

Health Aspects of Flame Retardants in Textiles

Report for
Bundesministerium für Frauenangelegenheiten und
Verbraucherschutz
Radetzkystraße 2
A-1031 Wien

Geschäftsfeld Toxikologie
Bereich Lebenswissenschaften



DISTRIBUTION

- Fair copy Bundesministerium für Frauenangelegenheiten und Verbraucherschutz
- Copies 1 - 3 Bundesministerium für Frauenangelegenheiten und Verbraucherschutz
- Copy 4 Österreichisches Normungsinstitut, Verbraucherrat
- Copy 5 Archiv Toxikologie, Österreichisches Forschungszentrum Seibersdorf

Health Aspects of Flame Retardants in Textiles

CONTENTS

Contents	1
Summary	3
General information	4
1. Introduction	5
2. Overview on flame retardants	6
2.1 Mechanism of actions	6
2.1.1 Process of burning	6
2.1.2 Mechanism of flame retardancy	6
2.2 Types of flame retardants	8
2.3 Production, Use	9
2.4 Textiles to be impregnated	10
3. Prerequisites of a risk evaluation	11
3.1 Risk - benefit considerations	11
3.2 Minimum set of information	12
4. Toxicological hazard of flame retardants	13
4.1 Possible hazards	13
4.2 Testing strategies	13
5. Exposure	15
5.1 Dermal exposure	15
5.1.1 Examples for dermal exposure	16
5.2 Exposure by inhalation	18
5.3 Oral exposure	20
5.4 Indirect exposure	21
5.5 Minimum requirement	21
6. Risk evaluation	22
6.1 Methods of risk evaluation	22
6.2 Initial health risk assessment	23
6.3 Refined risk assessment	24
6.4 Risk management	24
7. Regulations	25
7.1 Situation at present	25
7.2 Possible regulations	26
7.3 Responsibilities	26
7.3 Draft of a Standard	29
8. References	29

Annex	31
Outline of a Standard on "Evaluation of flame retarded textiles"	31
1. Introduction	31
2. Scope	31
3. Definitions, Abbreviations	31
4. Basic requirements	31
5. Evidences and data to be presented	32
5.1 Need and benefit	32
5.2 Evidence of efficiency	33
5.3 Description of the flame retarding chemical to be used	33
5.4 Physico-chemical properties of the flame retarding chemical	33
5.5 Toxicological properties of the flame retarding chemical	34
5.6 Ecotoxicological properties of the flame retarding chemical	35
5.7 Environmental fate of the flame retarding chemical	35
5.8 Intended uses of the final textile product	35
5.9 Properties and characteristics of the final product	35
5.10 Default data	35
5.11 Experience with humans	35
6. Exposure estimation	36
6.1 Dermal exposure	36
6.2 Exposure by inhalation	37
6.3 Oral exposure	38
6.4 Indirect exposure	38
7. Risk assessment	39
7.1 Methods	39
7.2 Initial risk assessment	39
7.3 Refined risk assessment	40
8. Risk management	41
9. Testing	41
9.1 Toxicity testing	41
9.2 Physico-chemical properties	41
9.3 Leaching	42
9.4 Efficiency of reduction of flammability	42
10. Default data for estimating human exposure	42
10.1 Textiles	43
10.2 Human data	44
10.3 Other data	45
11. Simplification of the risk assessments	45
11.1 EHEs	45
11.2 Characteristics of the flame retardants	46

Health Aspects of Flame Retardants in Textiles

SUMMARY

It was the aim of the study to describe critical properties and critical conditions, which form the basis of a health risk evaluation of flame retardants used to impregnate textiles. A second aim was the development of a draft of the health-related part of a new Standard on flame retardants in textiles.

This report presents first an overview on the mode of action of flame retardants, the different types available and their uses. The next part describes possible toxicological hazards and exposure situations, which are of importance when applying flame retardants in textiles. Based on the characterisation of hazard and exposure an assessment of the risk of flame retardants can be performed and is described in the report.

It is proposed that not the flame retardant itself but the flame retardant-textile-system is assessed because of the various uses of textiles, the different exposure scenarios and the resulting great differences in human exposures. The risk evaluation of the reduced flammable textile could be performed within a certification procedure of the impregnated textile.

A draft of a Standard is presented, with the intention to diminish the risk of flame retarded textile products to the consumer.

This report concentrates on the risk to the health of consumers and it therefore does not treat other issues as e.g. environmental problems that could arise with flame retardants.

Health Aspects of Flame Retardants in Textiles

GENERAL INFORMATION

Responsible personnel

Study director
and report preparation: Dr. Heinz Hofer

Sponsor

Bundesministerium für Frauenangelegenheiten und
Verbraucherschutz
Radetzkystraße 2
A-1031 Wien

Study monitoring:

Dr. Franz Fiala
Österreichisches Normungsinstitut
Verbraucherrat
Heinestraße 38
A-1021 Wien

Internal study code

BKA5

Time schedule

Date of contract: 29 April 1998
Date of report: see front page

Location of laboratories

and archives

Österreichisches Forschungszentrum Seibersdorf Ges.m.b.H.
A-2444 Seibersdorf, Austria.

Archives

All raw data and a copy of the final report are retained for
10 years. The data are not destroyed without the prior
information of the sponsor.

Health Aspects of Flame Retardants in Textiles

1. INTRODUCTION

It was the aim of the study to describe critical properties and critical conditions that form the basis of a health risk evaluation of flame retardants used to impregnate textiles.

A second aim was the development of a draft of the health related part of a new Standard on flame retardants in textiles.

This report presents first an overview on the mode of action of flame retardants, the different types available and their uses.

The next part describes possible toxicological hazards and exposure situations that are of importance when applying flame retardants in textiles.

Based on hazard and exposure an assessment of the risk of flame retardants can be performed. A draft of a Standard is presented, with the intention that certification based on this Standard would diminish the risk of flame retarding products to the consumer.

This report concentrates on the risk to the health of consumers and it therefore does not treat the following issues that also enter into an overall evaluation of flame retardants:

- Early stages of the life cycle of a flame retardant, that is production or formulation with the fabrics to be protected. Effects to the health of workers are not considered.
- Late stages of the life cycle as recycling or disposal.
- Environmental effects during the whole life cycle of the product.

Abbreviations used:

TDI: Tolerable daily intake in $\text{mg}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$.

EHE: Estimated human exposure in $\text{mg}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$.

NOAEL: No observed adverse effect level in $\text{mg}\cdot\text{kg}^{-1}\cdot\text{d}^{-1}$.

2. OVERVIEW ON FLAME RETARDANTS

Personal losses by fire occur mostly in residences where furniture, wall coverings and clothes are frequently the fuel [5]. One of the possibilities to diminish personal and property losses caused by a fire is the use of flame retardants.

Monographs on flame retardants are found e.g. in [5] and [10].

2.1 Mechanism of actions

2.1.1 Process of burning

To understand the action of a flame retardant first the process of ignition and burning is described in short:

Fire is a gas-phase reaction. Thus, in order for a substance to burn, it must become a gas.

As with any solid, a textile fabric exposed to a heat source experiences a temperature rise. If the temperature of the source (either radiative or gas flame) is high enough and the net rate of heat transfer to the fabric is great, pyrolytic decomposition of the fibre substrate will occur. The products of this decomposition include combustible gases, non combustible gases and carbonaceous char. The combustible gases mix with the ambient air and its oxygen. The mixture ignites, yielding a flame, when its composition and temperature are favourable. Part of the heat generated within the flame is transferred to the fabric to sustain the burning process and part is lost to the surroundings.

2.1.2 Mechanism of flame retardancy

Flame retardant systems for synthetic or natural polymers can act physically and/or chemically by interfering at particular stages of burning [5]:

- By cooling. Endothermic processes triggered by the flame retardants cool the substrate.
- By forming a protective layer. The heat transfer is impeded, fewer pyrolysis gases are

evolved, and the oxygen is excluded.

