CHEMSERVICE

INDUSTRY RISK MANAGEMENT OPTION ANALYSIS FOR

ORGANOTIN SUBSTANCES CLASSIFIED AS TOXIC FOR REPRODUCTION CATEGORY 1B

Final report

prepared for

Global Organotin Stewardship Council (GOSC)

27 August 2025

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Substance Names: -

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Final report

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List of abbreviations and acronyms

AfA	Application for Authorisation
BAT	Best Available Technique
CAD	Chemical Agents Directive - Directive 98/24/EC
CLH	Harmonised classification and labelling
CMR	Carcinogenic, Mutagenic, or toxic to Reproduction
CMRD	Carcinogenic, Mutagenic and Reprotoxic Directive - Directive 2004/37/EC
COM	European Commission
CSR	Chemical safety report
C&L	Classification & Labelling Inventory
C-PVC	Chlorinated PVC
DBT	Dibutyltin compound
DET	Diethyltin compound
DOT	Dioctyltin compound
DU	Downstream user
ECHA	European Chemicals Agency
ES	Exposure scenario
ED	Endocrine disrupter
eSDS	extended Safety Data Sheet
EU	European Union
GOSC	Global Organotin Stewardship Council
HvE	Humans via the Environment
i-RMOA	Industry risk management option analysis
MS	Member State
MSCA	Member State Competent Authority
OBS	Organic-based stabilisers
OC	Operating condition
PBT	Persistent, bioaccumulative, and toxic
PVC	Polyvinyl Chloride
RAC	Risk Assessment Committee
RMO	Regulatory management option
RMOA	Regulatory management option analysis

RMM	Risk management measure(s)
SEAC	Socio-Economic Assessment Committee
SML	Specific migration limit
SVHC	Substance of very high concern
TEPPFA	The European Plastic Pipes and Fittings Association
TBT	Tributyltin compound
U-PVC	Unplasticized PVC
vPvB	Very persistent and very bioaccumulative
WWTP	Wastewater Treatment Plant

EXECUTIVE SUMMARY

An industry Risk Management Option Analysis (i-RMOA) has been conducted on different chemical substances, following a request from the Global Organotin Stewardship Council (GOSC). The chemicals covered in this study are organotin substances classified as Toxic for Reproduction, Category 1B, according to the CLP Regulation.

The objective of the i-RMOA is to undertake an analysis on the organotins in scope of the study, covering different aspects related to substance definition, hazard identification, risk assessment, and potential impacts of different policy options. For the project, the most up to date information available has been gathered and evaluated, via interaction with the sponsor and downstream users to collect relevant data. These interactions have been managed through the responses to ad-hoc questionnaires, specifically prepared for this activity. Finally, previous information available from public literature has been reviewed and used to provide adequate context to the assessment.

Following the evaluation of all data available, a number of Risk Management Options (RMOs) were selected as being potentially relevant for the substances in scope of the i-RMOA. A non-exhaustive analysis of potential impacts from each of the policy options has been undertaken, and each of the RMOs has been evaluated based on a specific i-RMOA methodology. This includes the assessment of different factors that allow to perform a semi-quantitative evaluation of the efficiency, practicability, proportionality, and consistency of each RMO. Based on the data from the substances (e.g., risk assessment) and the expected impacts under each RMO, the different factors are given a score and the RMO with the highest score is selected as the most appropriate one, following a critical evaluation of the results obtained, including an estimation of the uncertainty linked to the assessment.

The conclusion of the study is that organotins are substances that may pose certain risks for humans in specific industrial activities, but they are very valuable chemicals in these applications in which their substitution is not possible. The RMO evaluation has concluded that a regulatory action based on developing and enforcing harmonised Occupational Exposure Limits to be applied uniformly across Europe would be the best regulatory option.

Some of the organotins evaluated in the i-RMOA are currently going through processes to generate updated toxicological and ecotoxicological data. While the study has been conducted using the information available at present time, it cannot be excluded that the conclusions may need to be reviewed once new information on the properties of organotins becomes available.

1. RMOA DEFINITION, METHODOLOGY AND SCOPE

The purpose of a Regulatory Management Option Analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a chemical substance or a group of substances, and to identify the most appropriate instrument to address a concern. RMOA is a voluntary step, and it is not part of the processes as defined in the REACH Regulation[1].

For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State (MS) of the European Union (EU) or the European Chemicals Agency (ECHA), in this last case at the request of the European Commission (COM), may carry out this case-by-case analysis in order to conclude whether the concern regarding the substance is relevant. An RMOA can conclude that regulatory risk management at EU level is required for a substance, and therefore implementing a Regulatory Management Option (RMO) is necessary, or that on the contrary, no specific regulatory action is needed. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision-making involving Member State Competent Authorities (MSCA) and COM. The RMOA is in general subject to discussions and comments in the Risk Management and Evaluation platform (RiME+) meetings.

The RMOA document provides the outcome of the analysis carried out by the authoring MSCA. In that document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance, and which is the most appropriate instrument to address a concern. With this document COM, the other MSCAs, and stakeholders are informed of the considerations of the RMOA submitter. In case the relevant authority may propose the development of further RMOs, this shall not be considered as initiating additional regulatory processes. Since the document only reflects the views of the authority developing the RMOA, it does not preclude other MS or COM from considering or initiating other RMOs which they deem appropriate.

Industry can also decide to carry out an Industry RMOA (i-RMOA). Companies or industry sectors that take the initiative to prepare an i-RMOA may use its conclusions to anticipate and assist during regulatory reviews and challenges. It may also help industry to contribute credibly to the RMOAs developed by authorities, and to any subsequent decision processes at EU level. It should be noted that the approach followed by industry may differ from that used by authorities; this is because regulators will typically limit their focus to existing legislative instruments at hand to address concerns of chemicals, whereas companies may explore

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Consolidated version 10/10/2024. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20241010&qid=1741710379878

broader actions that could imply other types of risk management actions, such as voluntary commitments to reduce risk under predefined limits, or to progressively reduce uses of certain chemicals in some applications. For this reason, when industry undertakes an i-RMOA this is usually referred to as “Industry Risk Management Option Analysis”. This is the concept that Chemservice uses in its i-RMOA methodology, which is aligned with other stakeholders (e.g., Eurometaux). The methodology is described in detail in Annex I of this i-RMOA.

In the present case, an i-RMOA has been developed at the request from the Global Organotin Stewardship Council (GOSC). This association has commissioned an i-RMOA focused on organotin substances that are classified as Toxic for Reproduction, Category 1B (Repr. 1B), according to the CLP Regulation[2]. Due to this classification, these substances may be subject to different regulatory risk management activities individually. The objective of this action is to define the best RMO that can be applied to these substances as a group.

For the development of the i-RMOA, publicly available information has been used. Data of the substances, their properties, and their function have been collected and analysed. Furthermore, an exchange of information has taken place with the sponsor (GOSC members) and some downstream users (DUs), which have supplied part of the data used to develop the i-RMOA. Where no citation is explicitly included during the analysis, it can be assumed that the information has been collected via direct interaction with GOSC members and DUs.

[2] Regulation (EC) No 1272/2008 of the European Parliaments and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP). Consolidated version 10/12/2024. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20241210&qid=1741711088847

2. SUBSTANCES COVERED IN THE I-RMOA

This section introduces the different substances that are evaluated in the present i-RMOA. Information on the substance identity, uses, and volumes has been collected from open literature sources and interactions with GOSC members and DUs. These interactions have been managed through the responses to ad-hoc questionnaires, specifically prepared for this activity. The information received through these questionnaires is used in the evaluation of RMOs (**Section 4**), where the impact of potential policy scenarios is discussed in detail.

The substances covered by the i-RMOA are organotins currently classified as Repr. 1B in their REACH registration dossiers, either via harmonised classification or through self-classification by industry. These substances are listed in **Table 1**:

Table 1. List of substances covered in the i-RMOA

Abbreviation	Name	CAS	EC
Bu2Sn(ITTP)2	diisotridecyl 3,3'-[(dibutylstannylene)bis(thio)]dipropionate	84896-44-6	284-461-5
DBTA	Dibutyltin di(acetate)	1067-33-0	213-928-8
DBTAcAc	Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	245-152-0
DBTC	Dibutyltin dichloride	683-18-1	211-670-0
DBTE	2-ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	10584-98-2	234-186-1
DBTL	Dibutyltin dilaurate	77-58-7	201-039-8
DBTLMC	Dibutylbis(dodecylthio)stannane	1185-81-5	214-688-7
DBTO	Dibutyltin oxide	818-08-6	212-449-1
DOTE	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	15571-58-1	239-622-4
DOTC	Dichlorodioctylstannane	3542-36-7	222-583-2
DOTL	Dioctyltin dilaurate	3648-18-8	222-883-3
TBTC	Tributyltin chloride	1461-22-9	215-958-7
TBTO	Bis(tributyltin) oxide	56-35-9	200-268-0
*	Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dibutylstannane	93925-42-9	300-344-4
**	Tin bis(2-ethylhexanoate)	301-10-0	206-108-6

In the case of DBTE, no Repr. 1B classification (harmonised or self-classification) is available in its REACH registration dossier. However, a high proportion (78%) of Repr. 1B classifications are displayed for this substance in the C&L Inventory[3]. For this reason, it has been considered relevant to include it in the list of substances to be assessed[4].

Although all these substances are also classified in relation to other hazard properties (see **Table 19**), the common classification as Repr. 1B includes them in the group of Carcinogenic, Mutagenic, and Reprotoxic chemicals (CMR). The Eurostat Glossary[5] defines CMR substances as those that make up the first and most toxic category of the toxicity classes into which hazardous chemicals can be subdivided, according to EU legislation, considering toxicity as the measure of the degree to which a substance is capable of causing damage to living organisms.

This means that, due to the classification as Repr. 1B, the regulatory pressure currently faced by these substances in the EU is very high, and therefore, the likelihood that European authorities will consider applying RMOs to them is also very high. From an industry point of view, the completion of this i-RMOA is considered essential to avoid the inclusion of the organotin substances in any unjustified regulatory action.

2.1. Organotin definition and types

Organotin refers to a broad group of substances containing at least one tin (Sn) atom covalently bonded to different organic functional groups (RPA, 2005). Therefore, the chemical structure of these substances always has at least one tin-carbon bond (Sn-C). These substances are classified into four main groups based on the number of organic functional groups bonded to Sn (i.e., mono-, di-, tri-, and tetra-organotin substances). Substances with one C-Sn bond are referred to as mono-substituted organotin substances, two C-Sn bonds are known as di-substituted organotin substances, and so on (TUV, 2017). The organic functional groups are mainly alkyls (i.e., methyl, ethyl, butyl, etc.), but they may also contain other chemical species (e.g., ester, oxide, phenyl, etc.).

According to these definitions, the substances covered in this i-RMOA can be classified as follows:

[3] C&L Inventory for DBTE: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/30838

[4] The REACH registrants of the substance DBTE will soon update the registration dossier to include new scientific evidence and test results that complement the justification for not classifying this substance as Repr. 1B.

[5] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Carcinogenic,_mutagenic_and_reprotoxic_(CMR)

Table 2. Classification of the substances covered in the i-RMOA

Abbreviation	Main Group	Main Organic Group	Class
Bu2Sn(ITTP)2	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTA	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTAcAc	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTC	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTE	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTL	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTLMC	di-substituted organotin	butyl	Dibutyltin (DBT)
DBTO	di-substituted organotin	butyl	Dibutyltin (DBT)
DOTE	di-substituted organotin	octyl	Dioctyltin (DOT)
DOTC	di-substituted organotin	octyl	Dioctyltin (DOT)
DOTL	di-substituted organotin	octyl	Dioctyltin (DOT)
TBTC	tri-substituted organotin	butyl	Tributyltin (TBT)
TBTO	tri-substituted organotin	butyl	Tributyltin (TBT)
*	di-substituted organotin	butyl	Dibutyltin (DBT)
**	di-substituted organotin	ethyl	Diethyltin (DET)

It can be noted that ** (Tin bis(2-ethylhexanoate)) is the only substance in this list based on the Sn^{2+} chemistry, while all the other substances covered in this RMOA are Sn^{4+} based.

2.2. Identity and substance definitions

Tables in this sub-section provide basic information for proper identification of each substance covered in the i-RMOA, along with links to further sources of information as published by ECHA.

