed intake of 8 mg of toy material/day (or 100 mg or 400 mg depending on the type of material), result in a lower risk to the health of children? If not, please give reasons why an approach based upon migration limits derived from the classification limits is not appropriate for reducing the risk to children from CMR substances in toys. If such migration limits could result in a reduced risk, would the relevant parts of EN71 constitute a suitable migration test?
2. Are the migration limits set out in the food contact materials legislation appropriate to ensure that the use of food contact grade materials in toys poses no risk to the health of children in respect of their CMR content in particular in case of toys intended for children under 36 months of age or other toys intended to be put in the mouth?

If not:

   a. Would use of those food contact migration limits at least pose less risk than either the concentration or migration limits mentioned in question 1 above?

b. Could food contact material migration limits be adapted so that the use of compliant material in toys would pose no risk, for example by use of a correction factor, or through supplementary migration testing, perhaps in a different test medium?

3. If the Committee is of the opinion that the relevant parts of EN 71 are not an appropriate test to generate migration data relevant to children's use of toys, are there any other tests that might be used instead? If the Committee is of the opinion that no suitable test exists, are there any existing tests that might be so adapted or further developed? The Committee is invited to give advice on the essential parameters that the test should simulate e.g. sucking, chewing, saliva and gastric acid test medium. Would different test procedures be needed for hard and soft polymers? Should the safe limits for migration of CMRs from toys be set at 10% of the tolerable daily intake (or the limit values) for food, and would an ingestion level of 8mg/day (and 100 mg and 400 mg) as used for metals be appropriate in the case of polymeric toy materials? If not, what alternative values or approach would be more appropriate?

4. The Committee is invited to provide additional comments or guidance to assist the Commission in the further development of safe limits for organic CMR substances in toys.

3. OPINION

3.1. General comments

The European Standardisation Organisation (CEN) has established European Standards for the safety of toys (EN 71-1 to EN 71-11). Among these, EN 71-3 (migration of certain elements), EN 71-4 (Experimental sets for chemistry and related activities), EN 71-5 (Chemical toys (sets) other than experimental sets), EN 71-7(Finger paints - Requirements and test methods), EN 71-9(Organic chemical compounds – Requirements), prEN 71-10 (Organic chemical compounds – Sample preparation and extraction) and EN 71-11 (Organic chemical compounds – Methods of analysis) refer to the safety of chemicals in toys. All of these standards may include substances classified as CMR.

Only three standards (EN 71-9, EN 71-10 and EN 71-11), based on the final report of the work of CEN/TC 52/WG 9, were evaluated by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE 2004). In 2007, the Scientific Committee on Health and Environmental Risks (SCHER 2007) was requested to evaluate these three "postulated" revised standards before publication in the Official Journal of the European Union. SCHER noticed that the standards were based on the report submitted earlier to CSTEE, agreed with the comments made by CSTEE and set exposure limits as well as made several additional comments and suggestions for improvement with respect to proper risk assessment of organic chemicals in toys (SCHER 2007).

Among the several comments made by the CSTEE and SCHER on the CEN report (CEN/TC 52/WG 9) and Standards EN 71-9, EN 71-10 and EN 71-11, the following are the main concerns that SCHER would like to further underline with respect to exposure and migration of chemicals from toys:

1. *Different polymers and dyes may be present in different areas of the toy.*

2. *Procedures need to be specified to ensure that sampling is representative*

3. *The term simulant is used only to imply a simulant for saliva, and it is unlikely that water is a good simulant. It may be appropriate for water-soluble compounds but not for lipophilic compounds. Gastric juice needs to be simulated. This statement would include water as a suitable simulant for sweat.*

4. *The use of a device to ensure the adequate mixing of a sample with extraction fluid is required, e.g., head over heels extraction.*

5. *The sample handling for the head-space analysis of solvents and monomers is still missing.*

6. *In determining monomers and solvents with the static head-space technique,it appears to be assumed that the total amount present in the solid test material is evaporated.*

7. Reference is made to components intended to mimic cosmetics. Comparison against the compositional requirements for real cosmetics is recommended. However, in the case of young children there is a high likelihood of oral consumption.

