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The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) commenced on 17 July 1990. As required by Section 5 of the Act, a Chemical Gazette is published on the first Tuesday in any month or on any days prescribed by the regulations.

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In accordance with section 60E(6) of the *Industrial Chemicals (Notification and Assessment) Act* 1989, notice is hereby given by the Director that a decision has been made on each request to vary the draft Priority Existing Chemical report on HBCD.

A copy of the decisions can be obtained at www.nicnas.gov.au/news

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2 HBCD - DECISIONS ON REQUESTS FOR VARIATIONS

1. AMTRADE International Pty Ltd.

Request 1.1
The pure HBCD is classified as Category 1 Environmental hazard for both Acute and Chronic Toxicity (on p203 (in the Draft Report) & page 207 (in the sample MSDS)), ***however,*** in Section 14 of the Sample MSDS, this NICNAS Draft Report does NOT classify it as Class 9 UN 3077 Packing Group III, ENVIRONMENTALLY HAZARDOUS, SUBSTANCE,SOLID, N.O.S (HEXABROMOCYCLODODECANE). For the IMDG Code its must additionally be classified as a Marine Pollutant.

Proposed Variation**:** The Sample MSDS on page 208 must correctly identify in Section 14 – Transport Information, that the pure HBCD is Dangerous Goods UN 3077 by Sea and Air and that there is currently an Exemption from being transported as Dangerous Goods by road and rail when in packages and IBCs.

Justification**:** This is required in this Report as Shipping by sea to Tasmania requires UN 3077 & Marine Pollutant! Plus transporting by Air in Australia also requires UN 3077.

Decision 1.1
Variation approved. The sample MSDS will be revised to include ADG classification of HBCD as a dangerous good.

Request 1.2
Under Current Risk Management (p197-201) there is no significant discussion of elimination and substitution of HBCD use in final products under OH&S, nor of management of wastes containing HBCD.

Proposed Variation**:** For more information on elimination and substitution of HBCD see the UN *POPRC7 Report: Risk Management Evaluation on HexaBromoCycloDodecane* (30 pages) which is available at:
http://chm.pops.int/Convention/POPsReviewCommittee/POPRCMeetings/POPRC7/POPRC7ReportandDecisions/tabid/2472/Default.aspx

Justification**:** This information is required in this Report to help companies find appropriate alternatives to HBCD that is currently in their products. Without some clear directions the fact that HBCD is a problem does not help companies importing or using HBCD in their products to solve the problem.

Decision 1.2
Variation approved. Information on alternatives will be added in Chapter 12 of the report. The information to be added is provided below.

"Alternatives to HBCD
HBCD is used as a flame retardant primarily in building insulation composed of expanded or extruded polystyrene foam and also in textiles and other products. Emissions from HBCD-containing materials will be a potential long-term source to the environment. A large volume of HBCD ends up in articles, mainly in polystyrene (XPS, EPS) used in the construction and building sector. Alternatives to use of HBCD include flame retardant substitution,

resin/material substitution and product redesign (UN POPRC7 Report: Risk Management Evaluation on HBCD, October 2011).

Product redesign and alternative insulating material have been suggested for EPS and XPS, for which an alternative chemical to HBCD is not currently available. Product redesign can involve ensuring that insulation is not placed in contact with flammable material. The types of alternative insulating materials include polyisocyanurate and phenolic foams and insulating blankets (fiber batts or rolls) that may contain rock wool, fiber glass, cellulose or polyurethane foam. Technical alternatives to HBCD containing EPS/ XPS include: blown-in or spray-applied insulation materials such as rock wool, fiber glass, cellulose, or polyurethane foam. Loose-fill cellulose insulation is commonly manufactured from recycled newsprint, cardboard, or other forms of waste paper. Loose-fill insulation can also be poured in place by using materials such as vermiculite or perlite.

Technically and commercially feasible alternative chemicals to HBCD are available for textile treatment and high impact polystyrene (HIP) products. Several of these are halogen-free and are therefore considered to be better alternatives for the environment and health (ECHA 2009, SWEREA 2010, KLIF 2010).

Some of the chemical alternatives currently available are arylphosphates (for HIP) and ammoniumpolyphosphate and pentaerythritol for textile back coating. Brominated chemicals such as tetrabromocyclooctane and dibromoethyldibromocyclohexane, are also commercially available as flame retardants for use in EPS applications in North America. However there are concerns about the environmental or health properties of these substances, including persistence and bioaccumulative effects and endocrine and mutagenic effects in mammalian cells in vitro (LSCP 2006, BSEF 2011).

A new polymeric fire retardant has reportedly been developed recently (http://www.dow.com/licensing/newsletter/archive/2011/may/201104c.htm). The substance is claimed to be non PBT and suitable for processing in EPS and XPS. The company developing this product has reportedly started licensing this technology to FR manufacturers to produce commercial quantities,

The US EPA has launched a program called Partnership on Flame Retardant Alternatives to HBCD to evaluate chemicals that can substitute for HBCD. Through the voluntary partnership on HBCD alternatives, chemical manufacturers, associations representing building and construction materials manufacturers, state governments, nongovernmental organizations, and other interested parties will evaluate chemicals that might substitute for HBCD. The alternatives will be evaluated by factors such as cancer hazard potential, genotoxicity, persistence, and bioaccumulation, according to information presented at the meeting. A timeframe for the project has not been indicated”.

2. Dow Chemicals (Australia) Ltd.

Request 2.1
p.22, line 2 - XPS foam typically contains <3% HBCD so suggest that this value is used instead of 5% as more representative of the typical content level of HBCD in foams.

Decision 2.1
Variation approved. HBCD concentration in XPS changed to <3%. NICNAS was informed by an Applicant that they do not deal with EPS or XPS but think that “usually the amount of FR into EPS is approx. 8-12%” and on this basis 5% was included in the report.

Request 2.2
P.28 4.6.4 - Add the word insulation board after XPS to distinguish it from the office equipment. Suggested sentence then becomes; Imported finished articles which contain HBCD in plastic parts include XPS insulation boards, office equipment such as inkjet printers, projectors, scanners and ventilation units for offices.

Decision 2.2
Variation approved. Text modified as suggested above.

Request 2.3
p.32 footnote - This also assumes 100% migration of all the HBCD from the article into sweat. This is not probable as mostly the back of the textile is coated and the HBCD is bound in the matrix.

Decision 2.3
Variation partly approved.

NICNAS Response 2.3
Migration of 100% of HBCD from the article into sweat is assumed in the absence of any data. As HBCD is not chemically bonded there is a possibility for the chemical to migrate out of a product and collect at the surface in the process known as “blooming” (Section 2.1). The displacement of surface coatings through wear and tear over time also results in public exposure. These factors have been taken into consideration to determine HBCD exposure by the dermal route. The sentence will be revised to “Also, wearing of more clothing in colder climates reduces the area of exposed skin**,** additionally back coating of textiles with HBCD further reduces dermal exposure.”

Request 2.4
p.36 middle of page bullet under indoor air exchange rate is negligible. This seems unrealistic that there is no air exchange at all.

Decision 2.4
Variation not approved.

NICNAS Response 2.4
The assumption of negligible air exchange rate is considered as the worst-case scenario. This is consistent with the approaches used in the EU, US and Canada in the absence of any data.

Request 2.5
p.39 5.3.4 Food Consumption This section does not appear to take into account the 2011 report by EFSA (EFSA Journal 2011:9 (7):2296) which includes an extensive amount of new food monitoring results.

Decision 2.5
Variation approved.

NICNAS Response 2.5
The results of the EFSA 2011 monitoring will be added to this section of the report. The EFSA monitoring programme consisted of an analysis of HBCD in food samples across 32 dietary surveys from European countries in the period 2000-2010. The surveys were then entered into a comprehensive database and the HBCD total dietary exposures were estimated for different age groups. The dietary exposures from the EFSA 2011 report were lower than the UK study cited in the draft HBCD report (Table 5.5). However, EFSA acknowledged in their methodology that deviations observed in dietary exposure between surveys are influenced by varying food consumption patterns and survey methodologies in the different European countries. The UK values are used in the dietary exposure estimation primarily due to the similarity in methodologies of food consumption data used by the UK and Australia. A brief description of the EFSA report and a table of results will be included in this section.

Request 2.6
p. 40 Table 5.5. Please provide more information on how the numbers were obtained. Were typical diet assumptions for the UK used? Are UK and Australian nutritional habits similar? Which dataset for HBCD food concentrations was used? The EFSA monitoring program resulted in lower numbers also for the UK.

Decision 2.6
Variation not approved.

NICNAS Response 2.6
The studies indicated in Table 5.5 are described in the paragraphs preceding it. As mentioned in the 2nd paragraph of Section 5.3.4 (p39), the UK values were total dietary exposures from all food groups tested, using a similar methodology to that used in the Australian total diet surveys. The UK and Australian methodologies are in accordance with internationally-accepted principles. In addition, the nutritional habits in Australia and the UK are considered similar. The EFSA monitoring program for the UK in Table 15 on p55 include the same numbers cited in the HBCD report (Table 5.5, p40) and taken forward in the assessment.

Request 2.7
p.42 Table 5.7 HBCD levels in lipid component of human breast milk from overseas studies Please specify how non- detects were treated in the individual studies as that can have significant impact on mean and median levels

Decision 2.7
Variation approved.

NICNAS Response 2.7
There was limited information on the treatment of non-detects in most of these studies. Where available, the descriptive statistics are provided in the table. A paragraph will be added after Table 5.7, addressing the treatment of non-detects in the overseas breast milk studies, as follows: "The studies appear to be exhibiting log normal distributions. For a log normal distribution with <50% non-detects, the median value is not affected and there is minimal impact on the mean value, as this is predominantly determined by the small number of very high individual values."

Request 2.8
p.44 The last sentence of the second para starting 'This value is within the range……We do not support this sentence. In particular the level of 6.9ng/kg lw chosen as a 'typical' level is not within the range of the means or medians of the other 26 studies . It seems odd to have near 30 studies at hand with largely lower levels but then pick one of them and use the 75th percentile. At least this should be pointed out in the text.

Decision 2.8
Variation not approved.

NICNAS Response 2.8
Most of the studies in Table 5.7 did not provide individual values for HBCD levels. The Abdallah & Harrad (2010) paper has individual values from a reasonable number of samples and was further analysed as described on page 35 and indicated that the samples exhibit a log normal distribution. For a log normal distribution of samples, the levels chosen as the typical and reasonable worst-case values (75th and 95th percentiles, respectively) are appropriate because of the high variability of the results, as explained in Section 5.3.2 (p35). These percentile values are expected to be significantly above the majority of study medians due to the log normal nature of the distribution of HBCD levels, however the selected values are within the range of individual values seen in a number of the larger studies.

Request 2.9
P.59 Last sentence before section entitled HBCD granules Starting 'Using Equation 1 …….These calculations are not clear, please add an example since the numbers calculated seem high.

Decision 2.9
Variation approved.

