

#### **Comments and references to responses on ECHA's Draft 6th Recommendation for 1-bromopropane** (n-propyl bromide) (EC number: 203-445-0)

The present document compiles the comments received during the public consultation on the draft 6th recommendation for inclusion of substances in Annex XIV of REACH for 1-bromopropane (n-propyl bromide) (EC number: 203-445-0). The public consultation took place between 1 September and 1 December 2014. Some of the comments submitted contained additional attachment(s), accessible at <a href="http://echa.europa.eu/documents/10162/13640/6th">http://echa.europa.eu/documents/10162/13640/6th</a> rec comref attachments bromopropane en.zip. Those comments are indicated accordingly in the table below.

For each of the comments there is also a reference to specific section(s) of a document containing the responses to comments ("Response document", available at <u>http://echa.europa.eu/documents/10162/13640/6th axiv rec response doc bromopropane en.pdf</u>). The responses in the Response document are arranged by thematic block and level of information (see more detailed explanations at the beginning of that document).

**PUBLIC VERSION** 

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#### I - General comments on the recommendation to include the substance in Annex XIV

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2513	Albemarle Europe	Albemarle Europe SPRL acts as the European headquarters of Albemarle Corporation, a	
2014/10/17	SPRL,	global developer and manufacturer of specialty chemicals, headquartered in Baton	C.1.2. Generic

	Company, Belgium	<ul> <li>Rouge, Louisiana, USA. Amongst its activities, Albemarle Corporation produces n-propyl bromide (nPB) at one site in Magnolia, Arkansas, USA.</li> <li>Albemarle Europe SPRL submitted a registration dossier on n-propyl bromide by 1st December 2010, acting as an importer. Since 100% of the substance put on the EU market by Albemarle Europe SPRL is exclusively used by our European customers as an intermediate under strictly controlled conditions, the substance was registered as such.</li> <li>nPB supplied by Albemarle Europe SPRL is used solely as a precursor in the manufacturing of pharmaceutical products such as the anticonvulsant and mood-stabilizing drug Valproic acid that is used in the treatment of epilepsy amongst others. During this process, nPB is completely consumed and is not present in the final product. Due to the substance' exclusive use as intermediate, there is no risk of wide dispersive uses.</li> <li>Intermediates are legally exempted from the Authorization procedure in accordance with the provisions of Article 2 Paragraph 8 of the REACH Regulation. In ECHA's "Draft background document for 1-bromopropane" from 1st September 2014, it is also acknowledged that "the registered use as an intermediate in manufacture of chemicals appears not to be in the scope of authorisation" (p. 2).</li> <li>We would like to ask the Member States Committee to take into account the fact that nPB put on the EU market by Albemarle Europe SPRL is only used as an intermediate in pharmaceutical applications and is therefore exempted from Authorisation.</li> </ul>	exemptions
2521 2014/10/31	Company, Netherlands	PB only as an intermediate under strictly controlled conditions and that it's therefore outside the scope of Authorisation	C.1.2. Generic exemptions
2617 2014/11/25	Individual, United Kingdom	The use of n-propyl bromide for degreasing of metals increased in the UK with the enforcement of the VOC directive. Producers and resellers positioned n-propyl bromide as a drop in replacement for other VOC solvents (such as TCE)based upon the associated risk phrases prior the reclassification to an R60 Cat 2 CMR. The main driver was/ is the 2 mt threshold limit for n-propyl bromide based on the past risk phrase (R20), instead of a 1 mt threshold for other solvents (R40/R45). This avoided investment in sealed/CLOSED (state-of-the-art) cleaning equipment meeting binding	A.2.6. Used as a safer replacement for carcinogenic solvents, e.g. trichloroethylene

