

## COMMENTS AND RESPONSE TO COMMENTS ON AUTHORISATION

**Substance name:** Bis(2-ethylhexyl) phthalate (DEHP)

**EC number:** 204-211-0

**CAS number:** 117-81-7

**Broad information on use applied for (title):** Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

**Consultation number:** 0008-02

**Applicant name:** VINYLOOP FERRARA S.p.A.

**Consultation period:** 13/11/2013 - 08/01/2014

Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 144 <b>Date:</b> 2014/01/08	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Non-governmental organisation (NGO) <b>Name of org/company:</b> European Environmental Bureau (EEB) <b>Country:</b> Belgium					several alternatives are provided; substances, processes and alternative methods. However, the system doesn't allow us to submit them all together.		<a href="#">Comment 144 Attachment.doc</a>

Applicants' response:								
The applicants have realized that several of the questions raised by the stakeholders call for the same answer. As a consequence, and in order to keep this document as synthetic as possible, the full text answers are reported below the table whereas only the answer reference is listed here.								
QUOTE								Answer ref.
Alternatives to DEHP used in the production of recycled soft PVC articles include alternative materials and alternative technologies that avoid the use of DEHP. Many downstream users are phasing out DEHP and PVC and therefore different alternatives are available in the market.								R001, R002, R003, R004
Insufficient information is provided in the public consultation								R005, R006, R007
Adequate control of workers and consumers exposure to DEHP is not demonstrated It is very difficult if not impossible to assess the exposure to DEHP due to the lack of information provided in the public consultation.								R006
The scope of the application is too general								R007
Mixture toxicity of phthalates is disregarded								R006
The application should follow the socio economic authorization route								R006, R008
Review period Authorisation should not be granted for DEHP use in recycled soft PVC. However if it is finally granted, the review period should be as short as possible due to the availability and suitability of safer alternatives in the market.								R010, R011, R015
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
Ref.No: 135 Date: 2014/01/08	Affiliation: BehalfOfAnOrganisation Type/Role in the supply chain: Industry or trade association Name of org/company: ACEA - European Automobile Manufacturers Association Country: Belgium					According to our information, technical alternatives for DEHP are available but lead time for a proper substitution is not sufficient for automotive products, see also enclosed file.		<a href="#">Comment 135 Attachment.pdf</a>
Applicants' response:								

No comment								
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 126 <b>Date:</b> 2014/01/08	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Non-governmental organisation (NGO) <b>Name of org/company:</b> BUND <b>Country:</b> Germany					See 7. "other comments".		<a href="#">Comment 126 Attachment.doc</a>
<b>Applicants' response:</b>								
<b>QUOTE</b>								<b>Answer ref.</b>
It is possible to replace DEHP with alternatives; this has been demonstrated by various companies. Alternatives include chemicals as well as other plastic materials. Plastics that have elastic properties even without any addition of plasticisers are preferable. Only recently RIVM published a report that identifies suitable alternatives to applications of DEHP and other phthalates (1).								R003, R004
Children's exposure to DEHP is too high and needs to be eliminated								R006
Application too unspecific								R007
Mixture effects are not taken into account								R006
Procedure should follow the socio economic authorization route								R006, R008
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 118 <b>Date:</b> 2014/01/08	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Non-governmental organisation (NGO) <b>Name of org/company:</b> CHEM Trust <b>Country:</b> United Kingdom					DEHP has already been replaced by many companies in numerous applications with different alternatives (see overview		<a href="#">Comment 118 Attachment.doc</a>

						reports referred to in the non-confidential attachment).		
<b>Applicants' response:</b>								
<b>QUOTE</b>								<b>Answer ref.</b>
DEHP has already been replaced by many companies in numerous applications with different alternatives (see Ref 1-3) and the development of safer alternatives has been ascribed to regulatory measures (Ref 4). Granting this authorization would undermine those companies' efforts that already substituted DEHP with less toxic alternatives and help laggards to make continued profits from toxic chemicals which have already been replaced by other substances, materials or technical solutions and are available on the market.								R002, R003, R012
CHEM Trust considers that the authorization application is not specific enough with regard to the use and should therefore not be accepted. The application covers a large variety of different consumer products (except for a few excluded ones) which would lead to human and environmental exposure during the production, use and disposal. We would have expected the broad scope to be a reason for a rejection during the ECHA conformity check, as the applicant seems to seek a general authorization and not a use-specific one.								R007
Limited information provided in public consultation								R003
Procedure should use "Socio-economic route" instead of "adequate control" In our opinion it is not appropriate to consider the authorization of DEHP through the adequate control route but instead the socio-economic route should be applied: DEHP is classified as a reprotoxic substance and it is a known endocrine disrupter.								R006, R008
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 106 <b>Date:</b> 2014/01/08	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Non-governmental organisation (NGO) <b>Name of org/company:</b> Health and Environment Alliance <b>Country:</b> Belgium					see appended document		<a href="#">Comment 106 Attachment.pdf</a>
<b>Applicants' response:</b>								
<b>QUOTE</b>								<b>Answer ref.</b>

