Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Inorganic ammonium salts

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

ECHA/SEAC/RES-O-0000005359-66-03/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 3 March 2015) and SEAC's opinion (adopted 10 June 2015)

3 March 2015

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

10 June 2015

ECHA/SEAC/RES-O-0000005359-66-03/F

Opinion of the Committee for Risk Assessment

And

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical names:	**Inorganic ammonium salts**
EC No.:	Not relevant
CAS No.:	Not relevant

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinion.

PROCESS FOR ADOPTION OF THE OPINION

France has submitted a proposal for a restriction in accordance with Article 129 of the REACH Regulation together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***18 June 2014***. Interested parties were invited to submit comments and contributions by ***18 December 2014***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Agnes Schulte**

Co-rapporteur, appointed by RAC: **Yvonne Mullooly**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***3 March 2015*.**

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Cees Luttikhuizen**

Co-rapporteur, appointed by SEAC: **Flaviano D'Amico**

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***10 March 2015***.

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***18 March 2015***. Interested parties were invited to submit comments on the draft opinion by ***18 May 2015***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***10 June 2015***.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by a simple majority*** of all members having the right to vote. A minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

OPINION

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction by the dossier submitter on inorganic ammonium salts (as modified below) is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

Substance	Conditions of restriction
Entry [#]. Inorganic ammonium salts	1. ***Articles*** *containing cellulose mixtures treated with inorganic ammonium salts, intended for the purpose of insulation shall not be placed on the market or used, after "dd/mm/yyyy[1]", where the release of ammonia from the article in a 24 hour period, during the duration of the test[2] would result in an emission of ammonia greater than 3 ppmV (2.12 mg/m³).* 2. *Cellulose* ***mixtures*** *treated with inorganic ammonium salts intended for the purpose of in situ insulation, shall not be placed on the market or used after "dd/mm/yyyy", where the release of ammonia in a 24 hour period during the duration of the test would result in an ammonia concentration greater than 3 ppmV (2.12 mg/m³).* *The technical specification documentation and any associated packaging, as relevant, should clearly indicate the conditions of use including the maximum loading rate permitted of the cellulose mixture, given in density and thickness, to comply with the maximum 3 ppmV (2.12 mg/m³) emission limit for ammonia in a 24 hr period.* 3. *By way of derogation to point 2 above, mixtures of cellulose insulation treated with inorganic ammonium salts which are only used for the manufacture of cellulose insulation articles do not have to comply with the 3 ppmV (2.12 mg/m³) emission limit of ammonia where it can be shown that the*

[1] RAC recommended the transition period to be fixed following discussions at SEAC
[2] Test/test method to be confirmed by CEN. The Commission confirmed their intension to develop, by the entry into force of this regulation, technical specifications for the testing of mixtures or articles containing cellulose treated with inorganic ammonia salts under standard room parameters (size, ventilation) at 90% relative humidity for a period of at least 14 days were followed.

	article placed on the market or used has been tested and complies with paragraph 1.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on inorganic ammonium salts (as modified below) is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

The conditions of the restriction proposed by SEAC are:

Column 1. Designation of substance	Column 2. Conditions of restriction
Inorganic ammonium salts	Shall not be placed on the market in cellulose insulation from [24] months after of entry into force of this Regulation, unless: - Emission of ammonia gas of such materials is below 3 ppm according to the horizontal measurement/test methods of Technical Specification CEN/TS 16516 and: - Specific test parameters are applied in terms of duration (14 days), relative humidity (90 +/- 5), "Attic insulation" area specific emission rate (1.25 $m^3.m^{-2}.h^{-1}$), and "Wall insulation" area specific emission rate (0.5 $m^3.m^{-2}.h^{-1}$). Cellulose insulation thickness and density are adapted to the foreseen use.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

Justification for the opinion of RAC

INTRODUCTION

The proposal is to limit the concentration of ammonia that is emitted in any 24 hour period from insulation mixtures or articles containing cellulose treated with inorganic ammonium salts to 3 ppmV (2.12 mg/m^3), rather than to limit the type or quantity of inorganic ammonium salt that can be used to treat cellulose.

The Forum with their draft advice (September 2014) noted of their preference to set a concentration limit for the content of inorganic ammonium salt found in the insulation material. However, based on the information submitted in the dossier and through the public consultation, RAC is not in a position to advice on such a concentration limit due to lack of information on the contributions of solubility, pH, and temperature to any subsequent emissions.

Therefore, the justification for RAC's approach is that information is not currently available on the type, stability or quantity of the various inorganic ammonium salts nor the water content of the insulation material that would be required to substantiate a restriction based on a content limit for ammonium salts. RAC considers that a group entry for inorganic ammonium salts, specifying an emission limit for mixtures of cellulose insulation and for insulation articles containing cellulose treated with inorganic ammonium salts, is appropriate.

From the available information, RAC considers that the relative humidity is the main key environmental factor that contributes to the release of ammonia from treated cellulose insulation and the testing of such materials or articles needs to be conducted under standard room conditions (which should be defined in a technical specification of the standard test method) with the exception of relative humidity which should be set at 90%.

In addition, as the final conditions of use of such materials and articles will vary from Member State to Member State it is particularly important for cellulose mixtures that the conditions of use are laid down in technical specifications and packaging labels as relevant.

RAC considers that for any articles manufactured from cellulose mixtures treated with inorganic ammonium salts intended as insulation articles, it is the final article that is required to comply with the restriction. The obligation will be on those placing on the market cellulose mixtures treated with inorganic ammonium salts or insulation articles made from cellulose treated with inorganic ammonium salts, to develop a stable mixture or article that achieves this requirement.

IDENTIFIED HAZARD AND RISK

Targeting of the information on hazard and exposure

Cellulose insulation is primarily used to insulate attic spaces (90%) and internal walls of buildings rather than floors or the external walls of such premises.

There are two primary categories of cellulose insulation used and placed on the market:
(1) loose fill material (mixture) that is blown into the area or space to be insulated and
(2) compressed cellulose which is sold as rolls or in rigid, semi rigid panels of insulation (articles).

It is estimated that up to 12% of cellulose insulation is composed of a blend of flame retardants and antifungal compounds while the remaining 85-90% of the material is composed of cellulose fibres from recycled materials such as paper, transport boxes, phone books etc.

RAC is not aware of the use of cellulose mixtures treated with inorganic ammonium salts in composite integration/construction panel type insulation articles, solely intended for outdoor exterior use (e.g. cladding). RAC considers that cellulose insulation articles containing inorganic ammonium salts, solely intended for outdoor exterior use, are unlikely to result in exposure to the indoor environment, although specific evidence for this is lacking.

RAC also considers that cellulose insulation treated with inorganic ammonium salts intended for use on the interior surface of an exterior wall or within the cavity area between the internal and external wall can result in exposures to the indoor environment and is therefore not considered the same as an article intended for outdoor exterior use.

Insulation is an important market outlet for recycled cellulose materials. Currently, across the EU, boric compounds are the primary substances used to treat cellulose insulation material to achieve the specifications for flame retardant requirements.

Following the classification of boric acid as toxic to reproduction Category 1B under CLP, in 2011, the French Authority (CCFAT/DHUP Direction of habitat, urban planning and landscapes) took the decision to no longer issue technical approvals, for the use of boric salts in cellulose insulation materials in France. As a result, the cellulose insulation sector suddenly changed to inorganic ammonium salts (in powder form) as an alternative flame retardant with limited experience in the treatment process. By the end of 2012, 20,000 homes in France were insulated with cellulose insulation that had been treated with inorganic ammonium salts.

Information on hazard(s)

Complaints and reports of smells in homes resulted in the French Authorities undertaking investigations. These detected ammonia in homes that were recently insulated with cellulose insulation which had been treated with inorganic ammonium salts. Following these investigations the French Authorities concluded that the source of the complaints was ammonia coming from the recently installed cellulose insulation material treated with inorganic ammonium salts.

Exposed people from the sites insulated with cellulose insulation treated with inorganic ammonium salts were examined in two studies (CCTV[3], 2013a,b, Annex 3, 4). The French poison control centres (CCTV) found respectively 15 (of 19 exposed) people and 22 (of 43 exposed) people had complaints (mainly mild or moderate symptoms of irritation of mucous membranes). The residents complained about irritation of the eyes, cough, nasal irritation, irritation of the pharynx, other respiratory signs (difficulty in breathing, bronchiolitis) and bronchospasm (listed in almost the same order of frequency in both studies).

CCTV considered in the majority of cases the causality of ammonia as likely to be caused by the cellulose insulation material that was treated with inorganic ammonium salts. In some cases symptoms were reported to start 2-3 days after installation and persisted for up to 16 days after cessation of exposure. Symptoms disappeared following removal of the insulation material.

The dossier also reported that the ECIMA[4] recorded 115 reports of complaints in France

[3] French committee of toxic vigilance.
[4] European Cellulose Insulation Manufacturers Association.

while many complaints were made on Internet forums. As the information given on the nature of the symptoms (either smell or/and irritation) and the likelihood of a link was not assessed, these records do not add to the overall evidence of residents suffering from irritation symptoms. The dossier submitter proposed that this information may support the number of cases being underestimated.

The toxicity of gaseous ammonia related to the observed clinical signs was characterised as irritation to the respiratory tract and eyes following acute and sub-acute inhalation exposure (for days or some weeks). Summaries of other hazards resulting from systemically available ammonia and from dermal and oral exposure are reported in the dossier. They were not considered for the risk assessment of this proposal as other hazards do not correspond to the local irritation effects on the mucous membranes. In this opinion the description of the hazards is targeted to the endpoint 'irritation to the respiratory tract (and eyes)'.