Table 3. Bu2Sn(ITTP)2

Name	Diisotridecyl 3,3'-[(dibutylstannylene)bis(thio)]dipropionate
Abbreviation	-
EC number	284-461-5
CAS number	84896-44-6
Structure / Formula	C40H80O4S2Sn
Substance Infocard	https://echa.europa.eu/substance-information/-/substanceinfo/100.076.755
REACH Registration	https://chem.echa.europa.eu/100.076.755/overview
Estimated tonnage band	10 – 100

Table 4. DBTA

Name	Dibutyltin di(acetate)
Abbreviation	DBTA
EC number	213-928-8
CAS number	1067-33-0
Structure / Formula	C12H24O4Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.012.663
REACH Registration	https://chem.echa.europa.eu/100.012.663/overview
Estimated tonnage band	10 – 100

Table 5. DBTAcAc

Name	Dibutylbis(pentane-2,4-dionato-O,O')tin
Abbreviation	DBTAcAc
EC number	245-152-0
CAS number	22673-19-4
Structure / Formula	Not available
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.041.032
REACH Registration	https://chem.echa.europa.eu/100.041.032/overview
Estimated tonnage band	100– 1.000

Table 6. DBTC

Name	Dibutyltin dichloride
Abbreviation	DBTC
EC number	211-670-0
CAS number	683-18-1
Structure / Formula	C8H18Cl2Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.010.610
REACH Registration	https://chem.echa.europa.eu/100.010.610/overview
Estimated tonnage band	10 – 100

Table 7. DBTE

Name	2-Ethylhexyl 4,4-dibutyl-10-ethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetetradeconoate
Abbreviation	DBTE
EC number	234-186-1
CAS number	10584-98-2
Structure / Formula	C28H56O4S2Sn
Substance Infocard	https://echa.europa.eu/substance-information/-/substanceinfo/100.031.066
REACH Registration	https://chem.echa.europa.eu/100.031.066/overview
Estimated tonnage band	10 - 100

Table 8. DBTL

Name	Dibutyltin dilaurate
Abbreviation	DBTL
EC number	201-039-8
CAS number	77-58-7
Structure / Formula	C32H64O4Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.000.946
REACH Registration	https://chem.echa.europa.eu/100.000.946/overview
Estimated tonnage band	100 – 1.000

Table 9. DBTLMC

Name	Dibutylbis(dodecylthio)stannane
Abbreviation	DBTLMC
EC number	214-688-7
CAS number	1185-81-5
Structure / Formula	C32H68S2Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.013.353
REACH Registration	https://chem.echa.europa.eu/100.013.353/overview
Estimated tonnage band	1 – 10

Table 10. DBTO

Name	Dibutyltin oxide
Abbreviation	DBTO
EC number	212-449-1
CAS number	818-08-6
Structure / Formula	C8H18OSn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.011.317
REACH Registration	https://chem.echa.europa.eu/100.011.317/overview
Estimated tonnage band	100 – 1.000

Table 11. DOTE

Name	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4- stannatetradecanoate
Abbreviation	DOTE
EC number	239-622-4
CAS number	15571-58-1
Structure / Formula	C36H72O4S2Sn
Substance Infocard	https://echa.europa.eu/substance-information/-/substanceinfo/100.036.005
REACH Registration	https://chem.echa.europa.eu/100.036.005/overview
Estimated tonnage band	1.000 – 10.000

Table 12. DOTC

Name	Dichlorodioctylstannane
Abbreviation	DOTC
EC number	222-583-2
CAS number	3542-36-7
Structure / Formula	C16H34Cl2Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.020.531
REACH Registration	https://chem.echa.europa.eu/100.020.531/overview
Estimated tonnage band	Intermediate use only

Table 13. DOTL

Name	Dioctyltin dilaurate
Abbreviation	DOTL
EC number	222-883-3
CAS number	3648-18-8
Structure / Formula	C40H80O4Sn
Substance Infocard	https://echa.europa.eu/substance-information/-/substanceinfo/100.020.804
REACH Registration	https://chem.echa.europa.eu/100.020.804/overview
Estimated tonnage band	100 – 1.000

Table 14. TBTC

Name	Tributyltin chloride
Abbreviation	TBTC
EC number	215-958-7
CAS number	1461-22-9
Structure / Formula	C12H27ClSn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.014.508
REACH Registration	https://chem.echa.europa.eu/100.014.508/overview
Estimated tonnage band	Intermediate use only

Table 15. TBTO

Name	Bis(tributyltin) oxide
Abbreviation	TBTO
EC number	200-268-0
CAS number	56-35-9
Structure / Formula	C24H54OSn2
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.000.244
REACH Registration	https://chem.echa.europa.eu/100.000.244/overview
Estimated tonnage band	Intermediate use only

Table 16. *

Name	Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dibutylstannane
Abbreviation	*
EC number	300-344-4
CAS number	93925-42-9
Structure / Formula	-
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.091.180
REACH Registration	https://chem.echa.europa.eu/100.091.180/overview
Estimated tonnage band	10 – 100

Table 17. **

Name	Tin bis(2-ethylhexanoate)
Abbreviation	**
EC number	206-108-6
CAS number	301-10-0
Structure / Formula	C16H32O4Sn
Substance Infocard	https://echa.europa.eu/es/substance-information/-/substanceinfo/100.005.554
REACH Registration	https://chem.echa.europa.eu/100.005.554/overview
Estimated tonnage band	100 – 1.000

2.3. Specific applications, sectors of use, and volumes

According to the information included in their REACH registration dossiers, as well as to feedback received from GOSC members and DUs, the uses related to these substances can be categorized as shown in **Table 18**:

Table 18. Substance applications

Abbreviation	Catalyst	Intermediate	Stabiliser
Bu2Sn(ITTP)2			**X**
DBTA	**X**	**X**	
DBTAcAc	**X**	**X**	
DBTC		**X**	
DBTE			**X**
DBTL	**X**	**X**	**X**
DBTLMC			**X**
DBTO	**X**	**X**	**X**
DOTE			**X**
DOTC		**X**	
DOTL	**X**	**X**	**X**
TBTC		**X**	
TBTO		**X**	
*			**X**
**	**X**		**X**

Some of the listed substances do not have a specific use and can be employed in two or even three of the considered applications. Six of them are used by DUs as reactive processing aids (catalysts) in the production of adhesives and sealants, coatings and paints, foams, and polymer preparations and compounds. As catalysts they are used in a number of important industrial processes, including the production of polymeric materials (e.g., polyurethane, polyurethane foam, polyester, or self-crosslinking silicone polymers), and in silicon curing. Silicone-based finished products containing these catalysts stand out for their elastomeric properties and water repellence (Ghazi, 2018).

The use as intermediate is defined for nine of these substances. This means that these substances are produced for the purpose of being fully consumed during the production of another substance (use of the substance in the synthesis of other organotin materials). Furthermore, in the case of four of these substances, this is the only defined use. This is evidenced in the case of DOTC, TBTC, and TBTO because their REACH registration dossiers are based on Article 18 of the REACH Regulation (Registration of transported isolated intermediates). However, the DBTC REACH registry is a full type dossier and, although the Lead Registrant only supports the use as an intermediate, there is a co-registrant that declares the industrial use as an additive for the production of rubber tyres. Taking into account that this co-registrant dossier has not been updated since 2019 and this use is not covered by the lead dossier, it has not been further considered in this assessment.

Finally, nine of these substances are used as stabilisers, mainly in the production of Polyvinyl Chloride (PVC). These organotin compounds are a high performing class of PVC stabilisers providing excellent early colour retention during processing, as well as transparency and clarity, together with long-term heat stability. Due to these outstanding technical properties, organotin stabilisers have a much higher cost in the market than other stabilisers. For this reason, they are only used in the applications where these properties are required and specified by the customers, and the use of other stabilisers cannot ensure the same technical properties for those applications.

The main applications of PVC stabilised with these organotin substances are construction applications, such as panels, roofing profiles, flooring, and pipes and fittings, or production of films, among others.

2.4. Hazard information and classification

This section describes the main information on the substances evaluated in the i-RMOA related to their classification under the CLP Regulation covering different sources, mainly Annex VI to the Regulation (harmonised classifications), and information found in the REACH registration dossiers for each substance (self-classifications). Data is presented in **Table 19**.

It needs to be noted that the ECHA C&L Inventory has not been used as a source of information for this section, except in the case of DBTE (see **Section 2**). Although this inventory continues to be accessible in the ECHA website, it is acknowledged that the original goal for which it was created (to serve as a platform for industry to agree on the classification of substances) has not been met. While the inventory could have been useful in the early days of REACH (e.g., to advance information on potential classification of substances while the registration process was completed), today it is more a source of confusion than a helpful reference. Many substances in the inventory still show a long list of classification entries that are not supported by the data that has been generated (and extensively reviewed in some cases) and not accepted by the main suppliers of the substances in question. For the sake of clarity, the information from registration dossiers or the harmonized classification agreed by EU authorities is reported as the most reliable information available.

Table 19. Hazard information and classification of organotin substances

Substance	Harmonised classification (Annex VI of CLP)	Self-classification
Bu2Sn(ITTP)2	Not listed	Repr. 1B; Muta. 2; Acute Tox. 3; Skin Irrit. 2; Eye Irrit. 2; Skin Sens. 1; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTA	Repr. 1B; Muta. 2; STOT RE 1	Skin Corr. 1B; Skin Sens. 1B ; Eye Damage 1; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTAcAc	Repr. 1B; STOT RE 1	Repr. 1B ; Muta. 2 ; Acute Tox. 4; Skin Corr. 1C ; Eye Damage 1; Skin Sens. 1 ; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTC	Repr. 1B; Muta. 2; Acute Tox. 2; Acute Tox. 3; Acute Tox. 4; Skin Corr. 1B; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	Repr. 1B; Muta. 2; Acute Tox. 3; Acute Tox. 4; Skin Corr. 1B; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTE	Not listed	Muta. 2; Acute Tox. 3; Acute Tox. 4; Skin Irrit. 2; Skin Sens. 1; Eye Irrit. 2; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTL	Repr. 1B; Muta. 2; STOT RE 1	Repr. 1B ; Muta. 2; Eye Irrit. 2; Skin Sens. 1 ; STOT RE 1; STOT SE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTLMC	Not listed	Repr. 1B; Muta. 2; Acute Tox. 4; Skin Irrit. 2; Skin Sens. 1; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1
DBTO	Repr. 1B; Muta. 2; Acute Tox. 3; Skin Irrit. 2; Eye Dam. 1; STOT RE 1	Repr. 2; Acute Tox. 4 ; Skin Irrit. 2; Eye Dam. 1 ; STOT RE 1; Aquatic Chronic 2
DOTE	Repr. 1B; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	Repr. 1B; Acute Tox. 4; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1
DOTC	Repr. 1B; Acute Tox. 2; STOT RE 1; Aquatic Chronic 3	Repr. 2; Acute Tox. 2 ; STOT SE 1 ; Aquatic Chronic 3
DOTL	Repr. 1B; STOT RE 1	STOT SE 2
TBTC	Repr. 1B; Acute Tox. 3; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	Repr. 1B; Muta. 2; Acute Tox. 1; Acute Tox. 3; Skin Irrit. 2; Skin Sens. 1; Eye Dam. 1; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1
TBTO	Repr. 1B; Acute Tox. 3; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1	Repr. 1B; Acute Tox. 3; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1
*	Not listed	Repr. 1B; Muta. 2; Flam. Liq. 3; Acute Tox. 4; Eye Dam. 1; STOT RE 1; STOT SE 1
**	Repr. 1B[6]	Repr. 1B; Skin Sens. 1B; Eye Dam. 1 ; Aquatic Chronic 3

[6] Tin bis(2-ethylhexanoate) has a harmonised classification as Repr. 1B due to its inclusion in the "2-ethylhexanoic acid and its salts" group of substances.

2.5. Status of the substance(s) under REACH

The specific regulatory status of these substances under REACH are described below:

Bu2Sn(ITTP)2

- Registered under REACH
  - 1 active registrations
- Not included in any previous RMOA
- Not identified as Substance of Very High Concern (SVHC)
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20
- Not PBT nor vP/vB
- Not Endocrine Disrupter (ED)

DBTA

- Registered under REACH
  - 4 active registrations
  - 2 inactive registrations (Ceased manufacture/import)
- Not included in any previous RMOA
- Not identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3, 20, and 30
- Not PBT nor vP/vB
- Not ED

DBTAcAc

- Registered under REACH
  - 1 active registrations
- Included in an RMOA, performed by the Swedish Chemicals Agency on January 2020, concluding that the substance should be considered as SVHC.
- Identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3, 20, and 30
- Not PBT nor vP/vB

- Not ED

DBTC

- Registered under REACH
    - 2 active registrations
    - 3 inactive registrations (Ceased manufacture/import)
- Not included in any previous RMOA
- Identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 20 and 30
- Not PBT nor vP/vB
- Not ED

DBTE

- Registered under REACH
    - 2 active registrations
    - 2 inactive registrations (Ceased manufacture/import)
- Not included in any previous RMOA
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20.
- Identified as PBT
- Not ED

DBTL

- Registered under REACH
    - 12 active registrations
    - 3 inactive registrations (Ceased manufacture/import)
- Not included in any previous RMOA
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entries 3, 20, and 30.
- Not PBT nor vP/vB
- Not ED

DBTLMC

- Registered under REACH

- 3 active registrations
- 2 inactive registrations (Ceased manufacture/import)

- Not included in any previous RMOA
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20.
- Not PBT nor vP/vB
- Not ED

DBTO

- Registered under REACH
  - 11 active registrations
  - 1 inactive registrations (Ceased manufacture/import)

- Not included in any previous RMOA
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entry 20.
- Not PBT nor vP/vB
- Not ED

DOTE

- Registered under REACH
  - 4 active registrations
  - 2 inactive registrations (Ceased manufacture/import)

- Included in an RMOA, performed by the Austrian CA on August 2014, concluding that the substance should be considered as SVHC.
- Identified as SVHC
- Included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3, 20, and 30.
- Not PBT nor vP/vB
- Not ED
- There is a testing proposal under consideration by ECHA (no information on potential requested studies).

