**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restrictions on

**Inorganic ammonium salts**

**Non-confidential**

**ECHA/RAC/RES-O-0000005359-66-02/D**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| --- | --- | --- |
| Substance name | EC number | CAS number |
| Inorganic ammonium salts | - | - |

### 10 March 2015

General Comments and specific information requests

## Specific information requests:

1. Do you have information on (i) which type/forms of cellulose insulation products (e.g. cellulose foam and other forms of cellulose insulation) are sold by your company or in your country? (any information on quantities would also be useful) (ii) whether any of these products do contain ammonium salts? (iii) If yes, which inorganic ammonium salts are used as additives, in which form (power or liquid?) and what is the minimum concentration required to achieve the flame retarding standards? (iv) what is the average insulation thickness (in cm) of each cellulose insulation material and is there any information on the expected/measured release of ammonia (post treatment) per unit volume of the insulation material?
2. Do you have (i) information about how many homes (or non-domestic buildings) are insulated using cellulose materials (with or without inorganic ammonium salts) per year from your company/or in your MS? (ii) any monitoring data/studies on ammonia measurements that may have been undertaken in properties insulated with cellulose insulation materials treated with inorganic ammonium salts? If yes, please provide detailed information of the monitoring data/studies undertaken (iii) is the proposed test method viable and what are the cost of these tests?
3. Do you have any information on (i) alternatives blends (in particular of other than boron-based formulations) that can be used as additives to blends based on inorganic ammonium salts? (ii) alternative (stabilising) techniques, employed by manufacturers/formulators to ensure that emissions of ammonia from the inorganic ammonium salts are kept at a minimum level (i.e. not above 3 ppm?).
4. Are you aware of any reported cases (e.g. from National Poison centres or the hospitals) of (i) public showing irritation (eyes, nose, breathing etc.) following exposure to ammonia or other complaints (e.g. urine like smell) due to use of inorganic ammonium salts as additives in cellulose insulation materials of their housings?) (ii) workers/professionals having suffered from similar symptoms during/after installation of cellulose insulation? If yes, please provide with relevant details of the incidence (date/ cellulose insulation material used/number of persons affected/symptoms/severity /treatment etc.).
5. (i) Are there any specific economic (e.g. specific type of costs) or social impacts to sectors or economic operators that ECHA's scientific committees should take into account when formulating their opinions? (ii) Are you aware if in your territory there is any national legislation on the use of ammonium salts in insulation materials (if yes, any available data on their socio-economic impacts)?

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| **Ref.** | **Date/type/Org./****Related to section** | **Comments** |
| **1031** | **Date:** 2014/08/25 16:07**Type:** MemberState**MS name:** Sweden**Related to:** (A)**Company name confidential:** **No** | **Comment:**The Swedish Chemicals Agency's general comment is that the proposed restriction would be more appropriate for the Construction Products Regulation (Regulation (EU) No 305/2011).**Specific comment:**The proposed analysis method opens up the possibility of national parameters (see A.1.2 Scope and conditions of restriction and the wording: “Cellulose insulation thickness and density are adapted to the foreseen use”). This means that the same product can be approved in one Member State and not in another Member State. |
| **Dossier submitter response:**Thank you for your comments.Representatives of DG ENTR/B1 have been consulted by the dossier submitter and explained that “safeguard procedures” in Construction Products Regulation (CPR) serve to decide market restrictions to construction products (cellulose insulation here) and not to chemicals or additives of the products (inorganic ammonium salts in this case). CPR’s main objective is to harmonise at EU level the test methods performed on products and to ensure that the product performances reached and declared by manufacturers are calculated using the same test methods. This view has been confirmed by the COM to ECHA following a consultation from ECHA scientific dossier manager.Specific comment: Insulation thickness varies among Member States depending on national weather conditions and building regulations. Loading rate compliance should be aligned with each Member State building regulation requirements with regard to insulation (R rating). |
| **RAC Rapporteurs comments:**With regards to the appropriateness of the CPR it has been clarified during the discussion at RAC, with Forum and by the COM report (COM(2014/)511) in line with the dossier submitter’s response that the restriction of a substance in an construction product is outside the scope of this legal framework. Differences in the thickness and density of cellulose insulation products among Member States should be acceptable as long as the limit of ammonium gas emission (as it will be agreed) is not exceeded.  |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |
| **1038** | **Date:** 2014/08/27 12:35**Type:** MemberState**MS name:** Germany**Company name confidential:** **No** | **Comment:**The German CA supports the proposed restriction. |
| **Dossier submitter response:**Thank you for your support. |
| **RAC Rapporteurs comments:**Noted. |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |
| **1171** | **Date:** 2014/11/20 15:33**Type:** Individual**Company name confidential:** **No** | **Comment:**Introduction: it must be pointed out forcefully that a general ban on ammonium salts makes the development of harmless flame retardants for the cellulose insulation industry almost impossible. Chemically, you have to evaluate certainly the wide range of these diversity salts. Two product groups have a decisive role. I.) Ammonium phosphates and II.) Ammonium sulfatespoint I.)There are so-called short-chain ammonium phosphate compounds, Mono-Di and Tri-ammonium phosphates, their responsiveness at warm and rather damp climate is high and the risk that ammonia could be formed is very high. An alternative are so-called ammonium poly-phosphates whose molecular chains are higher than 500. These kinds of products are sluggish in reaction and the risk of building Ammonia is extremely low. On the economic evaluation following should be noted: Mono-di-tri ammonium phosphates are used in the fertilizer industry in large quantities. The production costs are rather low comparatively. Current market prices are below EUR 1,000 per tonne. Ammonium poly-phosphate, which were developed specially for the flame-retardant industry is around EUR 3,000 to 5,000 per tonne. Assessment:  Ammonium phosphates are due to their chemical properties an indispensable compound of flame retardants specially in the production of cellulose insulation and their share amounts approx. to 30% in the blendNevertheless, it seems economically feasible to replace short-chain Mono-Di-Tri Ammonium phosphates by safe Ammonium-poly-phosphates which almost excludes the risk of formation of Ammonia. II. Ammonium sulfate is also one of the effective flame retardant components in the cellulose insulation Industry. Trials have confirmed, however, that it is possible, under certain preconditions to generate Ammonia. Ammonium sulfate has a high efficiency as a flame retardant and with a market price of less than € 300 per tonne this component is of great importance for the general calculation, as its share is up to 60% in the blend. Therefore Ammonium sulfate is one of the most decisive cost factors in the production of suitable flame retardants. There exists alternatives for sure but development of these possible new formulations, however, will need a lot of time and will generate high costs From our point of view, these new mixtures will increase the price by at least 30-50%. Summary: We point out, as a producer of flame retardants, that we can not accept a general ban on all Ammonium salts. With the granting of a reasonable transition period - however, it should be possible to develop flame retardants with components consisting of ammonium compounds, such like ammonium polyphosphates which are uncritical. You have to take under economically consideration, that these flame retardants of the new generation, will be more expensive approximately by up to 30-50% and so competition would be further bonded, which would certainly cost market share. Kind regards  Jörg SteingraeberHäffner International GmbH  |
| **Dossier submitter response:**Thank you for your comments.In line with this comment, our proposal is not a general ban of inorganic ammonium salts and gives the possibility to industry to use stable ammonium salts in the conditions of the test.The quantitative information on the price of new formulation is valuable and we thank you for that. Your estimate of increased price for these new formulations (30-50%) is fully consistent with our calculations used for socio-economic analysis. |
| **RAC Rapporteurs comments:**The above information from a producer of flame retardants indicates that there are differences in the potential for emission / generation of ammonium gas depending on the ammonium salt used. According to this comment it appears that the order of potency is: ammonium polyphosphate < ammonium sulfate< ammonium phosphate. However, the specific conditions affecting the release of ammonium gas and information on the quantity (e.g. max. release of ammonia) is not available. The comment is of interest to RAC, however, it does not allow to specify a certain ammonium salt that should be restricted or to identify another that could be excluded. RAC supports the dossier submitter’s proposal not to ban the use of ammonium salts in cellulose wadding but to set an emission limit as this allows for the continued use of ammonium salts and techniques to achieve compliance below a level where the risk is controlled. |