- By dilution. Substances, which evolve inert gases on decomposition, dilute the fuel in the solid and gaseous phases. The concentration of combustible gases fall under the ignition limit.
- Reaction in the gas phase. The free radical mechanism of combustion processes which takes place in the gas phase could be interrupted by flame retardants.
- Reaction in the solid phase. One mechanism is the accelerated breakdown of polymers. The reduced viscosity enables a withdrawal from the flame. Secondly the flame retardant can cause a layer of carbon to form on the polymer surface, e.g. by dehydrating action.

Co-additives are often used. A typical co-additive is antimony trioxide which increases the action of e.g. brominated flame retardants.

Some compounds may also act as smoke suppressants.

Reduced flammability can also be obtained by using highly cross linked polymers such as polyimides or polyphenylen-terephthalamide (Kevlar) without additional flame retardants. Their use is restricted by technical and financial reasons.

The action of flame retardants in case of fire can be:

- The flammability is reduced. The product does not ignite under the influence of a certain external heat source.
- The flame spread rate is reduced (if an ignition had occurred after extended operation of an external heat source). The time until a full fire has developed is prolonged.

The result is, that

- fire could be prevented at all
- or at least the escape time from rooms or buildings is prolonged
- and the fire has not fully developed at the time of arrival of the fire brigade. The probability to extinguish the fire is increased.

2.2 Types of flame retardants

Flame retardants are usually classified according to chemical structure or durability.

The main chemical classes of flame retardants are listed with some representative examples:

- Inorganic compounds.
Aluminium trihydroxide, ammonium polyphosphates; antimony trioxide. This group represents the greatest volume of production (ca. 50 %).
- Halogenated compounds.
Brominated and chlorinated compounds are in use. Ca. 25 % by volume. A great amount of different molecules were developed. Tetrabromobisphenol A and decabromodiphenyl ether are the highest volume representatives of this class. Chlorinated paraffins are important examples of chlorinated products.
- Organophosphorus compounds.
Phosphate esters as e.g. triphenyl phosphate form the main subgroup. Products containing phosphorus and halogens or nitrogen are also important. Ca. 20 % by volume.
- Nitrogen based compounds.
Melamine compounds are examples.

Classification according to the durability of the finish of textiles:

- Non durable flame retardants, as for example boric acid, aluminium sulphate, ammonium salts, phosphates. These substances can be applied to mattresses, draperies or theatre curtains which are only rarely washed.
- Semidurable flame retardants, e.g. by phosphorylation of cellulosic fibres or by a combination of cyanamide plus phosphoric acid. These flame retardants are used for example for tents, carpets or curtains. The impregnation is resistant to water but not to dry cleaning or repeated (50 or more) washings.
- Durable flame retardants. Textiles for clothes are mainly impregnated durably with e.g. organic phosphorus compounds or organic, brominated phosphorus compounds.

The inclusion of a flame retardant to a fibre could be performed by addition to the polymer or by chemical reaction with an other monomer to form the polymer. The reactive flame retardant is usually a durable one. Additive flame retardants might range from non-durable to

durable.

From the point of view of the risk evaluation of flame retardants not the durability but the leachability is more relevant. Leaching from impregnated textiles by aqueous or oily solutions could occur e.g. by sweat or sun cream when being in contact with the skin. Dissolved flame retardants could affect the skin or enter the body.

Categories L1 to L3 are proposed on a trial base for the purpose of evaluation of flame retarding chemicals:

- Category L1: "good leachability" of > 10 % from the impregnated textile under standard conditions, see section 5.1.
- Category L2: "medium leachability" between 0.1 and 10 %.
- Category L3: "low leachability" of < 0.1 %.

Flame retardants used in furniture / textiles include the following compounds, according to [5]:

- Organic phosphates such as tri-alkyl or tri-aryl phosphates, tri-chloroalkyl phosphates, dialkyl phosphites, tetrakis-(hydroxymethyl)phosphonium chloride and related structures.
- Halogenated compounds such as polybrominated diphenyl ethers (found in over 50 % of treated furniture) and chlorinated paraffins (rainproof applications).
- Inorganic compounds such as antimony trioxide, ammonium bromide, boric acid and aluminium hydrate.

Performance and selection criteria for flame retardants:

- Effectiveness, efficiency.
- Passing low or high level tests on flame retardancy depending on the purpose.
- Not affecting the processing characteristics of the polymer.
- Only minor changes of the properties of fibres by the addition of a flame retardant, as e.g. strength, rigidity, colour, gloss or heat resistance.
- Durability. Stability.
- Costs.

2.3 Production, Use

About 600 000 tons of flame retardants are produced per year (1992) world-wide [9]. More data on production are found in [5]. The plastic industry is the largest consumer of flame retardants (ca. 95 %). The use of flame retardants in paper and textiles amounts to ca. 10 000 tons per year (1992) in Europe.

2.4 Textiles to be impregnated

Flame retardants can be found in textiles of various uses, see the following Table.

The duration and frequency of the contact with skin is proposed as a categorisation of impregnated textiles on a trial base because the intensity of the contact with skin is of great importance in the evaluation of flame retardants.

- Category C1 is proposed for a possible "long term contact": Frequent and long contact occurs with clothes, sleep wear, bed linen, and furniture fabrics. A worst case situation with 24 hours permanent contact per day over the lifetime is assumed.
- Category C2 is proposed for "repeated exposure", for intermittent events for a few hours per day at most. Examples would be the exposure to carpets or curtains.
- Category C3 is proposed for "limited exposure" on few occasions for at most 1 hour. This situation occurs e.g. for wall lining or tents or for installation or repair of sunshades etc.

Type of textile	Category C1 long term	Category C2 repeated	Category C3 limited
<u>At home:</u>			
clothes	x		
sleep wear	x		
bed linen, blankets	x		
mattresses			x
upholstered furniture covers	x	x	
furniture fabrics	x	x	
carpets		x	
textile wall lining			x
curtains		x	
<u>In bureaux, in public buildings, in transport systems:</u>			

upholstered furniture covers	X	X	
furniture fabrics	X	X	
carpets			X
textile wall lining			X
curtains		X	X
sunshades, sunblinds			X
tarpaulins			X
<u>At work:</u>			
protective clothes for workers or firemen	X	X	
technical fabrics as e.g. belts, ropes			X
sunshades, sunblinds			X
tarpaulins			X
<u>Others:</u>			
tents (military or private)			X
flags			X

Fibres which are impregnated:

Wool, cotton, linen, cellulose, polyester, polyacrylic, modacrylic, viscose, nylon, polypropylene, etc.

3. PREREQUISITES OF A RISK EVALUATION

3.1 Risk - benefit considerations

The risk of fire can be diminished in some situations by the use of flame retardants. On the other hand the application of a flame retardant itself could present a health risk. This is because every chemical substance can be toxic in some situations.

Both points of view are expressed in the discussion on regulations of flame retardants in the EU. Whereas especially UK enforces in the last years the use of low flammable material or the use of flame retardants, other countries as e.g. Germany are more cautious because of the possible risks to the health.

Because there could be a risk to the health (and the environment) by the introduction of a flame retardant a first requirement is that the flame retardant is of actual benefit in lowering the risk to burning. For example the benefit of impregnating the sleep wear, the bed linen and

the mattresses of children should be described and estimated before going on to the health risk evaluation. More obvious is probably the benefit of impregnating bed linen and mattresses in hotels to prevent ignition from small glowing sources, especially from smouldering cigarettes or the impregnation of military tents.

If there would be no relevant need and no benefit of impregnating a textile then there should be no risk to the health at all. No risk from possible toxicological properties of a flame retardant is only obtained in case it is not produced.

The same applies to the efficiency of a flame retardant. If the flame retardant is not effective and efficient in protecting from fire in the special situation, then there should be no risk to the health at all by the use of flame retarding materials.