8. With respect to inhalation in particular, there is an issue of the combined releases from all the toys around a child, not just a single toy.

9. The migration studies have only been performed with plastic foils using an aqueous extraction medium. No toys or toys materials have been investigated.

10. The variation of the data obtained from the different studies by the different participating laboratories cannot be estimated. This does not permit evaluation of the uncertainties of the limit values and action limits. Although there are estimates of RSD of the analytical results for the different analytes given in EN 71-11, the uncertainties of the limit values are a function of the whole process and difficult to estimate.

3.2. Question 1

- **The limits for most organic CMRs in toys are set at the individual concentration limits established for the classification of CMR substances in mixtures. By comparison, would migration limits for CMR substances set at, for example, 10% of the above limits (i.e. release of 10% of the maximum allowed content during migration testing), in combination with an assumed intake of 8 mg of toy material/day (or 100 mg or 400 mg depending on the type of material), result in a lower risk to the health of children?**
- **If not, please give reasons why an approach based upon migration limits derived from the classification limits is not appropriate for reducing the risk to children from CMR substances in toys.**
- **If such migration limits could result in a reduced risk, would the relevant parts of EN71 constitute a suitable migration test?**

In accordance with previous opinions by CSTEE, CMR categories 1 and 2 (now categories 1A, 1B according to the CLP regulation) non-thresholded carcinogens should not be present in toys as intentionally added components. Indeed, the acceptance for those chemicals of a non-threshold mechanism makes the definition of a safe level virtually impossible.

The only approach that can be followed is the definition of an acceptable level of risks (i.e. 1 x 10^{-6} additional tumour incidence for adults, to be eventually adjusted for children, the main users of toys). In this respect, children (especially those under 36 months of age) can be considered more vulnerable due to higher levels of exposure to some chemicals and also because they may be more susceptible to the induced effects, due to their physiological status (i.e. immature metabolic and immune system, proliferative tissues).

Nevertheless, the TSD limits the presence of CMR substances in toys (except for nitrosamines and some metals, for which specific limits, based on migration tests are defined) to a maximum concentration, corresponding to limits established for the classification as CMR in mixtures. A derogation to this limit of content is accepted when CMR substances are present only in inaccessible parts of toys. The default values for the

limits related to CMR substances categories 1 and 2 are: ≤ 0.1% for mutagens and carcinogens and ≤ 0.5% (≤ 0.3% according to the CLP regulation) for reproductive toxicants. However, some CMRs have specific concentration limits assigned. A number of problems can arise from this approach, due to the fact that classification limits set for mixtures are applied to articles (as the toys should be considered):

1. The percentage composition refers to the toy as a whole, to components of the toy and to distinct, microstructural parts of the toy. However, a CMR substance present in a specific part of the toy may not be homogeneously distributed, so that the local % concentration could be higher in that specific part and possibly above the limit.
2. Limits are cut off values, defined for a practical approach to be used for regulatory purposes.
3. The classification of mixtures as CMR is based on the presence of at least one of the CMR substances above the classification limits, without taking into account possible interactive effects of the CMR substances in the mixture, hence in the toys.

These considerations make the suitability of the classification approach applied to toys quite limited.

According to TSD, CMR category 3 limits (now category 2, according to the CLP regulation) are 10-fold higher than for the other two categories: ≤ 1% for mutagens and carcinogens and ≤ 5% (≤ 3%, according to the CLP regulation) for reproductive toxicants. The above considerations apply also to these limits, in addition to the absence of any scientific base for the 10 fold difference with respect to limits for CMR categories 1 and 2.