The identification of an alternative that is only a substance as opposed to a material or technique is a central contention of this application. ... in essence saying they won't consider alternative materials / designs, because they make only the one substance that has multiple uses; so the multiple uses must continue to be made by using a single plasticizer that works for all uses, and that doesn't cost differently to that substance.								R013	
Unproven assertion of adequate control (...) because the CSR is confidential and NOT available in the public consultation								R006, R008	
Reference number and date:	Submitter:	Alternative:						Attachments:	
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling		
<b>Ref.No:</b> 98 <b>Date:</b> 2014/01/08	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Other <b>Name of org/company:</b> Allgemeine Unfallversicherungsanstalt <b>Country:</b> Austria					Technical improvements and alternatives for the final articles		<a href="#">Comment 98 Attachment.docx</a>	

Applicants' response:								
QUOTE							Answer ref.	
Some of the contributing exposure scenarios in the applications demonstrate open or partly open use or handling (e.g. PROC 5, PROC 6, PROC 8b, PROC 9, etc.). Sampling or substance transfers as well as other procedures are possible in closed systems. Thus as alternative techniques we propose using such well-established techniques instead of (semi) closed or (semi) open systems that still can lead to significant exposure to the substance and might cause health impairments of workers. Available alternative techniques according to existing best practice methods (e.g. closed systems) should be a must for granting authorisations.							R006	
In all the mentioned articles in Table ES2-SL-C: (Service life consumer: Exposure from consumer articles) PVC can easily be substituted by well-established other substances that are partly known for centuries. wood, laminate flooring, marble, ... instead of PVC flooring cotton, linen, rubber, other polymers ... instead of PVC gym mats leather, metal, other polymers ... instead of PVC seating for outdoor use and so on							R002, R003	
Furthermore the exposure scenario associated with the application dossier does not give any exposure assessment that demonstrates adequate controlled conditions. That makes it impossible to propose alternative techniques.							R006, R005	
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
Ref.No: 60 Date: 2014/01/07	Affiliation: Individual Type/Role in the supply chain:  Name of org/company:  Country: United States		phthalate alternative	Confidential		I direct the Chemicals Policy and Science Initiative of the Lowell Center for Sustainable Production at the University of Massachusetts Lowell. With our sister institute, the Massachusetts Toxics Use Reduction Institute, we have conducted significant research with companies across supply chains on alternatives to DEHP in a number of applications. Please see attached report where collaborative Green Screen Assessments were used to evaluate the hazards associated with eight alternatives identified for DEHP in wire and cable applications. These alternatives could be used in other DEHP applications. A second report examines alternatives to DEHP and other phthalates in a range of consumer product applications. These alternatives include alternative polymers which achieve similar flexibility and performance	CLP varies by substance/alternative	<a href="#">Comment 60 Attachment.pdf</a>

						<p>http://www.sustainableproduction.org/download/s/PhthalateAlternatives-January2011.pdf Our general conclusions have been that safer, cost-effective and functional alternatives to DEHP as a plasticizer in PVC applications are available for most applications. Suitable alternatives will vary by specific use, however. These alternatives may include alternative polymers that achieve flexibility through polymer manipulation without the addition of chemical plasticizers. It is important that any alternatives assessment to DEHP at least identify alternative polymers that could be used. Our experience is that to evaluate potential alternatives for a chemical like DEHP, used as a plasticizer in a number of different applications, it is critical to evaluate alternatives on based on an evaluation its functional use and performance needs for a particular application. Chemical and polymer alternatives may vary given the particular application. Given the multiple uses of DEHP, all of which have different possible alternatives, it may not be appropriate to issue a broad authorization for this substance.</p>		
<b>Applicants' response:</b>								
<b>QUOTE</b>							<b>Answer ref.</b>	
Chemical Hazard Assessments of Alternative Plasticizers for Wire & Cable Applications							R002, R004	
Referen ce number and date:	Submitter:	Alternative:					Classification and Labelling	Attachments:
		Type	Gener ic name	EC Numbe r	CAS Num ber	Description of technical alternative		
Ref.No: 39 Date: 2014/01 /07	Affiliation: Individual Type/Role in the supply chain:					I am the Director of the Massachusetts Toxics Use Reduction institute (TURI), which has studied both technical and substance alternatives to DEHP. Our basic conclusion is that alternatives are available, but that the specific alternatives vary by specific use.		<a href="#">Comment 39 Attachment.pdf</a>