When evaluating the risk of a substance to the health it is a prerequisite to know the intrinsic hazard of the substance and also to describe the exposure scenarios and to estimate the human exposures. Hazard and exposure are described in the next two chapters 4 and 5.

The risk management of a flame retardant-textile-system is based on the comparison of the benefits and the risks of a product. Alternative products are compared and risk reduction measures are set.

3.2 Minimum set of information

An overall evaluation of flame retardants must therefore comprise as a minimum:

- Evidence of the necessity to lower the flammability of a material.
- The evaluation of the efficiency of the selected flame retardant.
- Basic set of data on toxicological hazards.
- Basic set of data on ecotoxicological hazards.
- Description and estimation of the exposure.
- Health and environmental risk evaluation.

4. TOXICOLOGICAL HAZARD OF FLAME RETARDANTS

4.1 Possible hazards

Flame retardants do not belong to one uniform chemical class, see 2.2. Therefore all possible toxicological endpoints (or hazards) should be considered. These include:

- Local irritation to the skin and mucous membranes. The exposure of the outer human surface is likely for some uses of fire resistant textiles.
- Sensitisation of the skin (and the respiratory organs) can occur at low concentrations and is therefore and because of the probable contact with impregnated textiles of importance.
- Acute to long term (or chronic) toxicity. Acute toxicity is of less importance except perhaps for nondurable and leachable flame retardants. Chronic toxicity usually occurs at much lower concentrations as the acute toxicity and it should therefore be considered also if flame retardants are leachable to only a low degree or if dusting off is a source of exposure. Dioxins (possibly produced from halogenated flame retardants in case of fire) may cause acute and chronic toxicity at very low concentrations.
- Genotoxicity, mutagenicity. Genotoxic properties are basic information on chemicals and provide a first screen for possible carcinogenic effects.
- Carcinogenicity. A few flame retardants as tris-(2,3-dibromo-1-propyl)phosphate are already banned because they showed to be carcinogenic.
- Effects to the reproduction including teratogenicity are also of interest even at low level exposures.
- Neurotoxicity. Some organophosphorus compounds are neurotoxic. This property should therefore be considered for this class of compounds.

Information on the toxicokinetics of the flame retardants are useful to evaluate the risk of toxicological hazards. Especially information on the absorption through the skin are desirable to estimate the actual systemic burden.

The information on the toxicological properties should be available for the flame retarding chemical itself and if applicable also to reaction or degradation products.

4.2 Testing strategies

The different endpoints of toxicity need different testing methods which are mostly performed in a tiered approach. Basic, screening, short term and low cost information are usually obtained first. For impregnated textiles some endpoints as sensitisation after repeated skin contact has immediate relevance. Others as e.g. reproduction toxicity gain importance if the flame retardant dissolves to some degree and becomes available systemically.

For flame retardants used in textiles the basic set is proposed to contain 3 tests:

- Skin sensitisation can occur even at very low exposure and must be considered at all applications of flame retardants in textiles.
As a by-product the performance of the test would also yield qualitative data on the primary skin irritation from the dose range finding test.
- Ames test for detecting point mutations. The test is mainly used as a screening for carcinogenicity.
- Subacute 28-days oral toxicity study with rats. This investigation gives first information on the toxic effects produced after repeated exposure to a chemical. It is indispensable and can not be replaced by other - short term - studies or other information at present. This study is also included in the base set for the notification of new chemical substances. A No Observed Adverse Effect Level (NOAEL) can be derived and from this a Tolerable Daily Intake (TDI) by applying safety factors (see 6.1).
An acute toxicity study is available in most cases. It is useful as a dose range finder for the 28-days toxicity study but is less relevant for the risk assessment.

Data for the basic set should be available for each flame retardant, independently of its use or leachability.

Specific effects as e.g. neurotoxicity occurring with some members of the organophosphorus compounds should be observed.

5. EXPOSURE

Three routes of exposure to flame retardants in textiles are possible: peroral, dermal, by inhalation. Other routes as e.g. intravenous are of no importance.

Although the dermal route seems at first to be of major importance for impregnated textiles the examples given below demonstrate that also the other routes could yield relevant human exposures in some situations.

When estimating the exposure of humans the occurrence of degradation or reaction products of the flame retardant should also be considered.

5.1 Dermal exposure

Dermal exposure occurs when wearing clothes or by contact with bed linen, carpets or furniture fabrics, etc.

Factors which are of importance for dermal exposure:

- The availability of the flame retardant. The substance must be liquid or become dissolved in order to migrate to and penetrate into the skin. An extraction (leaching) of the substance from the fibres must occur. The extractability depends on the chemistry of the flame retardant, the impregnation process, the extraction medium and other conditions such as time and temperature. Leaching could occur by sweat, blood, urine, skin creams, body lotions or other extraction media. The extraction will also depend on the durability or the inclusion of the flame retardant in the polymer matrix. Non-durable salts are more likely prone to leaching than reactive flame retardants which form a constituent of the polymer. Extractability should be determined experimentally. There is no standard for the extraction of flame retardants but a standard [8] exists for a similar situation, i.e. for the extraction of medical devices including compression bandages and first aid dressings which also come into contact with the skin. The extraction is performed with physiological saline (as a model for sweat) and with vegetable oils or oleum neutral for 24 h at 37 °C. The procedure is a worst case extraction when compared with most practical situations but it is useful for an initial evaluation. More refined evaluations of the estimated human exposure (EHE)

would use more realistic extraction procedures.

- Absorption: The substance must permeate through the skin and become absorbed in order to produce toxic effects to organs other than the skin (i.e. to produce systemic effects). Local effects - as e.g. sensitisation - might occur without complete absorption of the substance.

Different parts of the skin or the mucous membrane are permeable to a different degree.

In most cases the dermal absorption rate has not been determined experimentally and a worst case, i.e. 100 % absorption, is assumed.

- The concentration of the flame retardant in the textile (3 to 30 % depending on the nature of the flame retardant; in specific cases up to 50 %). Assuming a mean density of the fabric of 400 g/m² the maximum amount is 200 g flame retardant per m² textile, i.e. also per m² skin in case of clothes.
- The area of the skin in contact. The total human body surface is ca. 2 m².
- Loss of flame retardants with time by volatilisation, sublimation, dusting off, washing out. The mean permanence time of liquid flame retardants is given as 3 years in normal use conditions [1].
- The duration and frequency of the contact with skin can be estimated in most cases without too much difficulties at least when employing worst case assumptions to keep on the safe side, see also section 2.4.
- The average human body weight is generally assumed as 70 kg (or 5 kg if children are involved).
- In some cases the flame retardancy is obtained by impregnating one side (back-coating) of the fabric, so that no direct contact with the skin occurs.

From these parameters an estimated human exposure (EHE) in units of mg chemical per kg body weight and per day can be calculated.

5.1.1 Examples for dermal exposure

An estimation of the EHE for upholstered furniture was performed by [1]:

EHE = 0.005 mg.kg⁻¹.d⁻¹ was obtained.

Two examples of initial estimations of the EHEs are presented:

Example A, a category C1/L3 product (see 2.2 and 2.4):

Night-dress (100 000 mg/m²).

Impregnated with 20 % flame retardants.

Leachability in 24 h: 0.01 %.

Contact area: 1.5 m².

Contact duration: 8 h/d.

Frequency: 7 d/week.

Complete (100 %) absorption through the skin.

Body weight: 70 kg.

$EHE = 100000 \times 0.2 \times 0.0001 \times 1.5 \times (8/24) \times (7/7) \times (1/70) = 0.014 \text{ mg.kg}^{-1}.\text{d}^{-1}$.

Example B, a category C3/L2 product:

Curtain (500 000 mg/m²) in a public building.

Impregnated with 30 % flame retardants.

Leachability in 24 h: 5 %.

Contact area: 0.04 m² (one surface of 2 hands).

Contact duration: 0.05 h/d (= 3 min/d).