There is no evidence from the observed occupational cases and from those residents making complaints, and living in houses that were recently insulated with cellulose insulation, that ammonia emissions were related to other health effects including de-novo generation of asthma. Asthma-like symptoms were observed in two out of five workers of a plumping company who experienced irritation symptoms after cellulose wadding insulation had been laid down at the construction sites (Annex 4 of the Background Document). The follow-up visit to a physician did not confirm that the asthma was related to the wadding material (negative challenge test) in one case, and in the other case the symptoms disappeared in a few weeks (which contradicts the diagnosis of asthma). Other studies mentioned in the dossier that referred to case reports of occupational asthma were of limited validity as individuals were not exclusively exposed to ammonia, provocation testing (confirming that ammonia was the monocause) by a physician is lacking (Lee et al., 1993, Weir et al. 1989), and in the study of Ballal et al. 1998, a higher risk of asthma was reported for smokers only.

The odour of ammonia gas is pungent. Exposed people may feel affected by the unpleasant odour (smell was recorded in CCTV 2013a,b), but the odour alone does not cause any harm. RAC shares the view of the dossier submitter that the unpleasant odour of ammonia or the general discomfort from the pungent odour it causes, is not considered for the hazard assessment.

For the irritation effects on the respiratory tract and eyes, the dossier proposes a LOAEC of 50 ppmV (35 mg/l) using the Verbek et al. study (1977) as a key study. In that study, self-reporting of symptom ratings for the sum of symptom scores were increased and mild eye and throat irritation occurred at 50 ppmV following 30, 60 or 120 min of exposure.

In addition, RAC finds the study of Smeets et al. (2006) informative. It estimated the intranasal lateralization threshold (LT) of ammonia vapour which is an objective measure of sensory irritation. Within a 2-week period the odour threshold and the LT was obtained twice in 24 healthy, non-smoking volunteers using a static and a dynamic test method (airflow 20 l/min). In this study mean LTs for ammonia were found at 31.7 (static) and 60.9 ppmV (dynamic). In the same range Wise et al. 2005 reported LTs of 37-67 ppmV ammonia.

Smeets and co-authors noted that in individuals, some fluctuations in LT (as well as in odour threshold) is reported to occur due to differences in nasal patency, time of day, health conditions. The mean on the results of static and dynamic methods (46.44 ppmV) is similar to the 50 ppmV of the Verbek study.

The summarised data on the dose-response effectiveness of ammonia vapour (Table 6 of the Background Document, on studies evaluated by the Nordic Expert Group (2005) indicated that symptoms of irritation could occur even at lower concentration than 50 ppmV ammonia. Increased ratings for symptom scores and olfactory symptoms at 10-20 ppmV were reported in 33 volunteers. The original publication (No. 80 in the Nordic Expert Group

document, which is only an abstract (Hoffmann et al., 2004)) concluded that the ratings were relatively low (without details at 10 and 20 ppmV ammonia). The corresponding full publication of Ihrig et al.(2006), stated that the mean intensity of respiratory and irritative symptoms lies between 'not at all' and 'hardly at all' even at 50 ppmV. Unfortunately the eye irritation reported in 9% of volunteers at 50 ppmV in the abstract was not documented as a separate effect by Ihrig et al. (2006). RAC takes this study as supportive for the LOAEC of 50 ppmV.

Increased average ratings of eye discomfort (burning, irritated or running eyes) were recorded for 12 healthy volunteers exposed to 5 and 25 ppmV during 3 hours of exposure (Sundblad et al., 2004). Three participants experienced secretion from the nose, and two reported increased cough after exposure to 25 ppmV. Sundblad et al. found that significantly higher discomfort of the eyes was already self-reported at 5 ppmV ammonia. These were estimated as an average pre/post exposure increase of 3.6 mm in a 0-100 mm visual analogue scale (VAS). Although the effect was concentration-related (14.8 mm reported at 25 ppmV), the levels of severity gained were minor. Six mm in the self-rating corresponded to 'hardly at all, while 'somewhat' corresponded to 26 mm on the 100 mm VAS scale. Other irritation effects observed at 25 ppmV ammonia were also in this scale. Nose burning, irritation or runny nose reached 15.3 mm and throat or airway discomfort reached 14.2 mm on the VAS scale.

RAC is aware of some degree of variability in the irritation threshold. Based on the available information RAC chose 50 ppmV as a robust LOAEC. This value is mainly based on the Verbek study and the recent studies of Smeets et al. that use the objective lateralization threshold method to estimate the irritation threshold.

Calculation of the DNEL

Based on the LOAEC of 50 ppmV, a short-term DNEL was calculated by the dossier submitter. An assessment factor of 3 was proposed to adjust the LOAEC to a NOAEC and an intraspecies factor of 10 was used to cover differences in susceptibility among individuals in the general public.

RAC considers an assessment factor of 3 as appropriate to adjust for the lack of a NOAEC.

JRC (2005, The INDEX project) referred to a study of Shim and Williams (1986) who observed that 80% of 60 asthmatics claimed about an exacerbation of asthma following exposure to household cleaners containing ammonia.

Among the cases reports (Annex 4 of the Background Document) there was one case of asthma decompensation of a known asthmatic, a 6-year old child. Although other causes were not addressed, the data may provide some indication that there is a potential of a more severe course of the asthmatic symptoms. This case could be related to the observation that known asthmatics are expected to be particularly vulnerable to respiratory irritants. In contrast, the study of Sigurdarson et al. (2004) (cited in Nordic Expert Group, 2005) could not find changes for pulmonary function or bronchial hyper reactivity after metacholine challenge when 6 healthy volunteers and 8 subjects with mild asthma were exposed to 16-25 ppmV ammonia for 30 minutes.

Sensitivity in terms of a response to a lower minimum effect concentration cannot be excluded for asthmatics, as no data is available (to the knowledge of RAC) that establishes a lower LOAEC for ammonia in this group.

Although an exacerbation of symptoms in people with an asthma history cannot be excluded, RAC proposes to apply an assessment factor of 10 (default value for consumers) to sufficiently protect all parts of the population including children, elderly and asthmatics.

Table 1: Short-term DNEL for the general public exposed to gaseous ammonia (for the endpoint 'irritation to the respiratory tract')

LOAEC	Correction for lack of NOAEC AF	Intraspecies differences AF	DNEL LOAEC/ (3 x 10)
50 ppmV (35 mg/m³)	3	10	**1.7 ppmV** (1.3 mg/m³)

Conclusion: RAC concluded that the description of the hazards should be targeted to the endpoint 'irritation to the respiratory tract (and eyes)'. RAC has considered the degree of variability in the irritation threshold, and based on the available information RAC has chosen 50 ppmV as a robust LOAEC. RAC concurs with the calculation of a short-term DNEL and considers the assessment factor of 3 as appropriate to adjust the LOAEC to a NOAEC.

Information on emissions and exposures

Seventeen homes insulated with cellulose insulation were tested by the French Authorities, 14 of which made complaints (CETE, 2013). At three of the 14 sites the level of ammonia concentrations from measurements using diffusion tubes (8 h, detection limit (DL) 2.5 ppmV) grossly matched the concentrations from spot measurements (DL 0.25 ppmV). At two of the sites no ammonia was detected and this may or may not be explained by the point in time when the measurements were undertaken.

The ammonia concentrations at eight other sites were ≤ 2 ppmV in the spot measurements (at the attic or the living-area or both) and were negative in the diffusion tube method (which is consistent as it is below the detection limit of the diffusion tube). The highest value measured was 3.1 ppmV. This data (CETE, 2013) is not published.

In addition another set of (spot) measurements from the French committee of toxic vigilance coordination reported from three properties (in 2012) and four properties (in 2013). Ammonia was found at six of the seven properties.

The maximum concentration measured was 9 ppmV (at one property), up to 3 ppmV (at two properties) and below 1 ppmV (at three properties) (CCTV, 2013 1,b).

As all measurements were retrospective, it is unclear what time lag existed between the installation of the insulation and the beginning of the symptoms. RAC considers that as complaints about odours followed rather rapidly after installation of the material and that the values measured by the French Authorities may have underestimated the concentrations in the early phase after installation. This conclusion is also supported by dynamic testing of the cellulose insulation material, under controlled conditions using the test chamber method according to the principles of test method EN ISO 16000 Standards for the characterisation of volatile pollutant emissions from building products (series of reference standards for the regulatory labelling of volatile organic compounds [COV]) and in particular, the emission test chamber method: *EN ISO 16000-9: Indoor air – Part 9: Determination of the emission of volatile organic compounds from building products and furnishing – Emission test chamber method (AFNOR,2006)*that was undertaken by CSTB. Eleven samples, of treated cellulose insulation, were tested in accordance with the test chamber method EN ISO 16000-9. This revealed that under conditions of high relative humidity (>70%) ammonia is emitted from the material but that emissions levels decrease with time. This evidence supports the RAC's conclusion that measured values may have underestimated the ammonia concentrations in the early phase after installation. RAC agrees that the evidence reported in the dossier, linking the complaints of ammonia odours with the cellulose insulation material containing inorganic ammonium salts is sufficient to

conclude that the use of inorganic ammonium salts in cellulose insulation was the root cause of the irritative effects on eyes and respiratory tract reported in the complaints.

The key factors that contribute to the release of the ammonium salts from cellulose insulation are

- Relative Humidity (>70%);
- Loading rate (density/thickness) of cellulose insulation used.

The "type/area" of insulation is also important, with cellulose insulation material in the attic emitting more ammonia than cellulose insulation from walls. As a consequence any measures to ensure compliance of attic insulation with the emission limit value should also ensure compliance with wall type insulation.

The alkaline pH and moisture content of the cellulose insulation and of any material that may come into contact with the insulation *in situ* also plays a role in promoting emissions. However, there is insufficient scientific information in the dossier to determine what levels of moisture in the material are critical to this release.

In addition, the dossier submitter tested different types of attic insulation and found there was also a variation of ammonia emissions within different suppliers. However, they were not able to establish the reasons for this and whether it related to the type and concentration of ammonium salt used, moisture content or pH etc.

