

## **Committee for Socio-economic Analysis (SEAC)**

Opinion

on an Annex XV dossier proposing restrictions on

**Inorganic ammonium salts**

**Draft**

10 March 2015

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**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 Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

<b>Chemical names:</b>	<b>Inorganic ammonium salts</b>
<b>EC No.:</b>	Not relevant
<b>CAS No.:</b>	Not relevant

This document presents the opinion adopted by 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 OPINIONS**

**France** has submitted a proposal for a restriction 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 SEACThe 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**.

## OPINION

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*** 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 proposed restriction is as follows:

Column 1. Designation of substance	Column 2. Conditions of restriction
Inorganic ammonium salts	Shall not be placed on the market in cellulose insulation from [12] months after of entry into force of this Regulation, unless: <ul style="list-style-type: none"> <li>- Emission of ammonia gas of such materials is below <b>3 ppm</b> according to the horizontal measurement/test methods of Technical Specification CEN/TS 16516 and:</li> <li>- Specific test parameters are applied in terms of duration (14 days), relative humidity (90 +/- 5), "Attic insulation" area specific emission rate (1.25 m<sup>3</sup>.m<sup>-2</sup>.h<sup>-1</sup>), and "Wall insulation" area specific emission rate (0.5 m<sup>3</sup>.m<sup>-2</sup>.h<sup>-1</sup>). Cellulose insulation thickness and density are adapted to the foreseen use.</li> </ul>

## **JUSTIFICATION FOR THE OPINION OF SEAC**

### **JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS**

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 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**

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 (The proposed restriction)

RMO 2: Composition based restriction

RMO 3: Authorization

RMO 4: Construction Products Regulation<sup>1</sup>

RMO 5: Providing information to retailers and consumers through labelling

RMO 6: Voluntary agreement from industry

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<sup>1</sup> 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.

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

This last criterion is a logic consequence of the Commission Implementing Decision requesting the French Republic to initiate an EU restriction procedure by submitting a dossier within 3 months, in accordance with Article 129.3 of REACH<sup>2</sup>. 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<sup>2</sup> (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

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<sup>2</sup> 2013/505/EU: Commission Implementing Decision of 14 October 2013 authorising the provisional measure taken by the French Republic in accordance with Article 129 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) to restrict the use of ammonium salts in cellulose wadding insulation materials (notified under document C(2013) 6658)

can serve as the most appropriate legislative framework to assess 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. The two existing European associations seem to lack the capacity to promote and to effectively monitor an eventual voluntary agreement at EU scale and in any case may not have the motivation to do so.

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 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, page 13 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, page 66) 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 page 90) 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 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.

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.

Option within this RMO 1 is further 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**

### **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 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 DS 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 1).

**Table 1: 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 <sup>3</sup>	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**

<sup>3</sup> 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.

financially attractive option. The proposed scenario by the dossier submitter is based on consultation with the different stakeholders. SEAC also notes the following:

- 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.
- 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 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.
- 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 2).

**Table 2: 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 3.

**Table 3: 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 euros 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 hinderance 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 4).**

**Table 4: 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 5).**

**Table 5: 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 appendixes. 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 (table 6/appendixes). In all other cases proportionality was demonstrated but sometimes took longer to reach.

**Table 6: 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	<i>Not proportionate</i>	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 (see appendixes). 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**

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 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**

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 opinion.

### Basis for the opinion of SEAC

The Background Document, provided as a supportive document, gives the detailed grounds for the opinion.

Appendix 1: No sensitivity analysis

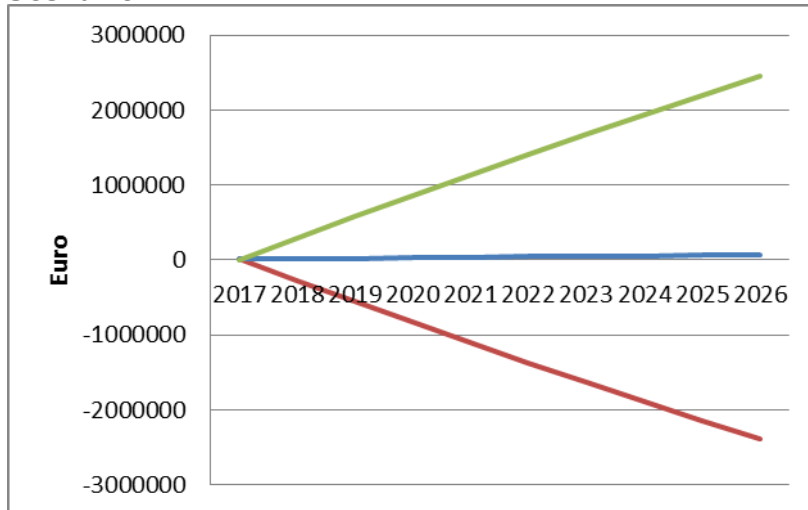
Graphical output:

Red=costs

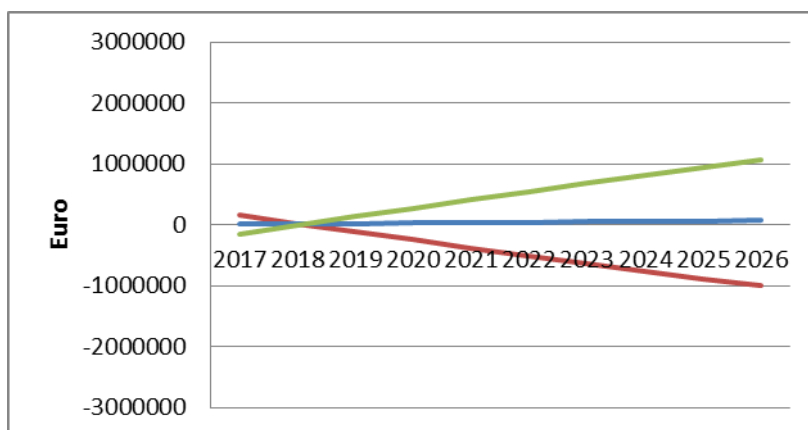
Blue=benefit

Green=net benefit of restriction (benefits-costs)

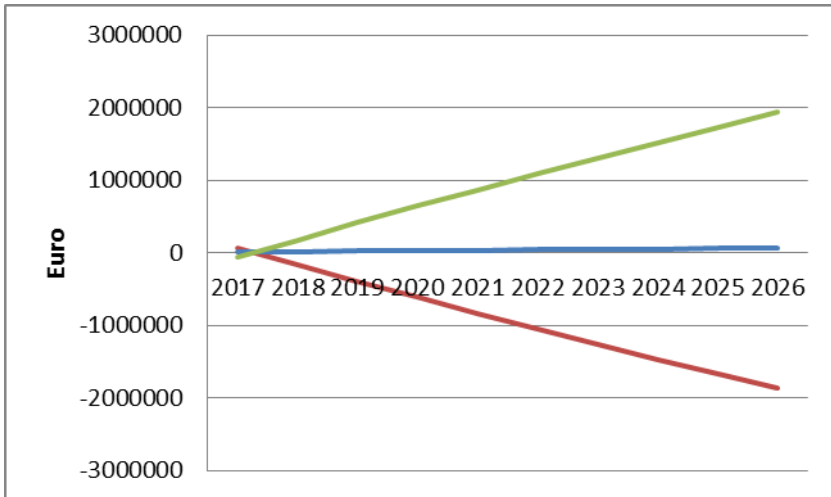
**Scenario A**



**Scenario B**



**Scenario C**



Appendix 2: Reduced number of cases (50%)

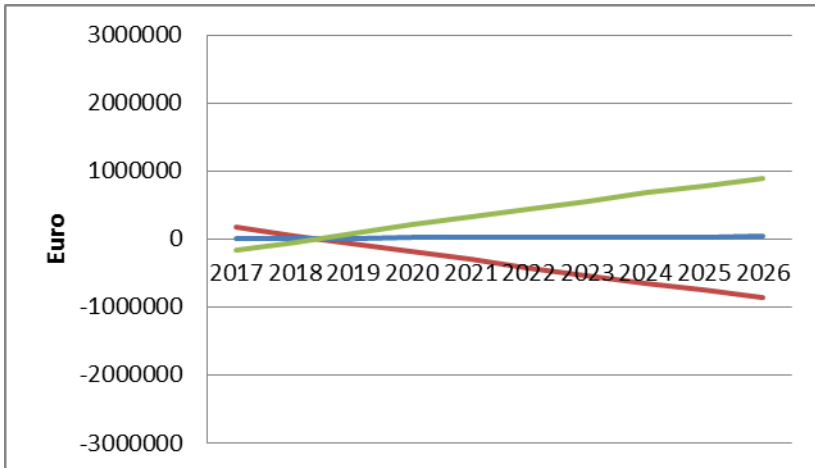
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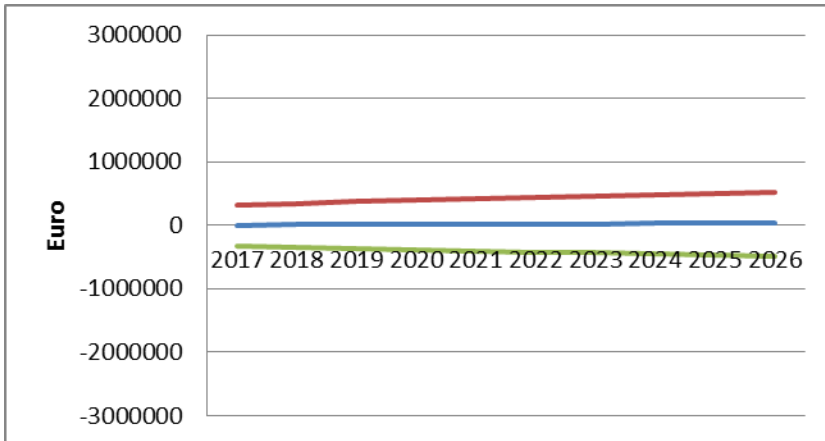
Blue=benefit