NICNAS Response 2.9
The assumptions are provided on page 53 for the values of f_{resp}, A_{inh}, V_{air}, and cf. The report will be revised to clarify the parameters used in Equation 1 in obtaining the typical and worst-case internal inhalation exposures from HBCD powder. The text under Table 6.3 in page 59 will be modified to: "From Table 6.3, the concentrations… addition and weighing tasks. The median (0.27 and 6.19 mg/m^3 for addition and weighing tasks, respectively) and 90th percentile values (1.1 and 10.5 mg/m^3 for addition and weighing tasks, respectively) in powder shown in Table 6.3 are used as the typical and reasonable worst-case levels for HBCD in air (C_{air}). The exposure duration is assumed to be 0.5 h/d for the addition task and

0.5 h/d for the weighing task. Using Equation 1 and the parameter assumptions (Section 6.3.2), the typical and worst-case internal inhalation exposures…"

Request 2.10
P 85. Significant discussion on differences between the Davis 2003a and Davis 2004 aerobic soil tests. Variation to report is not specified. NICNAS assumes that it is being requested that the differences in the two studies need to be highlighted.

Decision 2.10
Variation approved.

NICNAS Response 2.10
NICNAS agrees with the arguments made regarding concentration influences on degradation rates, and acknowledge this in the summary of the report. For example, under Table 7.7 "Additionally, some concentration dependence could be found. For example, tests with high concentrations (e.g. 3–4 mg HBCD/kg sediment) showed slower degradation than those with low test concentrations (e.g. 0.025 mg HBCD/kg sediment)."
.
The report has been amended, as follows:
"Results from this study are in contrast to those obtained in the other two studies (Davis, 2003a; 2005). All three studies were performed on soils collected from the same place and the exposure periods were comparable in these studies. The differences were the longer pre-stabilisation period (35 d) used in the Davis et al. (2003a) study as compared to 15 d in the Davis et al. (2004) study, the addition of activated sludge to the microcosms and the use of much higher concentrations in Davis et al. (2004) to assess the route of breakdown. Higher concentrations appear to result in slower degradation rates and it is also possible that the microorganisms present in the sludge may have affected the degradation rates of HBCD in that study."

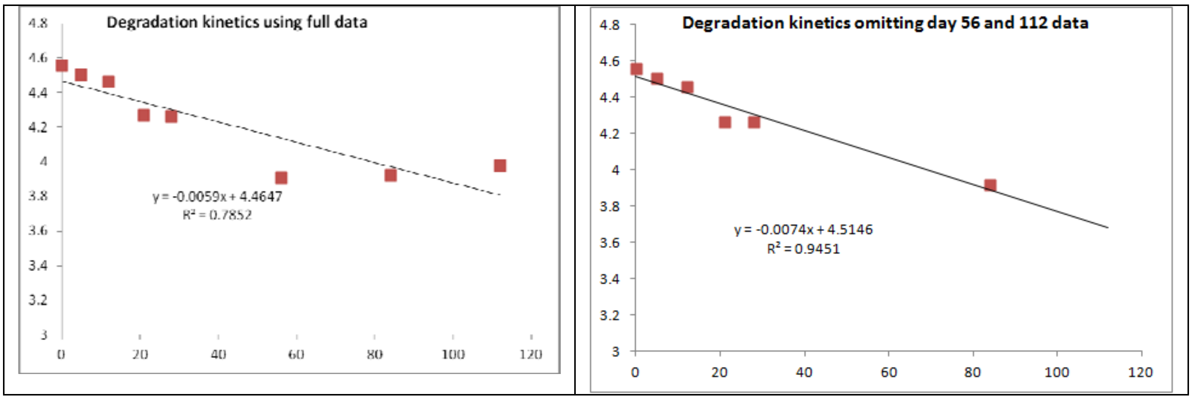
Request 2.11
P 87. The first order kinetics constant for degradation of HBCD in the aerobic sediment has been calculated incorrectly (0.0059). Also, the primary degradation half-lives under aerobic and anaerobic conditions in water/sediment systems(i.e.,117 d and 73.5 total HBCD) were also calculated incorrectly.

The correct value was originally reported in 2006 in the publication by Davis and coworkers titled "Biodegradation and Product Identification of [14C]-Hexabromocyclododecane in Wastewater Sludge and Freshwater Aquatic Sediment". In that publication the correct first order degradation rate for HBCD in aerobic and anaerobic sediment were listed as kViable = 0.0074 & 0.0109, respectively.

Decision 2.11
Variation not approved.

NICNAS Response 2.11

The rate constants were derived through the raw data provided in the original test reports. The value of 0.0074 in the Davis et al publication appears to have been derived through omission of the day 56 and day 112 data points in order to obtain a better correlation coefficient as shown in the following two diagrams:



These omissions do not appear to be justified. The DSEWPaC calculated value of 0.0059 reflects all the available day 0-112 results and will be retained in the report. Similarly for the anaerobic aquatic sediments, the rate constant was derived using the full data set from the original test report, and this value will be retained.

Request 2.12
P.144 para 3 starting A clear NOAEL for effects ….The text here should reflect the conclusions taken later on where potential effects on fertility were judged not relevant for hazard classification or the risk assessment.

Decision 2.12
Variation not approved.

NICNAS Response 2.12
Pages 144 and 145 provide an overall summary of the effects of HBCD on the reproductive system in laboratory animals. It discusses the doses at which changes in reproductive parameters were observed. The hazard classification of HBCD is discussed later in the report in Section 8.4.

Request 2.13
P.144 last para …Consider adding comments related to the van der Ven 1-gen study here.

Decision 2.13
Variation approved. The following comments were added to the last para:
"The most sensitive effects in this study were decreased mineral density in trabecular bone in F1 females, decreased concentration of apolar retinoids in liver in F1 females and increased immune response in F1 males, all of which were induced at low doses. Marked decreases in liver apolar retnoids were observed in both male and female rats."

Request 2.14
P.145 3rd para 1st sentence 'liver apolar retinoids'…As the relevance of the potentially decreased liver apolar retinoids is completely unknown, this should not be claimed to be an adverse effect.

Decision 2.14
Variation not approved.

NICNAS Response 2.14
As mentioned in the report, retinoids are reported to regulate transcription of numerous genes via the retinoic acid receptors (RAR) and thus play an important role in a multitude of processes including embryonic growth, skeletal morphogenesis, vascularisation and reproduction (see also: Mark M, Ghyselinck NB & Chambon P (2009). Function of retinoic acid receptors during embryonic development. Nuclear Receptor Signaling 7 e002). Retinoid system is implicated in the development and functioning of testes and in the development and maintenance of bone tissue, both of which were affected in F1 animals of the 1-generation study by Van der Ven et al. (2009). Significant decreases in liver retinoid levels (up to 32% in females) were noted in F1 animals in the study which correlated well with some of the developmental effects seen in these animals.

Request 2.15
P.150 last sentence before Effects on enzyme induction.... We strongly disagree with this sentence and suggest to remove. The relevance of such in vitro mechanistic assays for in vivo toxicity is highly questionable. Often in vivo studies show very different results for a variety of reasons. HBCD was examined in many in vivo studies which (in terms of an ‘endocrine effect’) only indicate a secondary effect on the thyroid axis of rats, which is not even correctly depicted by the in vitro assays.

Decision 2.15
Variation approved. Sentence deleted. The studies do however suggest that HBCD may have the potential to bind to some hormone cell receptors.

Request 2.16
P.153 first sentence start ‘Additional in vivo …..This was attempted by the van der Ven study with non convincing results of questionable statistical and biological significance. Additionally, none of the many other animal studies picked up any issues with immune related parameters such as blood cell counts. We suggest that the relevance of the cited in vitro studies to the in vivo situation should be discussed.

Decision 2.16
Variation approved. Text added as follows:
“Results from these studies need to be interpreted with caution as the protein binding assays and cell lysis experiments were carried out in an in vitro situation in natural killer (NK) cells isolated from human blood. There are always limitations to in vitro tests as the physiological milieu could also have effects on cell lysis and protein binding function of the NK cells. Additional in vivo studies are required to further investigate the effect of HBCD on the immune system.”

Request 2.17
P.161 3rd para RE: Lilienthal et al. 2009...The reported observations are difficult to interpret from the publication. A number of issues indicate that this study should not be used as a basis for a conclusion on developmental effects:

The sample sizes for the measured endpoints are small (n = 4-6/group). The animals were taken from the study reported by Van der Ven et al, 2009 that reported a sample size of 6/sex/group. Some of the animals must not have contributed to the data of the Lilienthal et. al, 2008 study. Reasons are unclear.

The animals have been transported between laboratories for the study. This may have had an influence on the results.

Measured catalepsies are latencies, which are censored (i.e. a maximum of 180 sec is used as a measurement). Censored data are limit values rather than real data, and their quantitative analysis can be challenging. Special statistical tests have been developed handle such data, but the authors do not mention any special statistical tests, thus it can be assumed that the data were not analysed with the appropriate methods. Some of the catalepsy data do not follow a clear dose response and it is unclear how much they influence the data modelling and how much weight should be given to similar values for a different dose. It is to be noted that the error bars in the figures are standard errors of the mean (not standard deviations) and do not represent the raw data variability that was much larger.

The critical effect dose from which the effects were considered as truly substance related was taken from human clinical experience and not from historical data of the same rat strain. This renders the evaluation difficult in particular as a very low number of animals was investigated, there was a considerable variation in the raw data and no historical control values for the effects observed in the same strain of rats and the same laboratory were provided.

The study was a dietary study. It is unclear from the publication whether average daily intakes of HBCDD were calculated on the basis of measured concurrent feed intake or estimated from historical control data.

The discussion addresses the differential effects in males and females for catalepsy in terms of enzyme induction (females being more sensitive than males). On the other hand, evoked potentials are reported to be effected in males but not in females. The authors only stated that sex-related effects are not uncommon. No comments were made about the finding that in one case females were reported to be more affected and in the other case males.

Given the above mentioned inconsistencies in the study, it is impossible to decide from the data provided whether the reported effects were within the variability of this strain of rats, were an artefact of the statistical method used or represent a real effect. Thus this study is unsuitable to be used for classification purposes.

Decision 2.17
Variation not approved.

NICNAS Response 2.17
The above mentioned study is on page 159, para 3. NICNAS has not used this study to draw any conclusions. The first line of the 3rd paragraph on page 159 of the report notes that the studies only provide 'indications' of developmental neurotoxicity. They do not conclusively prove that HBCD has developmental neurotoxicity. NICNAS is aware of the limitations of these studies in which very few animals per group were used or only one dose was administered to the animals, and has therefore not used them in deriving any conclusions.

Request 2.18
P.161 3rd para RE: Eriksson et al. 2006…These conclusions were derived from a single insufficiently described research report using non-validated test methods in one gender of mice (males) with significant defects in study design and analysis.

The study used a low number of animals and did not correct for litter effects, which is a critical confounding issue that must be controlled for in this type of study design and statistical analysis (Piegorsch et al., 1991; Weil, 1970).

Thus, there is no way to determine statistical significance until the appropriate analysis is conducted.

These and many other deficiencies in the Eriksson et al. 2006 study have been summarized in a recent review of brominated flame retardants and neurobehavioral observations (William and DeSesso, 2010).

The EU TC NES reached a similar conclusion that these data lack robustness and interpretability and can thus not be used for hazard or risk assessment.

Decision 2.18
Variation not approved.

NICNAS Response 2.18
The above mentioned study is on page 159, para 3. NICNAS has not used this study to draw any conclusions. The first line of the 3rd paragraph on page 159 of the report notes that the studies only provide 'indications' of developmental neurotoxicity. They do not conclusively prove that HBCD has developmental neurotoxicity. NICNAS is aware of the limitations of these studies in which very few animals per group were used or only one dose was administered to the animals, and has therefore not used them in deriving any conclusions.