It is the SCHER opinion that the presence of CMR category 3 (or category 2 according to CLP regulation), when characterized by a threshold mechanism, can be accepted, pending a case-by-case evaluation. This evaluation should be based on available toxicological data (to derive a TDI) compared with exposure data, in order to identify possible risks.

The SCHER supports the concept that exposure levels can be defined on the basis of "good quality" migration data (at least for dermal and oral route of exposure), not simply on the toys composition. However, in some cases migration tests can be waived. Indeed, when the exact composition is known, assuming 100% migration of the chemical under consideration, and when the exposure level is below the safe reference value (TDI or partial TDI allocated to exposure from toy use), there is no need to perform any tests.

The answer to the question about the possibility of setting limits for CMR substances by considering a 10% migration of the above-described classification values (i.e. release of 10% of the maximum allowed content during migration testing) starts with the consideration that this 10% value originates from the CSTEE opinion that toy represents only 10% of the total exposure to CMRs. A parallel can be made with the 10% used as the allocation factor for the exposure coming from the diet in the case of metals. However, this value cannot necessarily be valid for all different CMRs. In addition, this value would account just for oral exposure, whereas in the use of toys, dermal and inhalation routes should also be considered.

By applying the proposed migration approach in combination with a daily assumed intake of toy material (defined depending on the type of material), common migration limits should be derived for all different CMR substances, independently on their physico-chemical and toxicological properties. On this basis, although in many cases the risk to the health of children is lower, by setting migration limits at 10% of the classification limits does not necessarily mean that the risk is negligible or unlikely.

Furthermore, although in many cases the risk could be lower, this does not necessarily mean that it is an acceptable one.

The SCHER recommends the identification of exposure levels through appropriate migration tests (see below). In addition, exposure to the same chemical simultaneously from several toys and/or from other possible sources should also be considered. Furthermore, the migration due to the sucking activity is not the only source of exposure to toys, due to the following reasons:

i) sucking and chewing can results in the ingestion of small particles of toy material; therefore, bioavailability should be derived by the combined information on migration in saliva, and migration in gastric juice combined with information about intestinal absorption;

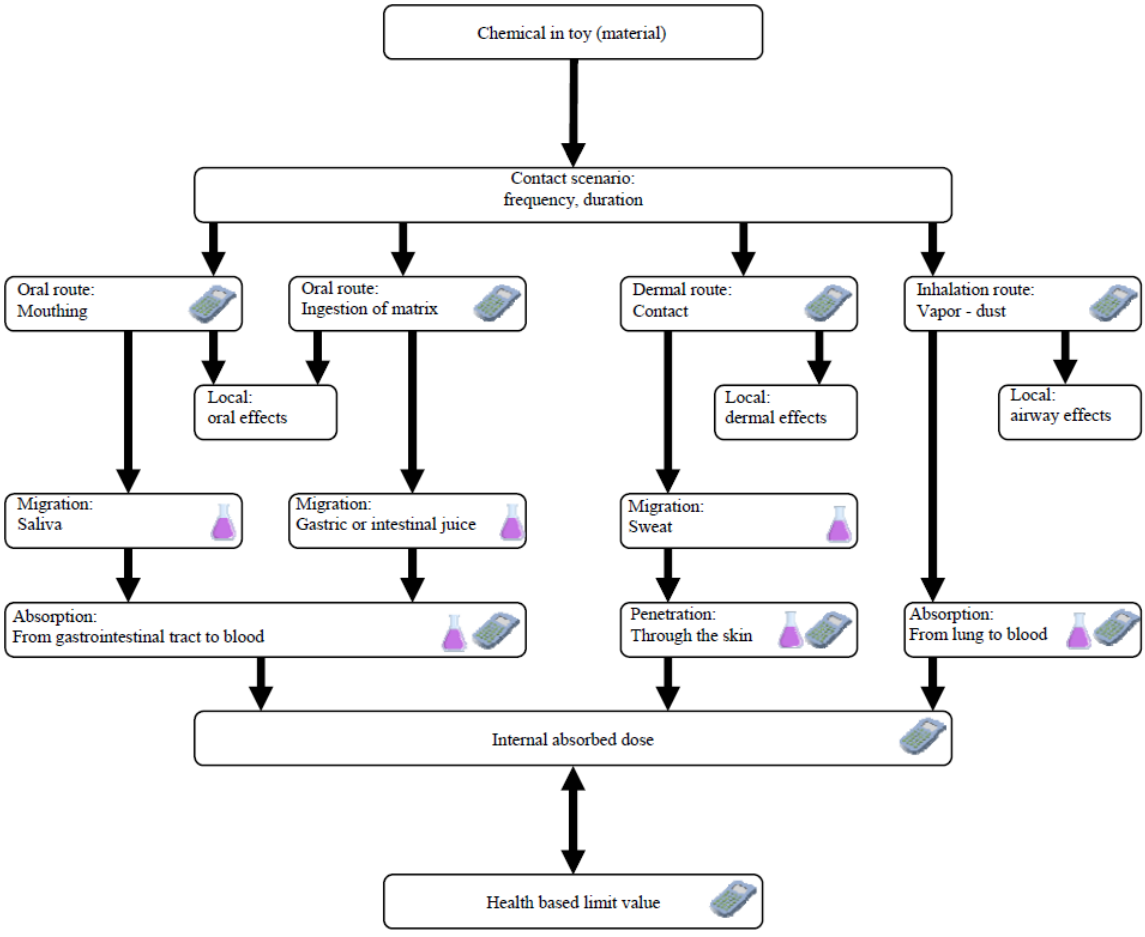
ii) CMR substances could be adsorbed by dust particles, big enough to be ingested;