Another factor that impacts on the level of ammonia in a specific area is a lack of ventilation. The installation of a ventilation system in homes may cause the diffusion of ammonia into the living space (as obvious in one complaint in CCTV, 2013a) instead of limiting the ammonia emissions in the attic space.

The insulation technique also impacts on the ammonia concentration (e.g. the airtightness of the floor, waterproof structural elements that prevent the insulation material from becoming wet following water penetration or condensation). The presence of such techniques as vapour barriers prevents exposure to humidity, while high pH materials will increase the amount of ammonia released into the living space. The dossier submitter however indicated that the cellulose insulation material might become humid after installation and then emit ammonia. It is not currently clear to RAC whether a suitable technique using water proof packaging (of rolls or panels of insulation material) is feasible and available.

As the actual measured data in homes is of very limited use for a number of reasons e.g. the small number of samples taken, the sampling technique & more importantly the timing of the sampling following installation, an assessment of exposure under worst case exposures conditions was provided by the dossier submitter based on test data from the dynamic chamber tests. These tests have demonstrated that emissions, under worst case environmental conditions, will peak and then decrease with time. Eleven samples of cellulose insulation material treated with inorganic ammonium salts in powder form and two samples of bio insulation material treated with liquid inorganic ammonium salts were tested to establish which samples emitted the most ammonia.

The emission results from the bio based insulation showed that this material did not emit ammonia levels of concern. Note: Bio insulation is treated with liquid rather than powder ammonium salts. It is not technically possible to treat cellulose insulation with liquid ammonium salt.

Four of the cellulose insulation samples that emitted the highest amount of ammonia were subsequently tested further in a test chamber that was scaled to represent a standard reference room in accordance with the CEN/TC 16516 standard. Although the air flow rate

from the CEN standard is lower than the value indicated in the REACH guidance[5] RAC considered the use of the CEN reference room parameters acceptable.

Table 2: Emission profile of categories of insulation materials tested in the static test and dynamic test chamber

Insulation Material	Max conc. of NH_3 ppmV emitted (24hr static[6])	Max conc. NH_3 ppmV (Dynamic chamber test[7])
Category 1 Insulation material	**573**	**316**
Category 2 Insulation material	116	57
Category 3 Insulation material	105	85
Category 4 Insulation material	15	6
Bio based insulation	4-5	1.2

The test chamber loading rate of 12 kg per m² equated to the cellulose insulation loading rate in France. This was based on a cellulose insulation thickness of 30 cm. RAC notes that insulation is measured in terms of its 'R' value or 'U' value (W/m^2 K). While both values are a measure of insulation effectiveness, either value can be used and extrapolated to the other. The R value is generally referenced in the USA, while U values are generally referenced in the EU. The lower the U value, the better the insulation material.

The R value for Cellulose Insulation[8] is in the order of 3.2-3.8 per inch thickness, with 12 inches providing approximately an R Value of 38.4-45.6. This equates to a European U value of between 0.145 and 0.12.

Data from the EURIMA[9] indicate U values in the EU range between 0.75 in warmer regions to 0.13 in colder regions. Therefore, RAC considers the loading rate of 30 cm/12 inches to represent the worst case loading conditions in the EU. Information received during the public consultation also indicated a loading rate of 30 cm.

Test Chamber results establish that the main environmental factor affecting the release of ammonia is relative humidity, particularly when the RH increases above 70%. The test chamber results demonstrated that up to 50% RH, the emission rate of ammonia from

[5] REACH Guidance R15 ECOTOCTRA & ConsEXPO 0.6 air exchanges per hour (Bremmer *et al*, 2007).
EN ISO Standard 16000-9 0.5 air exchanges per hour.
Chartered Institute Building Services Engineers CIBSE Guidance B (ventilation 2004) 3 air exchanges per hour.
[6] Static test is a test undertaken over 24 hours where no air exchange occurs.
[7] Dynamic testing was undertaken over a period of 28 days under ISO Standard conditions 16000-9.
[8] Source: US Department of Energy. http://energy.gov/energysaver/articles/types-insulation
[9] *www.**eurima**.org/**u-values**-in-europe/*

cellulose insulation is constant, however above 50% RH the emission rate increases exponentially.

Table 3 outlines the average conc. of ammonia emitted from the least stable category of material (Category 1 insulation material) tested which was determined from the following RH 50, 70 and 90%.

Table 3: The average conc. of ammonia emitted from Category 1 material at 50, 70 and 90% values of Relative Humidity (RH) (Source, table 12 of the Background Document)

RH (%)	NH_3 (ppmV)	G (mg/h)
50	4	0.168
70	50	2.1
90	250	10.5

Table 3 demonstrates a significant variation in ammonia emissions between 70 and 90% RH. RAC concluded, based on the scientific data available, the equivalent worst case RH for the living area would be less than 70% RH. Values above 70% RH in the living area would result in the formation of moulds within the home. Findings of the OQAI report[10] which recorded RH levels in French homes between October to April and May to September during the period 2004/2005 reported a 95%ile RH value of 64.7%, further supports the RAC's conclusion. While RAC agrees that the RH values in the living area would be less than 70%, RAC also agrees that a RH concentration of 90% could be reached under worst case conditions (depending on the weather conditions) at certain times of the day for a number of days during the year, in the attic area.

Using the well mixed room model the distribution of ammonia in the living area was calculated.

Between 20 and 50% RH, the dossier submitter assumed a constant emission rate equal to the emission at 50% RH. For ammonia emissions above 50% RH the dossier submitter took into account experimental data up to 80% RH. Table 3 shows there is a significant variation in ammonia emissions between 70 and 90% RH (50 ppmV to 250 ppmV). This distribution gave a concentration of up of 3.736 ppmV NH3 in the living room when the RH distribution was between 20 and 50%.

When ammonia exposures were calculated for the living areas based on RH values between 50 and 70% RH, the resulting median was estimated to be 7.948 ppmV and 95%ile of 21.38 ppmV.

These estimated exposures also correlate with the measured data, thus confirming that the least stable cellulose treated material found on the French market, exceeded the derived DNEL under expected conditions of relative humidity in the home when it was loaded at a rate to achieve the R value requirements under French building standards.

In the presence of water inorganic ammonium salts dissolve and an equilibrium is formed between the ionised and the unionised forms. Depending on pH and temperature, relatively more ammonia (NH_3) will be formed (e.g., at pH7, 0.4%; at pH 8, 10%; at pH 9, 50%), which can be liberated as a gas.

$$NH4^+ + H_2O \leftrightarrow NH_3 + H_3O^+$$

[10] OQAI (2007). Observatory for indoor air quality – National housing campaign: State of the air quality in French housing, Final report, Report DDD/SB-2006-57 (updated May 2007).

Emissions of ammonia have occurred after the cellulose insulation was installed. Solid ammonium salts that are used to treat cellulose insulation can release the ammonium ion in wet/humid conditions crucially when the RH is >80% which is close to the breakpoint in humidograms of several inorganic ammonium salts[11,12,13]. Such conditions could be reached at certain parts of the day in the attic space when the external climate is also humid.

In addition, pH is an important factor influencing NH_3 release. The potential for release of the dissolved ammonia gas is largely governed by the alkalinity (pH) of the solution. pH towards higher values (pH 10-12) will result in a significant loss of NH_3. Lime, plaster and cement are all alkaline and can theoretically react when in contact with the ammonium salts in the cellulose insulation. In one residents complaint, the release of ammonia occurred after the laying of a concrete screed, so it is possible that this may have promoted the reaction, while in another residents complaint release is reported to have occurred when the insulation was in contact with Placoplatre® plasterboard partitions.

During the public consultation on the Annex XV report industry suggested that a derogation should be considered for composite integration/construction panels such as cladding which are intended for outdoor use only. As a follow-up, Industry was asked for more information on the composition of these outdoor articles. No additional information was brought to RAC's attention that cellulose insulation (containing ammonium salts) is used in these outdoor applications.

As the risk of exposure to ammonia from cellulose treated with inorganic ammonium salts occurs when ammonia is released into the indoor environment, RAC considers that insulation articles, such as outdoor cladding/ construction panels, when structurally designed for outdoor exterior are unlikely to result in exposures to the indoor environment.

RAC does however note that loose fill cellulose insulation treated with inorganic ammonium salts and used to insulate the cavity area in external walls or insulation articles such as panels designed to be used to insulate the external wall of a home from the inside could pose an exposure risk. Therefore such products should be covered by the proposed restriction.

Conclusion: RAC notes that the evidence reported in the dossier is sufficient to conclude that the use of inorganic ammonium salts in cellulose insulation was the root cause of the irritative effects on eyes and respiratory tract reported in the complaints. Concerning the key factors that contribute to the release of the ammonium salts from cellulose insulation RAC considers that (i) the loading rate of 30 cm/12 inches to represent the worst case loading conditions in the EU (ii) while RH values in the living area would be less than 70%, RAC also agrees that a RH concentration of 90% could be reached under worst case conditions (depending on the weather conditions) at certain times of the day for a number of days during the year, in the attic area. In addition, while the air flow rate from the CEN standard is lower than the value indicated in the REACH guidance[14] RAC considered the use of the CEN reference room parameters acceptable.

Characterisation of risk(s)

Ammonia concentrations have been estimated using the Well-Mixed Room model based on the data from the chamber tests for the least stable cellulose insulation material tested at levels of relative humidity in the home living area between 70-90% (worst-case approach).

[11] http://www.atmos-chem-phys.net/6/755/2006/acp-6-755-2006.pdf
[12] https://uwspace.uwaterloo.ca/bitstream/handle/10012/3683/Rocsana%20Pancescu%20Thesis_5_.pdf?sequence=1
[13] https://pubweb.bnl.gov/~xujun/research/98JPCpaper.pdf
[14] REACH Guidance R15 ECOTOCTRA & ConsEXPO 0.6 air exchanges per hour (Bremmer *et al*, 2007).
CEN Standard 16000-9 0.5 air exchanges per hour.
Chartered Institute Building Services Engineers CIBSE Guidance B (ventilation 2004) 3 air exchanges per hour.