		emission limits for the workplace and exhaust emissions. This and the continued promotion of n-propyl bromide as environmentally friendly solvent in leading surface cleaning magazines in 2014 leads to a situation whereby companies are still led to believe the substance is a safer alternative to other substances, which in turn retains the use of this substance in OPEN top style equipment. In some cases NPB is even promoted as a SAFER alternative to other SVHC's!	
2679 2014/11/26	Individual, France	After Reading the document "Approach for prioritisation of SHVCs", i'd like you to consider the following.	A.2.1. Volume in the scope of authorisation is overestimated
		1) n-propyl bromide (nPB) is not a PBT: it has a ODP (ozone depletion potential) of 0,011 and an atmospheric lifetime of 24,7 days (Wuebbles et al, 2008). Global warming potential is very low (0,031) and nPB hydrolyses in water (half life 23,4 days). Therefore there is no need for environmental reasons to give 1-Bromopropane a high priority for inclusion into Annex XIV.	A.2.2. Disagree with WDU score: The substance is not used by professional workers
		2)The estimated volume for this use is less than 500mt. This makes it medium with a score of 9 instead of 12 as suggested.	A.2.3. The substance is not a PBT and therefore not a priority for
		3) Concerning the WDU (Wide dispersion use). nPB is used in Industry and only in hermetic degreasing machines specially designed to avoid contamination or hazards.	inclusion in Annex XIV
		Moreover, there is a distillation of the dirty solvent for continuous recycling. As a result of the use, some solvent is ultimately contained in waste which consists mainly of the soil removed from the parts. Professional Use is categorised by multiple actors each at low scale. This does not happen with 1-Bromopropane used as a solvent. 1- Bromopropane is not used as a solvent wipe. 1-Bromopropane based solvents are not supplied to consumers. Therefore i consider that the score associated with WDU should be 5 for IND and not 10	A.2.4. Disagree with the total priority
		Therefore the total score: = $IP + V + WSU = 1 + 9 + 5 = 15$ (much lower than 23 recommended by ECHA)	
2761 2014/11/28	Company, Netherlands	On September 3, 2014, the European Chemicals Agency (ECHA) has published its 6th draft recommendation for prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV), submitted for public consultation, under	Thank you for your comment.
		Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH.)	<i>Responses referring to the confidential attachment</i>

		Confidential attachment removed	removed.
2814 2014/11/28	Norway, Member State	The Norwegian CA supports the prioritisation of 1-bromopropane (n-propyl bromide) for inclusion in Annex XIV.	Thank you for your comment.
2854 2014/11/28	SERVUM SARL, Company, France	As 1-bromopropane (n-propyl bromide)is a very efficient and easy replacement to Trichloroethylene and Perchlorethylene and as it is by far less dangerous, and as there is so far no equivalent , its use can save a number of lives. So even if it is not harmless and as there is no equivalent it would be very damageable to block some possibilities to replace carcinogen products ( even as a provisory before a better solution or a different machine can be installed), specially in France where the law is particularly difficult. 2854_II n'existe pas de substituts évidents au perchloroéthylène selon l'Anses.pdf	A.2.6. Used as a safer replacement for carcinogenic solvents, e.g. trichloroethylene
2885 2014/11/28	Enviro Tech Europe, Company, United Kingdom	<ol> <li>1-Bromopropane or n propyl bromide (N-PB) There should be no priority to include N-PB in Annex XIV of REACH. The substance is not a PBT or vPvB and is only used in industrial processes in relatively small volumes. Most of the volume consumed in Europe is as an intermediate and therefore outside the scope of authorization and what is used as a solvent is used in a controlled manner. As further explained below, ECHA's conclusions are drawn based on erroneous and/or incomplete information on the volume and actual uses of the substance in question (from the available registration data under REACH). Article 58.3 of REACH provides that priority shall normally be given to substances with (i) bioaccumulative and toxic ('PBT') and very persistent and very bioaccumulative ('vPvB') properties, or (ii) wide dispersive use, or (iii) high volumes.</li> <li>Inherent properties ('IP') of N-PB (score 1)</li> <li>N-PB has been classified as SVHC under Article 57.c) of REACH toxicity for reproduction ('CMR') properties. N-PB is not a PBT or vPvB substance. Hence, based on the first criterion of Article 58.3 of REACH, it is not a priority for inclusion in the Annex XIV. ECHA has attributed the lower possible score 1 on the basis of that criteria.</li> <li>Wide Dispersive Use ('WDU') (scored 10 should be changed to 5) Pursuant to ECHA, the registered uses of N-PB within the scope of Annex XIV authorisation include uses at industrial sites (formulation and use as a solvent in mixtures for vapour degreasing and surface cleaning) and by professional workers (use as a solvent in mixtures for vapour degreasing and surface cleaning). Based on the second criterion of Article 58.3 of REACH, as implemented in Guidance document "Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) 10 February 2014", ECHA has therefore attributed a medium priority score 10.</li> </ol>	<ul> <li>A.1.1. General, recommendation process:</li> <li>4. Information taken into consideration for the draft recommendation</li> <li>5. New information and next steps towards the final recommendation</li> <li>A.1.5. Aspects not considered in ECHA's prioritisation:</li> <li>4. Control of risks</li> <li>A.2.1. Volume in the scope of authorisation is overestimated</li> <li>A.2.2. Disagree with WDU score: The substance is not used by professional workers</li> <li>A.2.3. The substance is not a PBT and therefore</li> </ul>