DOTC

- Registered under REACH
  - 2 active registrations

    - 3 inactive registrations (Ceased manufacture/import)

- Included in an RMOA, performed by the Netherlands on June 2015, concluding that the substance no need for regulatory follow-up action.
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entries 20 and 30.
- Not PBT nor vP/vB
- Not ED

DOTL

- Registered under REACH
    - 10 active registrations
- Included in an RMOA, performed by the Swedish CA on February 2020, concluding that the substance should be considered as SVHC.
- Identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3, 20, and 30.
- Not PBT nor vP/vB
- Not ED
- ECHA rejected an industrial testing proposal to perform an OECD 414 study (pre-natal developmental toxicity study).

TBTC

- Registered under REACH
    - 1 active registrations
    - 2 inactive registrations (Ceased manufacture/import)
- Not included in an RMOA
- Not identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20.
- PBT or vP/vB (Under assessment)
- Not ED

TBTO

- Registered under REACH
    - 3 active registrations

- Not included in an RMOA
- Identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20.
- Identified as PBT
- Not ED

*

- Registered under REACH
    - 1 active registrations
    - 1 inactive registration (Ceased manufacture after draft evaluation decision)
- Not included in an RMOA
- Not identified as SVHC
- Included in the Annex XVII of REACH (Restriction list): entries 3 and 20.
- Not PBT nor vP/vB
- Not ED

**

- Registered under REACH
    - 10 active registrations
    - 3 inactive registrations (Ceased manufacture/import)
- Included in an ECHA's ARN: Organic inorganic tin compounds without hydrocarbyl substituent[7]
- Not identified as SVHC
- Not included in the Annex XIV of REACH (Authorisation list)
- Included in the Annex XVII of REACH (Restriction list): entry 3.
- Not PBT nor vP/vB
- Not ED

A summary of the entries of Annex XVII to the REACH Regulation (Restrictions on the manufacture, placing on the market and use) affecting these substances is provided next:

- Entry 3. Liquid substances classified as reproductive toxicants shall not be used in:
    - ornamental articles intended to produce light or colour effects
    - tricks and jokes

[7] https://echa.europa.eu/documents/10162/c2304fd8-caad-30cd-865e-7cd055e4e51b

- games for one or more participants

- Entry 20. Organotin substances shall not be placed on the market, or used:
  - where the substance is acting as biocide in free association paint
  - where the substance acts as biocide to prevent the fouling by micro-organisms, plants or animals
  - where the substance is intended for use in the treatment of industrial waters
  - (only applicable to TBT class) in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin
  - (only applicable to DBT class) in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin, except for articles regulated under 1935/2004 Regulation[8]
  - (only applicable to DOT class) in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:
    - textile articles intended to come into contact with the skin
    - gloves
    - footwear or part of footwear intended to come into contact with the skin
    - wall and floor coverings
    - childcare articles
    - female hygiene products
    - nappies
    - two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits).

- Entry 30. Substances which are classified as reproductive toxicant category 1B and are listed in Appendix 6 to the REACH Regulation shall not be placed on the market, or used, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
  - either the relevant specific concentration limit specified in Part 3 of Annex VI to CLP Regulation
  - or the relevant generic concentration limit specified in Part 3 of Annex I of CLP Regulation
  - except if they are:
    - medicinal or veterinary products
    - cosmetic products
    - motor fuels
    - mineral oil products intended for use as fuel in mobile or fixed combustion plants
    - fuels sold in closed systems
    - artists' paints

[8] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

- medical devices
- included in Appendix 11 of the REACH Regulation

2.6. Legal requirements under other EU legislation

This section describes specific EU legislation different from REACH and CLP that may impact the substances in scope of this i-RMOA that fall under the scope of action of ECHA. **Table 20** summarises the specific pieces of legislation that are relevant for any of the analysed organotins.

- Regulation 450/2009/EC – Food Contact Active and Intelligent Materials - CMR Substances not allowed for use. This Regulation establishes specific requirements for the marketing of active and intelligent materials and articles intended to come into contact with food. According to Article 5(2)(c)(i), CMR substances may not be used in components of active and intelligent materials and articles.
- Regulation 1223/2009/EC - Cosmetic Products Regulation, Annex II - Prohibited Substances. This Regulation contains in its Annex II substances which are banned from use in any cosmetic products marketed for sale or use in the EU.
- Regulation 10/2011/EU - Plastics Food Contact and Articles Regulation, Annex I, Section 1 - Authorised Substances. This Regulation contains in Section 1 of its Annex I the Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives, and polymer production aids. Substances not included in this list cannot be used in the production of plastics materials and articles intended to come into contact with food. These substances may have an associated specific migration limit (SML).
- Regulation 10/2011/EU - Plastics Food Contact and Articles Regulation, Annex I, Section 2 – Group restriction of substance. This Regulation contains in Section 2 of its Annex I the group of substances for which a restriction applies. For each group, a SML applicable to the sum of the substances within the group has been defined.
- Regulation 66/2010/EC - Ecolabel - Restrictions for Hazardous Substances/Mixtures. Pursuant to Article 6(6) of this Regulation, the ecolabel must not be awarded to goods containing substances or mixtures classified according to the CLP as toxic; hazardous to the environment; and CMRs. Nor are products allowed the ecolabel award when they contain SVHCs (per Article 57 of REACH).
- Regulation 305/2011/EU - Construction Product Regulation - Article 6(5) - SDS and Declaration. This specific provision requires SDSs and information on hazardous substances (i.e., SVHCs) contained in construction products be provided with the declaration of performance.

- Regulation 305/2011/EU - Construction Product Regulation - Annex I (3) - Hazardous Substances. This Regulation stipulates that construction works must not have a high impact on human health or the environment as a result of: giving off toxic gas; emissions of dangerous substances, Volatile Organic Compounds (VOC), greenhouse gases, or dangerous particles into indoor or outdoor air; release of dangerous substances into drinking water, ground water, marine waters, surface waters or soil. According to the ECHA webpage, hazardous substances are those included in Table 3 of Annex VI to CLP, the Candidate List of SVHCs, Annex XIV of REACH (Authorisation List), Annex XVII of REACH (Restrictions List), F-gases subject to emission limits/reporting per Regulation 517/2014/EU, and VOCs listed in the Ambient Air Directive 2008/50/EC.
- Regulation 2017/745/EU - Medical Devices Regulation - Hazardous Substances. This Regulation lays down rules concerning the placing on the market, making available on the market, or putting into service of medical devices for human use and accessories for such devices in the Union. It defines hazardous substances based on its Annex I (general safety and performance requirements), including for chemical, physical, and biological properties. According to the ECHA webpage, hazardous substances are those included in Table 3 of Annex VI to CLP, REACH Candidate List of SVHCs, and Directive 2000/54/EC's Annex III (Biological Agents list).
- Regulation (EU) 2017/746 - In Vitro Diagnostic Medical Devices Regulation - Hazardous Substances. This Regulation lays down rules concerning the placing on the market, making available on the market, or putting into service of in vitro diagnostic medical devices for human use and accessories for such devices in the Union. Hazardous substances for purposes of this Regulation are those not meeting the requirements of their Chapter 2 and Annex I. According to the ECHA webpage, hazardous substances are those included in Table 3 of Annex VI to CLP, REACH Candidate List of SVHCs, and Directive 2000/54/EC's Annex III (Biological Agents list).
- Directive 89/391/EEC - Occupational Safety and Health (OSH) Framework Directive - Hazardous Substances. The object of this Directive is to introduce measures to encourage improvements in the safety and health of workers at work. It applies to risks arising from chemical, physical and biological agents at the workplace. According to the ECHA webpage, hazardous substances are those included in Table 3 of Annex VI to CLP, and Directive 2000/54/EC's Annex III (Biological Agents list).
- Directive 92/58/EEC - Workplace Signs - Minimum requirements and signs on containers and pipes. This Directive lays down the requirements for safety and health signs at work that employers must provide where workers are still at risk despite other preventive measures. According to their annexes, storage areas and containers containing chemical substances or mixtures that are classified as hazardous according to the CLP Regulation must be duly marked and/or labelled. This Directive requires

employers to ensure proper signage is posted in areas where hazards cannot be avoided or reduced. According to the ECHA webpage, hazardous substances are those included in Table 3 of Annex VI to CLP.

- Directive 92/85/EEC - Protection of Pregnant and Breastfeeding Workers Directive - Annex I+II. This Directive defines in its Annexes I and II those substances to which pregnant workers and workers who have recently given birth or are breastfeeding may not be exposed. Employers are obligated to prevent the exposure of these workers to any agents that may have adverse health effects on either mother or child.
- Directive 94/33/EC - Young People at Work – Banned substances. The aim of this Directive is to lay down minimum requirements for the protection of young people at work. The banned substances are biological and chemical agents, in accordance with Article 7 and points 2 and 3 of the Annex. Young persons (under 18 years of age) may not be exposed at the workplace to these substances. According to the ECHA webpage, these banned biological and chemical agents are those included in risk groups 3 and 4 under Directive 2000/54/EC, Table 3 of Annex VI to the CLP Regulation, and Annex I of Directive 2004/37/EC.
- Directive 98/24/EC CAD - Chemical Agents Directive, Article 2(b)(i) – The CAD sets out the minimum requirements for protecting workers from risks to their safety and health - arising or likely to arise - from the effects of chemical agents in the workplace or the use of chemical agents at work. According to the ECHA webpage, substances with Harmonised Classification and Labelling (CLH) (i.e., Table 3 of Annex VI to the CLP Regulation 1272/2008/EC) must be considered.
- Directive 2000/53/EC - End-of-Life Vehicles Directive - Hazardous Substances. This Directive lays down measures which aim, as a first priority, at the prevention of waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of life vehicles and their components so as to reduce the disposal of waste, as well as at the improvement in the environmental performance of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-of life vehicles. Hazardous substances are those defined by Article 2(11) of this Directive.

- Directive 2001/95/EC - General Product Safety Directive - Hazardous Substances. The purpose of this Directive is to ensure that products placed on the market are safe. According to the ECHA webpage, substances included in Table 3 of Annex VI to the CLP Regulation, Annex III of Directive 2000/54/EC (Biological Agents), Candidate List of SVHCs, and REACH Annexes XIV and XVII (Authorisation and Restriction lists) can be considered hazardous for purposes of this Directive.
- Directive 2004/37/EC - Carcinogenic, Mutagenic and Reprotoxic Directive (CMRD), Annex I - Substances, mixtures, and processes. The CMRD sets out the minimum requirements for protecting workers against risks to their health and safety - arising or likely to arise - from exposure to CMR substances at work. This Directive applies to substances classified as Category 1A and 1B CMRs, derived from the CLP Regulation's Table 3 of Annex VI (1272/2008/EC). Employers are obligated to minimize worker exposure to these agents as far as possible and must arrange for medical surveillance of workers exposed to these substances.
- Directive 2008/56/EC - Marine Environmental Policy Framework Directive - Hazardous Substances. This Directive establishes a framework within which MS shall take the measures necessary to achieve or maintain good environmental status in the marine environment. Hazardous substances for purposes of this Directive are those considered in Article 3(8) and Annexes I and III.
- Directive 2008/98/EC - Waste Framework Directive, Annex III - Waste - Hazardous Properties. This Directive lays down measures to protect the environment and human health by preventing or reducing the generation of waste, the adverse impacts of the generation and management of waste, and by reducing overall impacts of resource use and improving the efficiency of such use. The Annex III of this Directive defines the properties of waste which render it hazardous.
- Directive 2014/68/EU on Pressure Equipment – Group 1 Fluids per Article 13(1)(a). This Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies. Hazardous substances defined in Article 13(1)(a) are considered Group 1 fluids for purposes of classifying pressure equipment in accordance with this Directive.