Frequency: 3 d/week.

Complete (100 %) absorption through the skin.

Body weight: 70 kg.

$EHE = 500000 \times 0.3 \times 0.05 \times 0.04 \times (0.05/24) \times (3/7) \times (1/70) = 0.0038 \text{ mg.kg}^{-1}.\text{d}^{-1}$.

The 2 examples with EHEs differing only by a factor of ca. 4 show that categories L for leachability and C for contact intensity alone are of restricted value because - as expected - other parameters also play an important role in the exposure estimations.

The conclusion is that the EHE has to be estimated for each situation individually. No further use is therefore made of these categorisations for leachability and contact duration in the rest of the report and in the presentation of a draft of a Standard. A further conclusion is that also the risk evaluation can not be performed for the flame retardant but has to be performed for the flame retardant-textile-system and the specific situation.

One possible way to reduce the enormous amount of exposure situations for all possible flame

retarded textiles would be to define "standard end products" with "standard uses" and calculate the product of those factors which could be estimated:

E.g. the standard end product and standard use "night dress" could be characterised by worst cases of specific weight (e.g. 100 000 mg/m²), concentration of flame retardants (e.g. 20 %), contact area with the body (ca. 1.5 m²), contact duration (ca. 8 h) and frequency (7 d/week), absorption (worst case of 100 % unless better data are available) and body weight (70 kg).

This gives a combined factor of 143.

$$\text{EHE} = 143 \times L.$$

The leachability L is very much dependent on the flame retardant itself, the fibre and the procedure of impregnating the fibre or the complete textile fabrics. Unless one accepts a worst case condition of e.g. 10 % leaching in 24 hours it would be necessary to have data on the leaching from the impregnated textile fabric under consideration.

Such "precalculated" EHEs where only one variable parameter (leaching) is left could be prepared in advance and could facilitate the exposure evaluation.

For the elaboration of a list of standard end products and standard uses an expert for textiles should be consulted.

5.2 Exposure by inhalation

Inhalation of the flame retardant or its degradation products could occur:

- By volatilisation or sublimation of the flame retardant. The vapour pressure is then a useful measure and should be available for each flame retardant. From the vapour pressure it is possible to calculate the saturation concentration in a room.

Example:

An unbound flame retarding chemical of a molecular weight of 200 and a vapour pressure of 10⁻³ Pa would produce a saturation room concentration of about 0.1 mg/m³ in non ventilated rooms.

Inclusion in the polymer matrix of the fabric would impede the evaporation of a flame

retardant. For a more refined evaluation it would be necessary to determine the vapour pressure of the flame retardant when incorporated in the actual textile fabric.

The use of e.g. impregnated night wear and bed-linen could result in a higher local concentration of the flame retardant in the breathing zone if quilt and pillow impede the equilibrium with the room air.

The human exposure can be calculated from the concentration in air by considering a respiratory volume of ca. 20 m³/d and an absorption rate of ca. 75 % if no other information are available.

The example from above would yield an EHE = 0.021 mg.kg⁻¹.d⁻¹.

- By releasing volatile degradation products.
E.g. formaldehyde is released from some tri-alkyl phosphates [1]. It is therefore necessary to know possible degradation products.
- By abrasion from the impregnated textiles and by dusting off. The mean life time of a textile fabrics is about 3 years [1].

Example:

An assumed dusting off over the time from 5 m² of bed linen (ca. 150 g/m²; content of ca. 10 % flame retardants). 10 % are set free to the air linearly over the time of 3 years:

$5 \times 150\,000 \times 0.1 \times 0.1 / (3 \times 365 \times 24) = 0.3 \text{ mg flame retardants to the air / h.}$

Further assumption: 10 % of the dust is available for inhalation. The rest sediments. Room volume = 40 m³ and a low air exchange = 0.2 h⁻¹.

The steady state room concentration would then be: 0.003 mg/m³ and the EHE for 24 h exposure per day: 0.0009 mg.kg⁻¹.d⁻¹ which should not be neglected as it is not very much lower than the dermal exposures in the examples above.

- Theoretically also by the action of micro-organism. It was proposed that arsine, stilbine and phosphine could be produced by micro-organisms from the flame retardants used to treat mattresses and that these toxic compounds could induce the Sudden Infant Death Syndrome.

A UK health expert working group concluded that there is no evidence for a link between sudden infant death and the presence of antimony (and associated low levels of arsenic

impurities) or phosphorus additives [1].

- By releasing fumes or toxic gases in case of fire or fire development [1], [2]. This may range from usual toxic gases as CO to the production of dioxins in the cases of halogenated flame retardants. Toxic products of combustion is a rather complex field where no internationally accepted standard method for determining the toxicity of combustion gases exists.

Reduction of the calculations of the EHE for "standard end products" and "standard uses" in the case of exposure by inhalation could be tried as with the dermal route. In the "precalculation" of EHEs two variable parameters are left: the molecular weight and the vapour pressure for which no reasonable worst case could be derived because of the very wide range of vapour pressures.

5.3 Oral exposure

One realistic way of oral entry of flame retardants is the sucking on impregnated textiles. An estimation of the exposure could be performed in analogy to the dermal exposure.

Example:

Sucking on 100 cm² textile (ca. 150 g/m²; content of ca. 20 % flame retardants) for 3 h/d with an efficiency of extraction in 24 h of e.g. 0.1 % could result in an uptake of:

$$0.01 \times 150\,000 \times 0.2 \times 0.001 \times (3/24) = 0.04 \text{ mg,}$$

that is equivalent to an EHE of 0.008 mg.kg⁻¹.d⁻¹ for a baby.

This again is of the same order of magnitude as in the examples for dermal exposure.

A list of standard end products and standard uses which is probably not very long could be elaborated. The leaching is left as a variable parameter in this reduction of the calculation of the EHE.

5.4 Indirect exposure

Exposure may also occur indirectly via the environment. Flame retardants may be released to water or air during manufacturing, processing or disposal. They could be inhaled or may find their way to drinking water or food and could be ingested by humans. Models are available to estimate this exposure [3].

5.5 Minimum requirement

For a first evaluation of the exposure of humans a minimum set of data is proposed:

- Description of the intended use of the flame retardant and of the impregnated textiles.
Reason: to enable the establishment of exposure scenarios.
- Leachability from the impregnated textile under standard conditions.
Reason: Important parameter to estimate the dermal and oral exposure.
- Vapour pressure of the flame retardant.
Reason: This is the major parameter needed to estimate the room (saturation) concentration and from this the inhalatory uptake.
- Molecular weight of the flame retardant.
Reason: The other parameter needed to estimate the room (saturation) concentration and from this the inhalatory uptake.
- Chemical structure.
Reason: To enable a first judgement on the possible occurrence of degradation products.

For the environmental exposure (and the indirect exposure of humans via the environment) some further data would be needed for the flame retarding chemical:

- Production or use volume.
- Melting point and boiling point.
- Octanol-water partition coefficient.
- Water solubility.

With these data a first estimation of the EHE of the different exposure routes can be performed as outlined in the previous chapters.

6. RISK EVALUATION

6.1 Methods of risk evaluation

The method of risk evaluation is only outlined here. For the description of risk evaluations see e.g. [4].

Although the inherent toxicological hazard of each flame retarding chemical is invariable the risk evaluations are not performed for the chemical itself but for each flame retardant-textile-system separately because the exposure scenarios and the estimated human exposures are variable. A second reason is the necessity to demonstrate the need and benefit for the specific application of a flame retardant to enable a risk management by evaluating the risk to benefit relation.

Quantitative risk evaluations are performed for effects where a NOAEL could be determined. This is the case for repeated dose toxicity or reproduction toxicity studies.