Request 2.19
P.161 3rd para 2nd sentence ….This indicates that the substance may be present at potentially toxic levels in breast milk. This seems to contradict the findings of the exposure/risk assessment which did not find potentially toxic levels.

Decision 2.19
Variation approved. Text modified as follows:
"HBCD is a very lipophilic compound, which is persistent and tends to accumulate in the fat in many species, including man. This indicates that the substance has the potential to accumulate to toxic levels in human milk".

Request 2.20
P.161 2nd paragraph ….While the noted human biomonitoring studies have identified HBCD in human milk, it is important to put the levels in perspective. A recent human biomonitoring equivalent assessment (Aylward and Hays, 2011) has determined that the available biomonitoring data for HBCD indicate that the central tendency of lipid-adjusted concentrations in serum and milk in the general population is approximately 1ng/g lipid, with variations in individuals up to approximately 20 ng/g lipid. These concentrations are 6000- to more than 100,000-fold lower than the lipid adjusted concentrations of HBCD in laboratory animals at the PODs selected for recent risk assessment evaluations by Health Canada and the European Union.

Decision 2.20
Comment noted. No specific variation requested. The HBCD levels in breast milk mentioned in the report are put into perspective in the discussion on human biomonitoring data in Section 5.5. It should also be noted, as mentioned in the report, that reporting of monitoring data is complicated by the observation that the distribution of individual results covers orders of magnitude in concentration.

Request 2.21
P.187 Table 10.3….. We suggest that it may be preferable to present separate MOE for inhalation and dermal as well in order to depict where the main concern arises.

Decision 2.21
Variation partly approved. The following sentence added to Section 10.5, 191:
"Generally, risk from dermal exposure is higher when compared to inhalation exposure, except when weighing and repackaging powder formulations where risks from inhalation is either similar or higher than that from dermal exposure".

Request 2.22
P. 189 Section 10.3.4….. In general the wording in this section should reflect that an MOE <100 does not necessarily indicate a risk. The EU risk assessment regards some MOE<100 as safe. Which safety margin would be regarded as sufficient for different scenarios is not discussed here at all. The applied exposure levels are probably considerable over estimates and are driven by the EASE dermal estimates which are known to result in large numbers. In addition it may be helpful to include an assessment taking typical PPE (overalls, gloves etc.) into account.

Decision 2.22
Variation not approved.

NICNAS Response 2.22
A MOE of 100 or greater is usually considered safe as it represents the conservative default uncertainty factors of 10 each for both intra- and inter-species variability used for risk characterization (Page 180). Only few HBCD health effects studies have been conducted according to OECD guidelines are available. The NOAEL selected for risk assessment was from a single 2-generation reproductive study, which highlights the need to use an uncertainty factor of 100. Indeed there are other studies that indicate even lower NOAELs based on neurodevelopment and behavior. However, NOAEL from those studies were not

selected as the studies were not conducted to proper guidelines and need further confirmation of the effects noted in the studies. For these reasons a conservative margin of safety of 100 was used for risk assessment.

NICNAS conducts risk assessment using unmitigated exposure for the purpose of determining risks and setting recommendations.

Request 2.23
p.190 Second para "The commonly used HBCD products in Australia are the EPS foam products in the building industry and treated textiles in upholstered articles and blinds."

Please modify the sentence to include XPS as well. Suggest to revise the text as follows; "The commonly used HBCD products in Australia are the EPS and XPS foam products in the building industry and treated textiles in upholstered articles and blinds."

Decision 2.23
Variation approved. p.190 Second para will be changed to "The commonly used HBCD products in Australia are the EPS and XPS foam products in the building industry and treated textiles in upholstered articles and blinds".

Request 2.24
P191 3rd para
Sentence : "The main occupational use of HBCD in Australia is in expanded polystyrene insulation panels"….As in previous comment please add XPS

Suggested wording
"The main occupational use of HBCD in Australia is in expanded and extruded polystyrene insulation panels."

Decision 2.24
Variation approved. The sentence on P191 3rd para will be changed to "The main occupational use of HBCD in Australia is in expanded and extruded polystyrene insulation panels".

3. European HBCD Industry Working Group.

Request 3.1
On page xix of the report, the acronym "BSEF" is identified as "Bromine Scientific Environment Program". We believe that this should say "Bromine Science and Environmental Forum", in line with other references to BSEF in the report. We would therefore suggest correcting this.

NICNAS Decision 3.1
Variation approved. BSEF has been changed from 'Bromine Scientific Environment Program' to 'Bromine Science and Environmental Forum'.

4. Expanded Polystyrene Australia (EPSA).

Request 4.1

The Priority Existing Chemical - Draft Assessment Report - Page xvi to be amended to read:

"Recommendation 4 (to industry)
Manufacturers and importers of flame retardant articles should voluntarily phase out the import and use of HBCD chemical, and articles containing the chemical, as an interim measure to support the objectives of the Action Plan in Recommendation 6".

For Flame Retardant EPS Resins the 5 year phase out period for HBCD will commence once there are equivalent Flame Retardant grades of EPS offered for sale in Australia that offer Technical & Commercial equivalence to the range of properties currently offered for FR grade EPS using HBCD.

Justification of Proposed Variation
EPSA was represented in Sydney and Melbourne by its members to review the Draft report by NICNAS in early Dec 2011.

It is recognized by NICNAS that there are Global efforts being undertaken in Europe, Canada and USA to find alternatives to HBCD for use in Flame Retardant EPS. There has been some success in finding a safer ingredient than HBCD, but it is in the early stages of evaluation and proving by the EPS Raw material manufacturing industry. It has to be proven before there will be a ramp up of global scale manufacture of this alternative flame retardant additive to replace HBCD.

In Australia the risk profile for HBCD has already diminished significantly, as the major user of granular HBCD was by Huntsman Chemical Company Australia to manufacture FR grades of EPS. However, Huntsman closed its EPS operations in Australia in January 2010.

The draft recommendation presented by NICNAS are based on European or USA data and in some cases theoretical modeling of theoretical models to establish risk profiles for HBCD in Australia where there is no data.

EPSA contends that this grossly exaggerates the risks within Australia posed by HBCD. In Australia:-

1. There is no manufacture of HBCD raw material yet there is in USA/Europe
2. There is no manufacture of EPS raw material in Australia, it is all imported, since January 2010. This is towards the end of the NICNAS PEC review period.
3. The usage rate of EPS per head of population in Australia is about one sixth of that reported for some Euro countries.
4. The population per land mass for Australia is significantly lower than that of Europe or USA
5. Cumulatively, the position for Australia with respect to the use of HBCD in EPS will result in a significantly lower risk profile.

The other markets where HBCD is used is in the Textile and injection moulded grades of HIPS, although even these application areas are miniscule by comparison to their equivalents in USA/Europe. These market areas should be encouraged to commence a move away from HBCD, since there are viable alternatives to HBCD available for these applications.

The Australian EPS Industry is dependent upon imported EPS raw materials, primarily from Asia region, and as such, the recommendation proposed by NICNAS must recognize that the Australian EPS industry will follow rather than lead the Global efforts to introduce an alternative to HBCD use in FR grade EPS.
There is mention within the Stockholm report that other raw materials can substitute for EPS, or that EPS without HBCD can be made fire safe by placing a fire resistant material as a lining to the EPS faces when used in construction. This may be allowed in some countries but is unacceptable within Australia due to our Building Codes and Regulations. The Australian Building Code has strict requirements on the fir properties of EPS for use in construction and these attributes can only be achieved from EPS which contains HBCD.

If NICNAS does not amend its draft recommendation for phase out of HBCD use for EPS, it is putting at risk an industry which is favored by the Climate Change initiatives within Australia where it is recognized how important the role of insulation is to reduce Greenhouse gas emissions to reach 2020 targets.

In conjunction with the Sandwich panel industry,(EPS foam laminated with colour bond steel for coolrooms, transportable homes and residential low energy homes), the EPS industry would represent in excess of a Billion dollars of local value add industries.

Under the current recommendation, EPS may not be able to continue if the 5 year phase out is done without an equivalent replacement to HBCD in place.
As the health & environment risks from Moulded EPS resin articles are very low as documented in the report, then a delay in phase out of HBCD containing EPS Resins should occur.

The following information contained in the Priority Existing Chemical - Draft Assessment Report clearly supports the view that the planned phase out should be deferred till there is Technical & Commercial equivalent flame retardant readily available for EPS use.

Suitable Fire Retardant Replacement for EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page 197

12.1.1 Occupational health and safety
Elimination and substitution

"Currently, no suitable replacement for HBCD in the EPS industry was reported to be available."

Scope of HBCD Usage in EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page xiii

Overview

Environmental exposure

The majority of HBCD (>95%) is used to produce flame retardant EPS resins

Human Health Risk Characterisation

The Priority Existing Chemical - Draft Assessment Report indicates on Page 191 in Section 10.5 Conclusions

– there is very low level of risk to the public & workers exposed to in-process & end use EPS products as these products contain HBCD at very low concentrations. Moreover, the risks are low as HBCD is incorporated into the Plastic Matrix.

There is other relevant supporting documentation in
EPS Molders Association (US) - "HBCD Use & Application in EPS Foam Insulation" published on 24/6/09

a) It is also proven that leaching of HBCD from polystyrene foam insulation is insignificant. Under forced laboratory conditions to measure the release of HBCD from polystyrene foam, results indicate that only 0.05% or less leached out of the foam within a four week period at which stage the leaching ceased altogether.

b) Currently there is no technically suitable or commercially available alternative to brominated flame retardants for use in EPS. Although the industry has been actively engaged in research and development to find an alternative, a viable solution has not been identified. Manufacturers have recognized certain requirements that should be met before HBCD substitutions can be identified and implemented:

• Provide equal or better flame retardance;
• Result in equal or better performance and physical properties;
• Pose less risk to the environment and human health;
• Offer compatibility with existing manufacturing processes; and
• Are commercially available.

Decision 4.1

Variation partially approved.

NICNAS Response 4.1

NICNAS acknowledges that safer alternatives to HBCD, especially for use in EPS/XPS production are still in developmental stages, and that alternatives to HBCD (both halogenated and non-halogenated) for other uses are commercially available. Taking these into consideration, Recommendation 4 has been modified as follows:

"Given the risks identified from the use of HBCD, importers of HBCD and manufacturers and importers of HBCD containing products and articles should move away from the import and use of HBCD, HBCD products and articles containing HBCD, in applications where safer alternatives and technologies are commercially available to support the objectives of Recommendation 6".

5. EXPANZ International Pty Ltd.

Request 5.1
The Priority Existing Chemical - Draft Assessment Report - Page xvi to be amended to read:

"Recommendation 4 (to industry)
Manufacturers and importers of flame retardant articles should voluntarily phase out the import and use of HBCD chemical, and articles containing the chemical, as an interim measure to support the objectives of the Action Plan in Recommendation 6".

For Flame Retardant EPS Resins the 5 year phase out period for HBCD will commence once there are equivalent Flame Retardant grades of EPS offered for sale in Australia that offer Technical & Commercial equivalence to the range of properties currently offered for FR grade EPS using HBC".