	<b>Name of org/company:</b>  <b>Country:</b> United States					<p>Attached is Chapter 7 of our report, "Five Chemicals Alternatives Assessment Study," titled "DEHP". TURI performed alternatives assessments for DEHP used in resilient floor covering, medical devices for neonatal care, and wall coverings. As discussed in detail in the report, other phthalates and non-phthalate plasticizers and non-PVC material alternatives were found for all three applications, but the suitable alternatives varied depending on specific use. Given the multiple uses of DEHP, all of which have different possible alternatives, it may not be appropriate to issue a broad authorization for this substance.</p>		
<b>Applicants' response:</b>								
<b>QUOTE</b>								<b>Answer ref.</b>
Chapter 7. DEHP Five Chemicals Alternatives Assessment Study								R002, R004
Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 30 <b>Date:</b> 2014/01/06	<b>Affiliation:</b> Individual <b>Type/Role in the supply chain:</b>  <b>Name of org/company:</b>  <b>Country:</b> Japan					<p>January 6, 2014 Opinion of JPIA on Information on Use Applied for in Application for Authorisation (DEHP)</p> <p>Japan Plasticizer Industry Association (JPIA)</p> <p>[Preface] We, JPIA, welcome this opportunity given to comment on the above Application for Authorisation. JPIA is an industrial association of Japanese companies manufacturing and marketing plasticizer. JPIA is very interested in this Application for Authorisation, because we have a profound connection with EU through trading of Japanese articles containing chemical substances which would be required to submit the Application. This Application for Authorisation of DEHP presents the actual state of general handling of the chemical in its</p>		<a href="#">Comment 30 Attachment.doc</a>