A tolerable daily intake TDI is calculated by using the lowest NOAEL obtained from the different studies and dividing it by a safety factor which covers the possible differences between the species and the differences between individuals. Also the reliability and relevance of the investigations and the duration of the exposure is included in the choice of the safety factor which is generally between 10 and 2000. A factor of 10 is chosen if reliable human data from long term exposure are available. A factor of 100 is usually adopted if reliable subchronic to chronic toxicity studies with animals but no relevant information from human is available. The availability of only a 28-days toxicity study would increase the safety factor to ca. 300. Higher factors of up to 2000 are taken e.g. for data from rather short term exposure studies containing some deficiencies.

The relation of the estimated human exposure EHE of the specific scenario to the TDI is a measure of the risk.

If the calculated $TDI > EHE$, the applications of the flame retardant in the textile system can be tolerated.

$EHE > TDI$ on the other hand would necessitate either to reject the chemical or to set risk reduction measures or to revise the initial risk evaluation.

Genotoxic carcinogenicity or mutagenicity, where no threshold can be assumed, are treated qualitatively in initial risk assessments but could also be treated quantitatively.

Effects as sensitisation or skin irritation where usually no NOAEL is determined are treated qualitatively.

6.2 Initial health risk assessment

A first, "quick and dirty" risk assessment can be performed with the basic set of data for hazard and exposure as presented in the subsections 4.2 and 5.5.

Procedure and decisions:

- Calculate the EHEs for the different scenarios and the different routes of entry to the body. Take the highest EHEs from each route and add these EHEs (as far as meaningful) over the routes. An overall EHE is obtained.
- Calculate a TDI from the NOAEL by dividing typically by a safety factor of 300 (or as appropriate). If several studies are available, take the lowest NOAEL.
- If the calculated $TDI > EHE$, the applications of the flame retardant in the specific textile system can be tolerated.

$EHE > TDI$ would necessitate either to reject the chemical or to set risk reduction measures or to revise the initial risk evaluation using results from additionally performed tests.

- A positive standard sensitisation test in guinea pigs or positive and reliable reports on human sensitisation should exclude the flame retardant from the application in textiles.
- The same would apply for positive mutagenicity data. The only difference is that a positive mutagenicity test could be weakened (or confirmed) by further in vitro tests (also with other endpoints of genotoxicity) and by in vivo tests, whereas this possibility is not given for sensitisation.

6.3 Refined risk assessment

A revision of the evaluation could be meaningful if additional tests are performed or more realistic exposures could be estimated or actually determined exposure data become available. The effect of performing e.g. a chronic toxicity study would be that more meaningful results are obtained (compared to studies run only for shorter time) and that smaller safety factor can be used to estimate the TDI.

Also growing importance and widespread use of a flame retarding chemical or new applications of flame retarded textiles would necessitate a more advanced risk evaluation than the rather coarse initial assessment.

A more comprehensive evaluation of the exposure, the hazard and the risk follows. If $EHE > TDI$ risk reduction measures or rejection of the chemical has to be concluded.

6.4 Risk management

The risk evaluation is the basis for the risk management where decisions on possibly indispensable risk reduction measures or on rejection of the chemical are prepared. The risk management takes into considerations the need of the application of the flame retardant, technical, social and possibly also financial benefit of the flame retarded textile and on the availability and performance of alternative products.

Risk reduction measures could range from giving warning advices for a special situation to restriction of the textile product for certain applications until banning of the flame retarding chemical.

7. REGULATIONS

7.1 Situation at present

No regulation or directive exists specifically for flame retardants in Austria or the EU. Only the chemical law covers general aspects for all chemical substances. The chemical law does not require a risk assessment for flame retardants except when a new substance is notified or for a few high production volume chemicals.

A few flame retardants were banned in the EU for textiles: Tris-(2,3-dibromo-1-propyl)phosphate (79/663/EEC) and tris(1-aziridinyl)phosphine oxide and polybrominated biphenyls (83/264/EEC).

Only a few regulations exist in Austria on the obligatory use of low flammable material in certain situation, e.g. the "Bauarbeiter Schutzverordnung, BGBl 340/1994" where protective clothes made of flame resistant material are required for thermal cutting of e.g. metals.

Regional regulations by the fire polices deal with different building material. No regulation on the specifications of clothes, upholstered furniture etc. for private use is known.

The EU has published directives on construction products and on worker protection which contain some regulations on the use of flame resistant material.

Standards in the context of textiles and flame retardants are available on the definitions and on the specifications and testing procedures of products:

- ISO 4880:1997, Burning behaviour of textiles and textile products - vocabulary.
- ÖNORM F 1000 / Teil 2, Feuerwehr- und Brandschutzwesen; Begriffsbestimmungen, Brandschutz.
- ÖNORM B 3810, 1986, Brandverhalten von Bodenbelegen.
- ÖNORM B 3820, Vornorm, 1986, Brandverhalten von Vorhängen.
- ÖNORM B 3822, Vornorm, 1984, Brandverhalten von Ausstattungsmaterialien; Dekorationsartikel.
- ÖNORM B 3825, Vornorm, 1985, Brandverhalten von Ausstattungsmaterialien; Prüfung von Möbelbezügen.
- ÖNORM S 1452, 1985, Prüfung von Textilien; Bestimmung des Brennverhaltens;

Zünddauer, Kantenbeflammung.

- ÖNORM S 1456, 1985, Prüfung von Textilien; Bestimmung des Brennverhaltens von Bettenaufbauten.
- ÖNORM EN 71-2, 1995, Safety of toys - part 2: flammability.
- ÖNORM EN 469, 1995, Protective clothing for firefighters - requirements and testing methods for protective clothing for firefighting.
- ÖNORM EN 20340, 1993, Conveyor belts - flame retardation - specifications and test methods.
- The burning behaviour of various textile products (curtains, clothes, bedding, sunshades, tents, technical textiles) is described in the following international standards: EN1101, EN1102, EN1103, EN1624, EN 1625, EN 32952-1 to 4, EN ISO 6940, EN ISO 6941, prEN 12008, prEN 12009, ISO 10047.

7.2 Possible regulations

With the protection of the health of consumers in mind a regulation of the marketing and use of flame retardants and/or the impregnated products would be desirable.

Such a regulation could be by legal action as for plant protection agents or biocides.

Another way would be the certification of products following the regulations for medical devices where the EU directive 93/42/EEC forms the basis for the evaluation of the products during a certification procedure. This evaluation also includes a toxicological evaluation of the product with the ISO 10993 series [7] as a guiding document.

The application of Standards for the certification of a product could be a more flexible instrument than a regulation by directives or laws. It is certainly a more acceptable first regulation for the producers and could be transformed to a legal action in case it does not work satisfying.

This report proposes the development of a Standard on flame retarded textiles.

7.3 Responsibilities

For the design of a Standard it is important to discuss the possible role of parties involved in the life cycle of a textile product. Are there parties which will provide data on the flame retardants and on the fabrics, who is going to certify which product or procedure, etc.?

As described above the risk assessment should be performed for each end product (the impregnated textiles). It can be expected that only a small part of the producers of the end products has the knowledge to perform such a risk assessment by his own. On the other hand most of the producers of the flame retarding chemicals are probably able to perform these assessments.

Parties involved (omitting the trading companies) are:

- Producer of the flame retardant.
- Impregnation facility.

Impregnation with flame retardants can occur at different stages of the life cycle: as part of the production of the fibre, within the production plant of the fabric, of the ready fabric, of the end product. A certification of the impregnation process should be installed so that the transfer of appropriate data needed for the risk assessment of the end product is ensured.

- Producer of fibres.

Only involved in case he is also impregnating the fibres.

- Producer of fabrics.

A certification of the - impregnated - fabrics should be installed so that the transfer of appropriate data needed for the risk assessment of the end product is ensured.

- Producer of the end product.

He is responsible for the initiation of the risk assessment as part of the certification procedure of the end product.

Which data could be obtained from which party:

- Need and benefit of the impregnation.

As the need and benefit are related to the use of the end product, these points should be answered by the producer of the end products. Some support can be given by the producer of the flame retardants by preparing dossiers for standard end products and standard uses.