While RAC considers estimated exposures based on RH values above 70% to overestimate the expected ammonia concentrations in the living area, RAC notes that estimated emissions based on the least stable material, found on the French market, under conditions of 50% RH in the living area, were 3.736 ppm. In addition, the median value and 95%ile value under worst case RH conditions (50-70%) yielded estimated exposures of 7.948 and 21.38 ppm respectively. All of these values are above the derived DNEL resulting in all RCR's >1 and demonstrating that the risk is not controlled when the least stable material is used.

Table 4. Risk characterisation ratios (RCR) calculated based on emissions using the least stable material found in the French market

Relative Humidity (%)	**Sub acute inhalation DNEL for irritation**	**Living room**	
		Ammonia Concentration (ppmV)	RCR
20-50% RH	1.7 ppmV	3.736	**2.2**
50-70% RH Median		7.948	**4.7**
50-70% RH 95%ile		21.38	**12.6**

- *Which human populations or environmental compartments are at risk?*

The population at risk are the occupants of properties (primarily occupants of homes) that have been insulated with cellulose insulation treated with ammonium salts which emit ammonia after installation. The population at risk includes all groups of the human population including children and elderly people.

- *Evidence that the existing risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient*

Data in the dossier accounts for less than 200 complaints out of the estimated 20,000 homes insulated with cellulose insulation treated with inorganic ammonium salts. The number of real incidents and complaints reported in France, which is one of the primary Member State that has used cellulose insulation treated with ammonium salts, is an indication that current operational conditions recommended and implemented by the manufactures and/or importers are not sufficient.

As a consequence, (as a safeguard measure), the 2013 French order not only prohibits the placing on the market, sale distribution of cellulose insulation treated with ammonia salts but has also required cellulose insulation material to be removed from homes so no further complaints could reasonably be expected for consideration.

- *Evidence that the existing regulatory risk management instruments are not sufficient*

Construction Products (CP's) are currently regulated under Construction Product Regulations No: 305/2011(CPR). RAC has noted whilst there are currently no limitations on emissions (including ammonia) from CP's in the CP Regulations, where Article 58 deals with complying construction products which nevertheless present a risk to health and safety. *"Where, having performed an evaluation pursuant to Article 56(1), a Member State finds that, although a construction product is in compliance with this Regulation, it* ***presents a risk*** *for*

the fulfilment of the basic requirements for construction works, ***to the health or safety of persons*** *or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the construction product concerned, when placed on the market, no longer presents that risk, to withdraw the construction product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, which it may prescribe."*

Comments received from the Forum indicated from an enforcement perspective that the restriction could be better regulated under the European construction product legislation. The construction products legislation has a requirement for compliant construction products to be CE marked, making the checking of compliance easier. In addition, one Member State comments clearly supported the regulation of this issue under the Construction Products Regulations. The Commission, however, has indicated that the Construction Products Regulation serves to harmonise the test methods performed on construction products, and ensure that the product performances reached and declared by manufacturers are calculated using the same test methods. The prohibition or limitation of certain components in construction products is not the main aim of the Construction Products Regulations but left to be regulated by Member States or other EU legislation (such as REACH). Therefore, the current regulatory risk management instruments are not sufficient.

Conclusion: RAC considers that estimated exposures based on RH values above 70% may overestimate the expected ammonia concentrations in the living area. However, RAC notes that (i) estimated emissions based on the least stable material found on the French market under conditions of 50% RH in the living area, were 3.736 ppm and (ii) the median value and 95%ile value under worst case RH conditions (50-70%) yielded estimated exposures of 7.948 and 21.38 ppm respectively. Since these values are above the derived DNEL resulting in all RCR's >1 it is properly demonstrated that the risk is not sufficiently controlled when the least stable material is used. In addition, RAC concluded that the current regulatory risk management instruments are not sufficient to control the risks.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

This is a REACH Annex XVII restriction proposal by France targeted at the use of inorganic ammonium salts (which is used in powder form) as a flame retardant in cellulose insulation. Up until 2011 in France, boric acid was added to cellulose insulation as a flame retardant. However, following the classification of boric acid as toxic to reproduction Category 1B under the CLP legislation, the French Authority (CCFAT/DHUP Direction of habitat, urban planning and landscapes) no longer issued technical approvals for the use of boric salts in insulation materials. This resulted in the cellulose insulation sector changing to inorganic ammonium salts (in powder form) as the alternative flame retardant.

Following complaints from occupants and concerns surrounding the release of ammonia from cellulose insulation, the French Authorities introduced urgent national measures prohibiting the placing on the market, import, sale and distribution and manufacture of cellulose insulation containing inorganic ammonium salts as additives. Following consultation with the Commission it was confirmed the issue was not currently regulated under current EU Legislation (CPR). Therefore, action was necessary to address the risks.

As there is no significant import of insulation material, insulation materials are mainly produced in the EU Member States. The dossier identified six producers outside France producing cellulose insulation with ammonium salts. Although no cases were reported from other countries, RAC considers it likely that complaints could arise in other Member States as significant concentrations of ammonia are expected under comparable application

conditions using insulation material containing inorganic ammonia salts.

Consideration of the hazards associated with alternatives in the justification for action

While information received[15] from other Member States across the EU indicates the primary flame retardant product used in cellulose insulation is Boric Acid/boron compounds and not inorganic ammonium salts, inorganic ammonium salts are currently used in 5% of the cellulose insulation products in the EU (Source ECIA).

The public consultation revealed some information that ammonium polyphosphates may have a low potential to generate ammonia. However no evidence was provided on the amount of ammonia released from cellulose insulation treated with polyphosphates.

All (4) borate substances [boric acid, disodium tetra borates, tetra boron disodium heptaoxide hydrate, diboron trioxide] with harmonised classification as toxic to reproduction for both fertility effects and developmental toxicity (Repr. 1B; H360FD) are currently listed in the Candidate List of SVHC, which is the first step of the authorisation risk management process. Currently they are included in the ECHA's draft 6th Annex XIV recommendation (for inclusion to the Authorisation List).

Specific concentration limits between 3% and 5.5% apply for the 4 borate substances based on Annex VI of the CLP Regulation.

Two additional borate substances [disodium octaborates, tetrahydrate and anhydrate]] were submitted to ECHA by the NL for harmonised classification as Repr.1B. (H360FD). The classification proposal was adopted by RAC but at a generic concentration limit of 0.3% for mixtures These borate substances have been included in the 9th Draft ATP to CLP, sent to the Commission in January 2015 (for final decision).

The dossier submitter indicated (according to the information on ECHA's website) that there are hundreds of substances containing boron. RAC has not been provided with any information that would indicate which non-harmonised (non-classified as CMR) borate substances can be used as alternatives. If the 4 boron compounds are listed in Annex XIV of REACH, this will likely result to further research on the stabilisation of inorganic ammonium salts (or on other non-hazardous boron compounds) as suitable alternatives.

Justification for the opinion of SEAC

SEAC notes the Annex XV dossier to restrict the use of inorganic ammonium salts in cellulose insulation material was submitted by France based on article 129(3) of REACH. In accordance with this safeguard clause, the Commission authorised the provisional national measures taken by France to restrict the use of ammonium salts in cellulose insulation. France then initiated an EU wide restrictions procedure by submitting an Annex XV dossier to ECHA as required.

In section A.2.2 and D.2 of the background document, the dossier submitter justifies EU wide action by 'the need to avoid different legislations among the Member States with the risk of creating unequal market conditions'. SEAC concurs with this reasoning because it is in fact an explanation of the rationale behind the safeguard clause. In addition, SEAC notes that manufacturers and distributors of cellulose insulation are located in at least six different EU countries. This increases the likelihood of the same formulations being present (i.e. available on the market) in more than one EU country. Hence, the supply and use of

[15] Only six of the 40 manufacturers of cellulose insulation material inside the EU use inorganic ammonium salts as flame retardants.

cellulose insulation clearly has a cross-boundary component. This provides additional justification of the need for EU wide measures.

SEAC notes that based on the information currently available in the dossier the health concerns raised by French toxic vigilance data are not echoed by comparable information from other Member States. Although reported cases of health impact have largely been confined to France, SEAC concurs with the RAC's and the dossier submitters' view that such health risks are likely to arise in other Member States. Hence, despite the lack of concrete cases across the other Member States, SEAC concludes that the dossier submitter has provided sufficient justification that there is a need for action at EU wide basis.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC

RAC has noted the comments of MS's, the Forum and the Commission on the CPR Regulations. RAC agrees that a restriction under REACH would also achieve the desired effect and notes that currently under Annex XVII to REACH (Entry 47), cement (a key material used in construction products) is already regulated under REACH.

Justification for the opinion of SEAC

In this section the 6 identified risk management options are assessed, in conjunction with their effectiveness in reducing the risks and other key points for comparison of the options. The following options are presented in the dossier:

RMO 1: Restriction on ammonia emission ("proposed restriction")

RMO 2: Composition based restriction

RMO 3: Authorization

RMO 4: Construction Products Regulation[16]

RMO 5: Providing information to retailers and consumers through labelling

RMO 6: Voluntary agreement from industry

The dossier offers a structured approach to identify and describe the several RMO's. Except the RMO for authorisation, all RMOs are compared in a qualitative way for the following key criteria:

- Risk reduction capacity,
- Monitorability,
- Enforceability,
- Proportionality,

[16] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

- Practicability, and finally
- Coherence with Art. 129.

The route under Article 129 is followed in cases where urgent action is essential to protect human health or the environment. An RMO which results in an extended period before coming into effect does not correspond with the need for urgent action and would therefore score low when it comes to coherence with Article 129.