					<p>respective uses (including recycling). It also cites basis of argument available at present and widely recognized in the world from the scientific viewpoint for the areas concerning REACH Application for Authorisation such as toxicity, risk assessment, analysis of substitutes, socio-economic analysis. JPIA also gives full endorsement to it. Article 60 of REACH says: "an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a)." This means that nonscientific and predicative assessment and, in the lack of scientific data, excessive application of precautionary principle shall be avoided. From such the point of view, JPIA is convinced that the use applied for will be authorized. Important points of JPIA's request are as follows: [Request] JPIA believes that the content of the Application for Authorisation submitted with relation to respective uses of DEHP by ARKEMA FRANCE, Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna, DEZA a.s. VINYLOOP FERRARA S.p.A, (Stana RecyclingAB, Plastic Planetsrl) is valid based on the argument as below and requests your consideration to give an authorisation to the whole scope of application. [Justification for Request] 1. Reproductive toxicity JPIA has conducted various tests and studies to verify the difference in mechanism of action of DEHP in relation to the reproductive toxicity between rodents and primates (particularly human beings) for more than 10 years jointly with European Council for</p>		
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					<p>Plasticisers and Intermediates (ECPI) and American Chemical Council-Phthalate Ester Panel (ACC-PEP). By administering d4-labeled DEHP to marmosets (a primate species) and human volunteers and directly analyzing the urinary level of its metabolites (and their conjugates with glucuronic acid, or glucuronides), it has been shown that the metabolic machinery of DEHP such as excretion pattern and excretion rate differs between the primate including human beings and rodents and the absorption rate is lower in the formers, demonstrating that the primates has an extremely higher defensive function against toxic effects of DEHP than the rodents. 1), 2) Recent studies3), 4), 5), 6) have shown the difference in reproductive toxicity of DEHP and species difference in expression mechanism and others, indicating that DEHP does not produce toxic effects on reproduction in human beings. Concerning results from epidemiological studies was questioned about their validity7). According to Review by O. Albert, et al.8) (i) Although studies conducted in humans are limited in number, the results are quite different from those of studies using animals. (ii) Some differences in response have been noted among rats, mice, primates and humans. Further investigations are needed to clarify the reason for. Such the controversial toxicity issue should be discussed and judged based on the results from a massive bio-monitoring project (COPHES: Consortium to Perform Human Bio-monitoring on a European Scale) presently in progress in Europe and ECOCHIL Plan9) in Japan; as mentioned in the Proposition10) by advisors of EC, excessive application of precautionary principle should be avoided. 2. Substitutes Although DINP and DIDP are</p>		
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					<p>conceivably the candidates of substitute for DEHP and each plasticizer has its advantage and disadvantage in performance, there is no other plasticizer than DEHP from the view point of cost-performance balance still from now on. As for non-phthalate plasticizers such as DINCH and ASE cited for substitute candidates, their use is substantially limited and special (for medical devices, etc.). Due to their performance ((e.g.) workability, compatibility, oil resistance, etc.), considerable technical difficulties are anticipated for their substitution for DEHP. And in the course of their introduction to the market, verification of a new specification for general use will required and inevitably accompanied by long period and cost increase. Moreover, such substitution cannot following subjects; suppliability of raw materials and production technology (including patent issue) and lack of safety data; and, therefore, its socio-economic impact is expected to be very significant. 3. Risk assessment According to detailed risk assessments conducted in Europe, USA and Japan, as mentioned above, the major part of DEHP intake is derived from food and, in young children, intake from contact with DEHP-containing articles (mainly licking) is added and results in considerable risk (toxic effects, origin of risk, are seen in rodents but not in primates which can quickly metabolize DEHP; details are discussed earlier). This finding provides a basis for restricted use in toys as implemented in many countries. The conclusion shared by these risk assessments is: "risk is sufficiently controlled under current conditions of use" and the need of further restriction is denied. As said before, according to the Article 60 of REACH, "if the risk is sufficiently controlled as described by applicant, authorisation shall be</p>		
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					<p>granted". It follows that the use applied ought to be authorized. 4. Recycle DEHP has been applied to its wide use as plasticiser of soft vinyl chloride containing-products. Many of them are excellent in material-recycling performance, with many of used articles being remanufactured into mats, floorings and others. As seen in "&gt;2×2010 in 2020 Plan" and 2013 report of VinylPlus (Progress Report 2013), the recycling of soft vinyl chloride is very important for saving resource and energy. Since vinyl chloride-containing articles have a long service life (about 20-30 years), there will be many opportunities of their reusing for many years to come. To ensure a smooth recycling route is not only important but also very meaningful in view of reducing socio-economic loss. Moreover, as described in Vinyloop application, when compared to landfill or incineration, the recovery and reuse of soft vinyl chloride are more effective and useful from the view point of not only utilization of available resources but also waste processing of DEHP-containing articles.</p> <p>[References] 1) Kurata Y, Kidachi F, Yokoyama M, Toyota N, Tsuchitani M, Katoh M., Toxicological Science, 42, 49-56, 1998. 2) Tomonari Y, Kurata Y, David R M, Gans G, Kawasuso T, Katoh M., Journal of Toxicity and Environmental Health A., 69(17), 1651-1672, 2006. 3) E. Heger, et al., Environmental Health Perspectives, 120(8), 1137-1143, 2012 Human fetal testes xenografts are resistant to Phthalate-induced Endocrine disruption 4) Mitchel RT, et al., J. Clinical Endocrine &amp; Metabo. 97(3): E341-E348 (2012) Phthalates affect steroidogenesis by the Human Fetal Testis?: Exposure of Human Fetal Testis Xenografts to Di-n-Butyl phthalate. 5) Kurata, et al., The Journal of Toxicological Science Vol. 37, No. 1,</p>		
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						34-39, 2012. Metabolism of di(2-ethyl hexyl)phthalate(DEHP): comparative study in juvenile and fetal marmosets and rats. 6) Kurata, et al., Ibid, Vol. 37, No.2, 401-414, 2012. Metabolite profiling and identification in human urine after single oral administration of DEHP. 7) Michael A. Kamrin, Journal of Toxicology and Environmental Health, Part B, Volume 12, Issue 2 February 2009, pages 157-174 Phthalate Risks, Phthalate Regulation, and Public Health: A Review 8) Océane Albert, Bernard Jègou. Human Reproduction Update Advance Access published September 29, 2013, Vol. 0, No. 0 pp. 1-19, 2013 "A critical assessment of the endocrine susceptibility of the human testis to phthalates from fetal life to adulthood" (doi: 10.1093/humupd/dmt050 First published online: September 29, 2013) 9) <a href="http://www.env.go.jp/en/chemi/hs/jecs/">http://www.env.go.jp/en/chemi/hs/jecs/</a> 10) Chemical Watch Thursday November 7. 2013		
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#### Applicants' response:

No comment

Reference number and date:	Submitter:	Alternative:						Attachments:
		Type	Generic name	EC Number	CAS Number	Description of technical alternative	Classification and Labelling	
<b>Ref.No:</b> 22 <b>Date:</b> 2013/12/21	<b>Affiliation:</b> BehalfOfAnOrganisation <b>Type/Role in the supply chain:</b> Non-governmental organisation (NGO) <b>Name of org/company:</b>					Phase out of DEHP is necessary also in recycled materials due to it's harmful properties.		<a href="#">Comment 22 Attachment.doc</a>