iii) sweat migration test would be relevant if the toy is in contact with the skin;

iv) inhalation cannot be excluded and should be considered, depending on the physico-chemical properties of the chemicals to be evaluated.

The migration tests described in EN71, as indicated above, are not appropriate to determine the migration values.

It is recommended that a risk-based approach, as described in the RIVM report (2008), as opposed to a hazard-based classification limits approach, should be applied. This approach, illustrated in figure 1, considers different contact scenarios, oral exposure through mouthing and ingestion of the matrix, dermal exposure through direct contact, and inhalation of compounds released in the vapour form and indirectly through dust. This approach requires information on concentrations in simulants, frequency and duration of exposure, and absorption rate in order to define appropriate exposure levels to be compared with health-based limit values.



(From RIVM, 2008)

3.3. Question 2

Are the migration limits set out in food contact materials legislation appropriate to ensure that the use of food-contact-grade materials in toys poses no risk to the health of children with respect to their CMR content, in particular in the case of toys intended for children under 36 months or other toys intended to be put in the mouth?

- Food Contact Material (FCM) legislation is based on Regulation EC 1935/2004 that is the framework regulation laying down the general safety requirements applicable to all materials and articles intended to come into contact with foods. Under this framework, specific legislation is in place at the community level for plastics (Dir EC 2002/72/EC), ceramics, (Dir 84/500/EEC), regenerated cellulose (2007/42/EEC) and some individual substances (vinyl chloride, nitrosamines, certain epoxy derivatives). Therefore, in the FCM legislation Specific Migration Limits are currently established only for the above-mentioned materials.
- To test compliance with Specific Migration Limits (SMLs) in the FCM legislation, strictly dedicated systems for testing (food simulants, standard contact times and temperatures) were developed and they are currently applicable only to the above-mentioned materials, under the frame of the relevant EC Directives mainly dealing with plastic FCM. In some cases, compositional restrictions (maximum permitted amounts) are laid down or the SML are accompanied by restrictions for use only in some types of polymers. In other cases, a detection limit is given as SML, meaning that the substance should be virtually absent. Therefore, taking into account the strong characterisation of the SMLs and their connected compliance testing, any extension of their use to other types of materials (e.g. wood, paper, rubber, etc.) cannot be generalized, or at least requires further evaluation. This point is particularly relevant, taking into account the variety of materials that individually, or more frequently in combination, are used in toys.
- To say that a toy is safe if its materials comply with the FCM legislation would indirectly mean that toy materials could be submitted to the migration tests for FCM. The results of these migration tests would never be representative for toys in general due to the following reasons:

  a) The migration tests in the FCM system are performed under static conditions. This is not applicable to toys because it was demonstrated that the effect of mechanical actions (e.g. sucking, chewing) may increase the migration up to unexpected migration levels; also in media where the migrants are not well soluble e.g. migration of phthalates from soft PVC in saliva simulant (Bouma et al., 2002; Fiala et al., 2000). Even though the available knowledge on migration from FCM allows in most cases to predict migration under defined conditions typical for FCM, the eventual additional migration deriving from mechanical stressing action (licking, chewing, sucking) is not yet predictable with adequate confidence. Therefore any simulated or modelled migration test from toys should take into account this additional effect, e.g. dynamic tests, head over heels.

  b) To test compliance with SMLs, food simulants are established by the relevant legislation. In case of plastic FCM tests, the simulants are distilled water, 3% acetic acid, 10% ethanol, and olive oil. They are representative of food categories with respect to their extractive power for migrants in the plastic FCM. Saliva, sweat and gastric juice are not properly represented by the above-described food simulants. This could lead to the wrong estimation of the actual migration in conditions of use for toys. Moreover, available data do not allow deriving any 'general' correction factor to convert the migration into food simulants to

migration of the same compound into media simulating the contact with toys (saliva, sweat, gastric juice).

c) The FCM legislation and the relevant SMLs are based on toxicological evaluations, related only to the oral route. It is worth noting that in the FCM system, sensitization is not taken into account when not relevant to oral exposure, whereas it could be relevant for repeated dermal contact.

d) The available knowledge on migration phenomena from plastic in contact with foods allows predicting the possible behaviour of migrants when in contact with different test media. In fact, it could be reasonably anticipated that, under the same conditions of time and temperature, for the same polymer, when migrants are apolar their migration in the simulants for fatty foods (e.g olive oil, isooctane, etc.) would be generally higher than the migration in aqueous media, even in the presence of mechanical stress. The opposite situation could occur when migrants are polar and the contact media are aqueous. In fact, in this case it is well known, as previously mentioned, that mechanical action would enhance migration with respect to static conditions. It is worth noting that in the FCM system, the amount and type of toxicological data needed for the safety evaluation depends on the migration level. Therefore, if the migration levels obtained by means of static contact tests (FCM conditions) underestimate the migration under mechanically stressed "toy contact conditions," there is the possibility that the corresponding toxicological data used and suitable for FCM evaluation are no longer adequate for toys.

It can therefore be concluded that FCM legislation cannot be generally used to assess the risk to children from exposures to CMR in toys, but a case by case adaptation would be necessary.

3.3.1. Question 2a.

Would use of those food contact migration limits at least pose less risk than either the concentration or migration limits mentioned in question 1 above?

The SMLs from plastic FCM legislation cannot be applied as such to toys because they are settled on the basis of an exposure scenario not directly applicable to toys, since they only cover migration from plastic materials and consider exclusively the oral route.

Since for the application of both migration limits, as proposed in question 1) and food contact migration limits, no general conclusion on the risk posed by CMRs in toys can be drawn, it is not possible to make any comparison saying that one approach is more appropriate or conservative than the other.

Furthermore, even if it would be possible to estimate that the risk is lower by using one of the two approaches, this does not necessarily mean that there is no risk or that the risk is negligible.

3.3.2. Question 2b.

Could food contact material migration limits be adapted so that the use of compliant material in toys would pose no risk, for example by use of a correction factor, or through supplementary migration testing, perhaps in a different test medium?

The adaptation of the SML from FCM by introducing a correction factor would need additional scientific knowledge, currently not available.