Contrary to ECHA's findings, however, the use of N-PB is limited to industrial u	se. not a priority for
Specifically, pursuant to the ECHA's guidance on prioritization:	inclusion in Annex XIV
<ul> <li>Industrial use ('IND') is an "[a]pplication of the substance as such or in a mix</li> </ul>	ture in
an industrial process with the purpose of incorporating the substance into an ar	rticle, or <b>A.2.4. Disagree with the</b>
technically supporting the production process but not intentionally becoming pa	art of total priority
the product (processing aid). As a result of the use the substance has reacted,	or
become part of an article, or it has been released, and/or is contained in waste	from A.2.5. Most of the
this use. Uses are carried out at industrial sites (small or large)."	tonnage used as
	intermediate and the
<ul> <li>Professional use ('PROF') is an "[a]pplication [] in skilled trade premises.</li> </ul>	remaining uses are
Professional use may include the use of substances as such or in mixtures, in c	order to controlled under worker
deliver services to business or private customers. This may include sophisticate	ed exposure legislation
equipment and specialised, trained personnel. Uses by professional workers are	e
considered to take place in a wide-dispersive manner Compared to the use at s	single <b>C.1.1. General</b>
industrial sites, wide dispersive uses take place everywhere (corresponding to	a principles for
municipal structure) by multiple actors each at low scale. The risk managemen	t exemptions under Art.
capacity of the single actor is low, e.g. there is no site-based technical infrastru	acture to <b>58(2)</b>
control releases."	
N-PB is used as industrial solvent in vapour degreasing. The process occurs in	C.2.1. Art 58(2)
protected environment where workers exposure is reduced to 'low', the minimu	im exemption request for
possible level as per the workers protection legislation in place across the Euro	pean use in industrial vapour
Union. Expected exposure levels at the workplace with older machines are arou	and 20- degreasing due to CAD
23 ppm, which is ten/eleven times lower than the levels at which effects were	seen in
vertebrate animals studies triggering the classification of N-PB as a Cat. 2 repr	oductive
toxicant (250 ppm on males WIL rat species only, and 500 ppm in tests conduc	cted on
both males and females rats). Modern enclosed equipment which is replacing o	lder
equipment exposes workers to virtually no solvent. In practice, modern machin	nes only
allow equipment opening by workers when the solvent levels are below 20 ppm	n and air
flow is away from operator back into machine.	
Importantly, it should also be highlighted that workers are not constantly expo	sed to
20-23 ppm N-PB. As soon as the residual vapour comes out from the machine	it is
diluted by the size of the room. Therefore, the 20-23 ppm exposure limits are i	in fact
only short time exposure limits. The long term worker's exposure (Time Weight	ted
Average, 'TWA') is significantly lower.	
In particular, the handling of N-PB occurs in industrial sites operating in control	lled
environment and fixed machines. These machines clean parts and distil the dir	tv
solvent for continuous recycling. By contrast, professional use implies, as per	the
definition above, the participation of "multiple actors each at low scale". This	
requirement is not met in the case at hand. Moreover, N-PB is not used in cons	sumer