- Data on the impregnation.

Chemical(s) used, concentration and type of impregnation (additive, reactive) are obtained

from the impregnation facility.

- Physico-chemical, toxicological and ecotoxicological properties of the flame retarding chemical.

The producer of the flame retardant is usually the owner of these data or he has access to the data.

- NOAEL of the flame retardant. The producer of the flame retardant can usually provide a proposal for the NOAEL. There are several possibilities which body is going to check the proposed NOAEL: It could be the individual expert who performs the risk evaluation of the impregnated textile; it could be the national health authorities; or it could be a subgroup of the Technical Committee which could adopt the NOAEL for inclusion into a list of agreed NOAELs as part of the Standard.

- Leaching from the impregnated textile.

The source of these data is much dependent on the stage of the product at which the impregnation is performed. In many cases it will be the producer of the fabric. Help may be given by the producers of the flame retardants although the leaching is dependent on the fibre and on the impregnation process and has therefore to be determined on the flame retardant-textile-system.

The same as for leaching applies to the efficiency of reducing flammability.

- Description of the intended use.

Only the producer of the end product can give the descriptions or he gives references to standardised uses.

- Estimation of the human exposure.

Either standard situations are evaluated or the exposure estimation is performed as part of the risk assessment (see below).

- Preliminary risk assessments of standard situation.

For some typical flame retardants, end products and uses (as e.g. bed linen made of cotton and impregnated by a defined process) it may be possible to perform a preliminary risk assessment at an earlier stage than the end product. The producer of the flame retarding chemical could perform the preliminary assessment.

In the final assessment of the end product the result of the preliminary evaluation has then only to be checked for agreement with the actual parameters.

- Risk assessment.

The risk assessment of the end product as part of the certification procedure should be performed by the producer of the end product or by experienced contractors.

7.3 Draft of a Standard

An outline of a Standard on flame retarded textiles is proposed in the Annex. The outline is based on the considerations presented in chapters 1. to 7. It is assumed that the end products (the flame retarded textile products) undergo a certification procedure.

Some chapters are more elaborated than others because of the concentration of this report on health effects to consumers and also because some expertise on textiles and their uses would be needed to further develop the draft.

The Standard ISO10993 on medical devices was used as a first guide.

8. REFERENCES

- [1] EC, Preparation of a document on toxicity and ecotoxicity of flame retardants used in the industry of upholstered furniture and related articles, Final Report, Study contract No. ETD/91/B8-5300/MI/44, 1992.
- [2] Einbrodt H.J. and M. Weishoff-Houben, Orientierende Untersuchungen zur Toxizität von Brand- und Schwelgasen aus Polsterbezugsstoffen ohne und mit Flammschutzmittel, Bericht, Nov. 1994.
- [3] European Chemicals Bureau, EUSES Programme for the Evaluation of Substances, Version 1.00, 1997.
- [4] European Chemicals Bureau, Technical guidance documents in support of the commission directive 93/67/EEC on risk assessment for new notified substances and on commission directive 1488/94 on risk assessment for existing substances, 1996.
- [5] Flame Retardants: A General Introduction, Environmental Health Criteria 192, IPCS, WHO, 1997.
- [6] Hofer H., Flammschutzmittel in Textilien, Vorstudie, Vertraulicher OEFZS-Bericht

- A-3657, 1996.
- [7] ISO 10993, Biological evaluation of medical devices - Part 1 to 16.
 - [8] ISO 10993-12: 1997, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
 - [9] OECD, Risk Reduction Monograph No. 3: Selected Brominated Flame Retardants, Paris, 1994.
 - [10] Sutker B.J., Flame Retardants, Ullmann's Encyclopaedia of Industrial Chemistry, 5th Ed., Vol. A11, p. 123 - 140, 1988.

ANNEX

OUTLINE OF A STANDARD ON "EVALUATION OF FLAME RETARDED TEXTILES"

1. INTRODUCTION

The protection of consumers from possible toxic effects of flame retardants in textiles is the primary goal of this Standard. It can be achieved by performing a risk assessment, followed - if necessary - by risk reduction measures.

The risk assessment of flame retarded textile products requires a structured procedure that can be anticipated already at the designing stage of the flame retardants and of the textile fabrics.

2. SCOPE

The Standard presents the requirements, the prerequisites, the principles, the procedure and the decisions of the risk evaluation. In addition default data on standard end products and their uses are presented to facilitate the exposure evaluation.

3. DEFINITIONS, ABBREVIATIONS

Flame retardants

Flame retardant-textile-systems

Efficiency

Risk evaluation, risk assessment (synonyms)

Risk management

Estimated human exposure (EHE)

etc.

To be elaborated in a later step.

4. BASIC REQUIREMENTS

An evaluation of the risk to the health of consumers shall be performed for a specific textile-flame retardant-system and not for a flame retardant per se. The reasons are the specific exposure conditions for each textile-flame retardant-system with the resulting specific human exposure.

One possibility to enable such a specific evaluation is by certification of each flame retarded textile product. This certification includes a risk evaluation in addition to possible functional evaluations. The producer of the final product is responsible for initiation of the certification of his product.

The evaluation shall be based on the data and evidences described in chapter 5. and shall be performed according to chapters 6. and 7. At least the initial risk assessment as described in chapter 7.2 shall be performed.

A risk management shall follow the risk evaluation.

5. EVIDENCES AND DATA TO BE PRESENTED

The following data and evidences are a prerequisite to perform a risk evaluation and a risk management.

The "minimum set of data" shall be available for each flame retarded textile product respectively for each flame retarding chemical to enable an initial risk assessment, see chapter 7. Additional data on the chemical which are already available shall be integrated in the initial risk assessment.

5.1 Need and benefit

Minimum set of data: An evidence of a relevant risk to fire shall be presented for each textile product. Based on this risk to fire the need and the benefit of an application of a flame retardant shall be demonstrated. Also alternative methods to reduce the risk should be considered, such as the use of textile fabrics of inherently low flammability. No evidence has to be given if flame retarded textiles are required by legal regulations or by the national or by

international standards.

Remarks: No effort in further evaluations is justified if there is no evidence of a need and a benefit of the intended system. Because each chemical bears a - possibly very low - risk to the health, this risk shall only be accepted if there is also a need and a benefit. The benefit shall be technically by reducing a described risk to fire. A benefit which can only be expressed in commercial or financial terms is insufficient.

5.2 Evidence of efficiency

Minimum set of data: An evidence of the efficiency of reducing the flammability of each flame retarded textile fabric shall be presented.

Remarks: Only flame retardants which fulfil their duty shall be considered for further evaluations. The tests to be performed to demonstrate the efficiency are described in chapter 9.4.

5.3 Description of the flame retarding chemical to be used

Minimum set of data: The description shall include: chemical structure, CAS No., molecular weight, composition in case of flame retardant preparations, purity, impurities, synergists or stabilisers used, process of addition to or reaction with the textile fibres.

Remarks: A basic description of the chemical is needed for any investigation or evaluation to be performed.

5.4 Physico-chemical properties of the flame retarding chemical

Minimum set of data: Vapour pressure and molecular weight for each chemical in the flame retardant. Description of possible degradation and combustion products.

Remarks: The vapour pressure is one of the major parameters needed to estimate the uptake by inhalation.

Further physico-chemical data are needed especially for the environmental risk assessment.

5.5 Toxicological properties of the flame retarding chemical

Minimum set of data: A test for skin sensitisation, a test for point mutations in a bacterial system and a 28-days oral toxicity study with rats is required for each chemical in the flame retardant. Testing for specific effects for compounds of certain chemical classes (especially: neurotoxicity testing for organophosphorus compounds) shall be performed or otherwise evidence shall be given that the specific effect will not occur with the chemical under evaluation. The same data are required for possible reaction products of the flame retardant.