A systematic and comparative study between migration under food contact conditions and migration under "toys contact conditions" is therefore necessary. This could be done by means of experimental studies on representative classes of chemicals. It would be necessary to define reference contact conditions for testing toys, representative of the

actual contact between the toy and the child. In addition the test media should be representative of the possible contacts (oral, dermal, inhalation).

Therefore, suitable ad hoc migration testing should be developed for toys.

Finally, even though the SMLs for FCM cannot be used as such and not enough scientific knowledge is available to derive sound correction factors, the toxicological evaluations that are behind the SML could be used to evaluate the safety of the chemicals of concern.

3.4. Question 3

3.4.1. Question 3a

If the Committee is of the opinion that the relevant parts of EN 71 are not an appropriate test to generate migration data relevant to children's use of toys, are there any other tests that might be used instead? If the Committee is of the opinion that no suitable test exists, are there any existing tests that might be so adapted or further developed?? The Committee is invited to give advice on the essential parameters that the test should simulate e.g. sucking, chewing, saliva and gastric acid test medium. Would different test procedures be needed for hard and soft polymers?

In addition to the considerations expressed under the heading 'General comments,' these are the major concerns with respect to exposure and release of chemicals from toys, and suggestions for improvements:

1. When establishing safe migration limits, exposure to a chemical from all routes, multiple exposures, and exposure to the same chemical from several toys simultaneously should be considered.

   The standards EN 71-10 and EN 71-11 are based on peer reviewed methodology, but these methods have not been validated according to IUPAC (Horowitz, 1995) and ISO 5725. At present, reproducibility of these methods among various laboratories is not known because the methods were not subjected to a final validation exercise. However, these provisional methods are currently used within the industry as well as by authorities in EU Member States to guarantee the safety of toys. This is of great concern, because it is not known whether (i) the methods are reliable; and (ii) the results of analysis of toys in various laboratories are within a permitted reproducibility (RSDR). The implications of permitted maximum reproducibility of a standard t test method on the compliance of a product with respect to diisononyl phthalate release have been described in an earlier CSTEE document (CSTEE, 2001b). It was shown that test results with a permitted reproducibility (RSDR) of 20% (with 1 SD) may exceed the regulatory limit (in other words TDI) by 50%, but will pass the test. Allowance of 30% reproducibility (with 1 SD) will result in 90% excess of TDI.

2. The sampling of toy materials for the analysis should be representative of all accessible toy parts.

3. During sucking and chewing of toys, saliva will be exposed to chemicals in the toy composition. In addition, oral exposure to 8 mg of released particles, which will be ingested, may also occur. Thus, a combined exposure should be estimated by determining the migration of the chemical in the artificial saliva as well as in artificial gastric juice.

4. The use of water as simulant for saliva, sweat and gastric juice is not justified. The fortified saliva described in a JRC report (2001 EUR 19826 EN) is recommended.

5. The migration studies are performed at 20°C, but it has been shown earlier that migration of phthalates from toys increased with increasing temperature (20°C, 37°C

and 65°C) (CSTEE, 1999). The migration of chemicals from toys should be determined at 37°C.

6. The mechanical force applied for the migration studies, i.e. the head over heels method should be appropriately described in standard methods.
7. For simulation of sucking/chewing, replenishment of artificial saliva is required. For the validation of a method for the migration of chemicals from toys, 4 x 30 min migration (with recovery periods of at least 12 hours between each migration test) from a toy sample should be determined. The calculated average migration rate (μg/cm^2/min) then will be better representative of the real situation than that derived from 1 x 60 min migration investigation as described in EN 71-11.
8. The migration of chemicals in sweat under static conditions should be determined using artificial sweat as described in EN 1811. The migration of chemicals from half of the surface area of a toy should be considered for the calculation of bioavailability.
9. As the number of chemicals that may be present in toys is large, it is suggested that the methods of their migration from toys in each simulant should be validated for at least five appropriate chemicals of low, medium and high hydrophilic/lipophilic property.
10. Inhalation exposure of volatile and semivolatile chemicals from toys should be estimated under appropriate exposure scenario(s).
11. Determination of migration of chemicals from toys should be performed using real toy samples. This will cover the effects of various other chemicals present in the toy as well as the effects of chemicals, such as surfactants, which are used in the final finish of the toys.