<ul> <li>3. Volume ('V') of N-PB (scored 12 should be changed to score 9)</li> <li>ECHA has estimated that the volume of N-PB manufactured and/ or imported into the EU, and falling within the scope of REACH authorization requirement, is in the range 1000 to less than 10,000 metric tons. Hence, based on the third criterion of Article 58.3 of REACH, as implemented in the above mentioned Guidance document, ECHA has attributed a high priority score 12.</li> <li>However, ECHA's estimation is overstated. ECHA has assumed that 69% of the total volume of N-PB in the EU is used for intermediate and laboratory uses. However, ECHA did not take into consideration that: <ul> <li>The Lead Registrant does not support this estimation and knows it to be much lower.</li> <li>The Lead Registrant does not support this estimation is overated in the Technical Report on Ozone-depleting substance as a solvent within the EU is known to the European Environment Agency ('EEA') although is not declared in the Technical Report on Ozone-depleting substances 2013 (No 14/2014, ISSN 1725-2237). Indeed, it is referred to as 'confidential' (pp. 24-25). We have requested access to this information on the EUA. In the meantime, ECHA should be able access; it directly and confirm the low quantities used in the EU. Based on industry's own data it is estimated that N-PB is used as a solvent in quantity of maximum 300-500 tons. A volume of 300-500 tons corresponds to a medium priority score of 9.</li> <li>Moreover, other uses must also be exempted from the scope of the Annex XIV authorization requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'' (Article 58.2) REACH, further discussed in appropriate comment section).</li> <li>Total priority score for N-PB (23 should be changed to 15) Therefore the total priority score for N-PB should be: IP + V + WSU = 1 + 9 + 5 = 15. ECHA should accordingly downgrade the inclusion priority of N-PB from the initial score of 23 to 15.<!--</th--><th>products. Therefore the score associated with WDU should be 5 for IND and not 10 for PROF.</th><th></th></li></ul></li></ul>	products. Therefore the score associated with WDU should be 5 for IND and not 10 for PROF.	
<ul> <li>However, ECHA's estimation is overstated. ECHA has assumed that 69% of the total volume of N-PB in the EU is used for intermediate and laboratory uses. However, ECHA did not take into consideration that:</li> <li>The Lead Registrant does not support this estimation and knows it to be much lower.</li> <li>The industrial degreasing (solvent) use of the overall N-PB volume is minimal. Specific information on the use of the substance as a solvent within the EU is known to the European Environment Agency ('EEA') although is not declared in the Technical Report on Ozone-depleting substances 2013 (No 14/2014, ISSN 1725-2237). Indeed, it is referred to as 'confidential' (pp. 24-25). We have requested access to this information from the EAA. In the meantime, ECHA should be able access it directly and confirm the low quantities used in the EU. Based on industry's own data it is estimated that N-PB is used as a solvent in quantity of maximum 300-500 tons. A volume of 300-500 tons corresponds to a medium priority score of 9.</li> <li>Moreover, other uses must also be exempted from the scope of the Annex XIV authorization requirement and the overall volume must therefore be lowered accordingly. For instance, these are uses covered by any "specific [EU] legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled" (Article 58.2) REACH, further discussed in appropriate comment section).</li> <li>Total priority score for N-PB (23 should be changed to 15) Therefore the total priority score for N-PB should be: IP + V + WSU = 1 + 9 + 5 = 15. ECHA should accordingly downgrade the inclusion priority of N-PB from the initial score of 23 to 15.</li> <li>In comparison with the remaining twenty-two chemicals included in the Candidate List, this score would rather rank N-PB as a low priority. With a score of 5, N-PB by volume and industrial use only it goes down to a joint 11th on score rating.</li> </ul>	3. Volume ('V') of N-PB (scored 12 should be changed to score 9) ECHA has estimated that the volume of N-PB manufactured and/ or imported into the EU, and falling within the scope of REACH authorization requirement, is in the range 1000 to less than 10,000 metric tons. Hence, based on the third criterion of Article 58.3 of REACH, as implemented in the above mentioned Guidance document, ECHA has attributed a high priority score 12.	
<ul> <li>Moreover, other uses must also be exempted from the scope of the Annex XIV authorization requirement and the overall volume must therefore be lowered accordingly. For instance, these are uses covered by any "specific [EU] legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled" (Article 58.2) REACH, further discussed in appropriate comment section).</li> <li>4. Total priority score for N-PB (23 should be changed to 15) Therefore the total priority score for N-PB should be: IP + V + WSU = 1 + 9 + 5 = 15. ECHA should accordingly downgrade the inclusion priority of N-PB from the initial score of 23 to 15. In comparison with the remaining twenty-two chemicals included in the Candidate List, this score would rather rank N-PB as a low priority. With a score of 15, N-PB by volume and industrial use only it goes down to a joint 11th on score rating.</li> </ul>	<ul> <li>However, ECHA's estimation is overstated. ECHA has assumed that 69% of the total volume of N-PB in the EU is used for intermediate and laboratory uses. However, ECHA did not take into consideration that:</li> <li>The Lead Registrant does not support this estimation and knows it to be much lower.</li> <li>The industrial degreasing (solvent) use of the overall N-PB volume is minimal.</li> <li>Specific information on the use of the substance as a solvent within the EU is known to the European Environment Agency ('EEA') although is not declared in the Technical Report on Ozone-depleting substances 2013 (No 14/2014, ISSN 1725-2237). Indeed, it is referred to as 'confidential' (pp. 24-25). We have requested access to this information from the EAA. In the meantime, ECHA should be able access it directly and confirm the low quantities used in the EU. Based on industry's own data it is estimated that N-PB is used as a solvent in quantity of maximum 300-500 tons. A volume of 300-500 tons corresponds to a medium priority score of 9.</li> </ul>	
<ul> <li>4. Total priority score for N-PB (23 should be changed to 15)</li> <li>Therefore the total priority score for N-PB should be: IP + V + WSU = 1 + 9 + 5 = 15.</li> <li>ECHA should accordingly downgrade the inclusion priority of N-PB from the initial score of 23 to 15.</li> <li>In comparison with the remaining twenty-two chemicals included in the Candidate List, this score would rather rank N-PB as a low priority. With a score of 15, N-PB by volume and industrial use only it goes down to a joint 11th on score rating.</li> </ul>	• Moreover, other uses must also be exempted from the scope of the Annex XIV authorization requirement and the overall volume must therefore be lowered accordingly. For instance, these are uses covered by any "specific [EU] legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled" (Article 58.2) REACH, further discussed in appropriate comment section).	
	<ul> <li>4. Total priority score for N-PB (23 should be changed to 15)</li> <li>Therefore the total priority score for N-PB should be: IP + V + WSU = 1 + 9 + 5 = 15.</li> <li>ECHA should accordingly downgrade the inclusion priority of N-PB from the initial score of 23 to 15.</li> <li>In comparison with the remaining twenty-two chemicals included in the Candidate List, this score would rather rank N-PB as a low priority. With a score of 15, N-PB by volume and industrial use only it goes down to a joint 11th on score rating.</li> </ul>	