| **SEAC Rapporteurs comments:**The SEAC rapporteurs appreciate the comments received. The comments qualitatively underline the potential technical feasibility for a stabilized ammonium salt blend. Furthermore, the SEAC rapporteurs appreciate the information on the expected price increase of such stabilized blend. This information has been taken into account when drafting the SEAC opinion and proportionality assessment. It would be helpful to get more information on the *“required reasonable transition period”* (as noted in this comment) in order for industry to develop better stabilised ammonium blends based on polyphosphates.  |
| **1173** | **Date:** 2014/12/03 15:32**Type:** BehalfOfAnOrganisation**Org. type:** Academic institution**Org. name:** University of Ljubljana, Biotehnical Faculty**Org. country:** Slovenia**Company name confidential:** **No** | **Comment:**There is one producer of cellulose insulation in Slovenia. The production in Slovenia started in the end of year 2011. Company sell loose cellulose insulation packed in PE bags. They produce only one type of insulation with boric acid and fire retardant. Fire retardant according to supplier information is “Mixture of light metal compounds”. Exact composition of fire retardant is manufacturers trade secret. Manufacturer of the fire retardant is an EU chemical company. Slovenian producer has never used ammonium salts. In Slovenia there are many importers of cellulose insulation from EU producers. Some of these insulations probably contain ammonium salts. |
| **Answer 1:**There is one producer of cellulose insulation in Slovenia. The production in Slovenia started in the end of year 2011. Company sell loose cellulose insulation packed in PE bags. They produce only one type of insulation with boric acid and fire retardant. Fire retardant according to supplier information is “Mixture of light metal compounds”. Exact composition of fire retardant is manufacturers trade secret. Manufacturer of the fire retardant is an EU chemical company. Slovenian producer has never used ammonium salts. In Slovenia there are many importers of cellulose insulation from EU producers. Some of these insulations probably contain ammonium salts. Average insulation thickness for cellulose insulation in Slovenia:- 30 cm in roofs and attic- 22 cm in walls wood frame constructions  |
| **Answer 2:**For Slovenia there is lack of data on how many buildings are insulated with cellulose insulation. After the limitation of boron part of imported cellulose insulation contains ammonium salts. The ratio between Slovenian and imported cellulose insulation is around 40:60. |
| **Answer 3:**Alternatives without boron-based formulations are rare, expensive and not enough tested. These formulations are usually based on organic biocides. There is lack of performance data and human health during service life of such cellulose insulation. On my opinion boron–based formulations are the best choice. Boron provides biological and fire resistance. For biological resistance 3% to 5% of boron compounds per mass is needed, while for fire resistance much more then 5,5 % is needed. Because of the later, fire retardants have to be added. |
| **Dossier submitter response:**Thank you for your comments. Considering health effects of boron compounds with regard to reprotoxicity, we - as dossier submitter - do not consider them as desirable alternatives, although they are still legally allowed within the limit of 5.5% in mixtures. |
| **RAC Rapporteurs comments:**The information on the market in Slovenia that there are many importers and obviously only one producer and the observation that cellulose insulation contains ammonium salts supports the need for a community wide action (as proposed by the dossier submitter). RAC notes that the four borate substances with harmonised classification as Repr. (1B) [boric acid, disodium tetraborates, tetraboron disodium heptaoxide hydrate, diboron trioxide] are currently listed in the Candidate List of SVHC, which is the 1st step of the authorisation risk management process. One of the aims of authorisation is to replace the substance with suitable alternatives or technologies. If the 4 boron compounds are listed in Annex XIV of REACH it will likely result in other EU manufacturers further exploring the possibility of researching the stabilisation of inorganic ammonium salts as a suitable alternative especially as there is a current absence of knowledge on other suitable substances or techniques to boron compounds. Two additional borate substances [disodium octaborates] have been proposed for harmonised classification as Repr.1B. The proposed classification at a general concentration limit of 0.3% was adopted by RAC. |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |
| **1179** | **Date:** 2014/12/15 12:37**Type:** BehalfOfAnOrganisation**Org. type:** Company**Org. country:** Germany**Company name confidential:** **Yes** | **Comment:**The inorganic ammonium salts have been used as flame retardants in the building/insulation materials. However, the dominant market for inorganic ammonium salts is found in other industries, predominantly as fertilizer. The decomposition into ammonia and phosphate is a necessary property for fertilizers. The issue generated from an improper replacement of boron salts was based on new legislation and the necessity to supply in due time. The building/insulation industry selected inorganic ammonium salts based on acceptable properties as flame retardants. Other criteria were not sufficiently examined. Agro-chemicals (incl. inorganic ammonium salts) were available in large volumes. Other inorganic ammonium salts but especially those at a higher cost/Kg level have not sufficiently been considered due to price considerations. We therefore recommend to expanded the selection criteria for flame retardants and include properties beyond flammability testing. To restrict all inorganic ammonium salts, independent of their chemical structure is not reasonable. It is the dosage and not the substance itself which is the problem. Other parameters (e.g. concentration and pH value) can easily control the potential emission of ammonia gas. It seems essential to improve the functional testing of alternative flame retardants in their use as building/insulation material. Specific tests can be added to monitor and reduce the critical values, like it has been done for this ECHA initiative. We strongly recommend to improve the end use restrictions rather than to ban entire chemical clusters. Flame retardants free of inorganic ammonium salts: Inorganic flame retardants not using inorganic ammonium salts are now available for the building/insulation industry. They are dedicated to replace boron-salts as well and can be supplied in large volumes. Flame retardant properties as well as odor and degradation behavior are according to the industry expectation. However, it required effort in research, testing and production scale-up so that our market introduction was delayed and came after the introduction of the new legislation (replacement of boric acid/boron salts). […] is a startup company and specialized on flame retardants for cellulose materials. |
| **Answer 1:**The industry used predominantly flame retardants as powder. Wood fibre Industry uses a wet application process and recycled cellulose insulation uses a dry process. Often used are Ammoniumphosphate or -sulfates but also blends with organic components can be found. The insulation thicknesses vary a lot depending on the desired end use.The ammonia release depends on several parameters. It is a function of time, humidity, temperatur, the pH value and a material constant. Other parameters (e.g. diffusion, density, polarity) can influence as well. |
| **Answer 2:**No |
| **Answer 3:**Yes, but this is the core of our activity and we cannot dislose recipes or chemical details of our products. |
| **Answer 4:**No |
| **Answer 5:**The capacity of the specific industry to conduct research projects and to drive chemical developments toward new candidates seem quite limited. Hasty introduction of products or legislation may lead to improper technical solutions. |
| **Dossier submitter response:**Thank you for your comments.Our proposal is not a general ban of inorganic ammonium salts and gives the possibility to industry to use stable ammonium salts in the testing conditions. |
| **RAC Rapporteurs comments:**The rapporteurs support the dossier submitter’s proposal not to ban the use of ammonium salts in cellulose insulation material but to set an emission limit as this allows for the continued use of ammonium salts and techniques to achieve compliance below a level where the risk is controlled.While it is stated that the concentration (as well as pH) can easily control the emission of ammonia gas there is insufficient information to identify a safe concentration limits for the various ammonium salts and therefore is not suitable as an alternative risk management option.This comment confirms the assumption that there are already non-boron/non-ammonium salts flame retardants for cellulose material on the EU market. As the names of these flame retardants are not published the potential hazards & risks from their use as alternatives cannot be assessed. Irrespective of the unknown hazards of the alternatives, this information suggests that the SVHC identification of borates and the probably provisional ban of cellulose material containing ammonium salts in France in 2013 stimulated the development of alternative blends for cellulose insulation.  |
| **SEAC Rapporteurs comments:** See the dossier submitter's response. |
| **1180** | **Date:** 2014/12/15 16:39**Type:** BehalfOfAnOrganisation**Org. type:** Industry or trade association**Org. name:** Pinfa - Cefic**Org. country:** Belgium**Company name confidential:** **No** | **Comment:**General comments box (max 2500 characters)Ammonium salts are recognized to be non-toxic and have been developed as safer alternatives to previously used chemicals. The only risk with their use is a possible release of ammonia gas in conditions of high humidity and temperature, pH. In indoor environments this can cause potential irritation to the respiratory tract and eyes. Ammonium salts and ammonia gas are considered to have no long-term or chronic toxic effects. Ammonia salts and ammonia gas are not carcinogenic, mutagenic, teratogenic or impacting on the immune system. Ammonia gas occurs naturally e.g. from animal