	ChemSec <b>Country:</b> Sweden							
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Applicants' response:	
QUOTE	Answer ref.
Although ChemSec in principle is in favour of recycling we do not agree with the applicant on the basis for authorisation for formulation/use of recycled soft PVC containing DEHP. DEHP is a SVHC substance, classified as a reprotoxicant (1B) and therefore needs to be eliminated from all types of material flows. If DEHP get an authorisation for recycled plastic, EU population will be continuously exposed to this harmful chemical, which is not the intention of REACH. Recycled plastic materials will, if authorisation is given be seen as a hazardous product since it might contain DEHP which will limit the possibilities to use recycled plastic in many different products.	R0010
The applicant has applied for authorization through adequate control route. According to REACH article 60(3a), the adequate control route shall not apply for substances meeting the criteria in CMR or article 57(f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. DEHP has endocrine disrupting properties and since it is very doubtful that safe thresholds can be derived with sufficient certainty for EDCs adequate control route should not apply for DEHP.	R008

List of answers (full text):

R001	Alternative materials are not relevant to this AoA as they could neither be recycled by the applicant, nor be used by their downstream supply chain (converters), mainly for diverging technological requirements reasons
R002	We agree that many <u>upstream</u> users (producers of the article the applicants recycle once they have become waste) have been able to identify and move to technically and economically feasible alternatives to DEHP. However, given the fact that the Applicants recycle end-of-life waste (and not post-industrial) and given duration of this upstream lifecycle, the effects of this move is hardly measurable and significant concentrations of DEHP will remain present for decades in the waste.
R003	This AoA is carried out from the Applicant's perspective. This is in line with Article 60.5(b). Applicants are not in a position to recycle non soft-PVC material.
R004	Alternative plasticizers availability is not relevant to soft PVC waste recycling. Addition of DEHP to the recyclate is not in the scope of this AfA and DEHP is a largely unwanted impurity.
R005	The information claimed missing is not in the scope provided for the public consultation on alternatives under REACH Regulation.
R006	Information such as complete CSR is not relevant to the public consultation on the analysis of alternatives
R007	Uses of soft PVC recyclate containing DEHP have been defined as required under REACH and the guidances. Not all possible uses of soft PVC recyclate containing DEHP are covered by this application: a subset of applications in articles are not supported.
R008	The following RAC meeting report (p3, Relevance of endpoints, <a href="http://echa.europa.eu/documents/10162/13579/rac_24_dnel_dehp_comments_en.pdf">http://echa.europa.eu/documents/10162/13579/rac_24_dnel_dehp_comments_en.pdf</a> , 2013) confirms DEHP related AfA can be submitted under the adequate control route.
R009	The technologies available to the applicants is limiting the scope of waste streams that can be addressed in their facilities. The most typical waste treated is end-of-life cable waste (shredded material obtained from copper recovery). This waste stream contains only minor fraction of non-PVC (and DEHP free) material which cannot be recycled into a compound or into articles because of its largely crosslinked nature (only option is energetic valorization).

R010	Discontinuing PVC waste recycling, as suggested by third party, would prevent saving valuable resources and avoiding impacts as described in SEA. It would also leave large quantities of waste that have to be dealt with. Moreover, it would mean losing valuable experience in the field of soft PVC recycling, postponing recovery of post-consumer waste by decades.
R011	The applicants do not agree that technologies allowing to segregate <u>phthalate containing</u> soft PVC waste are available on the market and economically feasible. Third party has not given any example for such an hypothetical technology which, by the way, would have to be able to detect low concentrations to meet regulatory thresholds. More fundamentally, experience shows that, due to the combined age (legacy composition) and diversity of origin, virtually no single raw material (waste) lot is phthalate free. The same applies to DEHP containing waste. Excluding phthalate containing end-of-life soft-PVC waste would result in no recycling since the main plasticizers used to replace dEHP are phthalates (90% of use in Europe today).
R012	Ref 1 to 3 of this third party's comment do not apply to the uses (and applications, articles) covered in this AfA, see also answer R004 for Ref1 and some of the references that can be digged from the Ref3 database.
R013	This third party's comment seems to refer to the content of different Applications for Authorization, from different Applicants ...
R014	Volume information is kept confidential because its dissemination would undermine protection of applicant's commercial interests, as confirmed according to Article 118(2) of the Regulation (EC) No 1907/2006.
R015	Given the fact that the Applicants recycle end-of-life waste (and not post-industrial) and given duration of this upstream lifecycle, significant concentrations of DEHP will remain present for decades in the waste.