In the recommendations for the dossier submitter, SEAC already pointed at the potential applicability to address ammonia emissions through the Construction Products Regulation[2] (CPR) (RMO 4). The main aim of this Regulation is to harmonise conditions (e.g. European standards, technical assessments, CE-marking) for construction products. The first preamble in the Regulation underlines "…..*that construction works be designed and executed so as not to endanger the safety of persons, domestic animals or property nor damage the environment*."

Article 3 provides the requirements for construction products, introducing Annex 1 as basis for the preparation of standardisation mandates and harmonised technical specifications. The manufacturer has the responsibility for the construction product he places on the market (see article 4).

Annex 1 is introducing the following requirements for construction works:

"*The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbors, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:*

(a) the giving-off of toxic gas;

(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air."

Based on these obligations one might expect that ammonia emissions from cellulose insulation material would be covered by the CPR. According to the dossier and following communication between ECHA and Commission services, it has been concluded that REACH can serve as the most appropriate legislative framework to asses any risks from chemicals used in construction products for workers and general public.

The CPR does not affect the right of Member States to specify the requirements they deem necessary to ensure the protection of health, the environment and workers when using construction products. Safety requirements are set by national or even regional building codes under the condition that harmonized test methods are used. The market surveillance authorities of a Member State have the competence to instruct the concerned manufacturer(s) to bring their products into compliance with the obligations of the CPR.

The work to develop harmonised test methods has just started and it seems realistic to presume that a harmonised regulation of indoor emissions from cellulose insulation with ammonium salts will take a number of years. SEAC therefore concludes that, at least in the short term, the CPR is not the most appropriate EU wide measure.

SEAC agrees with the dossier submitter's assessment of RMO 3 (Authorisation), RMO 5 (Providing information through labeling) and RMO 6 (Voluntary agreement industry). It is for example indeed questionable whether ammonium salts could qualify as SVHC's as meant in article 57 and authorisation then would justify the substitution of ammonium salts in all uses, including for instance fertilizers. Also the arguments presented for RMO 5 and 6 are convincing SEAC that those RMOs are not the most appropriate EU wide measures with

sufficient risk reduction capacity. Further, RMO 5 of providing information to consumers and retailers through labelling does not seem to be sufficiently effective to avoid health risks related to ammonia emissions from cellulose insulation. Regarding a voluntary agreement (RMO 6) there is at present a lack of a strong actor able to lead the process and to prevent free-riding.

RMO 2 is a composition based restriction, restricting the placing on the market of cellulose insulation containing inorganic ammonium salts. Actually, this RMO would result in banning the use of inorganic ammonium salts for this application. SEAC does not agree with dossier submitters' view that this RMO would require an exhaustive list of all possible inorganic ammonium salts. Also in RMO 1 the assumption is that inorganic ammonium salts can lead to ammonia emissions, without having such a list. If ammonium salts are available that do not emit ammonia at all or emit below the proposed limit value, industry might have shifted to these salts already. SEAC's view is that – based on the available information - this RMO 2 would result in 100% risk reduction capacity, with a very high monitorability and enforceability.

The proposed restriction in RMO 1 introduces an emission limit of 3 ppm, in conjunction with a prescribed test method. This option offers industry a door open to the use of inorganic ammonium salts if manufacturers demonstrate that their cellulose insulation meets the established limit value. In that case a high risk reduction capacity would be achieved. Key for a successful implementation of RMO 1 is the use of stable inorganic ammonium salts or stabilization of the salts that are used at present. Concerning the technical feasibility of stabilization, SEAC has the following observations.

Paragraph A.1.2 of the Background Document, states: "Liquid impregnation leads to a better stabilisation of ammonium salts compared to a mix of powder (solid form of the salts)." Looking further for technical evidence regarding stabilization, the paragraph dealing with "Stabilization of the currently used powder formulations" (C.1.2,) is introducing this technique as "this option **seems** feasible both technically and economically". Also the rest of the text in that paragraph does not prove the technical feasibility of stabilization. In the paragraph dealing with implementability (E2.1.2.1) the dossier again states that "...the emission limit value of 3 ppm proposed by the restriction **seems** to be technically and economically feasible..." Manufacturers claim that their formulations are already stable and do not emit ammonia. However, the confidential test results point at the technical infeasibility for at least 3 out of 4 manufacturers as the reported emissions are far above the proposed limit value.

Parallel to the public consultation, and following consultation with the rapporteurs, ECHA has performed a targeted consultation with industry so as to obtain more technical evidence (October-November 2014). The first question mainly concerned the technical and economic feasibility of stabilization techniques (to ensure that emissions of ammonia are kept to a minimum level) and related additional costs for manufacturers and/or formulators. Six comments from industry were received in the frame of this consultation, some of them stating: "we don't know anything about these techniques" or "we have not tried yet to enclose the ammonium salts to block into the produce.....but nothing has been done until yet on this way." In one of the confidential comments a manufacturer stated: "However, since our product wasn't undertaken the proposed test, we can make no further indication on this question." One manufacturer wrote in his confidential reaction: "... we cannot accept a general ban on all ammonium salts." No test report was provided, the manufacturer claimed a reasonable transition period to develop flame retardants consisting of ammonium compounds which are uncritical, such like ammonium polyphosphates. According to this manufacturer these polyphosphates were developed specially for the flame retardant industry. Market prices for these types of ammonium based phosphates are currently € 3,000 – 5,000 per tonne, while mono, di and tri phosphates are available below € 1,000 per tonne. Late in the public consultation ECHA received a reply in which the manufacturer informed ECHA that they had developed a new ammonium based insulation product with the addition of another substance to prevent the release of ammonia. The manufacturer argues

that "..all the tests in their laboratories showed that the amounts of ammonia released were extremely small and well below any kind of safety threshold." This product was also tested by CSTB, using the test recommended by Anses, resulting in levels of ammonia below 3 ppm after the 28-day test. Results of that testing have not been presented to ECHA, even not in a confidential way.

During the public consultation on the draft SEAC opinion, information was requested on what would be a reasonable transition period. One comment referred to the time needed for an alternative to boric acid and stated: "…As an alternative is the only suitable way, neither 12, 18 nor 24 months are reasonable". Another comment stated: "…The proposed transition, also with 24 monthes, is far too short. Developping an ammonium-free and boron-free blend or in case of needing to develop a new stabilisated ammonium blend would need more time." No specific technical information was provided to explain what an "alternative reasonable" transition period (e.g. 18 or 24 months) could be. SEAC acknowledges that significant time may be needed to develop new blends of stabilised ammonium salts. On the other hand, it is anticipated that some fire retardant suppliers may already have developed stable ammonium blends. To give manufacturers sufficient time to find fire retardant suppliers with appropriate blends or to develop more stabilized blends, SEAC proposes a transition period of two years [24 months].

Based on the information received in public and targeted consultations SEAC concludes that, although technical feasibility has not been demonstrated in presented test results, at present at least 1 manufacturer claims to be capable delivering a product that complies with the proposed limit value of 3 ppm as proposed in RMO 1.

During the public consultation on the Annex XV report Industry requested to introduce an exemption for outdoor use of cellulose insulation with inorganic ammonium salts. Argument is that emissions would not result in ammonia concentrations in the living room. Exempting could be done by means of labelling. SEAC agrees that such an exemption would indeed not lead to an impact on indoor environment and further considers that the arguments used for RMO 5 are also valid for this option. Product labelling might however not prevent the unintentional indoor use of this type of insulation and enforceability might probably be complicated, if not impossible.

SEAC concludes that based on the available information at present the options RMO 1 and 2 are quite similar for all key criteria from a qualitative point of view. SEAC endorses the view that the proposed restriction is the most appropriate EU wide measure.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

The use of cellulose insulation treated with ammonium salts can be permitted provided the cellulose material does not emit ammonia in concentrations greater than 3 ppmV when tested under the specific conditions to be agreed by CEN.

RAC considers the proposed limit to be sufficiently protective because exposure estimates undertaken using the well mixed room model and the data from the most stable material tested (emission profile as set out in Table 5) resulted in estimated 95%ile ammonia emissions of 0.5 ppmV under RH levels <50% and 0.8 ppmV under RH conditions between 50-70%. These estimated emission values are all below the derived DNEL demonstrating the risk is controlled when the material emits ammonia less than 3ppmV. The RCR was 0.5 at the 95%ile of 0.8 ppmV.

Table 5: The average conc. of ammonia emitted from the most stable cellulose material tested[17] at 50, 70 and 90% values of Relative Humidity (RH) (Source: table 12 of the Background Document)

RH (%)	NH_3 (ppmV)	G (mg/h)
50	0.4	0.02
70	0.7	0.03
90	0.9	0.04

Tests were also undertaken to simulate conditions of migration of ammonia emissions from the attic to the living area (two chamber tests) using the least stable insulation material found. The results of the testing showed that concentrations in the living area chamber section of the two chambers were 80% of the emission concentrations in the attic area of the chamber tests. However, when these figures were adjusted for air flow, the corresponding concentrations in the living area were in the order of a twofold difference. Based on an emission profile of 3 pmmV at 90% RH, a concentration of 1.5 ppmV would be expected in the living area under worst case conditions.

Justification for the opinion of SEAC

Proportionality to the risks

The dossier submitter has made a socio-economic analysis of the proposed restriction using a break-even analysis to identify after how many years the benefits will exceed the costs. A break-even analysis was chosen as a large part of the costs for the industry will only occur once either immediately before or just after the entry into force of the restriction. The benefits as well as the remaining part of the costs of the restriction will occur after the restriction and will accumulate over time. The costs and benefits of the proposed restriction are assessed compared to a business as usual scenario (i.e. the situation that would continue without any restriction being adopted) including an anticipated yearly growth of the cellulose insulation sector (with or without the use of ammonium salts) of 2.2%. The dossier submitter used a discount rate of 4% throughout their analysis.