Table 20. Summary of legal requirements under other EU legislation

Substance	Reg. 450/2009	Reg. 1223/2009	Reg. 10/2011 A.I	Reg. 10/2011 A.I.2	Reg. 66/2010	Reg. 305/2011 Art. 6 (5)	Reg. 305/2011 A.I (3)	Dir. 2017/745	Reg. 2017/746	Dir. 89/391
Bu2Sn(ITTP)2							X			
DBTA	X	X			X	X	X	X	X	X
DBTAcAc	X	X			X	X	X	X	X	X
DBTC	X	X			X	X	X	X	X	X
DBTE							X			
DBTL	X	X			X	X	X	X	X	X
DBTLMC										
DBTO	X				X	X	X	X	X	X
DOTE	X	X	X	X	X	X	X	X	X	X
DOTC	X	X			X	X	X	X	X	X
DOTL	X	X	X	X	X	X	X	X	X	X
TBTC										
TBTO					X		X	X	X	
*										
**										

Table 20 (Cont.). Summary of legal requirements under other EU legislation

Substance	Dir. 92/58	Dir. 92/85	Dir. 94/33	Dir. 98/24	Dir. 2000/53	Dir. 2001/95	Dir. 2004/37	Dir. 2008/56	Dir. 2008/98	Dir. 2014/68
Bu2Sn(ITTP)2						X				
DBTA	X	X	X	X	X	X	X	X	X	
DBTAcAc	X	X	X	X	X	X	X	X	X	
DBTC	X	X	X	X	X	X	X	X	X	X
DBTE						X				
DBTL	X	X	X	X	X	X	X	X	X	
DBTLMC						X	X			
DBTO	X	X	X	X	X	X	X	X	X	
DOTE	X	X	X	X	X	X	X	X	X	
DOTC	X	X	X	X	X	X	X	X	X	X
DOTL	X	X	X	X	X	X	X	X	X	
TBTC										
TBTO						X	X	X		
*						X	X			
**										

2.7. Regulatory activities outside the EU

2.7.1. USA

The TSCA's New Chemicals Program (NCP) considers in its document of Chemical Categories (EPA, 2024) all organotin compounds, including mono-, di-, tri- and tetra-alkyl or phenyl organotin compounds, and organotin esters/oxides. This document lists general testing strategy required for Premanufacture Notice (PMN) of new substances that are members of the organotin family before consideration by EPA for commercial activity in the US.

At the State level, Minnesota has included DOTE and DOTL in the Toxic Free Kids Program as members of the Chemicals of High Concern list (4th update, July 2022), and California considers DOTE and DOTL in the list of reportable cosmetics ingredients and in the Safer Consumer Products Information Management (CalSAFER) system, to identify potential chemicals of concern in priority consumer products.

Regarding the US Food and Drug Administration's (FDA) legislation of food contact additives (21CFR), DOTE is limited for use only at levels not to exceed a total of 3 parts per hundred of resin, as stabilizer in vinyl chloride homopolymers and copolymers, according to 21CFR178.2650 (Organotin stabilizers in vinyl chloride plastics).

2.7.2. Canada

The Canadian Food and Drug Regulations (C.R.C., c.870), states that DOTE cannot exceed a total of 3% of the PVC resin, according to sections B.23.003, B.23.004, and B.23.006.

On the other hand, a group of vinyl processing facilities, manufacturers of tin stabilizers, and vinyl compounding facilities using tin stabilizers, as part of their industry-wide stewardship efforts (Tin Stabilizers in the Vinyl Industry: Environmental Performance Agreement: mono and dialkyltin stabilizers used mainly to produce vinyl compounds), developed a "Guideline for the Environmental Management of Tin Stabilizers in Canada" in consultation with Environment and Climate Change Canada (ECCC), for all vinyl compounding facilities using tin stabilizers (monomethyltins, monobutyltins, monooctyltins, dimethyltins, dibutyltins, and dioctyltins) in Canada, in order to prevent the release of these substances into the environment. In light of industry-wide efforts which help ensure these organotin compounds are not entering the environment in a quantity or concentration above a level that may be harmful to aquatic organisms, they have not been recommended to be added to Schedule 1, the List of Toxic Substances, of the Canadian Environmental Protection Act (CEPA). The agreement is reviewed and signed every 5 years. The current agreement renewal is anticipated in 2025.

2.7.3. South Korea

The following table (**Table 21**) summarises the regulatory status in South Korea of some of these substances:

Table 21. Regulatory situation in South Korea

Abbreviation	Toxic substances	Restricted substances	Substances subject to intensive control
DBTC	X		X
DBTO	X		
DOTE	X		X
DOTC	X		
TBTC	X	X	
TBTO	X	X	X

By the Korean Chemical Control Act (CCA) and its implementation rule, toxic chemicals shall meet relevant requirements, including submission of an import report of toxic chemicals, temporary control measures, import declaration and business permit, off-site risk assessment, labelling of hazardous chemical substances, etc.

Restricted chemicals in South Korea are prohibited from manufacture, import, sale, keeping, storage, transport, or use, except for specific purposes.

The status of the substances that are subject to intensive control in South Korea is similar to the SVHC status in the EU.

Substances not included in **Table 21** are not currently subject to any regulatory pressure in South Korea.

2.7.4. Australia

Australia has included several organotin families (dibutyltin, dimethyltin, and dioctyltin) for evaluation in the Australian Industrial Chemicals Introduction Scheme (AICIS) Rolling Action Plan. Three draft evaluation statements for these substances have been published until now.

3. RISK EVALUATION

The main information related to exposure, releases, and risk of a substance that meets the criteria to be classified as hazardous under the CLP Regulation is submitted by industry to ECHA through the Chemical Safety Report (CSR) that is part of the REACH registration dossier, and which summarizes the key elements of the detailed registration dossier (the CSR is required for all substances registered for production quantities >10 tonnes per year). ECHA and the MSCAs use this information to understand and evaluate the effects that a substance could have on human health and the environment. The CSR of a substance is not fully available to the general public. The public part of the information contained in the CSR is the Exposure Scenario (ES), defined for each use of the substance, which must be included in the extended Safety Data Sheet (eSDS) and delivered to the relevant actors in the supply chain. The ES contains all the recommended Risk Management Measures (RMMs) and Operating Conditions (OCs) that are considered to be relevant by the registrant for each specific use of the substance, in relation to ensuring adequate control of risks for both human health and the environment. RMMs and OCs are focused on the minimization of human exposure and environmental releases of the substance, through the implementation of actions, procedures, and systems that may include, among others, general and local exhaust ventilations, effluent treatment in wastewater treatment plants (WWTP), use of air emission abatement equipment, or use of personal protective equipment (PPE).

In the case of organotins, this information is publicly available to the supply chain via the ESs, as they are substances that carry a classification under CLP and are registered under REACH. Therefore, the assessment of exposure, releases, and risk of these substances can be performed. However, according to Article 18 of the REACH Regulation, the information requirements for intermediates are generally reduced and there is no requirement to carry out a chemical safety assessment. Therefore, CSRs and ESs are not available for those substances whose only use is as an intermediate (DBTC, DOTC, TBTC, and TBTO). Furthermore, the CSR and ESs for the substance DBTLMC is also not available at the time of this analysis.

3.1. Exposure to industrial workers

The CSRs and ESs available have been analysed. These documents define the RMMs and OCs that are applicable to guarantee the safe use of these substances in terms of human health and environment protection.

The values of the RCR for all the Process Categories (PROCs) related to the industrial[9] applications are summarised in **Table 22**.

[9] The ESs considered are those covering the different industrial uses of the substances and the PROCs involved. The RCR values are the highest of all the ESs considered, always for the combined routes.

Table 22. Exposure to industrial workers. RCR values

		PROCs																	
Substance	**Exposure Scenario**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8a**	**8b**	**9**	**10**	**12**	**13**	**14**	**15**	**21**	**24**	**28**
Bu2Sn(ITTP)2	Manufacture			0.033							0.82								
	Formulation of preparations			0.670		0.670		0.370		0.420	0.054								
	Production of polymers, masterbatches and compounds				0.350	0.330			0.860	0.990	0.990				0.200				
	Extrusion and moulding applications				0.650	0.640			0.720	0.110	0.210				0.200		0.710	0.710	
	Calendering						0.220												
	Spread or dip coating				0.035	0.033			0.030	0.032	0.032	0.037		0.002			0.071	0.071	
	Foam production by steaming				0.350	0.330			0.330	0.320	0.320		0.001						
DBTA	Manufacture			0.082	0.822				0.430	0.430	0.430					0.828			0.372
	Formulation or re-packing	0.014	0.019	0.082	0.822	0.413			0.430	0.430	0.430				0.014	0.828			0.372
	Intermediate	0.014	0.019	0.082	0.822	0.413			0.430	0.430	0.430					0.828			0.372
	Reactive processing aid	0.014	0.019	0.082	0.822	0.413			0.430	0.430	0.430					0.828			0.372
DBTAcAc	Manufacture			<0.01	0.333				0.406	0.406	0.406					0.207			0.251
	Formulation or re-packing			<0.01		0.333			0.406	0.406	0.406					0.207			0.251
	Industrial use			<0.01	0.333	0.333		0.222	0.406	0.406	0.406	0.235		0.224		0.207			0.251

Table 22 (Cont. 1). Exposure to industrial workers. RCR values

		PROCs																
Substance	Exposure Scenario	1	2	3	4	5	6	7	8a	8b	9	10	13	14	15	19	21	28
DBTE	Manufacture			0.033							0.350							
	Formulation of preparations			0.620		0.530		0.380		0.320	0.054							
	Production of polymers, masterbatches and compounds				0.673	0.670			0.920	0.990	0.990				0.290			
	Extrusion and moulding applications				0.810	0.810			0.745	0.272	0.372				0.286		0.781	0.781
	Calendering						0.443											
	Spread or dip coating				0.380	0.068			0.099	0.373	0.373	0.718		0.340			0.142	0.142
	Foam production by steaming				0.673	0.360			0.370	0.643	0.643		0.550					
DBTL	Manufacture	<0.01		0.084	0.836				0.082	0.082	0.082				0.070			0.082
	Formulation or re-packing			0.084	0.836				0.082	0.082	0.082				0.070			0.082
	Reactive catalyst - Intermediate			0.084	0.836			0.082	0.082	0.082	0.082	0.050			0.070	<0.01		0.082
	Stabilization process of plastics via calendering				0.836		0.046		0.082	0.082	0.082				0.070			0.082
DBTO	Formulation	0.203	0.387	0.265						0.106	0.282				0.235			0.506
	Catalyst	0.142	0.387	0.265	0.316					0.255	0.282	0.697	0.295		0.127			0.506
	Intermediate	0.203	0.148	0.051	0.517					0.106	0.201				0.235			0.506
	Cataphoretic coating			0.265							0.282		0.295		0.127			0.506

Table 22 (Cont. 2). Exposure to industrial workers. RCR values

		PROCs																
Substance	Exposure Scenario	1	2	3	4	5	6	7	8a	8b	9	10	13	14	15	19	21	28
DOTE	Formulation			0.020						0.061								
	Stabiliser						0.032			0.016				0.032			0.322	
DOTL	Manufacture	<0.01	<0.01	<0.01	0.091				0.091	0.031	0.031				0.286			0.031
	Formulation or re-packing			0.571	0.237	0.021			0.800	0.031	0.343				0.286			0.031
	Reactive catalyst - Intermediate	<0.01	<0.01	0.091	0.091	<0.01		0.171	0.800			0.021	<0.01		0.371			<0.01
	Stabiliser in calendering	<0.01	<0.01	<0.01	<0.01		0.286		<0.01	0.027	<0.01			0.063	<0.01			<0.01
*	Manufacture			0.450					0.050	0.050	0.050				0.017			0.050
	Formulation or re-packing			0.450					0.050	0.050	0.050				0.017			
	Adhesive and sealants															0.556		
**	Manufacture	0.426	0.116	0.116						0.363	0.166				0.203			0.766
	Formulation or re-packing	0.426	0.116	0.155	0.425	0.615				0.363	0.560			0.217	0.643			0.766
	Reactive processing aid in coatings	0.426	0.116	0.066	0.286	0.237		0.461	0.665	0.217	0.098	0.727	0.198		0.604			0.766
	Reactive process regulator in polymerisation	0.426	0.116	0.155	0.425	0.615	0.336			0.217	0.560		0.198	0.217	0.643			0.766

The definitions of the PROCs considered are provided next:

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes for formulation of preparations and articles
- PROC 6: Calendering operations
- PROC 7: Industrial spraying
- PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 12: Use of blowing agents in manufacture of foam
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation
- PROC 15: Use as laboratory reagent
- PROC 19: Manual activities involving hand contact
- PROC 21: Low energy manipulation of substances bound in materials and/or articles
- PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 28: Manual maintenance (cleaning and repair) of machinery

It should be noted that industrial workers are involved in the following stages of the life cycle (ECHA, 2015) of these substances:

- Manufacture
- Formulation and re-packing
- Use at industrial sites (DUs)

Therefore, the CSRs and EEs analysed are those developed for these life cycle stages.

RCR values below 0.7 can be regarded as low and, consequently, the exposure of industrial workers to these substances can be considered to be low as well. Therefore, the risk for these workers is sufficiently controlled as long as the RMMs and OCs described in the CSRs and ESs are observed.

