European Commission

RISK ASSESSMENT
by the Scientific Committees of the European Commission

QUESTION TO THE COMMITTEE

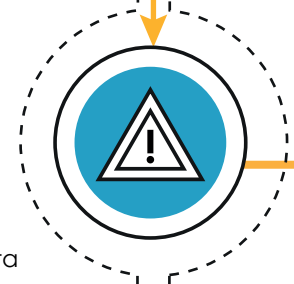
Sound scientific advice is vital to ensure a high level of health and environmental protection. Before making a legislative proposal, the European Commission asks the Scientific Committees to assess the potential risks; namely the probability and the severity of an adverse effect, in relation to the hazard and to the exposure.

Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)
Example: Flame retardant TCEP in toys

Are there risks when the flame retardant TCEP (tris(2-chloroethyl)phosphate) or its halogenated alternatives are present in toys at concentrations lower than those set up under current legislation? If there are risks, should there be a limit for TCEP? Are the risks for children under the age of 3, who very frequently mouth toys (and other objects), different from those for children over 3 years old?

HAZARD IDENTIFICATION

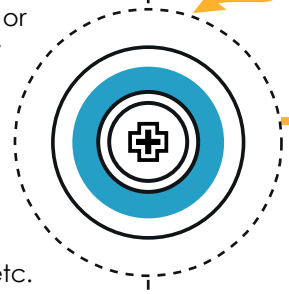
Hazard identification defines which chemicals, biological or physical agents are potentially harmful to human health or the environment. It can be based on the results of in vivo tests, in vitro tests, in silico methods, epidemiological studies, clinical studies, case reports and data from post-marketing surveillance.



Studies in rats and mice provide clear evidence that TCEP is carcinogenic and shows reproductive toxicity, with a threshold dose below which effects are no more evidenced. Based on the available data, TCEP is a suspected human carcinogen and a presumed human reproductive toxicant.

EXPOSURE ASSESSMENT

Exposure assessment defines the human exposure levels. It determines or estimates how, how much and how often the population is exposed to a substance. It also defines the source (drinking water, diet, consumer products, environment) and the route of intake among specific consumer groups like children, vulnerable groups, adults, etc.



Exposure to TCEP can occur through:
- **oral exposure through toys, textiles and furniture coverings which can be put in the mouth (sucking and chewing), through hand-to-mouth contact and through dust intake;**
- **dermal exposure through direct skin contact with toys;**
- **inhalation of indoor air.**

Considering all ways of exposure (except toys), 1- to 3-year old children are exposed to around 13 microgram TCEP per kg bodyweight per day.

DOSE-RESPONSE ASSESSMENT

The dose-response assessment describes the relationship between the extent of an adverse effect in an organism and the different concentrations or doses of a chemical. If there is a threshold amount below which a substance is safe and above which it is not, then the threshold amount is taken as the highest dose that can be taken without any observable adverse effects.

The provisional tolerable daily intake, calculated using a conservative approach, is 13 microgram per kg bodyweight per day.

Health and Food Safety

RISK CHARACTERISATION

Risk characterisation is the combination of information on hazard, exposure, and dose response to provide an estimate of the probability that identified specific adverse effects will occur in exposed people.

The estimated daily exposure for children is similar to the tolerable daily intake.
In light of uncertainties in the data on the effects of and the exposure to TCEP, the Scientific Committee considered that the estimated margins of exposure may not adequately protect human health.

THE SCIENTIFIC COMMITTEE'S OPINION

A full risk assessment is made up, based on the available scientific evidence and undertaken in an independent, objective and transparent manner. This assessment serves as a basis for the next steps of the risk management and policy making processes.

TCEP from toys will likely add to TCEP from other sources. Therefore the Scientific Committee concluded in its Opinion that no additional exposure from toys can be considered safe. The use of TCEP should be avoided in toys for children both below and above 3 years of age. The limit for TCEP in toys should be set at the detection limit of a sufficiently sensitive analytical test method.

RISK MANAGEMENT

BY THE COMMISSION AND THE LEGISLATORS

Risk management means the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

ECONOMICAL, SOCIAL, POLITICAL ASPECTS

PROPORTIONALITY AND PRECAUTIONARY PRINCIPLE

According to the precautionary principle, if a given policy or action might cause harm to the public or the environment and if there is still no scientific consensus on the issue, the policy or action in question should not be pursued. Once more scientific information becomes available, the situation should be reviewed. Under the proportionality rule, the action of the EU must be limited to what is necessary to achieve the objectives.

POLICY PROPOSAL

Considering the risk assessment and all other relevant aspects, the European Commission makes a legislative proposal, for instance to authorise or to forbid a certain substance, to define exposure limits or to set prevention and risk reduction measures.

LEGISLATION

The legislative proposals are discussed and adopted by the EU legislators: the European Parliament and the Council of the EU. For tertiary legislation, adoption follows Comitology and scrutiny procedures.

Commission Directive 2014/79/EU sets new stricter limit values for TCEP in toys for children under 3 years old and in other toys intended to be placed in the mouth.