SEAC considers a break-even analysis is suitable to assess the proportionality of this restriction as the cost or benefit estimations are uncertain in this restriction proposal.

Policy scenario definition

The dossier submitter has identified four options for a manufacturer of cellulose insulation with ammonium salts to comply with the proposed restriction:

1) Doing nothing as their product already complies with the proposed restriction;
2) Switch from their currently used ammonium-based formulation to boron-based formulations;
3) Stabilisation of their currently used ammonium-based formulation to comply with the proposed restriction;
4) Substitute their currently used ammonium-based formulation with a boron free and ammonium free based formulation.

The dossier submitter emphasises that it was not possible to determine *ex ante* which option will be adopted by a manufacturer. Several factors, such as if their current products

[17] Exposure levels in home were estimated using the well mixed room model and the results of the most stable material to determine if compliance could be achieved.

already comply with the proposed restriction and the acceptability of boron as alternative by the end-consumers, influence each manufacturer's response. Instead, the dossier submitter has calculated the proportionality for four different scenarios assuming different proportions, based on the volume of the total current production, of industry adopting the different options.

The dossier submitter has assessed the cost and benefits of the proposed restriction for the relevant actors based on some assumptions about how industry would react to the proposed restriction, combining the options for responses as defined above. As the most likely scenario, the dossier submitter anticipated that 90% of the volume of the current ammonium-based cellulose insulation would either be switched to boron-based formulations or manufacturers would do nothing as their product already complies with the proposed restriction. The remaining 10% would switch to a hypothetical ammonium- and boron free formulation at twice the price of the boron-based formulation. In addition to this most likely scenario, the dossier submitter has drafted three alternative scenarios (table 6).

Table 6: The various policy scenarios defined by the dossier submitter

Scenarios	Doing nothing (volume share)	Switch to boron (volume share)	Stabilisation (volume share)	Substitution (volume share)
A) Most likely scenario[18]	90%		0%	10%
B) Reasonable worst case	50%	0%	50%	0%
C) Optimistic for the industry	75%	0%	25%	0%
D) Unrealistic worst case	0%	0%	25%	75%

SEAC agrees with the dossier submitter that several factors will influence the manufacturers' response and considers that industry will select the most financially attractive option. The proposed scenario by the dossier submitter is based on consultation with the different stakeholders. SEAC also notes the following:

1. The ban on ammonium salts in France is the reason why companies switched back to boron. The market analysis in the dossier reports that in general ammonium-based cellulose insulation is specifically produced for a "niche market" of clients with an interest in ecological timber frame construction, and who would not accept cellulose insulation containing boron. According to the dossier submitter, those manufacturers have based their market communication on the fact that their products are boron-free. Therefore, there could be several marketing arguments for current manufacturers of ammonium-based cellulose insulation not to switch to boron as drop-in alternative. The dossier submitter`s assumption in the most likely policy scenario, that 90% of the volume of the current ammonium-based cellulose insulation would either be switched to boron-based formulations or manufacturers would do nothing, might be too high. In all other policy scenarios the option to switch to boron is excluded by the dossier submitter. The reasoning behind this exclusion could not be found.

2. A proportion of current volume that will be substituted by a hypothetical ammonium- and boron free formulation is not deemed appropriate to consider in scenario A. If the manufacturer cannot switch to boron, it is more realistic to assume the next option would be stabilisation, presented as a cheaper option by the dossier submitter, than substitution with a hypothetical formulation. Furthermore, this hypothetical blend does not exist yet and the time period for research and

[18] For clarification, SEAC has changed the name of the dossier submitter`s policy scenario A from baseline scenario to most likely scenario in this opinion as the dossier submitter already uses the term baseline scenario for the situation without the proposed restriction.

development is not known. As stabilisation is considered a cheaper alternative, the proposed restriction does not give much incentive to invest in such a hypothetical ammonium- and boron free formulation.

3. The unrealistic "worst" case scenario is considered by SEAC as not realistic due to the high percentage of manufacturers that would substitute with a hypothetical formulation. Therefore this scenario should be excluded from the proportionality assessment.

SEAC considers that there is not sufficient information available in the Annex XV restriction report or from the public consultation to make an accurate assumption on the share of the remaining options (doing nothing, switch to boron or stabilise) adopted by industry due to the proposed restriction. Therefore, the overall approach by the dossier submitter to make several alternative policy scenarios is endorsed by SEAC. SEAC slightly adapts scenario A, into a scenario in which 10% of the current volume would switch to a stabilised ammonium-blend and the remaining 90% of the current volume would either switch to boron-based formulations or do nothing as their product already complies with the proposed restriction. SEAC included the option to switch to boron in scenario B and C as no specific argumentation could be found in the Annex XV restriction report why this option should be excluded in different policy scenarios (table 7).

Table 7: The policy scenarios considered by SEAC

Scenarios	Doing nothing or switch to boron (volume share)	Stabilisation (volume share)
A)	90%	10%
B)	50%	50%
C)	75%	25%

Cost assessment

Cost for industry

The following relevant cost elements for industry have been identified and quantified by the dossier submitter:

- Cost of testing for ammonia emissions,
- Costs of stabilisation,
- Costs of substitution, and
- Costs related to obtaining new technical approvals at European level (ETAs) and national level (TA) for an altered product.

Other elements considered by the dossier submitter, but not believed to induce additional costs, are training costs, depletion of stocks and changes in production process and production equipment. The dossier submitter summarised the costs connected to each option in table 8.

Table 8: The costs elements connected to each manufacturer's option

Option	Testing	Changes of ETAs and TAs	Price differential of the blend
1. Doing nothing	Yes		
2. Substitution with boron-based blends	Yes	Yes	
3. Stabilisation	Yes	Yes (but minimal)	Yes (Factor 1.34)
4. Substitution with ammonium and boron free blends	Yes	Yes	Yes (Factor 2)

The dossier submitter has identified six manufacturers of ammonium based cellulose insulation material in Europe outside of France. The cost of testing for ammonia emission is estimated by the dossier submitter to be around €1000 per year per manufacturer based on estimations of ammonia emission costs by the French Scientific and Technical Centre for Building (CSTB). According to the CSTB expert consulted, in case a manufacturer of cellulose insulation would apply for a technical approval, the samples requested to carry out the tests would be provided by the company itself which would therefore carry some additional, but minimal, costs of sampling.

Stabilisation costs are estimated by the dossier submitter based on manufacturer information. The cost of a stabilised ammonium blend (€1000/tonne) is estimated to be factor 1.34 more compared to non-stabilised ammonium blends (€750/tonne).

The cost of using another formulation depends on the type of alternative formulation. If boron-based formulation is used, no cost increase is expected. The dossier submitter has assumed that the switch to a hypothetical ammonium- and boron free formulation would result in twice the price of the boron-based formulation.

The Construction Product Regulation requires manufacturers to obtain new technical approvals when different formulations or procedures are used. The costs related for new technical approvals were estimated by the dossier submitter to be €50,000 per manufacturer for an average duration of validity of 3 years. The dossier submitter considered the cost of TAs at national and European level as a one-off cost which will be incurred before or during the first year following the restriction. The dossier submitter used the maximum of €300,000 (€50,000*6 companies) of the total cost for technical approvals due to the restriction but assumes this is a possible overestimation of the costs for industry as it refers to the worst case of a company producing 100% of its production with ammonium salts and therefore needs to completely alter their production process.

SEAC considers the cost elements for industry identified by the dossier submitter as sufficient. The quantification and underpinning of the cost elements are considered adequate. SEAC agrees with the dossier submitter that *ex ante* it is unknown how many companies would have to alter their production process and apply for new technical approvals. The total cost estimate for the renewal of technical approvals by the dossier submitter is indeed probably an overestimation, but considered reasonable for use in the various policy scenarios in the break-even analysis.

Costs for consumers and government regulatory costs

The dossier submitter qualitatively assessed the cost of the proposed restriction for society as a whole (including costs to consumers and household, administrative costs and costs of the monitoring for Public Authorities) and concluded that these costs are marginal. The cost increase for industry is unlikely to be fully passed along the supply chain as manufacturers are afraid to lose market shares, and they seem to prefer and to be ready to partially reduce their profit margins, at least temporarily, instead of increasing their prices with the risk of becoming less competitive on the thermal insulation market.

SEAC did not find adequate justification in the Annex XV restriction report to support the dossier submitter`s view that the cost increases of industry are unlikely to be fully passed along the supply chain. How the cost increase is distributed over consumers and manufacturers however does not influence the proportionality assessment as welfare costs to society include all costs to both producers and consumers. The dossier submitter concluded that the costs of the monitoring for Public Authorities are marginal. The Forum has indicated that high testing costs might be hindrance for more enforcement. Both the Forum and SEAC were not able to quantify government regulatory costs and SEAC is thus unable to confirm the dossier submitter`s contention. However, it is not clear how much testing would be required.

Benefit assessment

Benefit elements

The dossier submitter has identified the benefits of the proposed restricted as:

- Odour nuisance and respiratory symptoms (which can, in principle, be measured by the Willingness To Pay (WTP) to avoid them),
- Costs Of Illness (COI) until the house is re-insulated, and
- In case of re-insulation, the costs of temporary re-housing and the costs of re-insulation including the cost to destroy the emitting cellulose insulation.

SEAC agrees with the identified elements as potential benefits of the proposed restriction. However, according to SEAC the costs of re-insulation are internalised by the manufacturing companies. SEAC will further reflect on these elements below.