Finally, it is recommended to identify the CMR substances that may be present in toys covered by EN 71-3, EN 71-4, EN 71-5, and EN 71-7, because CMR substances were not the focus of the investigation when these standards were prepared.

3.4.2. Question 3b

Would different test procedures be needed for hard and soft polymers? Should the safe limits for migration of CMRs from toys be set at 10% of the tolerable daily intake (or the limit values) for food, and would an ingestion level of 8 mg/day (and 100 mg and 400 mg) as used for metals be appropriate in the case of polymeric toy materials? If not, what alternative values or approach would be more appropriate?

When a TDI is available, meaning that a threshold to the effects caused by a CMR under evaluation can be established, the SCHER supports a 10% allocation factor (to estimate a partial TDI) for the exposure coming from the use of toys.

The use of an ingestion level of 8 mg/day of scraped off toy material; 100 mg of brittle material and 400 mg of semisolid toy material in defining possible exposure scenarios is supported by SCHER.

When a threshold mechanism is not applicable to CMRs, and a TDI is not available, setting a regulatory threshold as migration limits equal to 10% of the classification limits, due to the limitation of this approach (see the answer to question 1), is not scientifically justified and does not allow to draw any conclusions on the corresponding risk.

As an example, by using the above-mentioned exposure scenarios, this would result in 40 μg CMR/day per child in case of ingestion of 400 mg (or ml) of semisolid material, which can correspond to an unacceptable risk for some compounds and a sufficient protective level for others.

It is recommended that a risk-based approach in contrast to a hazard-based-classification-limits approach should be applied, as described in the answer to question 1.

Furthermore all routes of exposure should be considered including inhalation, especially for compounds with high vapour pressures.

3.5 Question 4

The Committee is invited to provide additional comments or guidance to assist the Commission in the further development of safe limits for organic CMR substances in toys.

Since the limit values are not based on toxicological criteria, establishment of health-based standards needs further evaluation combining toxicological information with estimated exposure data. This information can be used to establish a Margin of Exposure (MOE).

SCHER reiterates its recommendations presented in the opinion "CEN's response in the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys" (SCHER, 2007).

I. It is recommended to use relevant extraction medium rather than aqueous extraction media. However, the use of aqueous media may be acceptable if the log Pow is below 3 by using a correction factor (for example 5).

II. Standardized and validated chemical-analytical methods for measurement of migration should be applied.

III. Action limits for CMR and very toxic compounds are not acceptable as these compounds should not be present in toys. Thus, they should be determined directly in the toy using appropriate extraction procedures and sensitive chemical-analytical procedures.

IV. A comprehensive list of chemicals present in toys should be established and the margin of safety should be determined based upon exposure data and toxicological information.

V. In case of structurally related compounds, a combined limit value should be used for the group. For calculating an MOE, the lowest no-observed-effect levels (NOEL) for an individual member of the group should be used

4. LIST OF ABBREVIATIONS

CEN	European Standardisation Organisation
CLP	Classification, Labelling and Packaging (Regulation)
CMR	carcinogenic, mutagenic, and reprotoxic
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
FCM	Food Contact Material
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MOE	Margin of Exposure
NOEL	No-observed-effect levels
PVC	Polyvinyl chloride
RSDR	Reproducibility Relative Standard Deviation
SCCP	Scientific Committee for Consumer Protection
SMLs	Specific Migration Limits
TDI	Tolerable Daily Intake
TSD	Toys Safety Directive

5. REFERENCES

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