Justification of Proposed Variation
It is recognized by NICNAS that there are Global efforts being undertaken in Europe, Canada and the USA to find alternatives to HBCD for use in Flame Retardant EPS. There has been some success in finding a safer ingredient than HBCD, but it is in the early stages of a "limited" evaluation and proving by select EPS Raw material manufacturers. It has to be proven before there will be a ramp up of global scale manufacture of this alternative flame retardant additive to replace HBCD.

In Australia, the risk profile for HBCD has already diminished significantly, as the major use of granular HBCD was by Huntsman Chemical Company Australia to manufacture FR grade EPS. However Huntsman closed its EPS operations in Australia in January 2010. Since Huntsman's closure the demand for FR Grade EPS containing HBCD has been supplied via importers of EPS.

The Australian EPS industry is dependent on imported EPS materials, primarily from Asia region, and as such, the recommendations proposed by NICNAS must recognise that the Australian EPS industry will follow rather than lead the Global efforts to introduce an alternative to HBCD use in FR Grade EPS.

A premature phase out of HBCD will threaten the viability of the EPS industry in Australia, causing a likely closure. This not only threatens significant employment, but also threatens the Australian Climate Change initiatives where EPS is set to play a major role as insulation material to achieve reductions in global greenhouse gases.

There is mention within the Stockholm Convention report that other raw material can substitute for EPS, or that EPS without HBCD can be made fire safe by placing a fire resistant material as a lining to the EPS faces when used in construction. This may be allowed in some countries but is unacceptable in Australia due to our Building Codes and Regulations. The Australian Building Code has strict requirements on the fire properties of EPS for use in construction and these attributes can only be achieved from EPS which contains HBCD.

As the health and environment risks from moulded EPS resin articles are very low as documented in the draft report, a delay in phase out of HBCD containing EPS Resins should occur, until there is a Global release of an HBCS replacement for FR grade EPS raw materials.

The following information contained in the Priority Existing Chemical - Draft Assessment Report clearly supports the view that the planned phase out should be deferred till there is Technical & Commercial equivalent flame retardant readily available for EPS use.

Suitable Fire Retardant Replacement for EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page 197

12.1.1 Occupational health and safety
Elimination and substitution

“Currently, no suitable replacement for HBCD in the EPS industry was reported to be available.”

Scope of HBCD Usage in EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page xiii

Overview

Environmental exposure

The majority of HBCD (>95%) is used to produce flame retardant EPS resins

Human Health Risk Characterisation
The Priority Existing Chemical - Draft Assessment Report indicates on Page 191 in Section 10.5 Conclusions

– there is very low level of risk to the public & workers exposed to in-process & end use EPS products as these products contain HBCD at very low concentrations. Moreover, the risks are low as HBCD is incorporated into the Plastic Matrix.

There is other relevant supporting documentation in
EPS Molders Association (US) - “HBCD Use & Application in EPS Foam Insulation” published on 24/6/09

a) It is also proven that leaching of HBCD from polystyrene foam insulation is insignificant. Under forced laboratory conditions to measure the release of HBCD from polystyrene foam, results indicate that only 0.05% or less leached out of the foam within a four week period at which stage the leaching ceased altogether.

b) Currently there is no technically suitable or commercially available alternative to brominated flame retardants for use in EPS. Although the industry has been actively engaged in research and development to find an alternative, a viable solution has not been identified. Manufacturers have recognized certain requirements that should be met before HBCD substitutions can be identified and implemented:

• Provide equal or better flame retardance;
• Result in equal or better performance and physical properties;
• Pose less risk to the environment and human health;
• Offer compatibility with existing manufacturing processes; and

• Are commercially available.

Decision 5.1
Variation partially approved.

NICNAS Response 5.1
NICNAS acknowledges that safer alternatives to HBCD, especially for use in EPS/XPS production are still in developmental stages, and that alternatives to HBCD (both halogenated and non-halogenated) for other uses are commercially available. Taking these into consideration, Recommendation 4 has been modified as follows:

"Given the risks identified from the use of HBCD, importers of HBCD and manufacturers and importers of HBCD containing products and articles should move away from the import and use of HBCD, HBCD products and articles containing HBCD, in applications where safer alternatives and technologies are commercially available to support the objectives of Recommendation 6".

6. Insulated Panel Council Australasia Ltd (IPCA) and Metecno Pty Ltd.

Request 6.1
Overview "HBCD is not manufactured in Australia. It is imported into Australia as raw or technical grade powder or granules, in expandable polystyrene (EPS)", delete HBCD is no longer imported in powder form this sentence needs to be edited to reflect this it says it further down. It was reported in 2010 that the powder form of HBCD is no longer being imported into Australia this is very confusing.

"The risk of harmful effects by inhalation to workers handling the powder or granular formulations during importation and transport is likely to be negligible, except in the event of an accident or spill". Needs to be deleted.

Decision 6.1
Variation partially approved. Changes made to the text as follows:
"HBCD is not manufactured in Australia. It is imported into Australia as liquid dispersion, in expandable polystyrene (EPS)",..It was reported in 2010 that the powder form of HBCD is no longer imported into Australia".

The sentence "The risk of harmful effects by inhalation to workers handling the powder or granular formulations during importation and transport is likely to be negligible, except in the event of an accident or spill" is not deleted as powder formulations could be used in future, if not regulated. The following sentence is added on pages xiii and 185:

"Although powder formulations are currently not used in Australia, risks from powder formulations were estimated because powder formulations could be imported and used in future, if not regulated".

Request 6.2
Recommendation 4 (to industry): “Manufacturers and importers of flame retardant articles should voluntarily phase out the import and use of HBCD chemical, and articles containing the chemical, as an interim measure to support the objectives of the Action Plan in Recommendation 6.” This presupposes that alternatives are commercially available which they are not.

Change to

“Manufacturers and importers of the flame retardant articles should phase out the import and use of HBCD and articles containing HBCD when a viable commercial alternative is available to support the objectives of the Action Plan in Recommendation 6.”

Decision 6.2
Variation partially approved.

NICNAS acknowledges that safer alternatives to HBCD, especially for use in EPS/XPS production are still in developmental stages, and that alternatives to HBCD (both halogenated and non-halogenated) for other uses are commercially available. Taking these into consideration, Recommendation 4 has been modified as follows:

“Given the risks identified from the use of HBCD, importers of HBCD and manufacturers and importers of HBCD containing products and articles should move away from the import and use of HBCD, HBCD products and articles containing HBCD, in applications where safer alternatives and technologies are commercially available to support the objectives of Recommendation 6.”

Request 6.3
Environmental safety Recommendation 6 (to the Standing Council for Environment and Water (SCEW)
a. measures to discontinue introduction of HBCD into Australia for further processing over a 5-year period
b. measures to discontinue introduction of HBCD into Australia as part of finished articles
c. monitoring import and release of HBCD over a 5-year period
f. evaluation of the effectiveness of the reduction program by analysing sediments for HBCD levels at regular intervals.

Same issue for time frame change to

Recommendation 6 to the Standing Council for Environment and Water
a. measures to discontinue introduction of HBCD into Australia for further processing restrict importation of articles with HBCD once proven, environmentally safer, fire retardants which perform the same function are commercially available.
b. measures to discontinue introduction of HBCD into Australia as part of finished articles It is understood that SCEW are to develop an action plan, this recommendation could be more specific
c. log the import and release of HBCD over a 5-year period
f. evaluation of the effectiveness of the reduction program by analysing sediments for HBCD levels at regular intervals. Need to be more specific, it is understood that this may be for the

SCEW people to determine but should they be pointed in the right direction and also be told what means this analysis will take and who the likely laboratory will be?

Decision 6.3
Variation partly approved. Recommendation 6 has been modified as follows:

"It is recommended that the SCEW develop an Action Plan to address the currently unacceptable risk of HBCD levels in the Australian environment arising from production and use of products and articles containing HBCD, taking account of:

- The risk assessment of HBCD finds unacceptable risks to the environment and to workers involved in certain tasks with HBCD.
- HBCD has been subject to an assessment by the Technical Committee of the Stockholm Convention on Persistent Organic Pollutants and HBCD has been found to meet the criteria for a Persistent Organic Pollutant (POP) under the Stockholm Convention. It is currently under discussion for listing in the Stockholm Convention.
- Commercially available, safer chemical alternatives and technologies cannot be used for all applications of HBCD.

The Action Plan should constitute a national approach involving federal, state and territory agencies and should address the full life cycle of HBCD in Australia as a chemical entity, in products and in articles."

Request 6.4
P1 HBCD is used as a flame retardant in 'polyester' foam in domestic change to polystyrene.

Decision 6.4
Variation approved. Page 1 paragraph 3 the sentence will be changed to "HBCD is used as a flame retardant in polystyrene foam in domestic and industrial building insulation and in polystyrene beads that are used in insulation of articles such as housing for domestic electrical appliances and baby car seats."

Request 6.5
P4 "As they are not chemically bonded, additive flame retardants sometimes tend to bleed out of a product and vaporise or collect at the surface – a process known as "blooming", resulting in the gradual loss of flame retardancy. The degree (i.e. rate) at which blooming may occur is dependent on a number of factors, which include size and shape of the flame retarding molecule/polymer, geometric structure of the plastic matrix and stability of the flame retarding molecule/compound". This paragraph is vague, for use of HBCD in EPS how likely is this to occur?

Decision 6.5
Variation not approved.

NICNAS Response 6.5
This statement is applicable to all additive flame retardants including HBCD and highlights the difference between additive retardants and reactive flame retardants that are chemically

bound to the raw material. It has been reported that additive flame retardants migrate to the surface of articles during use of articles containing these chemicals, and it is noted that the rate is variable and not easily predicted.

Request 6.6
P4 "For additive flame retardants, compatibility with the polymer or the textile being treated avoids their migration to the surface, which results in the reduction of the permanency of the flame retardant property of the product". This makes no sense surely avoiding migration to the surface would increase the permanency of flame retardant property of the product.

Decision 6.6
Variation approved. Sentence modified as follows:
"For additive flame retardants, compatibility with the polymer or the textile being treated is important as it avoids their migration to the surface. Migration of flame retardants to the surface of polymer or articles blooming results in the reduction of the permanency of the flame retardant property of the product".

Request 6.7
P4 "During formulation the HBCD is encapsulated into a polymer matrix and is physically bound within the polymer matrix". This sentence is confusing in the context of the other comments.

Decision 6.7
Variation approved. Sentence modified as follows:
"HBCD, being an additive flame retardant, is not chemically bonded into the polymer structure, but is physically bound within the polymer matrix".

Request 6.8
P 22 "HBCD is not manufactured in Australia. It is imported into Australia as the raw or technical grade powder or granules, in EPS resin, as liquid dispersions and incorporated into the plastic of finished articles". DELETE

Decision 6.8
Variation partly approved. Sentence modified as follows:
"HBCD is not manufactured in Australia. It was imported into Australia as the raw or technical grade powder or granules, in EPS resin, as liquid dispersions and incorporated into the plastic of finished articles. However, latest information provided by the applicants indicate that HBCD is imported into Australia only as liquid dispersions, in EPS resin and incorporated into the plastic of finished articles".

Request 6.9
P23 "The service life of the boards is comparable with the life of the building, and a small percentage (<5%) is recovered for reuse at the end of a building's life (estimated at 20 years)". Change expected life of buildings is 50 years.