Green=net benefit of restriction (benefits-costs)

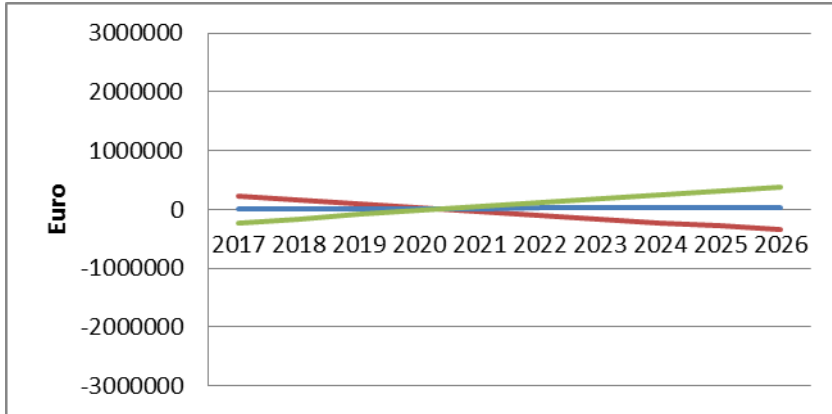
**Scenario A**



**Scenario B**



**Scenario C**



## Appendix 3: higher stabilization costs (factor 1.5 instead of 1.34)

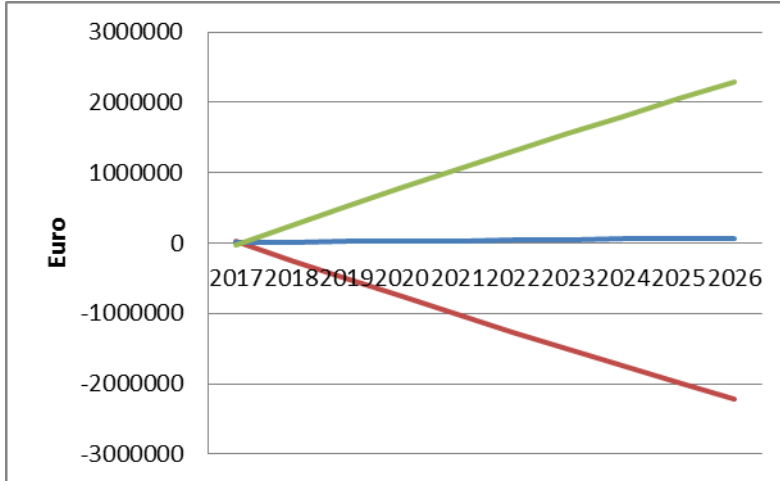
Graphical output:

Red=costs

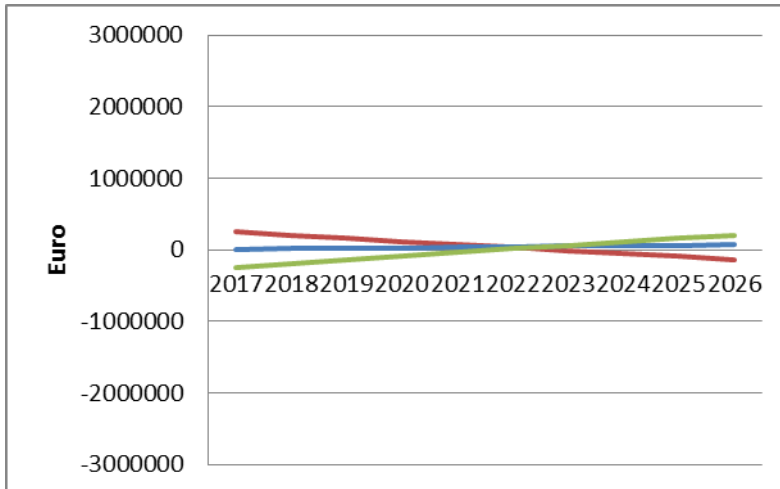
Blue=benefit

Green=net benefit of restriction (benefits-costs)