In the case of RCR values between 0.7 and 1, the risk for the industrial workers is close to becoming above the DNEL and, although compliant, a revision of the corresponding CSRs would be advisable, including the appropriateness of the tools used to make the estimations.

Some examples of the RMMs defined in these CSRs and ESs are the implementation of good basic standard of occupational hygiene, standard LEV in place during the manufacturing process (mainly in material transfer points and other openings), use of PPE as gloves, respirator, face-shield, etc. Other RMMs related to industrial workers are training, risk management practices, supervision, traceability, or certification. Regarding OCs, those defined in the specific CSRs and ESs related to frequency, duration, and amount of use, and product characteristics, must be observed.

It should be noted that, in general, it is expected that dermal and inhalation exposure to these substances might occur during industrial manufacturing. For this reason, RCR values are estimated considering these exposure routes. However, oral exposure to organotin substances is unlikely to occur because, as commented before, industrial hygiene standards are applied as RMM. These standards include prohibitions to eat, drink, or smoke in the processing area, and resting rooms separated from the manufacturing area.

RMMs and OCs to control the inhalation exposure are relevant for these substances due to the classification as Repr. 1B. The manufacturers and DUs of these substances in the EU must comply with the national laws transposing the European Directive dealing with Carcinogens, Mutagens and Reprotoxic substances at the workplace (2004/37/EC)[10], known as CMRD, as well as with the other legislation for health protection and safety at work. This includes exposure monitoring during manufacturing, which is performed periodically in order to ensure compliance. Due to the lack of legal OEL at European and national level for these specific organotin stabilisers, the OELs defined for tin (Sn) in the national legislation are used as reference. Some examples of these values are indicated in **Table 23** (IFA, 2024).

According to the responses to the i-RMOA questionnaire received from the manufacturers of organotin substances (GOSC members), monitoring results are always compliant with these OELs in the respondent sites where these tin compounds are produced. However, these data do not cover all the European organotin producers.

[10] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (CMRD). Consolidated version 08/04/2024: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20240408&qid=1720598028787

Table 23. National OEL values for Tin compounds

	Tin compounds, organic (as Sn)	
Country	**OEL – 8 hours (mg/m³)**	**OEL – Short term (mg/m³)**
Austria	0.1	0.2
Belgium	0.1	0.2
Denmark	0.1	0.2
France	0.1	0.2
Finland	0.1	0.3
Germany	0.1	0.2
Hungary	0.1	0.4
Ireland	0.1	0.2
Italy	0.2	-
Norway	0.1	-
Romania	0.05	0.15
Spain	0.1	0.2
Sweden	0.1	0.2

Finally, none of these organotins are identified as ED; DBTAcAc, DBTC, DOTE, DOTL, and TBTO are categorised as SVHCs; and DOTE is currently included in the Authorisation list. All of these substances are restricted under REACH in certain applications.

3.2. Exposure to professional workers

The CSRs and ESs available have been analysed. These documents define the RMMs and OCs that are applicable to guarantee the safe use of these substances in terms of protection to human health and the environment protection.

The substances Bu2Sn(ITTP)2, DBTA, DBTAcA, DBTL, DBTO, and DOTE do not show professional uses defined in their CSRs and ESs. Therefore, a risk assessment cannot be performed.

The values of the RCR for all the Process Categories (PROCs) related to the professional[11] applications are summarised in **Table 24**.

[11] The ESs considered are those covering the different professional uses of the substances and the PROCs involved. The RCR values are the highest of all the ESs considered, always for the combined routes.

Table 24. Exposure to professional workers. RCR values

		PROCs																
Substance	**Exposure Scenario**	**1**	**2**	**3**	**4**	**5**	**6**	**8a**	**8b**	**9**	**10**	**11**	**13**	**14**	**15**	**17**	**18**	**19**	**28**
DBTE	Professional use of products containing substance as a catalyst/process regulator							0.037			0.659	0.358	0.349						
DOTL	Reactive process additive										0.063	0.571							
*	Professional use of adhesive and sealants																	0.556	
**	Professional use in coatings	0.085	0.066	0.066	0.286	0.237		0.672	0.217		0.727	0.182	0.198		0.604				0.766
	Professional use in flexible foams, thermoplastics and elastomers; Use in rigid foams, adhesives and sealants	0.085	0.069	0.155			0.336		0.217	0.560				0.217					0.766
	Professional use in lubricants in high energy open processes	0.256						0.691								0.619	0.323		

The definitions of the PROCs considered are provided next:

- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC 5: Mixing or blending in batch processes for formulation of preparations and articles
- PROC 6: Calendering operations
- PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
- PROC 10: Roller application or brushing
- PROC 11: Non industrial spraying
- PROC 13: Treatment of articles by dipping and pouring
- PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation
- PROC 15: Use as laboratory reagent
- PROC 17: Lubrication at high energy conditions in metal working operations
- PROC 18: General greasing /lubrication at high kinetic energy conditions
- PROC 19: Manual activities involving hand contact
- PROC 28: Manual maintenance (cleaning and repair) of machinery

It should be noted that professional workers are involved in the following stage of the life cycle (ECHA, 2015) of these substances:

- Widespread use by professional workers

Therefore, the CSRs and EEs analysed are those developed for this life cycle stage.

RCR values below 0.7 can be regarded as low and, consequently, the exposure of professional workers to these substances can also be considered low. Therefore, the risk for these workers is sufficiently controlled as long as the RMMs and OCs described in the CSRs and ESs are observed.

In the case of RCR values between 0.7 and 1, the risk for the professional workers is close to becoming above the DNEL and, although compliant, a revision of the corresponding CSRs would be advisable, including the appropriateness of the tools used to make the estimations.

The RMMs recommended for the handling of these substances by professional workers are wearing suitable protective gloves and goggles, and respiratory protective equipment with 95% efficiency for spraying tasks.

3.3. Consumer exposure

The CSRs and ESs available have been analysed. These documents define the RMMs and OCs that are applicable to guarantee the safe use of these substances in terms of human health and environment protection.

The substances Bu2Sn(ITTP)2, DBTA, DBTAcAc, DBTL, DBTO, and DOTE do not show consumer uses defined in their CSRs and ESs. Therefore, exposure assessment is not applicable as there are no consumer-related uses for these substances.

It should be noted that entry 20 (applicable to DBTE, DOTL, and *) and entry 30 (applicable to DOTL) of Annex XVII to the REACH Regulation (restrictions) apply to articles supplied to the general public (consumers). Understandably, the articles produced with these substances that are available to the consumer meet the criteria (conditions and exemptions) established in these restrictions.

The values of the RCR for all the Product Categories (PCs) related to the consumer [1] applications are summarised in **Table 25**.

Table 25. Exposure to consumers. RCR values

		PCs				
Substance	**Exposure Scenario**	**1**	**9a**	**9b**	**24**	**32**
DBTE	Consumer use of products containing substance as a catalyst/process regulator	0.053				
DOTL	Reactive process additive in foams, sealants, polymer products	0.390		0.060		0.361
*	Consumer use of adhesive and sealants	0.073				
**	Consumer use in coatings		0.755			
	Consumer use in rigid foams, adhesives and sealants	0.514		0.017		0.327
	Consumer use of lubricants and greases in open systems				0.657	

[1] The ESs considered are those covering the different consumer uses of the substances and the PCs involved. The RCR values are the highest of all the ESs considered, always for the combined routes.

The definitions of the PCs considered are provided next:

- PC 1: Adhesives, sealants
- PC 9a: Coatings and paints, thinners, paint removers
- PC 9b: Fillers, putties, plasters, modelling clay
- PC 24: Lubricants, greases, release products
- PC 32: Polymer preparations and compounds

It should be noted that consumers are involved in the following stage of the life cycle (ECHA, 2015) of these substances:

- Consumer use

Therefore, the CSRs and EEs analysed are those developed for this life cycle stage.

RCR values below 0.7 can be regarded as low and, consequently, the exposure of consumers to these substances can also be considered low. Therefore, the risk for the consumers is sufficiently controlled as long as the RMMs and OCs described in the CSRs and ESs are observed.

In the case of RCR values between 0.7 and 1, the risk for the consumers is close to becoming above the DNEL and, although compliant, a revision of the corresponding CSRs would be advisable, including the appropriateness of the tools used to make the estimations.

According to the CSRs and ESs, no RMMs and OCs are required for the use of these substances by the general public.

3.4. Environmental emissions

The ratio of Predicted Environmental Concentration / Predicted No Effect Concentration (PEC/PNEC) is the widely accepted and applied risk indicator in environmental risk assessment models intended for screening and risk characterisation.

Table 26 summarises the highest PEC/PNEC ratio value observed for these substances according to the available CSRs and ESs:

Table 26. Environmental exposure. PEC/PNEC values

Substance	PEC/PNEC	Compartment	ES
Bu2Sn(ITTP)2	0.920	Soil	All of the ESs
DBTA	0.645	Sediment (marine water)	Manufacture Intermediate Reactive processing aid
DBTAcAc	0.357	Agricultural soil	All of the ESs
DBTE	0.720	Soil	Production of polymers, masterbatches and compounds Spread or dip coating Foam production by steaming
DBTL	0.125	Marine water	All of the ESs
DBTO	0.570	Predator's prey (freshwater)	Formulation Intermediate
DOTE	0.25	Sewage treatment system	All of the ESs
DOTL	<0.01	All	All of the ESs
*	0.079	Marine water	All of the ESs
**	0.756	Agricultural soil	Formulation or re-packing

The ratio PEC/PNEC is always below 1 for the assessed compartments (soil, marine water, etc.). This means that the risk of these substances on the environment is adequately controlled.

However, in the case of PEC/PNEC values between 0.7 and 1, the risk for the environment is close to becoming above the PEC and, although compliant, a revision of the corresponding CSRs would be advisable, including the appropriateness of the tools used to make the estimations.

The only organotin substances that are not classified as dangerous for the environment are DOTL and *. The other substances show environmental classifications (acute and chronic), ranging from Category 1to Category 3. Furthermore, the PBT properties of TBTC are under assessment, and DBTE and TBTO have been identified as PBT.

The manufacturers of these organotin substances have declared that they meet the emission levels defined in their production permits. This involves the performance of regular control of on-site emissions to the air and water through the utilization of both engineering and administrative controls. Air pollution equipment (e.g., dust collectors, scrubbers, and thermal oxidizers) is in place and, in some cases, the waste gas generated is incinerated. The sites are equipped with onsite WWTP for the collection, control, and treatment of the process water before release to the environment.

DUs who responded to the i-RMOA questionnaire stated that, according to their emission permits, emission controls are in place, but not specifically for monitoring these substances. This activity is related to substances managed in very high volumes, so specific tin emission measurements are not available nor required. Regarding wastewater, some of the respondents declared that they are using the Best Available Techniques (BATs) defined in their industrial sectors: storage and handling of liquid in bunded areas, regular bund testing, regular testing of process water and groundwater, etc. Most of them are collecting wastewater separately and sending it to their industrial WWTP.

3.5. Humans exposed via the environment

The exposure of Humans via the Environment (HvE) is considered in the available CSRs and ESs of these organotin substances.

In the case of Bu2Sn(ITTP)2, DBTE, and DOTE, and in view of the intended use considered under their ESs, the risk of indirect exposure of humans via the environment is considered to be negligible. For DBTO the assessment of HvE exposure has not been performed in the CSR as the tonnage used is below 100 tonnes per year.

The values of the RCR for the combined routes related to the HvE[2] exposure are summarised in **Table 27**.

Table 27. HvE exposure. RCR values

Substance	Exposure Scenario	RCR
DBTA	Manufacture	0.071
	Formulation or re-packing	0.017
	Intermediate	0.024
	Reactive processing aid	0.033
DBTAcAc	All of the ESs	<0.01
DBTL	All of the ESs	0.027
DOTL	All of the ESs	<0.01
*	All of the ESs	<0.01
**	Manufacture	0.283
	Formulation or re-packing	0.028
	Reactive processing aid in coatings	0.034
	Reactive process regulator in polymerisation	0.497

[2] The ESs considered are those covering the different HvE assessments of the substances. The RCR values are the highest of all the ESs considered, always for the combined routes.

RCR values below 0.7 can be regarded as low and, consequently, the HvE exposure to these substances can be considered to be low as well. Therefore, the risk can be regarded as sufficiently controlled.

4. SOCIO-ECONOMIC INFORMATION AND ALTERNATIVES

One of the main applications of these organotin substances is as stabilisers in the production of PVC articles. The particular properties which organotin substances provide to the articles include (but are not limited to) the following:

- Thermal stability
- Clarity
- Initial colour and colour stability
- Chemical and fire resistance
- Weather and UV resistance
- Adherence to other materials (e.g. metal foils)

If organotin stabilisers could not be used in PVC, the current users of organotin stabilisers would be obliged to switch to alternative stabilisers or to stop production. The most likely alternative is calcium-zinc based stabilisers. There has been a significant switch away from organotin substances to calcium-zinc based stabilisers already over the last 20 years, in such a way that many of the stakeholders responding to the i-RMOA questionnaire indicated that those substitutions which are relatively easy to achieve have already been implemented. Remaining uses of organotin stabilisers are much more dependent on the properties provided by these substances, and substitution is reported to be much more difficult.