2947 2014/12/01	LUBRICANT s.r.o., Company, Czech Republic	LUBRICANT s.r.o. is a distributor and user of nPB in mixture in Czech, Slovak and Poland. We have enough evidences, it is not so much dangerous to be included in SVHC. We sell less than 10 tons/y in these 3 countries, the solvent is used exclusively in sealed cleaning machines in industrial applications. 1-Bromopropane is not a PBT and nor is it vPvB. The total score is 0+3+5 = 8. Jiri Valdauf	<ul> <li>A.2.1. Volume in the scope of authorisation is overestimated</li> <li>A.2.2. Disagree with WDU score: The substance is not used by professional workers</li> <li>A.2.3. The substance is not a PBT and therefore not a priority for inclusion in Annex XIV</li> <li>A.2.4. Disagree with the total priority</li> <li>A.2.7. Disagree with SVHC identification</li> </ul>
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## **II** - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2679 2014/11/26	Individual, France	Considering the comments below, I believe the priority for inclusion of 1-Bromoprpane into Annex XIV is low and should not be considered at this time	Please see references to responses in section I.
2761 2014/11/28	Company, Netherlands	Confidential attachment removed	<i>Responses referring to the confidential attachment removed.</i>
2814 2014/11/28	Norway, Member State	In general, we are in favour that a regulation should enter into force as soon as possible. Hence we are in favour of the shortest LAD slot.	Thank you for your comment.
2854 2014/11/28	SERVUM SARL, Company, France	application not before 2019 and sunset 2024 to leave a benefit in case of provisory move 2854_Il n'existe pas de substituts évidents au perchloroéthylène selon l'Anses.pdf	B.1.1. General principles for setting latest application dates