WTP to avoid odour nuisance and respiratory symptoms

The dossier submitter assessed the possibility to attach a monetary value to odour nuisance and respiratory problems of ammonia using willingness to pay (WTP) studies. Specific scientific studies looking at the WTP for irritation or odour from ammonia have not been found by the dossier submitter. Instead, the identified studies looked at odour nuisance in a different context (animal waste facility, waste water plants, composting facilities etc.) and were considered by the dossier submitter to be too case specific to extrapolate from. In addition, the dossier submitter states that the available empirical evidence in terms of stated preferences does not fit the case of ammonia emissions. In this case, the occupants of the living unit might not be willing to pay in order to avoid odour nuisance and respiratory symptoms since they have already paid for the installation of a thermal insulation that was not supposed to emit ammonia.

SEAC partly agrees with the dossier submitter`s assessment. The benefits of the proposed restriction are health benefits that can be estimated using assumptions (e.g. concerning the frequency of health symptoms in the non-regulated compared to the regulated situation and on the price that people are willing to pay to avoid these symptoms). Studies on the willingness to pay for avoiding odour nuisance and respiratory problems of ammonia could not be identified as such by the dossier submitter and SEAC agrees that care has to be taken when extrapolating preferences from a different context. However, the dossier submitter also discards these estimates as not relevant for this case due to the fact the occupants already paid for the installation of a thermal insulation that was not supposed to emit ammonia. SEAC considers this line of argumentation as incorrect. The WTP to avoid odour nuisance and respiratory symptoms reflects people's preferences over the welfare losses from these impacts. Whether occupants already paid the installation of a thermal insulation or not is therefore irrelevant. Nonetheless, SEAC notes that the dossier submitter was not able to monetise the odour nuisance and respiratory problems of ammonia, therefore quantification of this part of the benefits was not possible.

Avoided Cost Of Illness

The dossier submitter has estimated the COI for the normal population, in case of exposure to ammonia. COI is estimated using the cost for a general medical consultation (by a General Practitioner (GP) with a simple clinical exam) and the cost of 5 days treatment of symptoms by a non-specific antihistamine. The full economic cost of the treatment is estimated at €49 per case at European level. It is likely that not all exposed people would consult a GP and be treated, so this estimate could be considered as a slight overestimation of the estimated costs. The number of exposed people is calculated using the incidence rate of affected houses found in France. The rate used is that in 0.5% of the houses insulated

with ammonium-based insulation ammonia will be emitted leading to two persons per house with symptoms. At current production rates this will lead to 150 exposed persons with symptoms in Europe per year.

SEAC considers the magnitude of the COI estimated by the dossier submitter for a single exposed person with symptoms to be appropriate. The number of exposed people in Europe is highly uncertain. This is based on the number of French cases. Outside France, no cases have been reported and no information is available on the likeliness for ammonia release from cellulose insulation in other countries. Therefore, the total COI estimate for Europe is uncertain and probably an overestimation if the incidence rate of cases in France is extrapolated to Europe.

Avoided costs associated with re-insulating

The dossier submitter uses the avoided costs of re-insulating as main element for estimating the benefits of the restriction. The costs associated with re-insulating are based on two components. First the cost of re-insulating itself (removal of the old insulation cost of replacement and cost of destruction of the old cellulose insulation) is estimated at €4000 per building. In addition, relocation costs during the re-insulating are estimated at €400. The dossier submitter based these estimations on information provided by the various stakeholders.

Internalisation of costs

The dossier submitter reflects on the possible internalisation of the costs of reinsulating by manufacturers. The dossier submitter considers that the costs of re-insulation are not already internalised by the manufacturers of the cellulose insulation as, even in case of ammonia emissions, the costs of re-insulation will be covered by the insurance companies and not directly by the manufacturers of the cellulose insulation. The dossier submitter estimates that, based on information from the French cases, the insurance companies of the installers or the manufacturers will pay for re-insulation costs.

The dossier submitter assumes that 100% of the emitting houses will be re-insulated although, due to the high costs of re-insulation, re-insulation might not be accessible to all consumers if the insurance companies would not pay for it. In such cases, people still living in emitting houses that are not re-insulated would continue suffering from the health symptoms, at least from time to time.

SEAC disagrees with the dossier submitter`s view concerning the internalised costs. According to SEAC re-insulating costs paid by manufacturers or insurance companies should be considered as internalised costs, as it is known that health cases can occur and the manufacturers can anticipate the expected cases of re-insulation. In the baseline scenario, the manufacturer considers paying these costs to be more beneficial for the company instead of alternative actions to eliminate the cases occurring. The re-insulation costs would thus have the same role as any other production costs, e.g. costs of raw materials or energy consumption. In each policy scenario, the cost structure for the company will change: costs of testing, certification, stabilisation and/or substitution will increase, whereas the costs of re-insulation will decrease (probably to zero). The net difference of the cost structure will be the additional cost of the restriction for the manufacturer. The internalisation decrease in re-insulating costs therefore affects the cost estimate of the proposed restriction and not the benefit estimate. It does not matter if these costs are covered directly by company itself or indirectly through the company's insurance company or not. The insurance premiums that companies pay to cover their liability risks belong to their regular cost structure and are part of the total private cost in the business as usual scenario. The costs of re-insulation are therefore internalised, even if they are paid by insurance companies.

In France, the insurance companies or the manufacturers paid for the re-insulating costs. In other European countries, due to differences in legal responsibilities, this might not be the case. Furthermore, not everyone suffering from odour nuisance or respiratory symptoms may link their symptoms to the cellulose insulation due to a possible time delay between installation and the resulting effects. SEAC considers there are some uncertainties surrounding the dossier submitter`s assumption of a 100% re-insulation. The 100% re-insulation rate assumed by the dossier submitter might therefore be too high. A relative high re-insulation rate is justified as it is reasonable to assume that in most cases the manufacturers or insulation company can be held accountable for the occurrence of the resulting effects. If not all ammonia emitting houses are re-insulated, some people will still suffer from odour nuisance or respiratory symptoms, at least from time to time. This may cause costs related to re-insulation to be lower than estimated, but costs related to health effects to be higher.

Proportionality

The dossier submitter has provided a break-even analysis of the most likely policy and the alternative policy scenarios compared to the business as usual scenario. The break-even analyses show that in case of the most likely policy scenario, the realistic worst case policy scenario and the optimistic policy scenario, the restriction becomes proportionate after one year. In the unrealistic worst case scenario the restriction is shown to be not proportionate.

In addition to the different scenarios, the dossier submitter has performed a sensitivity analysis using the most likely policy scenario in which the expected cases in Europe were reduced by a factor of 2 compared to the business as usual scenario. Besides that, the re-insulation rate was reduced from 100% to 75, 50 or 25%. With a reduced number of expected cases in Europe, the restriction would become proportionate 4 years after the introduction. In case of the reduced re-insulation rates, the most likely policy scenario is still proportionate in respectively two and five years after the introduction (75 and 50%). In the case of a reduced insulation rate of 25%, and without taken into account that the costs related to health effects would be higher, the restriction is showed to be not proportionate.

For the proportionality assessment SEAC slightly adapts the policy scenarios presented by the dossier submitter and assumes them as equally likely to occur (table 9).

Table 9: The policy scenarios considered by SEAC

Scenarios	Doing nothing or switch to boron	Stabilisation
A	90%	10%
B	50%	50%
C	75%	25%

For the restriction to be proportionate, the benefits of the restriction should outweigh the cost of the restriction. The benefits include the avoided health damage (nuisance and symptoms, measured by the WTP to avoid them); the COI for residents of emitting houses and any re-insulation done by these residents themselves (i.e. the part that is not internalized in the cost structure of the suppliers). Only the COI could be quantified.

The costs include the cost of enforcement and the net difference in costs for manufacturers between the business as usual situation (including re-insulation costs) and the policy scenario. The costs consist of ammonia testing and, dependent on the manufacturers' adaptations, renewal of ETAs or TAs and higher production costs due to stabilisation. The increase in production costs will be mitigated by the reduction in re-insulation costs. Only the costs for manufacturers could be quantified. SEAC uses the dossier submitter`s

estimates for the different cost and benefit elements (table 10).

Table 10: The main cost and benefit per element

Cost element	Euro (unit)
Ammonia emission testing	+ 1000 (manufacturer/year)
Renewal of ETAs or TAs	+ 50.000 (manufacturer/once)
Stabilization costs	+250 (tonne of stabilized ammonium salt blend)
Re-insulation costs	- 4.400 (ammonia emitting house)
Benefit element	
COI	+ 49 (exposed person with symptoms)

These policy scenarios are compared against the business as usual scenario as described by the dossier submitter. The graphical output of the break-even analysis can be found in the annex 6 of the Background Document. The analysis shows that the restriction is proportionate in all three policy scenarios within two years after introduction.

A sensitivity analysis has been performed on the following parameters: expected cases in Europe, the stabilisation costs and the re-insulation rate. The expected cases in the business as usual scenario are uncertain and affect both the cost and the benefit estimate. The stabilisation cost is the main cost element for manufacturers and the cost estimate is based on one stakeholder. In the sensitivity analysis, the cost of a stabilised ammonium blend is estimated to be factor 1.5 more compared to non-stabilised ammonium blends instead of a factor 1.34 as assumed by the dossier submitter. The re-insulation rate of 100% assumed by the dossier submitter might be too high and was therefore also included in the sensitivity analysis.

In case of a reduced number of expected cases in Europe in the business as usual scenario and with policy scenario B, proportionality was not demonstrated. In all other cases proportionality was demonstrated but sometimes took longer to reach.