Products made with calcium-zinc (and other non-tin) stabilisers tend to be less durable and have a shorter service life. They are more susceptible for weathering and losing their colour. There can be difficulty with turbidity since the alternatives tend to be dry mixtures rather than liquid, which particularly affects clear PVC sheets (used for roofing and other architectural purposes).

Stakeholders also reported that organotin alternatives can be difficult to use in particular article production processes. These problems can be very location-specific, since they can be dependent on very particular characteristics of the process machinery. For instance, large-scale calendering equipment tends to be built to order and constructed on-site, so that no two machines are identical, even for similar processes. Problems have been reported with plate-out, shorter processing windows and fume generation in some calendering operations.

Other stakeholders have reported that injection-moulding and extrusion of C-PVC (chlorinated PVC) pressure pipes and U-PVC (unplasticized PVC) very large pressure fittings are not possible without organotin stabilisers, although they have been substituted by calcium-zinc based

stabilisers in standard U-PVC pressure pipes and fittings PVC pressure pipes are important and cost-effective components used in water supply and heating, chemicals, oil and gas and general industrial applications, and they must comply with very stringent technical requirements. The processability window of U-PVC fittings formulations with Ca-Zn and organic-based stabilisers (OBS) is more limited. As a consequence, manufacturing of big diameter fittings and fittings with larger wall thickness without organotin stabilisers proves to be challenging. Furthermore, the consumption of Ca-Zn and OBS is up to 5x higher compared to the use of organotins (TEPPFA, 2023).

On the other hand, organotin stabilisers are required to provide resistance to harsh conditions (e.g. chemicals, heat etc). The organotin stabilisers are essential in C-PVC pipes used for the transport of aggressive chemicals. Furthermore, according to the information provided by TEPPFA, the comparison of corrosion depths of different U-PVC pipe grades with harsh chemicals shows considerably stronger chemical attack for the organotin-free U-PVC pipes. For this reason, the service life of the U-PVC piping systems manufactured without organotin stabilisers is considerably lower in strong chemical attack applications.

Stakeholders varied in the amount of time they considered would be needed to find feasible alternatives for organotin stabilisers in their applications. It was felt that some applications could be substituted relatively quickly (e.g., 24 months), whereas other would take 5-10 years or more, assuming that research and development activities and testing are successful. This means that, under this restriction, these applications would cease in the EU unless a sufficiently long derogation was granted.

In 2023, ECHA published an investigation report on PVC and its additives (ECHA, 2023), proposing some possible regulatory actions on these substances in the coming years, including their ban in the EU market. Part of this report is focused on the organotin stabilisers. In this report, ECHA recognised many of the problems associated with substituting organotin stabilisers with calcium-zinc, but also in its study considered the possibility that many organotin stabilisers could be substituted with MOTE – an organotin which it considered of no concern. Indeed, ECHA reports that many applications have already substituted DOTE completely with MOTE, for instance, packaging (ECHA, 2023).

However, this misunderstands how MOTE and DOTE are used as a mixed stabiliser. ECHA considers MOTE a substance of no concern only when it is used with a concentration of DOTE below 0.3% w/w (ECHA, 2023). However, MOTE is not available on the market in the EU at such a concentration, in large part because it needs a higher concentration of DOTE to perform effectively as a stabiliser. The lowest concentration of DOTE which tends to be used on the market is 6% w/w, which is lower than the limit at which authorisation is required (10% w/w), but clearly much higher than ECHA's 'no concern' concentration (ECHA, 2023).

This means that a ban on the use of MOTE with a concentration of DOTE above 0.3% w/w is effectively a ban on MOTE, and hence ECHA's proposed restriction (ECHA, 2023) is equivalent to a restriction on both organotin stabilisers. It also means that ECHA's assessment of the cost

of complying with such a ban are significantly underestimated (ECHA, 2023), since it ignores all those applications which have 'substituted DOTE' by switching to MOTE with a 6% w/w DOTE concentration.

Producers of semi-rigid films (e.g. for laminated furniture) reported having switched away from organotin stabilisers to calcium-zinc some time ago, due to market and regulatory pressure. The only remaining application using organotin stabilisers is a thin, transparent film, for which a non-MOTE/DOTE stabiliser is used. These stakeholders highlighted the widespread difficulty industry has faced in substituting organotin stabilisers out of longer-lived transparent applications (e.g., furniture), due to discolouration etc. This is only a small part of its market and little progress is anticipated on substitution in the medium term.

Finally, a ban of these substances would also apply to the recycling of PVC containing organotin stabilisers. It is not known how much PVC containing organotin stabilisers is currently recycled each year. This waste would have to be diverted to landfill or incineration in the EU and could also be exported for recycling outside of the EU. This would result in an increase in air emissions (from incineration, and possibly transport), and an increase in leaching and landscape impacts. These increases would decline over time as the stock of PVC containing organotin stabilisers declined following the restriction. There would be a reduction to zero of any health risks from exposure of EU workers in recycling plants to organotin stabilisers via dust generation (etc). These risks would be transferred to non-EU to the extent that waste containing organotin stabilisers was exported out of the EU for recycling.

The other main use of these substances is as catalysts used in a number of important industrial processes, including the production of polymeric materials, paints and coatings, and in silicon curing.

For example, DBTO is used in aqueous cathodic electrodeposition of urethane coatings for automotive and industrial applications (PMC, 2025). This substance is considered the standard catalyst for crosslinking in cathodic electrocoating. In the course of the process, a primer is applied to the surface of the components to protect them from corrosion and physical damage. Other areas in which DBTO is used as a curing catalyst include water-based polyurethane coatings, silicone-based systems, polyester resins and alkyd resins, where it has proven its worth as a catalyst for high-temperature transesterification reactions as required in the production of powder coating materials and alkyd resins. It is also employed in widely used paints, both oil paints and varnishes (BNT, 2025).

According to the responses by DUs to the i-RMOA questionnaire, a potential alternative to the use of DBTO as a catalyst in these processes, especially in automotive applications, are bismuth-based catalysts (e.g., bismuth carboxylate, bismuth oxide, etc.). However, its performance is weaker, the cost is higher, and the efficiency and market availability are lower compared with DBTO.

DOTL is a versatile catalyst used in various urethane cross-linking reactions and silanol condensation reactions (PMC, 2025). It is also used as a catalyst in polycondensation reactions in the production of thermoplastic polymers, adhesives and sealants, coatings, paints and thinners as well as paint removers (BNT, 2025). According to the responses to the i-RMOA questionnaire received from 9 DUs, only in one case an alternative substance (identity has been kept confidential) is considered, classified as non-hazardous, and with a similar cost. The other 8 companies declared that none of the alternatives tested can be considered suitable in technical and economic terms.

As a catalyst, DBTA is used in esterification reactions, transesterification reactions, and in condensation reactions (BNT, 2025). Specifically, this substance is used in silanol condensation reactions for caulk and sealant applications, in the production of blocked isocyanates for urethane coatings that are used in the automotive market, to cross-link urethane coating systems for both the automotive and industrial coatings markets, and transesterification of esters for the antioxidant and synthetic lubricant markets (PMC, 2025). None of the 4 respondents to the i-RMOA questionnaire for DUs indicated the existence of an available technical alternative.

DBTL catalyses esterification reactions, transesterification reactions, and polycondensation reactions and has become the industry standard for coatings, adhesives, solvents, and elastomers (BNT, 2025; PMC, 2025). As in the case of DBTO, the only available alternatives considered by DUs for this substance are the bismuth-based catalysts, but currently, they are double the price (compared with DBTL), and the technical performance is lower. A company said that their use result in more often needing to re-coat and that they make the products less durable. Another respondent indicated that other tested alternatives are chemically quite similar to DBTL, suggesting that the toxicological profile is also quite similar. In addition, some of them are already considered SVHC, and their use would ultimately lead to a regrettable substitution.

Finally, some of these organotin substances are used as intermediates in the production of other organotin compounds, being essential to obtain them. For example, TBTC is used as an intermediate in the synthesis of tributyltin oxide, which is used as a fungicide and a wood preservative.

It should be noted that in this use, the handling of these substances is restricted to the industrial field, not being used by professional workers and not being available to the general public (consumer). This means that the risk level of use of these substances in this use is low, since they are handled under very controlled conditions.

5. REGULATORY MANAGEMENT OPTIONS (RMOs)

To manage potential concerns related to a substance or group of substances, various RMOs can be explored. Each technical or legislative measure has its own advantages and limitations, which may differ depending on the specific case. A structured analysis of RMOs helps identify the most suitable approach (or combination of approaches) for the situation at hand. As an initial step, several potentially viable RMOs for addressing concerns related to organotin substances under the i-RMOA will be reviewed. Based on substance-specific factors, some of these RMOs may be deemed unfeasible and excluded from further consideration.

5.1. Identification and screening of possible RMOs

For the purpose of carrying out an initial regulatory screening, the following RMOs could be considered:

- CLH under CLP: considering the information shown in **Table 19**, only 5 of the 15 substances covered by this i-RMOA do not have a harmonized classification. However, all of them are self-classified by the industry as Repr. 1B. Therefore, starting a CLH process at this moment for these 5 substances does not provide any advantage to address the potential concerns regarding them.
  Although in the case of the 5 self-classified substances, a CLH proposal would be considered the previous regulatory step for leading to SVHC identification and inclusion in the candidate list, the CLH process under CLP is not strictly necessary to trigger subsequent RMOs to handle potential concerns (e.g., restriction). Therefore, the i-RMOA will evaluate further possible regulatory actions and not consider a CLH implementation as a final RMO.
- SVHC identification and Candidate listing: as substances classified as Repr. 1B, all of these substances might meet the conditions to be identified as an SVHC. In fact, some of them are already listed as SVHCs (DBTAcAc, DBTC, DOTE, DOTL, and TBTO). Therefore, it could be considered that this RMO could be extended to the rest of the substances and assess whether it provides some kind of value in the management of the concern.
- REACH authorisation: following indications in the previous item, this RMO could apply to all these substances, as they meet the conditions to be identified as SVHC. In the case of DOTE, the substance is already included in Annex XIV of REACH, and some of its manufacturers have already applied for authorisation.
  It is worth noting that, while SVHC identification and Candidate listing may be seen as an independent RMO, this is typically linked to the inclusion of the substance in REACH Annex XIV. For this reason, both RMOs will be merged into a single case, under the Authorisation procedure.

- Restriction under REACH: restrictions could potentially address situations of concern that may be identified by regulators. In the case of some of these organotin substances, currently there is significant political and regulatory pressure to evaluate the RMO in this broad EU context (ECHA, 2023). There are different possibilities regarding how a restriction could be applied to these substances. The following ones will be considered in this i-RMOA:
    - Full restriction of the use of the substances
    - Targeted restriction of some uses of the substances
- Development and implementation of OELs under workplace legislation (CMRD): CMRD applies to substances meeting the criteria of Repr. 1B under CLP. As previously noted (Section 3.1), the application of this legislation involves monitoring exposure to these substances. However, this activity is currently performed without OELs defined at the European level. As OELs are usually prioritised for chemicals posing significant concern to workers, in this context, this RMO may be relevant to all the substances under consideration.
- Other non-REACH related processes could be proposed for these substances (e.g., Voluntary Initiatives by Industry - VII). However, it is unlikely that these could result in more efficient RMOs than those related to REACH. While some of the REACH procedures could themselves take a significant amount of time until outcome, it is nevertheless assumed that keeping initiatives within the REACH framework (or under already existing initiatives) would allow for a more transparent and predictable evaluation of future regulatory actions on organotin substances.

Finally, it should be noted that other actions may be explored that do not in themselves constitute an RMO but are simply a compliance requirement. This may include, for example, updates of the REACH registration dossiers (e.g., CSRs) for some of the substances evaluated in this i-RMOA. Currently, CSRs appear to be up to date, with only a few very specific modifications for the adjustment of some RCR values in the CSRs being perhaps necessary (see Section 3).

Table 28 summarises the result of the preliminary screening of RMOs for these substances:

Table 28. Preliminary screening of RMOs

RMO	Considered for further evaluation?
Harmonised Classification and Labelling (CLH) under CLP	NO
SVHC identification and Candidate Listing	NO (merged into authorisation)
Authorisation under REACH	YES
Restriction under REACH	YES
Development and implementation of OELs under workplace regulation	YES
Other non-REACH related processes	NO

Moving forward, and based on the summary outlined in **Table 28**, the RMOs that will be analysed in detail are:

- RMO 1: Authorisation under REACH
- RMO 2: Full restriction under REACH
- RMO 3: Targeted restrictions under REACH
- RMO 4: Development of OELs under workplace regulation (CMRD)

5.2. Description of the selected RMOs

5.2.1. RMO 1: Authorisation under REACH

Due to their classification as Repr. 1B, these organotin substances meet the criteria for being identified as SVHC substances, which may lead to a subsequent inclusion of the substance in REACH Annex XIV – the authorisation list. This regulatory path is clearly described in REACH and would be in line with the scope of the Regulation, to promote substitution of SVHCs where technically feasible.