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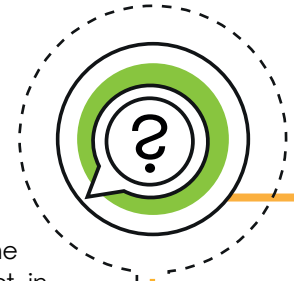
European Commission

RISK ASSESSMENT
by the Scientific Committees of the European Commission

QUESTION TO THE COMMITTEE

Sound scientific advice is vital to ensure a high level of health and environmental protection. Before making a legislative proposal (such as the market authorisation of a certain ingredient), the European Commission asks the Scientific Committees to assess the potential risks; namely the probability and the severity of an adverse effect, in relation to the hazard and to the exposure.

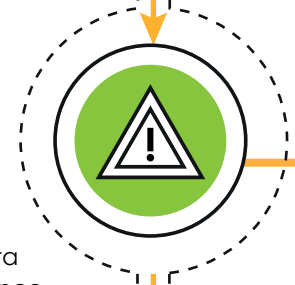


Scientific Committee on Consumer Safety (SCCS)
Example: Pigment Red 57 used in hair dyes

Pigment Red 57 is a colouring product used in non-oxidative hair dye, with a common maximum on-head concentration of 0.4%. Taking into account the scientific data provided, is the use of this product safe for consumers?

HAZARD IDENTIFICATION

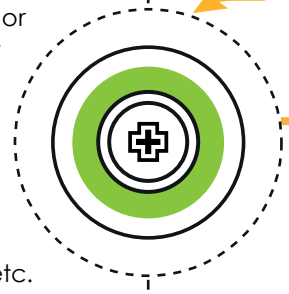
Hazard identification defines which chemicals, biological or physical agents are potentially harmful to human health or the environment. It can be based on the results of in vivo tests, in vitro tests, in silico methods, epidemiological studies, clinical studies, case reports and data from post-marketing surveillance.



Hair dyes in general may cause skin sensitisation and other adverse health effects. For cosmetics, animal testing has been banned in the European Union since 2013.

EXPOSURE ASSESSMENT

Exposure assessment defines the human exposure levels. It determines or estimates how, how much and how often the population is exposed to a substance. It also defines the source (drinking water, diet, consumer products, environment) and the route of intake among specific consumer groups like children, vulnerable groups, adults, etc.



Pigment Red 57 is used as a semi-permanent hair dye at a maximum concentration of 0.4% in finished cosmetic formulations.

DOSE-RESPONSE ASSESSMENT

The dose-response assessment describes the relationship between the extent of an adverse effect in an organism and the different concentrations or doses of a chemical. If there is a threshold amount below which a substance is safe and above which it is not, then the threshold amount is taken as the highest dose that can be taken without any observable adverse effects.

The exposure dose has been calculated to be 0.003 mg per kg bodyweight per day, for a typical non-oxidative hair dye formulation. This dose is considered very low.

RISK CHARACTERISATION

Risk characterisation is the combination of information on hazard, exposure, and dose response to provide an estimate of the probability that identified specific adverse effects will occur in exposed people.

The Scientific Committee on Consumer Safety considers that the available data do not indicate that Pigment Red 57 is toxic: at the low systemic exposure level in hair dye, it is not easily absorbed into the scalp.
However, Pigment Red 57 is also used in other cosmetic products as a colorant, which could lead to higher accumulated exposure for consumers who use several of these cosmetic products.

THE SCIENTIFIC COMMITTEE'S OPINION

A full risk assessment is made up, based on the available scientific evidence and undertaken in an independent, objective and transparent manner. This assessment serves as a basis for the next steps of the risk management and policy making processes.

The Scientific Committee on Consumer Safety sees no safety concern for consumers from the use of Pigment Red 57 in non-oxidative hair dye formulations at a maximum on-head concentration of 0.4%. Therefore, the Scientific Committee concludes that Pigment Red 57 does not pose a risk to the health of the consumer.

RISK MANAGEMENT

BY THE COMMISSION AND THE LEGISLATORS

Risk management means the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

ECONOMICAL, SOCIAL, POLITICAL ASPECTS

PROPORTIONALITY AND PRECAUTIONARY PRINCIPLE

According to the precautionary principle, if a given policy or action might cause harm to the public or the environment and if there is still no scientific consensus on the issue, the policy or action in question should not be pursued. Once more scientific information becomes available, the situation should be reviewed. Under the proportionality rule, the action of the EU must be limited to what is necessary to achieve the objectives.

POLICY PROPOSAL

Considering the risk assessment and all other relevant aspects, the European Commission makes a legislative proposal, for instance to authorise or to forbid a certain substance, to define exposure limits or to set prevention and risk reduction measures.

Commission Regulation (EU) 2015/1190 of 20 July 2015 has amended Annex III of the Cosmetic Regulation (EC) 1223/2009 by adding Pigment Red 57 with entry 296 laying down the specific conditions of use for this hair dye ingredient in line with the SCCS Opinion SCCS/1411/11.

LEGISLATION

The legislative proposals are discussed and adopted by the EU legislators: the European Parliament and the Council of the EU. For tertiary legislation, adoption follows Comitology and scrutiny procedures.

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