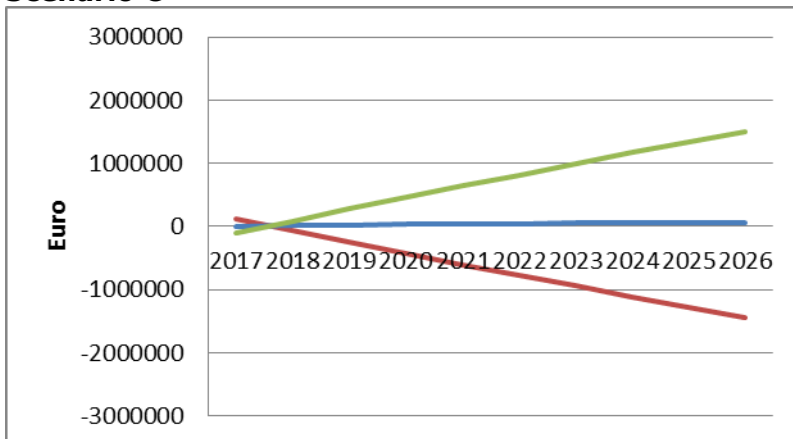
### Scenario A



### Scenario B



### Scenario C



## Appendix 4: 75% re-insulation rate

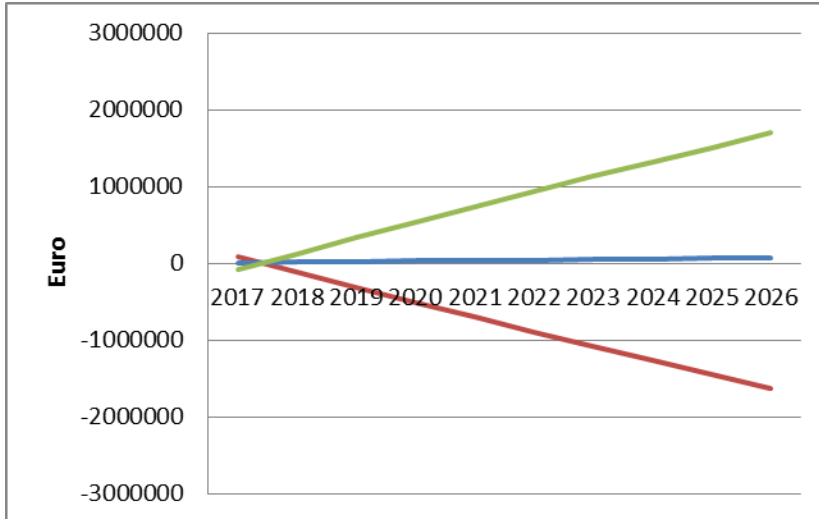
Graphical output:

Red=costs

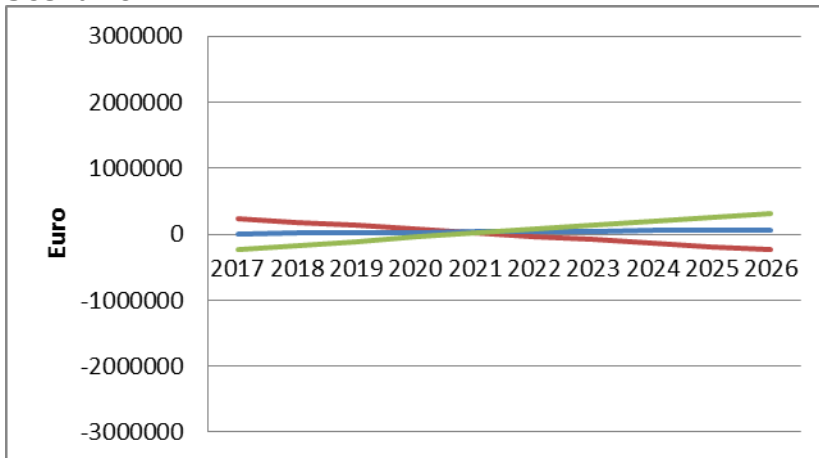
Blue=benefit

Green=net benefit of restriction (benefits-costs)

### Scenario A



### Scenario B



### Scenario C