When evaluating a possible authorisation of a substance, two scenarios could be envisaged, depending on whether authorisations would be granted or not granted. Under RMO 1, the assessment will focus on situations under which authorisations would be granted to all applicants requesting them for the longest possible review period. This option assumes that all Applications for Authorisation (AfA) submitted would be deemed acceptable by the relevant evaluating committees, the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) of ECHA.

It is worth noting that a non-granted authorisation would be equivalent to the outcome of RMO 2 for the relevant stakeholders, resulting in an effective ban on the use of the substance. Therefore, it could be assumed that impacts related to this scenario would be covered by the assessment of RMO 2. In reality, a non-granted authorisation would likely have even more negative consequences for industry than RMO 2, because the costs of putting together an AfA would need to be added to the possible impacts resulting from a ban on the continued use of

the substance. Still, for reasons of practicality, the two cases (RMO 2 and non-granted authorisations) will be considered analogues in the i-RMOA evaluation.

COM is currently revising the REACH Regulation in the context of the Chemicals Strategy for Sustainability (COM, 2020), adopted in 2020, as part of the European Green Deal[3]. The in-depth reform of the authorisation process under REACH is one of the COM's objectives with this upcoming revision. This is due to the high inefficiency of this process when it affects substances with a high number of users and applications. On the one hand, COM is delaying the processing of AfAs, failing to comply with the legal deadlines set by the REACH Regulation. On the other hand, several authorisation decisions have been the object of litigation before the European Courts. A recent judgment of the Court of Justice granted the action for annulment brought by the European Parliament against the COM's decision to authorise six categories of uses of chromium trioxide (Mullier, 2023). Some of the objectives of the reform of the authorization process would be to streamline procedures and reduce the need for individual authorizations.

Finally, it is important to understand that the REACH authorisation only applies to SVHC substances used in the EU. As a consequence, REACH does not regulate SVHCs entering the European market as part of imported articles that may have an impact on human health and the environment. Moreover, from an economic perspective, domestic articles are subject to stricter requirements than those that are produced abroad, putting actors from within the EU at a competitive disadvantage and thus impeding the intention of REACH to enhance competitiveness and innovation (Schenten, 2016).

5.2.2. RMO 2: Full restriction under REACH

Restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels. A restriction may apply to any substance on its own, in a mixture or in an article (produced in the EU or imported), including those that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers (ECHA, 2025). A restriction can be triggered on a substance when it is demonstrated that there are risks that need to be addressed on a Community-wide basis. According to the REACH Regulation, a restriction must be targeted to the effects or exposures that cause the risks identified, it has to be capable of reducing these risks to an acceptable level within a reasonable period of time, and it must be proportional to the risk.

A MS, or ECHA, at the request of COM, can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or the

[3] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

environment, which requires action on a Community-wide basis. Following the communication of the intention to prepare a restriction proposal in the Registry of Intentions, a restriction dossier is prepared by the interested party. The dossier will then be subject to different phases, involving public consultations and opinions from the relevant committees (RAC and SEAC) before COM takes a decision and the restriction is enforced. The restrictions in force are detailed in the Annex XVII of the REACH Regulation and new ones are added to it.

In the case of the organotin substances classified as Repr. 1B, an update of REACH Annex XVII could be proposed in order to cover potentially unacceptable risks derived for the manufacture, use and placing on the market of these substances. A direct ban on the manufacture, import and uses of organotin substances will be assumed for a deeper evaluation of the potential implications that this ban may have for manufacturers as well DUs and the EU society as a whole.

5.2.3. RMO 3: Targeted restrictions under REACH

RMO 3 would imply a variation of RMO 2 since the starting point would still involve a restriction process under REACH. However, RMO 3 would limit banned uses to those that have resulted in higher uncertainty in relation to the information available, as described in Section 3 of this i-RMOA. For example, those uses that, at this time and in the absence of a review of their CSRs and ESs, present RCR values higher than 0.7.

It is necessary to recall that certain uses of all of these substances are already restricted under REACH, so targeted restrictions are already in place.

5.2.4. RMO 4: Development of OELs under workplace regulation (CMRD)

This RMO would allow the continued use of these organotin substances. However, given the potential for workers to be exposed to these substances, the RMO would involve the establishment of OELs under the CMRD to ensure worker exposures were kept below safe limits. The setting of OELs follows a standard procedure, which in some respects is less burdensome than a restriction (since it does not require a full Annex XV dossier) but in others is more demanding (e.g., it requires individual MSs to set their own OELs and place them in national legislation).

The greater potential cost comes from firms needing to implement monitoring regimes to measure the exposure of their works to these organotin substances, and to introduce additional controls in the event that the OELs are exceeded. It is possible but unlikely that some firms would be unable to afford such additional controls, imply the need to close down. Reductions in exposures would bring benefits to workers in terms of reduced (perceived) risks from these substances.

5.3. Assessment of the selected RMOs

The RMOs (1 through 4) that have been identified and considered relevant for further assessment will be evaluated according to a specific methodology. Details on this methodology can be found in Annex I. Essentially, the different RMOs are analysed in relation to a series of criteria, in order to provide conclusions in relation to their effectiveness, practicality, broader impacts and regulatory consistency. Under these four criteria, different independent factors are evaluated, and each RMO analysed will be assigned a score (within the range +3 to -3) depending on the degree to which it is estimated that the RMO would impact on the factor, either positively or negatively. Finally, a series of weighting corrections are applied, depending on how significant the factors and criteria are expected to be in relation to the overall objective of applying the RMO. These corrections are consistent across the different RMOs evaluated, i.e., the same weighting is applied to the factors that are evaluated, irrespective of which RMO is analysed.

5.3.1. RMO 1: Authorisation under REACH

Effectiveness – Risk reduction capacity

The inclusion of these substances in Annex XIV of the REACH Regulation could prompt DUs to look for safer alternatives. Authorisation is considered to be a driver for substitution, encouraging companies to explore substitutes to reduce risks, especially if the substances pose significant health or environmental hazards. Although it will be complicated for main applications, residual uses would quickly be abandoned by users, leading to an effective elimination of risks. Hence, assuming that all authorisations would be granted, this RMO could be considered analogous to RMO 3 (targeted restriction), as they would lead to similar levels of risk reduction.

Thus, the score of this factor under the i-RMOA methodology is: **+3 / +2 (average +2.5) – high/medium positive impact**.

Effectiveness – Measurability / Monitorability

The conditions and timelines imposed by the Commission in the granted authorisations will define the degree of measurability and monitorability of this RMO. This includes periodically demonstrating compliance with any imposed monitoring programs, reviewing operating conditions, and assessing the effectiveness of risk management measures. Compliance with these conditions is crucial, as companies covered by the authorisation are subject to potential inspections by MSCAs. If these conditions are stringent (which is potentially possible for substances classified as Repr. 1B), the demonstration of compliance could be complicated. This will also depend on the company's experience in handling such substances (application of the CMRD), being more complex for those that have never done so and easier for those that already manage them.

Thus, the score of this factor under the i-RMOA methodology is: **-3 / -2 (average -2.5) – high/medium negative impact**

Effectiveness – Time until implementation

The time that may be required until authorisation is fully implemented would likely be longer than in the case of a restriction, because the classification of some of these substances as Repr. 1B is currently a self-classification by industry, and not a harmonised one.

Thus, the score of this factor under the i-RMOA methodology is: **+1 / +2 (average +1.5) – low/medium positive impact**.

Practicability – Implementability

Under a REACH authorisation, AfAs would need to be developed by the impacted stakeholders. Based on existing experience with the authorisation process (e.g., DOTE), it can be concluded that this is never a simple task for industry, particularly in cases where a complex supply chain may be involved. Authorisation would also result in the need to continue to monitor and verify that exposure is in line with the CSR that would be part of AfAs (and eventually accepted by RAC as part of a granted authorisation). While this would be expected to be feasible for industry, the fact that a review period is imposed on authorisation, resulting in periodic needs to review the content of AfAs and resubmit to ECHA, would result in continue needs to work on the implementation of the RMO.

Thus, the score of this factor under the i-RMOA methodology is: **-3 / -2 (average -2.5) – high/medium negative impact**.

Practicability – Enforceability

Regarding enforceability, the complexity for regulators to handle a relatively large number of AfAs would need to be considered. Furthermore, challenges related to the coordination between different MSCAs would move the scoring of this RMO into the negative area.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact**

Practicability – Manageability

Manageability should look at how capable of managing the progress of the RMO will the involved stakeholders be. It should also ensure that the administrative burden is proportional to the risks to be avoided. In this context, authorisation would appear as an excessively difficult RMO to manage for industry, particularly for the limited improvement in risk management that would be expected.

Thus, the score of this factor under the i-RMOA methodology is: **-3 / -2 (average -2.5) – high/medium negative impact**

Broader Impacts – Additional human health or environmental impacts

It could be anticipated that the excessive burden that this RMO would place on industry would lead to market uncertainty and to substitution initiatives by DUs which may involve replacement of these organotin substances for other materials even with less efficient performance. While the overall impact would not be as severe as under a full restriction (as this RMO is based on the fact that authorisations would be granted), negative overall impacts could be anticipated.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact**

Broader Impacts – Socio-economic impacts

Impact from a REACH authorisation could be expected to be comparatively in between the full restriction (RMO 2) and the targeted restriction (RMO 3). Since the assumption is that authorisations would be granted, continued use of these organotin substances could be allowed. However, socio-economic impacts could still be significant. First of all, the costs of preparing AfAs would need to be considered, not just the initial ones, but also all efforts related to preparing renewal applications would need to be factored in. Additionally, placing of a substance in the REACH authorisation list inevitably brings uncertainty to the market in terms of continued availability[4] of a substance for use in the EU market. It would appear that all these impacts are not proportionate for the level of risk improvement that could be gained.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact**

Regulatory consistency - Consistency with existing EU legislation

Evaluation of this factor under the RMO considered is largely dependent on the consideration around the risk assessment. Given that there are risks related to these substances, a REACH authorisation on these substances could be claimed as a consistent RMO. However, it is questionable that the impacts from this regulatory initiative would be proportionate to the risk that could be addressed.

Furthermore, authorisation itself as a REACH process is being questioned by the authorities within the revision of the Regulation. Therefore, it cannot be considered a consistent RMO in regulatory terms.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact.**

Regulatory consistency - Consistency with other EU policy objectives

As it has been previously discussed under other factors, even if a REACH authorisation would grant continued use of these organotin substances, the uncertainty that this RMO would bring to the market could push towards substitution of them in a scenario in which no equivalent

[4] It is worth noting that, while this i-RMOA assumes that authorisations would be granted, this would not be assured to applicants and impacted downstream actors at the beginning of the process. Therefore, even if authorisations were ultimately granted, situations of uncertainty in the market would not be avoided

alternatives are available. This again could lead to lower quality of products manufactured in the Union on the EU market, while still not addressing imports of articles containing these substances.

Thus, the score of this factor under the i-RMOA methodology is: **-1 – low negative impact**

5.3.2. RMO 2: Full restriction under REACH

Effectiveness – Risk reduction capacity

A full restriction on these chemicals could effectively lead to complete removal of the risks attributable to these substances. Indeed, under this scenario all uses of organotin substances (those included in scope of this i-RMOA) would be removed from the market after the entry into force of the restriction (or after the relevant transition period).

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

Effectiveness – Measurability / Monitorability

In order to monitor the results of a full restriction for organotin substances, the main parameters that would need to be considered are the effective removal of these chemicals from the market. Although this appears to be straightforward and could be monitored (e.g. via statistics or reporting requirements), there could be challenges in order to verify that all products would be free of these substances, particularly related to operations involving recycling.

Thus, the score of this factor under the i-RMOA methodology is: **+1 / +2 (average +1.5) – low /medium positive impact**.

Effectiveness – Time until implementation

A restriction under REACH could be effective in relation to the time it would require for its implementation. The REACH restriction process has well established periods for entry into force. Certainly, different technical and administrative steps described in the REACH Regulation would need to be observed, but from the point of view of timing, it could be regarded as one of the most effective RMOs available.

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

Practicability – Implementability

This factor evaluates how easy it would be for relevant stakeholders to implement an RMO. In principle, it can be anticipated that removing chemicals from the market is a simple action which stakeholders can understand and apply. However, practical implementation will pose certain challenges, particularly for applications for which there is currently no viable alternative that will provide the required properties. For example, discussions with stakeholders indicated that the substitution of DOTE in PVC rigid transparent sheets is

considered particularly difficult, and even other applications would take a number of years to substitute.