Decision 6.9
Variation not approved.

NICNAS Response 6.9
No changes have been made. NICNAS does not have supporting statistics so a more conservative value at the lower end of life expectancy is needed to be used.

Request 6.10
P31 "In this study, insulation foams made of EPS (1–2% HBCD)". 2% results should be excluded from this study as they do not represent normal practice of HBCD inclusion into EPS in Australia.

Decision 6.10
Variation not approved.

NICNAS Response 6.10
This paragraph in the report is describing an emission study by Kemmlein et al. (2003), which reports 1-2% HBCD levels in the insulation foams. The description accurately reflects the study. The study was conducted by the German Federal Environmental Agency.

NICNAS was not provided with specific Australian information to indicate that 2% levels are not usual practice during the assessment; however such information would not change the outcome of the calculation based on this study which found that inhalation exposure would be negligible even at 2%.

Request 6.11
P37 "Average bodyweights for infants, toddlers, children and adults are 5.8, 12.9, 46.9 and 60 kg, respectively". Is this really the average body weight of average Australians seems unlikely!

Decision 6.11
Variation not approved.

NICNAS Response 6.11
There are no default values for average Australian bodyweights especially for children thus these were estimated based on an equation of the US EPA in determination of bodyweights, provided in Appendix 3 of the report. The Australian Exposure Assessment Handbook (enHealth, 2003) references the US EPA model from the Exposure Factors Handbook (US EPA, 1992) as the primary source of information for bodyweight.

Request 6.12
P39 "HBCD was present in 15 of the 18 categories of foods. The dietary exposures were based on mean consumption data per food group and mean compound concentration. A high percentage of samples (60% to 91%) were below the LOD, so the estimated exposures to individual BFRs (HBCD and TBBPA) were determined by calculating 2 scenarios". If the 60-91% were below the limit of detection how could it have been found in 15 out 18 samples!

Decision 6.12
Variation not approved.

NICNAS Response 6.12
HBCD was found in 15 out of the 18 broad categories of foods although many individual results in these categories were below the LOD. The percentage of non-detects were for the total number of food samples tested.

Request 6.13
P50 "Australian industries widely use imported commercial grade HBCD and HBCD containing products". Do they really surely there must be a less confusing way to phrase this!

Decision 6.13
Variation approved.

NICNAS Response 6.13
The sentence will be changed to "Australian industries import a range of commercial grade HBCD for further formulation for industrial uses and HBCD containing products in the form of articles."

Request 6.14
P53 "Bodyweight of an average worker = 70 kg". Still seems low but different from earlier value!

Decision 6.14
Variation not approved.

NICNAS Response 6.14
The average bodyweight of 70 kg used in Section 6 is a value consistent with international regulatory approaches on worker bodyweight used in exposure estimation. The value is different from that used in the public exposure section because that value reflects the body weight of adults in the general population.

Request 6.15
P55 "HBCD is used in the polymer industry as an additive to impart flame-retardant properties to polystyrene foam, polystyrene articles and polypropylene articles. Workers in the polymer industry may be exposed to HBCD during compounding, conversion or molding activities. The occupational activities involved in this industry are described below". This is not done in Australia and most confusing to have this statement in the document.

Decision 6.15
Variation partly approved.

NICNAS Response 6.15
This information was provided to NICNAS by applicants and may not be the current practice in the Australian polymer industry, however, it is worth retaining this information to

document recent activities and inform recommendations that are appropriate to any recommencement of these activities in Australia. The paragraph was converted to past tense in the final report to reflect the historical practice. The text was modified as follows: "HBCD **has been** used in the polymer industry as an additive to impart flame-retardant properties to polystyrene foam, polystyrene articles and polypropylene articles. Workers in the polymer industry may **have been** exposed to HBCD during compounding, conversion or moulding activities. The occupational activities…"

Request 6.16
P 68 "Flame-retarded EPS resin containing HBCD was produced at 1 work site in Australia. Releases from handling of the raw material, based on an annual volume of 50 tonnes HBCD in its powder form, will result in an estimated release to water of 250 kg with a further 550 kg being released as solid waste (50 kg through handling and 500 kg as residues in bags)". As this is no longer done this whole calculation for environmental exposure need to be redone. This is then an estimated release of 1.6% cf estimates by EU of release during production and use of 0.1%.[i]

Decision 6.16
Variation approved. The paragraph in question has been re-written as follows:

"When the initial assessment for HBCD was undertaken in 2006, flame-retarded EPS resin containing HBCD was produced at one work site in Australia. Releases from handling of the raw material, based on an annual volume of 50 tonnes HBCD in its powder form, will result in an estimated release to water of 250 kg with a further 550 kg being released as solid waste (50 kg through handling and 500 kg as residues in bags). Advice received in 2011 is that this is no longer done. However since this process was being used in Australia till 2009 and since HBCD is a persistent chemical, the amount of HBCD released to the environment will persist for long periods in the environment, calculations relating to this activity have been retained. It is also possible that these activities will be recommenced in Australia unless regulated".

Request 6.17
P68 "The ESD provides release estimates for flame retardants falling into 3 categories of low, medium and high volatility. In this regard, the ESD does not define volatility groups based on flame retardant vapour pressure characteristics. The basis for assigning chemicals to the groups is not provided. One of the plasticisers, di(2-ethylhexyl) adipate (DEHA) that has a vapour pressure very similar to HBCD (6.27 x 10-7 hPa) has been assigned to the high volatility group in the ESD. Therefore, HBCD will be assumed to fall in the high volatility group and only these emission estimations are made here" An explanation of this would be greatly appreciated how could something be of low vapour pressure but be categorized as high volatility?

Decision 6.17
Variation not approved.

NICNAS Response 6.17
NICNAS appreciates that this statement appears counter-intuitive based on the reported vapour pressure of HBCD. However, as explained in the report, the ESD is non-specific as to groupings of substances into high, medium or low volatility. The ESD provides a vapour

pressure of $6.3X10^{-7}$ hPa for DEHA at 20^oC (Table 6.1, p45 of the ESD). This product is assigned to the high volatility group. The vapour pressure for HBCD is $6.27X10^{-7}$ hPa at 21^oC. The ESD seems to have very small changes to which groupings are made, for example, DEHP has a volatility reported of $2.2X10^{-7}$ hPa and is assigned to the medium volatility grouping. The classification for HBCD was chosen so as to be consistent with the DEHA value as reported in the ESD, noting further the ESD does not define the acronym.

Request 6.18
P69 "The ESD notes that for smaller sites (<750 tonnes of plastic per year) loss factors should be increased by a factor of 10. Again, the extent of such operations in Australia is unclear. For this assessment, it will be assumed that 50% of the processed HBCD is performed in plants processing <750 tonnes of plastic per year". Both assumptions seem highly arbitrary.

Decision 6.18
Variation not approved.

NICNAS Response 6.18
As information was not available to allow any further refinement, these assumptions were made in accordance with known and established practice, and are based on expert scientific judgment

Request 6.19
P73 "In order to consider this result quantitatively, an estimate of the surface area of insulation panels containing HBCD used in Australia each year is required. The dimensions of the panels are given as 600 mm x 300 mm x 2400 mm. This gives a surface area of 1 panel of approximately 4.7 m2 (total of 6 faces). For this exercise, the density of EPS insulation boards will be assumed to range from 0.016 to 0.048 g/cm3". Where have these figures come from most EPS in Australia is SL grade 13.5 kg/m^3 (not even in this range) and as for nominal dimensions?

Decision 6.19
Variation approved.

NICNAS Response 6.19
The calculations have been re-done using the advised density value. New calculations added to Section 7.2.2 of the report.

Request 6.20
P74 "The ESD suggests a service life of >10 years for plastics used in building and construction. The service life will be linked to the life of buildings they are used in. A service life of 20 years will be used for release estimates". 50 years more likely.

Decision 6.20
Variation not approved.

NICNAS Response 6.20
No changes have been made. NICNAS does not have supporting statistics so a more conservative value at the lower end of life expectancy is needed to be used.

Request 6.21
P79 "These factors indicate that, where released to the environment, HBCD will partition strongly to organic carbon and be unlikely to volatilise to the atmosphere". Goes against listing as highly volatile.

Decision 6.21
Variation not approved.

NICNAS Response 6.21
As explained in NICNAS Response 6.17, NICNAS do not consider HBCD to be highly volatile. It was assigned this grouping only for release estimations in line with the OECD Emission Scenario Document (ESD).

Request 6.22
P106 "Processing of HBCD technical grade granules occurred at one site only in Australia, with ultimate release of water to Melbourne Waters Western Treatment Plant at Werribee STP". Delete no longer occurs.

Decision 6.22
Variation approved. Modifications will be made to the text as follows:
"When the initial assessment for HBCD was undertaken in 2006, processing of HBCD technical grade granules occurred at one site only in Australia, with ultimate release of water to Melbourne Waters Western Treatment Plant at Werribee STP. Before this, the effluent liquid by-products are collected in a biological treatment plant on-site. The sludge is sent to a composting area to be used as compost later, and the liquid goes to the sewer. Advice received in 2012 is that processing of granules no longer occurs".

7. NSW Environment Protection Authority.

Request 7.1
Page xvi - Environmental Safety - Recommendation 6 (to the Environment Protection and Heritage Council (EPHC). Change any reference to EPHC to Standing Committee on Environment and Water (SCEW).

Decision 7.1
Variation approved. The report has been amended to give the current name.

8. Plastics and Chemicals Industries Association.

Request 8.1
Recommendation 4 of the HBCD Draft Assessment Report be deleted.

PACIA submits the following as the basis for variation of Recommendation 4:

- the objects of the *Industrial Chemicals (Notification and Assessment) Act 1989* identify one of the purposes as "providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibility for the regulation of industrial chemicals" (refer Item 5 of this submission)
- the meaning of "chemical" under section 6 of the *Industrial Chemicals (Notification and Assessment) Act 1989* does not include an "article" (refer Item 5.2 of this submission)
- NICNAS does not appear to have jurisdiction with respect to articles, as such, in accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989* (refer Item 5.3 of this submission)
- the HBCD Draft Assessment Report describes some of the "articles" where HBCD may be used:

"HBCD is used in the EPS resin form in domestic and industrial building insulation, packaging of industrial products and beanbag fills. HBCD is also used in XPS boards in domestic and industrial insulation and in automotive. Other uses are as a polypropylene resin in housing for domestic electrical appliances and as a textile coating additive in blinds, public seating and garments. A small amount of raw HBCD is used in the manufacture of flame retarded polystyrene masterbatch, which is used in an injection moulding process in the manufacture of ceiling fan covers."

- Recommendation 4 is directed to "Manufacturers and importers of flame retardant articles.."
- Recommendation 4 is very broad with significant practical and logistical issues impacting a very diverse range of products
- given the potential impacts on trade of articles, compliance with World Trade Organisation requirements and processes needs to be established
- Recommendation 4 is made in "an expectation of compliance"
- the HBCD Draft Assessment Report includes the following comment on HBCD alternatives:

"A report prepared for the European Chemicals Agency (ECHA) looked at potential alternatives to HBCD (ECHA, 2008). The report concluded that, although there are a number of alternative flame retardants available, none is suitable to replace HBCD in its main end uses i.e. extruded polystyrene (XPS) or expandable polystyrene (EPS) for insulation, as the required loadings of alternative flame retardants impair the structure and properties of the finished product to the extent that it is no longer suitable for use. Other forms of insulation in place of EPS and XPS could be used, but they could be less appropriate for some specific use scenarios or may incorporate different environmental issues, such as increased energy costs during transportation."