excretions. Therefore, the proposed restriction should target ONLY substances and applications where a risk of ammonium emissions at levels susceptible to cause irritation may occur, in order to avoid restricting products/applications where ammonium salts can provide fire safety performance without using possibly more toxic or problematic substances.Therefore, the restriction should fix an emission limit (the 3 ppm proposed by the French authorities is justified and appropriate) and should be precisely defined to cover only the three substances identified as problematic:- ammonium sulphate [CAS No 7783-20-2]- ammonium dihydrogenorthophosphate [CAS No 7722-76-1]- diammonium hydrogenorthophosphate [CAS No 7783-28-0]The specific local risk of ammonia gas irritation only occurs in cellulose based materials which are liable to accumulate humidity: ammonium salts should remain permitted in insulation products which are not subject to such risks because of treatment or structure.The risk is only indoors. We understand however that a ban in “indoor materials only” is not necessarily workable, as building companies might incorrectly use “outdoors” materials indoors. However, the ban should not cover products which are structurally designed for outdoor use (eg insulation built into exterior cladding).The ban should allow possibility for exceptions if it can be demonstrated that an ammonium salt, used to improve fire safety or achieve building fire resistance standards, is NOT subject to this specific risk (in indoor cellulose insulation material), eg because the salt is treated to ensure stability, or encapsulated in some way, or combined with other products, which prevent possible ammonia emissions. Such technologies are not yet on the market but could possibly be developed to enable continuing use of ammonium salts (a recognized, non-toxic, effective fire safety solution) and the ban should not prevent such positive innovation. |
| **Dossier submitter response:**Thank you for your comments.Our proposal is not a general ban of inorganic ammonium salts and gives the possibility to industry to use stable ammonium salts in the testing conditions. As pointed out, the 3 ppm emission limit is deemed appropriate.During the tests performed by the French CSTB in 2013, at least 3 different inorganic salts demonstrated the capability of gas-phase ammonia generating when incorporated in cellulose insulation. For the majority of inorganic ammonium salts (including ammonium polyphosphates), the behaviour upon hydration and the mechanisms to release ammonia can be normally considered quite similar. It cannot be ensured other ammonium salts than the 3 cited ones will not lead to ammonia emission. Therefore, a grouping entry based on the salts stability behaviour upon hydration – and not limited to the 3 substances identified in France - is considered justifiable. |
| **RAC Rapporteurs comments:**The proposal to limit only certain ammonium compounds has been considered in the restriction proposal and by RAC.Although some specific ammonium salts with potential to generate ammonium gas are identified, a comprehensive list of the ammonium compounds of concern excluding those compounds proven to be negative for ammonia release is not available. Thus, to prevent hazardous effect from any ammonium salt that could be used as flame retardant, it seems inappropriate that the restriction targets only selected compounds. In the absence of scientific evidence to support the statements that only 3 salts are problematic the rapporteurs agree with the proposed group entry approach of the dossier submitter.The RAC rapporteurs also support the dossier submitter’s proposal not to ban the use of ammonium salts in cellulose wadding but to set an emission limit as this allows for the continued use of ammonium salts and techniques to achieve compliance below a level where the risk is controlled.As the restriction proposal is on cellulose insulation material as it is intended to be delivered on the market either as loose material, solid rolls, panels, or other insulation articles containing cellulose material treated with inorganic ammonium testing of the material/products should be conducted on taking into account the final conditions of use of the product type which is on the market. When new products of encapsulated cellulose material will be developed and available which meet the (national) standards for insulation and fire resistance performance, these will also have to fulfil the conditions of the restriction like non-encapsulated cellulose material. Testing should be done on the final mixture material or article that is intended to be placed on the market. Testing of insulation material covered by plastic sheets or other suitable sheets should be considered when the Commission decides to launch a revision or amendment of the CEN/TS 16516 standard test in order to develop and validate specific standard test parameters to detect ammonia gas from loose and solid forms of cellulose insulation material. RAC will take possible exemptions for outdoor articles into consideration if these are structurally designed in a way that any indoor use and thus any relevant risk from indoor exposure is unlikely.In addition, the Forum’s advice on possible enforcement problems due to labelling or misuse of labelled material will be considered.  |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |
| **1192** | **Date:** 2014/12/18 13:54**Type:** MemberState**MS name:** Slovenia**Company name confidential:** **No** | **Comment:**According to the data we have the majority of cellulose wadding used in Slovenia does not contain ammonium salts. This is why we do not see any significant impact of this restriction. |
| **Answer 1:**In Slovenia there is one producer of cellulose insulation (form: loose cellulose insulatin packed in PE bags). There are also many importers from EU countries. Slovene producer does not does not use ammonium salts.In cellulose insulation which is put on Slovene market from other EU manufacturers there might be ammonium salt. Average insulation thickness for cellulose insulation in Slovenia:-30 cm in roofs in attic-22 cm in walls wood frame constructions |
| **Answer 2:**We do not have inforation how many homes or non-domestic buidings are insulated using cellulose wadding materials per year in Slovenia. We can say that the number is increasing in last five year due to the fact the type of construction has changed in a country. There is no monitroing data/studies on ammonia measurement available and we are not aware of this problem. We see that release of ammonia gas is possible when the construction is not made in a proper way.If you use ammonium salts with bad construction where diffusion might happen there might be a problem.This is not the case in Slovenia. But we do understand the potential problem of ammonia gas relaese. |
| **Answer 3:**According to the knowledge from a SI reasearcher alternatives without boron based formulations are rare, expensive and not enough tested. These formulations are usually based on organic biocides. There is lack of performance data and human health during service life of such cellulose insulation.At our opinion boron-based formulations are best choice due to the fact that boron provides biological and fire resistance. For biological resistance 3-5% of boron compounds per mass is needed, while for fire resistance much more than 5,5% is needed. Because of the later, fire retardands have to be added. |
| **Answer 4:**We do not have any data from National Poison Centres or the hospitals regarding the exposure to ammonia or other complaints.There are cases (no official evidence) that workers/ proffesionals were complaining regarding problems with irritation of eyes but it not clear that from the ammonia but might be more form the particles or dust and not using the protective glasses. |
| **Answer 5:**There is no national legislation on the use of ammonium salts in insulation material in Slovenia. |
| **Dossier submitter response:**Thank you for your comments. Considering health effects of boron compounds with regard to reprotoxicity, we – as dossier submitter – do not consider them as desirable alternatives, although they are still legally allowed within the limit of 5.5% in mixtures. |
| **RAC Rapporteurs comments:**The answers were noted (with some overlap to the response from the University of Ljubljana). The RAC rapporteurs note that the four borate substances with harmonised classification as Repr. (1B) [boric acid, disodium tetraborates, tetraboron disodium heptaoxide hydrate, diboron trioxide] are currently listed in the Candidate List of SVHC, which is the 1st step of the authorisation risk management process. One of the aims of authorisation is to replace the substance with suitable alternatives or technologies. If the 4 boron compounds are listed in Annex XIV of REACH it will likely result in other EU manufacturers further exploring the possibility of researching the stabilisation of inorganic ammonium salts as a suitable alternative especially as there is a current absence of knowledge on other suitable substances or techniques to boron compounds. Two additional borate substances [disodium octaborates] have been proposed forharmonised classification as Repr.1B. The proposed classification at a general concentration limit of 0.3% was adopted by RAC. |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |
| **1196** | **Date:** 2014/12/18 23:48**Type:** BehalfOfAnOrganisation**Org. type:** Industry or trade association**Org. name:** ECIA European Cellulose Insulation Association**Org. country:** Belgium**Company name confidential:** **No****Attachment confidential:** **No** | **Comment:** |
| **Dossier submitter response:**Thank you for your comments.We fully agree with the comment made. In this line, our proposal is not a general ban of inorganic ammonium salts and gives the possibility to industry to use stabilized ammonium salts in the testing conditions. |
| **RAC Rapporteurs comments:**Noted. The RAC rapporteurs consider there is a need to control via restriction the use of ammonium salts in cellulose insulation to ensure that the emissions from mixtures and articles contained in the home are controlled and supports the dossier submitter's proposal to limit the emission to less than 3 ppmV. |
| **SEAC Rapporteurs comments:**See the dossier submitter's response. |