Remarks:

- Skin sensitisation can occur even at very low exposure and must be considered at all applications of flame retardants in textiles.
The performance of the test also yields qualitative data on the primary skin irritation from the dose range finding test as a by-product. A proper skin and eye irritation test shall be performed in case a suspicion on possible irritant or corrosive effects arises.
- The test for point mutations in a bacterial system (Ames test) is mainly used as a screening test for carcinogenicity.
- The subacute 28-days oral toxicity study with rats gives first information on the toxic effects produced after repeated exposure to a chemical. It is indispensable and can not be replaced by other - short term - studies or other information at present. This study is also included in the base set for the notification of new chemical substances. A No Observed Adverse Effect Level NOAEL can be derived and from this a Tolerable Daily Intake TDI by applying safety factors, see 7.1.
An acute toxicity study is available in most cases. The study is useful as a dose range finder for the 28-days toxicity test but is less relevant for the risk assessment.

Toxicological information together with exposure estimations form the basis for the health risk assessment.

Further toxicity tests for local irritation, other mutagenicity endpoints, subchronic to chronic toxicity, reproduction, carcinogenicity and toxicokinetic investigations (especially absorption through the skin) are required for a more refined risk assessment, see chapter 7.3.

5.6 Ecotoxicological properties of the flame retarding chemical

To be elaborated in a later step.

5.7 Environmental fate of the flame retarding chemical

To be elaborated in a later step.

5.8 Intended uses of the final textile product

Minimum set of data: The description of the intended and also of foreseeable uses of the textile is needed to enable the establishment of exposure scenarios.

5.9 Properties and characteristics of the final product

Minimum set of data: Leaching, i.e. the extractability of the flame retarding chemical (or also of synergists or additives) from the flame retarded textile.

Remarks: The leaching behaviour of a flame retardant is a major parameter in the estimation of the human exposure. The determination shall be performed according to standardised methods.

For a more refined risk assessment the vapour pressure should be available for each flame retarding chemical after application to the textile fabric.

5.10 Default data

It is necessary to have some default values for parameters used in the exposure evaluation to standardise the estimation. These parameters are mean human body weight, mean body surface, mean surface of one hand, mean air exchange in rooms, mean respiratory volume, etc. Chapter 10. provides some of these data.

5.11 Experience with humans

Toxicological data obtained from occupational exposure during production or reports from accidental intoxication e.g. during transport shall be made available and shall be incorporated in the risk assessment.

6. EXPOSURE ESTIMATION

Three routes of exposure to flame retardants are of importance: peroral, dermal, by inhalation.

When estimating the exposure of humans the occurrence of degradation or reaction products of the flame retardant shall also be considered.

A description of the method of performing exposure estimations for chemicals are found for example in the "Technical guidance documents in support of the commission directive 93/67/EEC on risk assessment for new notified substances and on commission directive 1488/94 on risk assessment for existing substances" (European Chemicals Bureau, 1996). Some default data which could be useful for the estimation are presented in chapter 10.

6.1 Dermal exposure

Dermal exposure occurs when wearing clothes or by contact with bed linen, carpets or furniture fabrics, etc.

Factors which are of importance for dermal exposure:

- The availability of the flame retardant. The substance must be liquid or become dissolved in order to migrate to and penetrate into the skin. An extraction (leaching) of the substance from the fibres must occur. The extractability depends on the chemistry of the flame retardant, the impregnation process, the extraction medium and other conditions such as time and temperature. Leaching could occur by sweat, blood, urine, skin creams, body lotions or other extraction media.

Extractability shall be determined experimentally, see 9.3.

- Absorption: The substance must permeate the skin and become absorbed in order to produce toxic effects to organs other than the skin (i.e. to produce systemic effects). Local effects - as e.g. sensitisation - might occur without complete absorption of the

substance.

Different parts of the skin or the mucous membrane are permeable to a different degree.

In most cases the dermal absorption rate has not been determined experimentally and a worst case, i.e. 100 % absorption, is assumed.

- The concentration of the flame retardant in the textile.
- The area of the skin in contact.
- Loss of flame retardants with time by volatilisation, sublimation, dusting off, washing out.
- The duration and frequency of the contact with skin.
- The average human body weight.
- In some cases the flame retardancy is obtained by impregnating only one side (back-coating) of the fabric, so that no direct contact with the skin occurs.

From these parameters an estimated human exposure (EHE) in the units mg chemical per kg body weight per day shall be calculated.

6.2 Exposure by inhalation

Inhalation of the flame retardant or its degradation products could occur:

- By volatilisation or sublimation of the flame retardant. The vapour pressure is then a useful measure. From the vapour pressure it is possible to calculate the saturation concentration in a room.

Inclusion in the polymer matrix of the fabric would impede the evaporation of a flame retardant. For a more refined evaluation it is necessary to determine the vapour pressure of the flame retardant when incorporated in the actual textile fabric.

The use of e.g. impregnated night wear and bed-linen could result in a higher local concentration of the flame retardant in the breathing zone if quilt and pillow impede the equilibrium with the room air. A lower volume (ca. 2 m³) of equilibrium than the room volume is used for calculation.

The human exposure is calculated from the concentration in air by considering a default respiratory volume and an absorption rate.

- By releasing volatile degradation products.

E.g. formaldehyde is released from some tri-alkyl phosphates. It is therefore necessary to know possible degradation products.

- By abrasion from the impregnated textiles and by dusting off.
- By releasing fumes or toxic gases in case of fire or fire development. This may range from usual toxic gases as CO to the production of dioxins in the cases of halogenated flame retardants. Toxic products of combustion is a rather complex field where no accepted standard method for determining toxicity at combustion exists today.
- Theoretically also by the action of micro-organism. It was proposed - but could not be proofed - that arsine, stilbine and phosphine could be produced by micro-organisms from antimony and phosphorus containing flame retardants.

6.3 Oral exposure

One realistic way of oral entry of flame retardants is the sucking on impregnated textiles. An estimation of the exposure shall be performed in analogy to the dermal exposure.

The method for simulating sucking should reflect the sucking behaviour and conditions of infants and should be described in this or another Standard.

6.4 Indirect exposure

Exposure may also occur indirectly via the environment. Flame retardants may be released to water or air during manufacturing, processing and disposal. They could be inhaled or may find their way to drinking water or food and could be ingested by humans. Models are available to estimate this exposure (European Chemicals Bureau, EUSES Programme for the Evaluation of Substances, Version 1.00, 1997). These models shall be used to estimate the indirect exposure of humans.

7. RISK ASSESSMENT

7.1 Methods

- Quantitative risk evaluations are performed for effects where a no observed adverse effect level (NOAEL) could be determined. This is the case for repeated dose toxicity or reproduction toxicity studies.

A "tolerable daily intake" TDI is calculated by using the lowest NOAEL obtained from the different studies and dividing it by a safety factor which covers the possible differences between the species and the differences between individuals. Also the reliability and relevance of the investigations and the duration of the exposure is included in the choice of the safety factor which is generally between 10 and 2000. A factor of 10 is chosen if reliable human data from long term exposure are available. A factor of 100 is usually adopted if reliable subchronic to chronic toxicity studies with animals but no relevant information from human is available. The availability of only a 28-days toxicity study would increase the safety factor to ca. 300. Higher factors of up to 2000 are taken e.g. for data from rather short term exposure studies containing some deficiencies.

The relation of the estimated human exposure EHE of the specific scenario to the TDI is a measure of the risk, see 7.2.

- Effects as sensitisation or skin irritation where usually no NOAEL is determined are treated qualitatively.

7.2 Initial risk assessment

A first, "quick and dirty" risk assessment shall be performed with the basic set of data for hazard and exposure as presented in chapters 5. and 6.

Procedures and decisions:

- Calculate the EHEs for the different scenarios and the different routes of entry to the body. Take the highest EHEs from each route and add these EHEs (as far as meaningful) over

the routes. An overall EHE is obtained.