"Alternative fire retardants are available to replace HBCD in high impact polystyrenes (HIPS) but they are all required to be used at considerably higher loadings. Similarly, there are a wide range of different flame retardant formulations in textile coatings, although it is uncertain whether the human health and environmental impacts of these alternatives are any less than those associated with HBCD products. …."

- the NICNAS evaluation and Draft Assessment Report for HCBD does not give consideration to the consequences of removal of HBCD flame retardant from current uses, particularly in the absence of tested and approved acceptable alternatives. Such removal may have significant consequences and potential for damage to human life, environment (through fires) and property.

There are a range of issues surrounding building specifications and codes, BCA Regulations, impacts on building materials AS 1530.3 Indices (e.g. Ignitability Index, Spread of Flame Index, Heat Evolved Index, Smoke Developed Index etc), potential product de-selection of certain building materials in the absence of acceptable, tested and approved alternatives, and other issues. The potential impacts on businesses supplying the building industry are also significant.

- there has been no Regulatory Impact Analysis undertaken to inform Recommendation 4
- compliance with Office of Best Practice Regulation requirements needs to be confirmed

Practicality of recommendations for implementation

Recommendation 4**:** PACIA believes that implementation of Recommendation 4, in the absence of evaluation of the consequences and in the absence of regulatory impact analysis, could present unacceptable dangers to the Australian community and have significant economic consequences.

As the recommendation has not been "informed" by relevant processes the scope and scale of the recommendation does not appear to have been appreciated by NICNAS. The implications of removing HBCD in the absence of suited tested and approved alternatives has a wide intervention into a wide range of products ('articles')

"HBCD is used in the EPS resin form in domestic and industrial building insulation, packaging of industrial products and beanbag fills. HBCD is also used in XPS boards in domestic and industrial insulation and in automotive. Other uses are as a polypropylene resin in housing for domestic electrical appliances and as a textile coating additive in blinds, public seating and garments. A small amount of raw HBCD is used in the manufacture of flame retarded polystyrene masterbatch, which is used in an injection moulding process in the manufacture of ceiling fan covers."

Given the issues identified above there is a valid basis for deletion of Recommendation 4 from the HBCD Draft Assessment Report prior to its finalisation.

Decision 8.1
Variation not approved.

NICNAS Response 8.1
NICNAS acknowledges that safer alternatives to HBCD, especially for use in EPS/XPS production are still in developmental stages, and that alternatives to HBCD (both halogenated and non-halogenated) for other uses are commercially available. Taking these into consideration, Recommendation 4 has been modified as follows:

"Given the risks identified from the use of HBCD, importers of HBCD and manufacturers and importers of HBCD containing products and articles should move away from the import and use of HBCD, HBCD products and articles containing HBCD, in applications where safer alternatives and technologies are commercially available to support the objectives of Recommendation 6".

Request 8.2
Recommendation 6 of the HBCD Draft Assessment Report be deleted and replaced with the following text (with adjusted recommendation number):

Recommendation 6 (to the to the Standing Council for Environment and Water (SCEW)

PACIA submits the following as the basis for variation of Recommendation 6:

- there has been no Regulatory Impact Analysis to inform Recommendation 6 and the Recommendation makes no mention of the need for Regulatory Impact Analysis

- advice from NICNAS at the NICNAS HBCD Briefing held in Sydney on 7 December 2011 identified that the "5 year period" specified in Recommendation 6 was based on "assumptions" around possible timings of events in relation to the Stockholm Convention consideration of HBCD. These assumptions may or may not be valid

- in October 2011, the Stockholm Convention's Persistent Organic Pollutants (POPs) Review Committee agreed on the need to add the flame retardant HBCD to the Convention's Annex A, a list of POPs subject to an eventual ban. That recommendation will be submitted for final approval to a meeting of the Convention's parties in May 2013.

- the example of Perfluorooctane sulfonate (PFOS) provided in Item 6.3 of this submission identifies that the proposed Annex inclusion from "proposal" to "final" can change. There may also be options for consideration of "acceptable purposes" or "specific exemptions"

- for Australia, an amendment to the Stockholm Conventions Annexes only enters into force upon Australia's ratification of that amendment. Accordingly, Australia must undertake a domestic treaty-making process, which in broad terms, includes the following elements:

    -preparation of a Regulatory Impact Statement (RIS)

    -preparation of a National Impact Analysis

    -consideration by the Federal Cabinet and the Executive Council

An initial RIS on proposed listings is undertaken prior to the Conference of the Parties meeting. The technical implications of the listings must then be explored and resolved in greater detail. The initial RIS phase would need to be available for the May 2013 meeting

- based on past experience, the Australian treaty-making processes have been robust, consultative and inclusive

There are a range of matters identified under Item 8 of this submission and are again repeated as relevant to the considerations of Recommendation 6

- Recommendation 6 is very broad with significant practical and logistical issues impacting a very diverse range of products
- the HBCD Draft Assessment Report includes the following comment on HBCD alternatives:

"A report prepared for the European Chemicals Agency (ECHA) looked at potential alternatives to HBCD (ECHA, 2008). The report concluded that, although there are a number of alternative flame retardants available, none is suitable to replace HBCD in its main end uses i.e. extruded polystyrene (XPS) or expandable polystyrene (EPS) for insulation, as the required loadings of alternative flame retardants impair the structure and properties of the finished product to the extent that it is no longer suitable for use. Other forms of insulation in place of EPS and XPS could be used, but they could be less appropriate for some specific use scenarios or may incorporate different environmental issues, such as increased energy costs during transportation."

"Alternative fire retardants are available to replace HBCD in high impact polystyrenes (HIPS) but they are all required to be used at considerably higher loadings. Similarly, there are a wide range of different flame retardant formulations in textile coatings, although it is uncertain whether the human health and environmental impacts of these alternatives are any less than those associated with HBCD products. …."

- the NICNAS evaluation and Draft Assessment Report for HCBD does not give consideration to the consequences of removal of HBCD flame retardant from current uses, particularly in the absence of tested and approved acceptable alternatives. Such removal may have significant consequences and potential for damage to human life, environment (through fires) and property.

There are a range of issues surrounding building specifications and codes, BCA Regulations, impacts on building materials AS 1530.3 Indices (e.g. Ignitability Index, Spread of Flame Index, Heat Evolved Index, Smoke Developed Index etc), potential product de-selection of certain building materials in the absence of acceptable, tested and approved alternatives, and other issues. The potential impacts on businesses supplying the building industry are also significant.

Practicality of recommendations for implementation

Recommendation 6: PACIA suggests that this recommendation is less than helpful to the Standing Council for Environment and Water (SCEW)

- there has been no regulatory impact analysis to inform the recommendation and the recommendation makes no mention of the need for regulatory impact analysis

- no rationale has been provided for the 5 year timeframe (although NICNAS has suggested the timeframe relates to "assumptions" around possible timing of events in relation to the Stockholm Convention consideration of HBCD)

- SCEW will have its own processes (through the Department of Sustainability Environment, Water, Population and Communities) to prepare for the Stockholm Convention Conference of the Parties in May 2013 that will include initial regulatory impact analysis. If HBCD is included in one of the Stockholm Convention Annexes them Australian ratification would be informed by:

  -Preparation of a Regulatory Impact Statement

  -Preparation of a National Impact Analysis

  -Consideration by the Federal Cabinet and Executive Council

- the recommendation pre-empts the significant work that will be undertaken to support Australia's consideration

As a general comment, PACIA believes that there are important learnings from the HBCD assessment process and Draft Assessment Report for NICNAS, other relevant Government departments and agencies, and industry. PACIA would be pleased to participate in an appropriate dialogue.

Given the issues raised above there is a valid basis for variation of Recommendation 6 from the HBCD Draft Assessment Report prior to its finalisation. The variation sought is as follows:

It is recommended that the SCEW:

- notes the assessment of hexabromocyclododecane (HBCD) as a Priority Existing Chemical under the National Industrial Chemicals (Notification and Assessment) Act 1989; including the substance's:
  - environmental exposure
  - environmental hazard assessment
  - environmental risk characterisation
  - current environmental risk management

- notes that in October 2011 the Stockholm Convention's Persistent Organic Pollutants (POPs) Review Committee agreed to add HBCD to the Conventions Annex A. This recommendation will be submitted for approval by a meeting of the Convention's parties in May 2013
- supports initial Regulatory Impact Assessment of HBCD in preparation for the May 2013 meeting
- commits to Australia's domestic treaty-making process for consideration of ratification of an amendment to the Stockholm Convention Annexes

Decision 8.2
Variation partially approved**.** Recommendation 6 has been modified as follows:

“It is recommended that the SCEW develop an Action Plan to address the currently unacceptable risk of HBCD levels in the Australian environment arising from production and use of products and articles containing HBCD, taking account of:

- The risk assessment of HBCD finds unacceptable risks to the environment and to workers involved in certain tasks with HBCD.
- HBCD has been subject to an assessment by the Technical Committee of the Stockholm Convention on Persistent Organic Pollutants and HBCD has been found to meet the criteria for a Persistent Organic Pollutant (POP) under the Stockholm Convention. It is currently under discussion for listing in the Stockholm Convention.
- Commercially available, safer chemical alternatives and technologies cannot be used for all applications of HBCD.

The Action Plan should constitute a national approach involving federal, state and territory agencies and should address the full life cycle of HBCD in Australia as a chemical entity, in products and in articles.”

9. RMAX – A Division of Huntsman Chemical Company Australia Pty Ltd.

Request 9.1
The Priority Existing Chemical - Draft Assessment Report - Page xvi to be amended to read:

Recommendation 4 (to industry)
“Manufacturers and importers of flame retardant articles should voluntarily phase out the import and use of HBCD chemical, and articles containing the chemical, as an interim measure to support the objectives of the Action Plan in Recommendation 6”.

For Flame Retardant EPS Resins the 5 year phase out period for HBCD will commence once there are equivalent Flame Retardant grades of EPS offered for sale in Australia that offer Technical & Commercial equivalence to the range of properties currently offered for FR grade EPS using HBCD.

Justification of Proposed Variation
RMAX as a moulder of flame retardant EPS resins have a significant issue with a 5 year phase out of EPS Resins containing HBCD when there is NO Technical and Commercial equivalent chemical currently available to act as flame retardant in EPS Resins. To phase out without a suitable Fire Retardant replacement of EPS in place could mean that FR EPS is de selected in favour of other alternate materials. This would be a significant business risk to RMAX with approximately 100 direct and 50 indirect employees losing their jobs; it would also impact on the businesses of other EPSA members in the Australian EPS moulding industry.

Many flame retardants EPS applications call for stringent adherence to Burn Test characteristics that are currently met with the existing HBCD. These is no guarantee that replacement chemicals will work or be as effective. This could mean that many applications currently serviced by FR EPS may not be able to continue if the 5 year phase out is done without an equivalent replacement in place.

As health and environment risks from moulded EPS resin articles are very low as documented in the report, then a delay in phase out of HBCD containing EPS Resins should occur.