Table 11: The result of the break-even analyses of the policy scenarios including sensitivity analysis

Scenario	Years to reach proportionality			
	Without sensitivity analysis	**Reduced number of cases in Europe (50%)**	**Higher stabilization costs (€1125/tonne stabilized blend)**	**75% re-insulation**
A	One	Two	One	One
B	Two	*Not proportionate*	Five	Four
C	One	Four	One	One

SEAC notes that if proportionality is demonstrated, this is mainly reached through a decrease in production costs in the policy scenario and to a much lesser extent due to benefits from avoided COI. This decrease in production costs is caused by discontinuation of re-insulation costs for manufacturers. This indicates that, under the given scenarios and assumptions, it might be more beneficial for manufacturers to stabilise their product or switch to boron, than continue to pay for re-insulation costs. Therefore, manufacturers would be expected to progressively switch to stabilisation or boron in the business as usual scenario. There might be other unknown costs that would explain why such a switch has not (yet) happened. However, SEAC received no indications of any other cost elements to consider in the analysis. Another explanation could be that an information deficiency exists and the market behaved sub-optimally. Manufacturers might underestimate the need to

reinsulate and therefore continue to produce cellulose insulation as assumed under the business as usual scenario. This might be because of a time delay between the installation of the cellulose insulation and the recognition of faulty cellulose insulation emitting ammonia. Considering the long product life of cellulose insulation, such time delay can be substantial. The proposed restriction would prevent the installation of potentially faulty cellulose insulation during such time delay.

This analysis of proportionality did not take into account any other health benefits (measured by WTP to avoid odour nuisance and respiratory symptoms) due to lack of data and therefore underestimating the benefits. On the cost side, enforcement costs could not be estimated therefore underestimating the costs.

Three policy scenarios were considered by SEAC and their proportionality was assessed. All three policy scenarios demonstrated to be proportionate. One scenario did not reach proportionality in the sensitivity analysis when the number of expected cases in Europe is reduced. Based on the outcome of the proportionality assessment of the policy scenarios, including a sensitivity analysis, SEAC considers it likely that the proposed restriction is proportionate.

Practicality, incl. enforceability

Justification for the opinion of RAC

RAC considers that overall, the proposed restriction is a measured response to the situation that arose in France, as it prohibits the use of ammonium salts in cellulose (if the emission rate in standardised testing exceeds 3 ppmV) until such time as industry has undertaken research on the stabilisation of inorganic ammonium salts to achieve the proposed standard of 3 ppmV.

This is an important aspect of the proposal from the viewpoint that certain inorganic ammonium salts appear to be viable alternatives for treating cellulose insulation to the boron compounds which are included on Annex VI of the CLP regulation with a classification of toxic to reproduction 1B. While flexibility is afforded to industry to pursue research on inorganic ammonium salts, the proposal is clear that inorganic ammonium salts cannot be used to treat cellulose insulation unless they are able to achieve the limit of 3 ppmV in any one day when tested under worst case conditions over a period of 14 days. This emission level is the limit below which occupants will be protected.

Standard testing of the insulation material should demonstrate that the concentration of ammonia does not exceed 3 ppmV in any 24 hour period over a 14 day test duration when tested under conditions of 90% relative humidity. The standard room parameters should be as specified in the test methods of Technical Specification CEN/TS 16516. The CEN method needs some adaptations. CEN/TS 16516 defines a testing method for volatile organic compound emissions and it is based on ISO 16000 standard series. It has been clarified by the Commission in their consultations with CEN experts that CEN/TS 16516 could, in theory, be used for testing inorganic compounds. However, the conditions of the test chamber would need to be re-defined for ammonia. The measurement of released ammonia can be undertaken by ion chromatography following entrapment in an acid solution. As the release factor of ammonia is linked to the relative humidity and the loading in the test chamber, some harmonised conditions (reflecting the different standards for insulation in different regions/MS) would be needed on the loading factor for the panels/material.

RAC agrees with the Forum's view that those placing cellulose insulation on the EU market are responsible for demonstrating compliance with the above standard.

Manufacturers are responsible for testing the mixtures and articles placed on the market. However, builders and installers will need to follow installation instructions to prevent the release of ammonia in service life. Conditions of use should be provided by the manufacturer or importer placing the mixtures and articles on the market.

RAC notes that in order to explore whether an amendment to the standard is required or whether a Technical Report/Technical Specification would be sufficient to determine compliance, the establishment of an activity, e.g. a. working group by CEN could be beneficial.

In the absence of an amended CEN method, RAC agrees with the Forum that it may not be possible at this point in time to list an appropriate reference as a testing method in the proposed entry to Annex XVII.

RAC recommends that the Commission considers whether the Annex XVII entry can stipulate the requirement for the manufacturer to include documentation and labelling as relevant to the technical specification for the final conditions of use, in order to ensure compliance with this maximum allowable emission limit of 3 ppmV. Failure by builders and installers of insulation to comply with the conditions of use would then be considered not to comply with this restriction entry.

Justification for the opinion of SEAC

The ammonia emission limit value of 3 ppm under specific test conditions as specified in CEN/TS 16516 is a key element in assessing the implementability of the restriction. The level of 3 ppm is a health based limit value, which has a scientific basis, supported by the RAC opinion. For the restriction to be implementable however, this limit value should in addition prove to be a level that can be complied with by companies placing on the market the cellulose insulation materials. In other words, the limit value should be a level that can be practically achieved. If such is not the case, the restriction de facto means a total ban on the use of ammonium salts in cellulose insulation material. According to the dossier, complying with the limit value can possibly be achieved by using liquid formulations instead of dry solid formulations, by using technical means to stabilize the ammonium salts added in dry formulation to the cellulose material or by substitution to ammonium free formulations. From the dossier, it becomes clear that the liquid impregnation method is not applied due to the excessive moisture remaining in the cellulose materials, causing a reduced thermal insulation capacity. The Annex XV dossier does not provide clear evidence of technical possibilities to stabilize ammonium salts if added to cellulose insulation via solid formulations. Also the consultations did not clearly demonstrate that technical feasibility of stabilization of ammonium salts (added via solid formulations to cellulose insulation material) was proven. Only one cellulose manufacturer claimed that in testing their product the emission limit value of 3 ppm showed to be technically feasible. SEAC considers demonstrating technical feasibility a pre-marketing obligation for industry. Although the evidence is meagre, SEAC concurs with the view of the dossier submitter that the restriction as proposed in RMO 1 is implementable.

In section E.2.1.2.2 of the Annex XV dossier information is provided supporting the conclusion that analytical measurement of a level of 3 ppm and levels some order of magnitude below (depending on air sampling size etc.) is technically possible. Hence, SEAC considers analytical determination of ammonia levels in air is not a factor having an impact on implementability and enforceability of the restriction.

Section E.2.1.2.1 of the Annex XV dossier discusses the possibility of exempting cellulose insulation material used for outdoor installation from the restriction. Such could be achieved by applying labelling specifying the article is intended for outdoor use only. The SEAC concurs with the view of the dossier submitter that such exemption should not be granted given the market disturbance this could give and due to the large impact this would have on

market surveillance and enforcement. The material for outdoor use would not be different from the material applied as indoor insulation and enforcement would have to provide substantial effort in checking compliance.

SEAC takes note of and agrees with the Forum advice on the restriction proposal. SEAC agrees with the Forum advice that a reference to the CEN test method should be inserted in the text proposal for a restriction. The restriction scope should be clear and stakeholders will have to be able to ascertain compliance without having to refer to guidance or other documentation in order to find out how to prove compliance. The fact that test methods are not static documents and may change in time should however be taken into account. Such can be done by changing the reference to the CEN method including 'any future updates or amendments thereof'.

SEAC notes that the Forum cannot estimate the extent of post-marketing checks and additional costs. Comparable costs for testing of formaldehyde in wooden panels at a level of € 1,700 per test has been an hindrance for more enforcement. SEAC underlines the relevance of resources for inspectorates to fulfil their tasks, as stipulated in article 121 of REACH.

Monitorability

Justification for the opinion of RAC

The Forum expressed their concerns with respect to the costs to enforcement authorities having to undertake such complex chamber testing. In order to address these concerns the draft legal text may need to be adapted to make provision for (1) those actors placing the cellulose insulation on the EU market would be responsible for undertaking the testing to demonstrate compliance and for providing such test results to the relevant authorities, and (2) that the technical specification documentation and any packaging of the corresponding cellulose insulation material should clearly indicate the final conditions of use for mixtures and articles. This would mean that enforcing authorities could take action, as relevant, against both the manufacturer if the product is non-compliant and against the installer if it is not installed as per manufacturer's recommendations.

Justification for the opinion of SEAC

The dossier contains limited information on monitorability. Information is primarily found in section E.2.1.3. The text however is not entirely clear for instance on how monitoring is defined and could be organised. From the text it is not clear how the dossier submitter defines monitoring. Three indicators are presented, all based on monitoring of ammonia emissions, two of them requiring enforcement activities at member state level. Probably these two options may be merged because in practice they are probably the same. Monitoring the restriction via poison centres is a good third option and an important one as shown by the French toxicovigilance data.

The dossier states that monitoring activities will be carried out by the existing authorities responsible for the enforcement of REACH restrictions in the different Member States and by the laboratories that will be in charge of performing the ammonia emission tests. In principle this is correct however, the dossier should also reflect upon the role and responsibility of the manufacturer, importer and distributor. It should be clarified whether these actors in the supply chain have a pre-marketing obligation to comply with the restriction or should only be responsive at request of an enforcement authority. This will have a substantial effect on the monitorability.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions of RAC and SEAC.

Basis for the opinion of RAC

The main changes introduced by RAC as suggested in this opinion compared to the restriction proposed by the Dossier Submitter (France) in their submitted Annex XV restriction dossier are: a) provisions to clarify that both articles and mixtures of cellulose insultation material treated with inorganic ammonium salts are covered (b) provision to document and label the required technical specifications and b) a derogation for mixtures of cellulose containing ammonium salts that will not have to comply to the emission limit, if used to produce panels that have been tested and found to comply. The basis for these changes was the information received during the public consultation and the advice of the Forum for Exchange of Information on Enforcement.

Basis for the opinion of SEAC

SEAC has not proposed in its opinion any changes to the restriction provisions proposed by the Dossier Submitter (further to the modification of the transition period from 1 year to 2 years after the entry into force).

References (additional to the Background Document)

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