- Calculate a TDI from the NOAEL by dividing typically by a safety factor of 300 (or as appropriate).
- If the calculated $TDI > EHE$, the applications of the flame retardant in the textile system can be tolerated.

$EHE > TDI$ on the other hand necessitates either to reject the chemical or to set risk reduction measures or to revise the initial risk evaluation.

- A positive standard sensitisation test in guinea pigs or positive reports on a number of humans shall exclude the flame retardant from the application in textiles.
- Also a positive mutagenicity test shall exclude the flame retardant from the application in textiles. The only difference is that a positive mutagenicity test could be weakened (or confirmed) by further in vitro tests (also with other endpoints of genotoxicity) and by in vivo tests, whereas this possibility is not available for sensitisation tests.

Preliminary risk assessments for some frames, i.e. combinations of a flame retardant, a typical end product and a typical use could be performed by e.g. the producers of flame retardants. A provisional NOAEL could be proposed and an exposure could be estimated by applying reasonable worst case parameters (defaults). These preliminary risk assessments would facilitate the evaluation of individual flame retarded products by providing processed examples.

7.3 Refined risk assessment

The evaluation shall be revised if additional tests are performed or more realistic exposures are estimated or actually determined exposure data become available. The effect of performing e.g. a chronic toxicity study would be that more meaningful results are obtained (compared to studies run only for shorter time) and that a smaller safety factor can be used to calculate the TDI.

Also growing importance and widespread use of a flame retarding chemical necessitate a more advanced risk evaluation than the rather coarse initial assessment. A refined evaluation should deal for example with combustion gases of the flame retarded textile.

A more comprehensive evaluation of the exposure, the hazard and the risk follows.

If EHE > TDI risk reduction measures or rejection of the chemical shall be concluded.

8. RISK MANAGEMENT

The risk evaluation is the basis for the risk management where decisions on possibly indispensable risk reduction measures or on rejection of the chemical are prepared. The risk management takes into considerations the need of the application of the flame retardant, technical, social and possibly also financial benefit of the flame retarded textile and on the availability and performance of alternative products.

Risk reduction measures range from giving warning advices for a special situation to restriction of the textile product for certain applications until banning of the flame retarding chemical.

Risk management and possible risk reduction measures are included in the certification procedure.

9. TESTING

Tests shall be performed according to the OECD Guidelines for Testing of Chemicals (or equivalent guidelines) as far as appropriate tests are available. The OECD Principles on Good Laboratory Practice shall be applied.

9.1 Toxicity testing

The minimum set of data comprises:

- OECD guideline No. 406, Skin sensitisation.
- OECD guideline No. 407, Repeat dose 28-day oral toxicity study in rodents.
- OECD guideline No. 471, Genetic toxicology: Salmonella typhimurium, reverse mutation assay.

9.2 Physico-chemical properties

The minimum set of data comprises:

- OECD guideline No. 104, Vapour pressure.

9.3 Leaching

There is no standard for the extraction of flame retardants but a standard (ISO 10993-12: 1997, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials) exists for a similar situation, i.e. for the extraction of medical devices including compression bandages and first aid dressings which also come into contact with the skin. The extraction is performed with physiological saline (as a model for sweat) and with vegetable oils or oleum neutral for 24 h at 37 °C. The procedure is a worst case extraction when compared with most practical situations but it is useful for an initial evaluation and shall be used for the initial risk assessment of flame retarded textiles.

More refined evaluations of the estimated human exposure could use more realistic extraction procedures.

9.4 Efficiency of reduction of flammability

To be elaborated in a later step by experts on testing of flammability.

10. DEFAULT DATA FOR ESTIMATING HUMAN EXPOSURE

Several data as e.g. mean body surface are needed for the estimation of human exposure. To render the estimations more comparable between different experts some default data are presented here. These data shall be used in the initial risk assessment. Only in case it can be shown that they are not appropriate for a certain situation other data should enter the calculations.

Realistic mean or maximum values (without consideration of extreme situations) are presented to enable worst case estimations.

10.1 Textiles

Weight, area:

use of the textile	maximum weight per area (g/m ²)	maximum area (m ²)
clothes, divided in: underwear, shirt, trousers, gloves, cap, etc.	<i>to be elaborated in later steps of the Standard development</i>	<i>to be elaborated in later steps</i>
protective clothes		
sleep wear: pyjama, night-dress		
bed-linen: sheet, plumeau case, blanket, quilt, pillow case		
cover of mattresses		
cover of upholstered furniture		
etc.		

Content of flame retardants in the textiles:

use of the textile	maximum content (% w/w)
clothes	<i>to be elaborated in later steps</i>
etc.	

Contact duration and contact frequency with the human body

use of the textile	contact duration (min or h) per occasion	contacts per day	frequency of days with contacts per week
clothes	<i>to be elaborated in later steps</i>		
etc.			

Contact area with the human body during regular or occasional use (intended or not):

use of the textile	maximum contact area (m ²)	
	during regular use	during occasional use
clothes	<i>to be elaborated in later steps</i>	
etc.		

Estimated life time of textiles (shortest time when ca. 20 % of the textile are lost by wear, washing, abrasion, etc.):

use of the textile	life time (year)
clothes	<i>to be elaborated in later steps</i>
etc.	

10.2 Human data

parameter	value
mean body weight of an adult	70 kg
mean body weight of an infant	5 kg
mean body surface of an adult	1.94 m ²
mean surface of the trunk	0.569 m ²
mean surface of the face	0.12 m ²
mean surface of the hands	0.084
mean surface of the forearms	0.11 m ²
respiratory volume	20 m ³ / day
respirable fraction of inhaled chemicals	1
bioavailability for oral uptake	1
bioavailability for inhalation	0.75
bioavailability for dermal uptake	1
etc.	

10.3 Other data

parameter	value
mean bed room volume	40 m ³
lowest air exchange in rooms	0.1 h ⁻¹
etc.	

11. SIMPLIFICATION OF THE RISK ASSESSMENTS

11.1 EHEs

With the default data given in 10.1 to 10.3 it is possible to prepare the calculation of the EHEs as far as possible. The equation for the "precalculated" EHEs only contains 1 or 2 variable parameters. For example the dermal exposure from a night-dress is calculated as follows:

- K1 weight of the fabric per m²
- K2 Content of flame retardants in the textile
- L Leachability in 24 h
- K3 Contact area with the body
- K4 Contact duration (hours/day)
- K5 Frequency of contact (days/week)
- K6 Absorption through the skin. As in most cases the absorption through skin was not determined, a worst case of 100 % is assumed.
- K7 Body weight

K1 to K7 are taken from the Tables in chapters 10.1 to 10.3. The only variable parameter left is the leaching L which shall be determined for each flame retardant-textile combination. EHE is calculated to:

$EHE = K1.K2.L.K3.K4.K5.K6/K7$ or precalculated to:

$EHE = K.L$ when combining the K1 to K7 to a single factor K.

Analogous precalculations can be performed for the oral route and not as easy calculations for the inhalatory exposure so that a list is produced which facilitates the calculation of the EHEs for typical end products and uses:

use of the textile	EHE_{dermal}	$EHE_{\text{inhalatory}}$	EHE_{oral}

underwear, adult	$K_{\text{dermal,underwear}} \cdot L$	<i>to be elaborated in later steps. Vapour pressure and molecular weight are left as variables.</i>	/
underwear, infant			$K_{\text{oral,underwear}} \cdot L$
shirt			
trousers			
pyjama			
night-dress			
etc.			

11.2 Characteristics of the flame retardants

A further simplification of the risk evaluation could be tried by listing the TDI and other characteristics of the flame retarding chemical.

The question here is that probably the producer of the flame retardants can provide the data on his chemical but that a board (which board?) has to decide on the appropriateness and validity of the data so that they can be included in the Standard.

flame retardant	TDI	molecular weight	purity	degradation products	vapour pressure	etc.
Name 1						
Name 2						
etc.						