The following information contained in the Priority Existing Chemical - Draft Assessment Report clearly supports the view that the planned phase out should be deferred till there is Technical & Commercial equivalent flame retardant readily available for EPS use.

Suitable Fire Retardant Replacement for EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page 197

12.1.1 Occupational health and safety
Elimination and substitution

"Currently, no suitable replacement for HBCD in the EPS industry was reported to be available."

Scope of HBCD Usage in EPS Resin
The Priority Existing Chemical - Draft Assessment Report clearly states on Page xiii

Overview
Environmental exposure
The majority of HBCD (>95%) is used to produce flame retardant EPS resins

Human Health Risk Characterisation
The Priority Existing Chemical - Draft Assessment Report indicates on Page 191 in Section 10.5 Conclusions

– there is very low level of risk to the public & workers exposed to in-process & end use EPS products as these products contain HBCD at very low concentrations. Moreover, the risks are low as HBCD is incorporated into the Plastic Matrix.

There is other relevant supporting documentation in
EPS Molders Association (US) - "HBCD Use & Application in EPS Foam Insulation" published on 24/6/09

a) It is also proven that leaching of HBCD from polystyrene foam insulation is insignificant. Under forced laboratory conditions to measure the release of HBCD from polystyrene foam, results indicate that only 0.05% or less leached out of the foam within a four week period at which stage the leaching ceased altogether.

b) Currently there is no technically suitable or commercially available alternative to brominated flame retardants for use in EPS. Although the industry has been actively engaged in research and development to find an alternative, a viable solution has not been identified. Manufacturers have recognized certain requirements that should be met before HBCD substitutions can be identified and implemented:

- Provide equal or better flame retardance;
- Result in equal or better performance and physical properties;
- Pose less risk to the environment and human health;

- Offer compatibility with existing manufacturing processes; and
- Are commercially available.

Decision 9.1
Variation partially approved.

NICNAS Response 9.1
NICNAS acknowledges that safer alternatives to HBCD, especially for use in EPS/XPS production are still in developmental stages, and that alternatives to HBCD (both halogenated and non-halogenated) for other uses are commercially available. Taking these into consideration, Recommendation 4 has been modified as follows:

"Given the risks identified from the use of HBCD, importers of HBCD and manufacturers and importers of HBCD containing products and articles should move away from the import and use of HBCD, HBCD products and articles containing HBCD, in applications where safer alternatives and technologies are commercially available to support the objectives of Recommendation 6".

COMMENTS

1. Dow Chemical (Australia) Ltd.

Comment 1.1
HBCD is used widely in XPS foam insulation at levels <3% to enable PS foams to adequately meet fire performance requirements in buildings that are designed to enhance occupant safety. PS foam insulation also enables improved energy efficiency and supports targets for reduced CO2 emissions.

Dow Global Technologies LLC (DGTL) a subsidiary of the Dow Chemical Company has developed an alternative FR which has a superior environmental and health profile when compared to existing technologies. DGTL has already started licensing this technology to FR manufacturers to produce commercial quantities, This alternative (a polymeric FR) has been tested and found to be a non PBT substance that is suitable for processing in EPS and XPS. More information is available.
Links to the press releases are attached.
http://www.dow.com/news/corporate/2011/20110329b.htm

The first license is with Chemtura Chemtura's Corp News Site.

The ability to transition to this polymeric FR is subject to the availability of the alternative in adequate commercial quantities. This may still take time since the PS foam producers need to validate the alternative in their processes and produce & recertify their foam products with the new additive. Thus, the PS foam Industry needs sufficient time for a smooth transition from HBCD. We request that the legislative mechanism takes into account that sufficient time is needed for this process to occur.

NICNAS Response 1.1
NICNAS has noted the development of an alternative to HBCD that is suitable for processing in EPS and XPS and is in the process of commercialisation. NICNAS appreciates that the PS foam industry will need sufficient time for transition to the new flame retardant in EPS processing.

Comment 1.2
P 84. Significant discussion on the recovery of HBCD in the biodegradation studies.

NICNAS Response 1.2
Comments noted.
NICNAS thanks Dow for their extended discussion relating to the issue of recovery. While NICNAS agrees with the use of matrix spikes, this was not the basis of NICNAS's concern. As there was no mass balance reported, it was not possible to determine factors such as bound residues and volatiles. Nonetheless, NICNAS use of the recovered HBCD in the soil extracts to assess potential for degradation was considered to be appropriate. No amendments have been made to the report.

Comment 1.3
P 91. Information has recently become available (post- Sept. 2006) which provides evidence for the mineralization of 1,5,9-cyclododecatriene in an enhanced ready biodegradation test

(EBFRIP 2006b). A modified ready biodegradation test (based on the method for the determination of ready biodegradability as described in OECD Guidelines 301B) was performed to examine the aerobic biodegradation of trans, trans, trans-1,5,9-[^{14}C]cyclododecatriene (t,t,t-[^{14}C]CDT). Two nominal concentrations of t,t,t-[^{14}C]CDT, 0.2 and 1 mg/L, were added to reaction mixtures with an activated sludge inoculum. Extensive biodegradation (i.e., mineralization) of t,t,t-[^{14}C]CDT to $^{14}CO_2$ was observed in the study. After 63 days, the t,t,t-[^{14}C]CDT concentrations in the 0.2 mg/L reaction vessels decreased to ~8% of the originally applied concentration in the viable test mixtures, compared to ~96% for the corresponding abiotic controls (i.e., biologically inhibited). For test mixtures amended with 1 mg/L of the test compound, the t,t,t-[^{14}C]CDT concentrations in the viable test mixtures decreased to non-detectable levels (i.e., < 0.8%) after 77 days, compared to ~ 97% remaining in the corresponding abiotic controls. After 63-77 days, $^{14}CO_2$ production ranged from ~50-68% in the viable mixtures compared to ~ 1-2% in the abiotic controls. Taken together these results indicate that t,t,t- [^{14}C]CDT was mineralized to $^{14}CO_2$ by the activated sludge inoculum.

NICNAS Response 1.3
NICNAS thanks Dow for advising of this study. While the study has become available since 2009, it appears to be a company study that has never been provided to us. While NICNAS understands it was incorporated in a later European report (2008), this metabolite has not been a factor in NICNAS's decision making process and there did not appear to be any further need to assess it.

The NICNAS report mentions this metabolite (among others) as providing evidence that degradation of HBCD in the environment may occur through a process of sequential debromination. NICNAS notes it as a breakdown product in both aerobic and anaerobic soil/sediments. In the case of anaerobic sediments, the report notes that mineralisation was not observed. This indicates that the breakdown products themselves are persistent. However, the study in question only addresses the aerobic degradation and does not address anaerobic degradation of this chemical. NICNAS report does not make any observation as to the persistence of 1,5,9-cyclododecatriene under aerobic conditions other than to note that in the aerobic study where it was identified, it was not detected until after 21 days, and then increased to the end of the study. NICNAS also notes that at the end of the study, this metabolite was only present at <10%.

2. European HBCD Industry Working Group.

Comment 2.1
I am writing to you on behalf of the European HBCD Industry Working Group[1] with regards to the draft Priority Existing Chemical Assessment Report on hexabromocyclododecane (HBCD)[2], which is currently open for consultation. To this purpose, I would like to bring to your attention the following comments on the draft report, and one technical clarification, for consideration by the Australian Department for Health and Ageing.

International developments
As you may be aware, a review of HBCD is already ongoing and is well advanced at a global level under the UNEP[3] Stockholm Convention on Persistent Organic Pollutants. This represents a global effort on behalf of the Parties to the Stockholm Convention, including Australia, the HBCD industry and civil society to ensure an outcome that can fulfil a high

standard of environmental protection whilst taking into account the realities of industrial operations worldwide. In this respect, we believe it is appropriate for national regulations to consider carefully the proceedings of these international processes.

Within this context, on the 14th October 2011, the 7th meeting of the Persistent Organic Pollutants (POP) Review Committee[4], of the UNEP Stockholm Convention, adopted the Risk Management Evaluation (RME) for HBCD. The adopted RME acknowledges that HBCD should be listed under the Convention and that, in order to allow for certain time-limited critical uses of HBCD, a specific exemption for use of HBCD in expanded polystyrene (EPS) and extruded polystyrene (XPS) insulation foams could be given together, with a description of the conditions for production and for these uses[5].

Discussions on an agreed listing and on possible exemptions will continue at the next meeting of the POP RC in October 2012.

The European HBCD Industry Working Group is fully committed to working with the UN POP Review Committee and participates actively in this UNEP process. Industry will also continue to promote and implement the SECURE and VECAP[6] programmes as best practice to reduce emissions of HBCD to the environment.

About HBCD and alternatives

HBCD is used in very low quantities as a flame retardant in PS insulation foams (EPS and XPS). Any chemical alternative for HBCD needs to provide the same high standards of fire safety and to display an improved HSE profile. PS foams are primarily used in building insulation, where they provide improved energy efficiency and contribute to reduced CO_2 emissions. Furthermore, the production and use of PS foams is less energy intensive compared to other insulating technologies.

Whilst an alternative to HBCD has been announced and others are being identified, these are at present in the early stages of development. There is still a clear need for time to enable a smooth transition for the PS foams' highly integrated value chains. Transition requires time for testing, validation, qualification, production capacity adjustments and commercialisation. It will take several years before sufficiently large volumes of HBCD alternatives covering the needs of the entire global market will become available. In addition, available functional alternatives do not provide a universal solution to meet existing regulations. An appropriate timeframe is needed to ensure a realistic period of transition before HBCD can be phased out from the building and construction sector.

1 The HBCD Industry Working Group gathers HBCD producers and users in the polystyrene insulation foam sector, the major application of HBCD. The HBCD producers are represented by EFRA (the European Flame Retardants Association) and the HBCD users in the polystyrene insulation industry are members of PlasticsEurope (for expandable polystyrene) and Exiba (for extruded polystyrene).
2 http://www.nicnas.gov.au/Consultations.asp
3 UNEP: United Nations Environment Programme.
4 The POP Review Committee consists of 31 government-designated experts from Parties appointed by the Conference of the Parties of the Stockholm Convention (COP).
5 Risk management evaluation on hexabromocyclododecane, October 2011
6 Voluntary Emissions Control Programme: www.vecap.info

NICNAS Response 2.1

Comment noted. Information on the availability of HBCD alternatives will be included in the report. NICNAS is aware that an alternative polymeric flame retardant that is suitable for processing in EPS and XPS has been developed and is in the process of being commercialised.

NICNAS is also aware of international activities to identify alternatives to HBCD such as the US EPA initiative.

3. Insulated Panel Council Australia Ltd (IPCA) and Metecno PTY Ltd.

Comment 3.1
The review has been going since 2005 and initial investigations were begun in 2001 why has no environmental monitoring or other monitoring of actual HBCD levels in Australia been undertaken?

NICNAS Response 3.1
NICNAS's full assessment of HBCD commenced in 2006 following the industry's provision of available data. At that time, NICNAS noted that the lack of Australian monitoring data was disappointing. However, given the volume and quality of international monitoring data available and NICNAS's understanding of the chemical, NICNAS concluded that the lack of Australian monitoring data would not prevent the environmental risk assessment from being able to be undertaken and completed. Whilst Australian monitoring data would have allowed further refinement, NICNAS does not expect in this case that it would materially change the recommendations of the report. NICNAS also notes that industry has not provided any further data in this time.