			01/07/2013
			<ul> <li>/ sunset dates:</li> <li>2. ECHA's proposal for sunset dates</li> <li>3. ECHA's proposal for latest application dates</li> </ul>
2885 2014/11/28	Enviro Tech Europe, Company, United Kingdom	1-Bromopropane or n propyl bromide (N-PB) An estimated timing has been provided in the ECHA's Draft 6th Recommendation of Priority Substances,( Draft 6th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation), see in particular 1-bromopropane (n-propyl bromide) listing on page 1 and footnote 2 on page 4) which provides: "[a]ssuming that the Commission amendment of Annex XIV of the REACH Regulation on the basis of this sixth Recommendation would enter into force in summer 2016, the latest application date [for N-PB] would be February 2018". This is the earliest possible LAD proposed for the substances included in the 6th Draft Recommendation. The other attributed slots are May 2018 and August 2018. If ECHA decides to maintain the N-PB priority status and the proposed Annex XIV inclusion date, at the very minimum it should be moved to the last possible application slot, i.e., 24 months after N-PB's inclusion into Annex XIV. (As per the ECHA's Guidance document on Preparation of Draft Annex XIV entries for substances recommended to be included in Annex XIV general approach "latest application date slots will normally correspond to 18, 21 and 24 months after inclusion in Annex XIV" (see in particular page 5 (9)) This is because the N-PB industry is highly fragmented and comprises many SMEs with limited resources and know-how. Therefore, the industry would need at least the entire 24 months to prepare and submit the authorisation applications.	<ul> <li>B.1.1. General principles for setting latest application dates</li> <li>/ sunset dates:</li> <li>3. ECHA's proposal for latest application dates</li> </ul>

### **III - Comments on uses that should be exempted from authorisation, including reasons for that**

Number /	Submitted by	Comment	Reference to responses
Date	(name, submitter		
	type, country)		
2513	Albemarle Europe	see general comments	Please see references to
2014/10/17	SPRL,		responses in section I.
	Company,		
	Belgium		

2521 2014/10/31	Company, Netherlands	PB only as an intermediate under strictly controlled conditions and that it's therefore outside the scope of Authorisation	C.1.2. Generic exemptions
2666 2014/11/26	Individual, Germany	It may also be said that the users of this chemical are small number of specialist hi- Tech (hi-End) Product manufacturers who can afford it in their product pricing. This item is vital to ensure the hi-quality first time production cleaning process, and ensuring that this type of product manufacturing stays within the EU.	<ul> <li>C.1.1. General principles for exemptions under Art. 58(2)</li> <li>C.1.3. Aspects not justifying an exemption from authorisation</li> <li>A.1.5. Aspects not considered in ECHA's prioritisation:</li> <li>2. Aim &amp; proportionality of authorisation system - Authorisation is not a ban</li> </ul>
2761 2014/11/28	Company, Netherlands	Reactive raw material uses under controlled conditions should be exempted from authorisation We believe that the worker exposure risk is already adequately addressed under the current REACH dossier, (joint submission of the brominated compounds consortium members, dated February 2014), and the subsequent REACH SDS Annex for Exposure Scenarios. The operating conditions as derived from the extremely low DNELs in both documents are already legally binding. We don't see any benefit or additional value in using the authorization instrument to further control n-PB, and we think inclusion of the substance in to Annex XIV list as disproportionate, and unjustified. Use, Exposure, Risk Management Measures: According to the information collected by the REACH Consortium for Brominated substances, around 70% of n-PB is used for intermediate purposes, under strictly controlled conditions. It means that the lion share of 2/3 of n-PB uses, is exempt from REACH Title VII, and only the remaining 30% of industrial uses are subject to the authorization process under REACH (see volumes under the confidential section of this document). With repards to this remaining 20% of a PB uses, it is clearly shown in the current	C.1.1. General principles for exemptions under Art. 58(2) C.1.2. Generic exemptions C.1.3. Aspects not justifying an exemption from authorisation A.1.5. Aspects not considered in ECHA's prioritisation: 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban

		REACH dossier (n-PB joint submission of the brominated compounds consortium members, dated February 2014), that as a result of the extremely low DNEL's derived from the NTP carcinogenic study, the safe use of n-PB, can only be demonstrated if the use of substance are restricted to sealed and closed systems only. The current expose scenarios and operational conditions depicted in the current dosser and annexed to SDSs provided to downstream users, are already legally binding under the law of REACH. Moreover, the vapor degreasing equipment used nowadays is already enclosed and hermetically sealed to minimize exposure to workers and the environment, and are subject to occupational exposure levels significantly below the NOAEL identified in the CMR classification process. Given the facts that the use of n-PB is already highly regulated and restricted by the current exposure scenarios, and that the worker exposure risk is already adequately addressed under the REACH dossier and subsequent SDS, we consider any additional risk management, such as inclusion in the Annex XIV list, as disproportionate, and unjustified.	<ul> <li>3. Use specific scrutiny foreseen at application stage</li> <li>4. Control of risks</li> <li>A.2.2. Disagree with WDU score: The substance is not used by professional workers</li> <li>A.2.5. Most of the tonnage used as intermediate and the remaining uses are controlled under worker exposure legislation</li> <li>Responses referring to the confidential attachment removed.</li> </ul>
2814 2014/11/28	Norway, Member State	The Norwegian CA does not support that any exemptions from the authorisation requirement should be proposed.	Thank you for your comment.
2854 2014/11/28	SERVUM SARL, Company, France	Aerospace , Oxygen transport, dry cleaning : in all cases where a perfect degreasing is mandatory and where other solutions are long to implement 2854_II n'existe pas de substituts évidents au perchloroéthylène selon l'Anses.pdf	C.1.1. General principles for exemptions under Art. 58(2) C.1.3. Aspects not justifying an exemption from authorisation
2885 2014/11/28	Enviro Tech Europe, Company,	1-Bromopropane or n propyl bromide (N-PB)	C.1.1. General principles for

United Kingdom	Article 58.2) of REACH allows exempting from authorization requirement the uses or categories of uses of Annex XIV substances "provided that, on the basis of the existing specific [EU] legislation imposing minimum requirements relating to the protection of	exemptions under Art. 58(2)
	human health or the environment for the use of the substance, the risk is properly controlled."	C.1.3. Aspects not justifying an exemption from authorisation
	The risk related to the use and handling of N-PB as industrial vapour degreasing is already properly controlled by EU legislation on workers protection and, therefore, N- PB must be exempted from Annex XIV authorization for this specific use. Such measures already stem from EU legislation "imposing minimum requirements".	C.2.1. Art 58(2) exemption request for use in industrial vapour degreasing due to CAD
	Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work ('CAD'), as supplemented by Directives 2000/39/EC, 2006/15/EC and 2009/161/EU establishing lists of indicative occupational exposure limit values, imposes minimum requirements seeking to protect workers from the effects of chemical agents at the workplace, or as a result of any work "actively involving chemical agents", which are defined as "any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work". This would include, amongst others, industrial uses of N-PB.	
	CAD overall provides that the employers must (i) assess any risk to the safety and health of workers arising from the presence of those chemical agents, (ii) take appropriate protection and prevention measures to minimize its impact, (iii) establish procedures (action plans) which can be put into effect in case of accident, incident or emergency related to the presence of hazardous chemical agents at the workplace. Arguably, the use of a closed system production process for handling of N-PB assures compliance with these requirements. It guarantees that there will not be any exposure of workers to N-PB.	
	<ul> <li>Pursuant to ECHA's Guidance on the preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV of 21 August 2014, the existing specific EU legislation within the meaning of that Article 58.2) of REACH must:</li> <li>Control properly the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance, specified in Annex XIV (generally this legislation must specifically refer to the substance either by naming it directly or by referring to the group to which this substance belongs).</li> <li>Define the measures to be implemented by the actors and to be enforced by the authorities in a way that ensures the same minimum level of control of risks</li> </ul>	

throughout the EU and this level must be regarded as proper. This can include EU legislation that allows EU Member States to impose more stringent requirements that the specific minimum requirements set in the EU legislation in question. Legislation setting only the aim of imposing measures (e.g., EU legislation which provides Member States with the possibility to impose less stringent requirements that the suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of the measures to be implemented, is not regarded as sufficient to meet the requirements under Article 58.2).	
In principle, according to the ECHA's Guidance, where occupational exposure limits exist, the application for an exemption under Article 58.2) is more likely to succeed. Notwithstanding, in the case at hand, despite the absence of occupational exposure limits, the use of N-PB in controlled environment is such that no or low exposure of workers or the environment can reasonably be anticipated. Therefore, the EU legislation on chemical agents at work combined with the practical measures taken in the relevant industry sector to implement the CAD (i.e., closed systems) are sufficient to address the risk related to the industrial uses of N-PB. Based on the foregoing, no prioritisation is warranted for N-PB.	