Comment 3.2
No comment is made on reports that the major source of HBCD in the environment is thought to be from textile coatings!

NICNAS Response 3.2
Table 7.6 indicates that the major release (97.7% or 85,000 kg per annum) of introduced HBCD to the environment arises from the life cycle stage of "disposal" (of articles incorporating HBCD). Based on the use data reported in Table 4.2, the major source of HBCD in the environment can be concluded to arise from the disposal of the >88% (or >74,800 kg per annum) HBCD used in "Domestic and industrial building insulation; Packaging for industrial products; bean bag fill; other (incl. automotive)".

Comment 3.3
HBCD is no longer imported into Australia to be incorporated into EPS resin the environmental exposure limits need to be updated to reflect this.

NICNAS Response 3.3
This has been addressed in Decision 6.16, where the paragraph has been modified as follows:

"When the initial assessment for HBCD was undertaken in 2006, flame-retarded EPS resin containing HBCD was produced at one work site in Australia. Releases from handling of the raw material, based on an annual volume of 50 tonnes HBCD in its powder form, will result in an estimated release to water of 250 kg with a further 550 kg being released as solid waste (50 kg through handling and 500 kg as residues in bags). Advice received in 2012 is that this is no longer done”.

Comment 3.4
The review appears to be of a paper based nature strongly drawing on European information. Was an actual local survey of how products are made and used conducted?

NICNAS Response 3.4
When a chemical is declared a Priority Existing Chemical, importers and manufacturers of the chemical are required to supply information required for the assessment of the chemical. This includes:

- the physical and chemical properties of the chemical;
- the health and environmental effects of the chemical, including known human and environmental effects;
- the quantity, or proposed quantity, imported or manufactured;
- uses or potential uses of the chemical;
- the names of customers to whom the applicant or notifier has supplied or intends to supply the chemical;
- information on the manufacturing procedures, handling (including transportation) and storage of the chemical;
- information about occupational health and safety, public health and environmental matters, particularly exposure matters;
- copies of labels and MSDSs of the chemical and products containing the chemical; and
- a description of procedures in place to deal with emergencies involving the chemical.

Some of the above information was provided by the applicants for HBCD assessment. During the course of assessment NICNAS also requested applicants to provide the most recent data on the import quantities of HBCD and its products. The information provided was used for exposure and risk assessments. No information was provided on the atmospheric monitoring of the chemical in the workplace and in the absence of Australian data international HBCD use processes were reviewed and found to be similar to the description of the use processes provided by Applicants and therefore international data was used as a surrogate for Australian exposure. Information on the health and environmental effects of HBCD were sourced from international literature as these are dependent on the inherent properties of the chemical and is not dependent on the use of the chemical.

4. NSW ENVIRONMENT PROTECTION AUTHOTIRY.

Comment 4.1
Page xvii - Environmental Safety - Recommendation 6. Part b - Measures to discontinue introduction of HBCD into Australia as part of finished products and articles. It should be noted that Recommendation 6b is currently difficult to implement in Australia. We note that there are plans to address this matter as part of complying with requirements of international treaties.

NICNAS Response 4.1
Comment noted.

Comment 4.2
Page xvii - Environmental Safety - Recommendation 6."Part f – Evaluation of the effectiveness of the reduction program by analysing sediments for HBCD levels at regular intervals". The EPA believes that funding a program to analyse elements adequately is critical to its usefulness in evaluation. NICNAS will need to assist states in linking with industry to achieve this.

NICNAS Response 4.2
Comment noted. The recommendation notes that the development of an Action Plan should be a coordinated activity between Federal State and Territory agencies.

5. Plastics and Chemicals Industries Association.

Comment 5.1
NICNAS adherence to requirements of the *Industrial Chemicals (Notification and Assessment) Act 1989,* particularly with regard to timeframe obligations

Assessment of Priority Existing Chemicals has been a very extended process. HBCD was declared a Priority Existing Chemical (PEC) for a full risk assessment under the *Industrial Chemicals (Notification and Assessment) Act 1989* by notice in the Commonwealth *Chemical Gazette* of 7 June 2005.

Some six and a half years later stakeholders are providing comment for variation of the HBCD Draft Assessment Report.

The *Industrial Chemicals (Notification and Assessment) Act 1989* places certain obligations on the Director of NICNAS, and other persons. Obligations for the Director, amongst other things, include:

- Assessment of Priority Existing Chemical: section 57 and subsections 57(1), 57(5) 57(6) and 57(7). These subsections are reproduced below (underlining added):

"57 Assessment of priority existing chemical

(1) Where the Director receives an application or applications for the assessment of a priority existing chemical, he or she must cause the chemical to be assessed in accordance with section 60A and a report of the assessment to be prepared.

(5) Subject to subsection (6), an assessment is to be made and a draft report of the assessment to be completed under section 60C within 6 months after the day on which the last information required for the assessment is received.

(6) The Minister may extend the period for assessment and report by up to 6 months if it is not reasonably practicable for the assessment to be carried out thoroughly, and the report completed, within the period.

(7) Where the Minister extends the period for assessment and report, the Minister is to notify each applicant for the assessment of the extension immediately."
It is not clear to PACIA whether or how these obligations of the *Industrial Chemicals (Notification and Assessment) Act 1989* have been met.

NICNAS Response 5.1
The assessment of HBCD commenced in 2005 based on available data. Very little information on health and environmental effects of HBCD were provided by Industry. Analytical methods for measuring HBCD were also not developed. Understanding of HBCD's persistence was developing. For example in 2008, the Scientific Committee on Health and Environmental Risks (SCHER), after examining the EURAR commented that "SCHER supports most of the conclusions of this risk assessment. A possible exception is the PBT classification as new data seems to indicate a rapid decrease in HBCD in porpoises along the UK coast after the production was ended in that country (SCHER report 2008). Studies on the developmental effects of HBCD were also underway. Preliminary studies had indicated reproductive toxicity and neurotoxic effects in laboratory animals and more detailed studies were required to fully assess these effects in mammals.

It was therefore important to include the outcomes of these studies in the assessment report along with the international biomonitoring data for a comprehensive risk assessment.

The animal study that formed the basis of human health risk assessment (Ema et al., 2008) was published in 2008 and other important studies looking at developmental and neuro-behavioral effects of HBCD were published much later. NICNAS liaised with the study authors and accessed the draft report but these could not be included till publication of the final report.

Many of the studies on HBCD levels in human breast milk were published as late as 2011. As indicated in Section 1.3 of the "Introduction" in the report, studies up to June 2011 have been included in the report ensuring that the report is up to date and contains all the critical information. The data used for estimating infant exposure to HBCD via breast milk have been taken from studies conducted in 2008 onwards.

Comment 5.2
NICNAS jurisdiction with regard to "articles"
Items 5.2 and 5.3 of this submission deal with the Meaning of 'chemical' and 'article' and Jurisdiction of NICNAS with respect to 'articles' respectively.

PACIA's interpretation is that NICNAS does not have jurisdiction with respect to articles, as such, in accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Clarity on 'articles' is important because Recommendation 4 of the HBCD Draft Assessment report is directed towards *"Manufacturers and importers of flame retardant articles …"*

NICNAS Response 5.2
A key objective of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act) is to provide a national system of notification and assessment of industrial chemicals for the purposes of aiding in the protection of the Australian people and the environment by assessing the risks to occupational health and safety, public health and the environment that is associated with the importation, manufacture or use of the chemicals. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) administers the ICNA Act.

Under the ICNA Act an article is defined as "an object that:
(a) is manufactured for use for a particular purpose, being a purpose that requires that the object have a particular shape, surface or design; and
(b) is formed to that shape, surface or design during manufacture; and
(c) undergoes no change of chemical composition when used for that purpose except as an intrinsic aspect of that use;
but does not include a particle or a fluid".

Under the ICNA Act, "***chemical*** includes:
(a) a chemical element, including a chemical element contained in a mixture; or
(b) a compound or complex of a chemical element, including such a compound or complex contained in a mixture; or
(c) a UVCB substance; or
(d) a naturally-occurring chemical;
but does not include:
(e) an article; or
(f) a radioactive chemical; or
(g) a mixture"

While articles are excluded from the scope of the ICNA Act, NICNAS regulates the chemical(s) used in the manufacture of articles because of:

- potential exposure to the chemical during the manufacture of the article; and
- potential for release of the chemical from the article.

Chemicals Released from Articles

The public and the environment could be exposed to chemicals released from consumer articles via direct contact or indirectly via the environment. The release of chemicals from articles may occur via leaching, blooming, exudation, surface abrasion and/or during breakdown in the environment, and may occur at any time in the life cycle of the article, including during use, handling, disposal or storage.

When a determination is made that exposure of the public or the environment to a chemical in an article is likely due to the known chemical properties that indicate that it may leach from the article the risk assessment consideration is extended to all the sources of the exposure including chemical release from articles. Furthermore, an assessment into the release of the chemical from articles is likely when it is known that the chemical leaches from the article and that the chemical is deemed to be persistent and/or bioaccumulative and toxic. Therefore, NICNAS whilst focusing on regulating industrial chemical use may also consider the use of a chemical in the production of and release from finished articles during risk assessments.

Comment 5.3

Absence of consideration of consequences

The Draft Assessment Report recognises that suitable, test and approved HBCD alternatives may not be available or that for possible alternatives “it is uncertain whether the human health and environmental impacts of these alternatives are any less than those associated with HBCD products. …."

There is also no evaluation or consideration in the HBCD Draft Assessment Report as to the consequences of NICNAS recommendations to “phase out” the chemical and ‘articles’ containing the chemical. Some considerations may include:

- the lack of suitable, tested, and approved alternatives
- substitution where the alternative may not have characteristics that are “less than those associated with HBCD products”
- if products do not contain a flame retardant then the significant potential consequences for:

  -damage to human life

  -damage to the environment (fires)

  -damage to property
- impacts on building materials, life-cycle-analysis, carbon footprint, and consequences of substitution
- impacts on the building, automotive, electrical, appliance, and other sectors
- impacts on trade including compliance with World Trade Organisation requirements
- impacts on businesses

Recommendations to industry in the absence of regulatory impact analysis

The objects of the *Industrial Chemicals (Notification and Assessment) Act 1989* are helpful in providing clear intent of the role of NICNAS as a notification and assessment body and not a risk-management regulator. NICNAS provides information and makes recommendations about chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals (e.g. Poisons Scheduling, jurisdictional Poisons Control, Work Health and Safety, and the Environment).

Recommendation 4 to industry that “*Manufacturers and importers of flame retardant articles should voluntarily phase out the import and use of HBCD chemical, and articles containing the chemical, as an interim measure to support the objectives of the Action Plan in Recommendation 6*” has not been informed by regulatory impact analysis.

PACIA contends that Recommendation 4 is made in “an expectation of compliance” and that the requirements of the Office of Best Practice Regulation need to be met.

NICNAS Response 5.3

NICNAS aids in the protection of workers, the public and the environment from the potentially harmful effects of a wide range of industrial chemicals. NICNAS principally carries out risk assessments on chemicals based on adverse effects of the chemical and the measured or estimated exposure to the chemical. The outcomes of the risk assessment are provided to risk management bodies together with supporting information and recommendations concerning potential approaches to risk management. The risk management authorities consider appropriate approaches to address the risk posed by chemicals under their own regulatory practices.