Thus, the score of this factor under the i-RMOA methodology is: **+1 – low positive impact**.

Practicability – Enforceability

Enforcement of a broad restriction that will cover different substances and applications will pose significant challenges. This is particularly relevant for specific uses where no alternatives are available, as industry would have no incentives to substitute. The variety of substances covered, large number of products in which they are present, and waste streams to be checked would render enforcement activities complex. In parallel, unless specific derogations are introduced in the restriction, the use of imported articles manufactured with these organotin substances would also be impacted by the restriction. In this case, effective border controls to identify such products and prevent their placing on the market would have to be established.

Thus, the score of this factor under the i-RMOA methodology is: **-3 / -2 (average -2.5) – high / medium negative impact.**

Practicability – Manageability

Due to the potential complexity of the involved supply chains, coordination between different actors could make it very difficult to manage the full elimination of these organotin substances from the different types of products in which they are used. Administrative burdens to be expected (e.g. related to expected closure of production lines or even full shut-down of specific establishments) would appear to be excessive compared to the overall level of risk reduction that may be achieved.

Thus, the score of this factor under the i-RMOA methodology is: **-3 – high negative impact**.

Broader Impacts – Additional human health or environmental impacts

Several negative impacts can be anticipated under this factor. In the first place, it needs to be considered that certain products that are critical to ensure safety in key technological applications may be lost without proper alternatives. For example, pipes used to deal with highly corrosive chlorine streams are based on PVC stabilised with organotin stabilisers that would fall in the scope of the restriction. In this case, there are no viable alternatives materials that could replace PVC.

Under this factor, again the potential impact on recycling needs to be considered. If PVC waste containing organotin stabilisers can no longer be recycled, the fate of such waste would need to be reconsidered. This would lead to increased waste streams that would need to be collected in landfills or incinerated, which would have negative environmental consequences (starting with the fact that PVC is a persistent material, as highlighted by ECHA in its recent investigation report (ECHA, 2023)).

Thus, the score of this factor under the i-RMOA methodology is: **-3 – high negative impact**.

Broader Impacts – Socio-economic impacts

Although stakeholders indicated some potential for further substitution (for example, towards calcium-zinc stabilisers in the case of organotin stabilisers), in most cases, the scope for this is limited and would still require a number of years to complete. For some applications, it was considered that substitution away from organotin stabilisers is not currently possible. These include safety-critical applications such as pressure piping for the chemicals and oil and gas sectors. Removing these from the market would have significant costs in terms of replacement materials and/or reductions in safety. There would also be a reduction in the availability of waste materials for recycling, forcing the replacement with virgin materials.

Thus, the score of this factor under the i-RMOA methodology is: -**3 – high negative impact.**

Regulatory consistency - Consistency with existing EU legislation

Evaluation of this factor under the RMO considered is largely dependent on the consideration around the risk assessment. Given that there are risks related to these substances, a REACH restriction on these substances could be claimed as a consistent RMO. However, it is questionable that the impacts from this regulatory initiative would be proportionate to the risk that could be addressed, particularly if these would require an EU-wide regulatory action.

Thus, the score of this factor under the i-RMOA methodology is: **-1 / +1 (average 0) – low negative / positive impact.**

Regulatory consistency - Consistency with other EU policy objectives

A full restriction on the use of these organotin substances would create significant issues, particularly related to circularity due to its impact on recycling of PVC waste. This is against the objective to move towards a circular economy within the EU. The negative impact that this option would have on waste management would need to be considered.

Thus, the score of this factor under the i-RMOA methodology is: **-3 – high negative impact**.

5.3.3. RMO 3: Targeted restriction under REACH

Effectiveness – Risk reduction capacity

From the point of view of risk reduction, if the assessment is performed with the consideration that risks derived from the use of these organotin substances are mainly found in the restricted applications, it is evident that a ban on such uses would remove most of the identified risks.

Thus, the score of this factor under the i-RMOA methodology is: **+3 / +2 (average +2.5) – high positive impact**.

Effectiveness – Measurability / Monitorability

As discussed previously for RMO 2, elements are in place to monitor the efficiency and development of a restriction. Some challenges could be anticipated. However, these could be

regarded as less complex than in the case of a full restriction, as they would be limited to specific applications.

Thus, the score of this factor under the i-RMOA methodology is: **+2 – medium positive impact**.

Effectiveness – Time until implementation

Similarly to what was described under RMO 2, a restriction is likely the best option in terms of having timing for the RMO to be fully in place.

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

Practicability – Implementability

Practicability challenges would be limited to the restricted applications. Still, these should not be regarded as non-important.

Thus, the score of this factor under the i-RMOA methodology is: **+1 / +2 (average +1.5) – low / medium positive impact.**

Practicability – Enforceability

Similar concerns related to enforcement can be anticipated for RMO 3 as in the case of RMO 2. Specific systems to verify that these organotin substances are not being used by industry in the restricted applications would have to be implemented at the EU scale. It is likely that this will create complexity at the level of national authorities in charge of enforcement.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact**.

Practicability – Manageability

As in the case of RMO 2, it is assumed that supply chains involved on the restricted applications of these organotin substances would have difficulties to manage the consequences of the implementation of the restriction, although these supply chains are expected to be less complex to manage as compared to the ones that would be impacted under RMO 2. In any case, it does not seem that the risk to be reduced justifies the administrative burden that would be created for industry.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact**.

Broader Impacts – Additional human health or environmental impacts

For this factor, the main negative impacts would come from the restricted activities related to the manufacture of products that are critical to ensure safety in key technological applications or recycling activities.

Thus, the score of this factor under the i-RMOA methodology is: **-3 / -2 (average -2.5) – high / medium negative impact**.

Broader Impacts – Socio-economic impacts

This more specific RMO would allow the use of these substances to continue in unrestricted activities. However, if some of the restricted activities are related to critical uses, such as pressure pipelines, the associated loss of value would be large. This will affect various supply chains as well as end users.

Thus, the score of this factor under the i-RMOA methodology is: **-1 – low negative impact**.

Regulatory consistency - Consistency with existing EU legislation

A targeted restriction focused on specific applications where risks are identified would fit the current regulatory framework in Europe. Another question would be to clarify if such risks would merit an EU-wide action, or if the risks to be removed justify a regulatory action with significant impact to industry (and society as a whole), but in principle, the restriction would appear to be a consistent option.

Thus, the score of this factor under the i-RMOA methodology is: **+1 – low positive impact**.

Regulatory consistency - Consistency with other EU policy objectives

As discussed under RMO 2, this restriction option could have negative consequences for recycling of PVC waste streams, which go against the objective of moving towards a circular economy in Europe.

Thus, the score of this factor under the i-RMOA methodology is: **-2 – medium negative impact.**

5.3.4. RMO 4: Development of OELs under workplace regulation (CMRD)

Effectiveness – Risk reduction capacity

The implementation of OELs for these organotin substances would adequately reduce any risks that may be derived from their uses. Risks that may be related to these chemicals are focused on workplace exposure, so an OEL fits well with the nature of these substances. The fact that they would still be in use does not allow to score this RMO at the same level as a restriction, but the impact would still be significantly positive.

Thus, the score of this factor under the i-RMOA methodology is: **+2 – medium positive impact**.

Effectiveness – Measurability / Monitorability

An RMO based on the implementation of OELs is considered to be very positive under the measurability factor. OELs are based on values that can be measured, and their comparison against the established limits is easy to understand by the affected stakeholders. Indeed, some references to existing exposure limits already exist (see **Table 23**).

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

Effectiveness – Time until implementation

The OEL definition process could be relatively complex, potentially resulting in a rather long time until it can be fully implemented[5]. However, given the adequate level of priority, it could enter into force in a process of around 4-5 years. Furthermore, this RMO would not represent a novelty, since OELs have been under discussion for organotin substances for some time. Still for the sake of clarity the RMO is given a low positive score in the analysis.

Thus, the score of this factor under the i-RMOA methodology is: **+1 – low positive impact.**

Practicability – Implementability

Implementation of actions related to compliance with OELs should be relatively straightforward for industry. In fact, these are already in place at most companies (if not all) due to the application of the CMRD and because some exposure limits already exist for these chemicals. So, acknowledging that for some specific companies' efforts may still be required, the score for this factor should be highly positive.

However, it should be noted that the present i-RMOA does not evaluate what the final OEL value would be. It is possible that a very stringent OEL would be difficult to implement by industry. The OEL setting process does take into consideration the feasibility of the values proposed (via discussions at the Working Party on Chemicals and the Advisory Committee on Safety and Health at Work), which gives the industry the opportunity to provide comments on this aspect. Still, the uncertainty of this factor needs to be acknowledged within the i-RMOA.

Thus, the score of this factor under the i-RMOA methodology is: **+2 / +3 (average +2.5) – medium / high positive impact.**

Practicability – Enforceability

This RMO would require some efforts from enforcement authorities, as they would need to set up clear and effective schemes to ensure compliance. Such systems are already in place at the national level via the CMRD, and authorities are familiar with procedures to verify that industrial sites comply with exposure limits. Therefore, enforcement should be rather straightforward in this case.

Thus, the score of this factor under the i-RMOA methodology is**: +2 medium positive impact**.

Practicability – Manageability

Stakeholders should, in principle, not have particular difficulties in managing the RMO. However, it should be noted that the present i-RMOA does not evaluate what the final OEL value would be. It is possible that a very stringent OEL would be difficult to implement by industry. The OEL setting process does take into consideration the feasibility of the values proposed (via discussions at the Working Party on Chemicals and the Advisory Committee on

[5] See https://echa.europa.eu/oel-process

Safety and Health at Work), which gives the industry the opportunity to provide comments on this aspect. Still, the uncertainty of this factor needs to be acknowledged within the i-RMOA.

Thus, the score of this factor under the i-RMOA methodology is: **-2 / +1 (average -0.5) – medium negative/ low positive impact**

Broader Impacts – Additional human health or environmental impacts

Implementation of OELs for these organotin substances would not bring any added benefits or negative consequences. This would be a "business as usual" scenario in relation to this factor.

Thus, the score of this factor under the i-RMOA methodology is: **0.**

Broader Impacts – Socio-economic impacts

This RMO would allow the continued use of these organotin substances but would oblige firms to ensure that worker exposures to these chemicals were controlled to below the OEL. Many will already be monitoring organotin exposure due to the Repr. 1B existing classification. However, some firms could be required to install additional measures to reduce emissions and exposure levels.

Thus, the score of this factor under the i-RMOA methodology is: **-1 / 0 (average -0.5) – low negative / neutral impact.**

Regulatory consistency - Consistency with existing EU legislation

An RMO based on implementation of OELs for these organotin substances is fully in line with the current European regulatory landscape, as it develops one of the main tools to control risk to specific chemicals in the workplace (which is the relevant scenario for these stabilisers).

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

Regulatory consistency - Consistency with other EU policy objectives

This RMO is very consistent with other EU objectives, as it allows the continued use of valuable products while tackling potential risks from hazardous substances where they occur.

Thus, the score of this factor under the i-RMOA methodology is: **+3 – high positive impact**.

5.3.5. Overview of the scoring

Following the evaluation of all the RMOs identified as relevant, **Table 28** through **Table 31** provide an overview of the scoring assigned to the RMOs for each evaluated factor. This scoring includes weighting corrections for factors and criteria, as outlined in the i-RMOA methodology described in Annex I, resulting in an overall score for each one of the RMOs.

Table 29. Scoring of the RMO 1

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	2.5	2.00	5
	Measurability / Monitorability	-2.5	1.25	-3.13
	Timing to implementation	1.5	1.25	1.88
Practicability	Implementability	-2.5	1.00	-2.5
	Enforceability	-2	1.00	-2
	Manageability	-2.5	1.00	-2.5
Broader Impacts	Additional human health or environmental impacts	-2	1.50	-3
	Socio-economic impacts	-2	1.50	-3
Regulatory Consistency	Consistency with existing EU legislation	-2	1.00	-2
	Consistency with other EU policy objectives	-1	0.50	-0.5
			Overall RMO score	**-11.75**

Table 30. Scoring of the RMO 2

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	3	2.00	6
	Measurability / Monitorability	1.5	1.25	1.88
	Timing to implementation	3	1.25	3.75
Practicability	Implementability	1	1.00	1
	Enforceability	-2.5	1.00	-2.5
	Manageability	-3	1.00	-3
Broader Impacts	Additional human health or environmental impacts	-3	1.50	-4.5
	Socio-economic impacts	-3	1.50	-4.5
Regulatory Consistency	Consistency with existing EU legislation	0	1.00	0
	Consistency with other EU policy objectives	-3	0.50	-1.5
			Overall RMO score	**-3.38**

Table 31. Scoring of the RMO 3

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	2.5	2.00	5
	Measurability / Monitorability	2	1.25	2.5
	Timing to implementation	3	1.25	3.75
Practicability	Implementability	1.5	1.00	1.5
	Enforceability	-2	1.00	-2
	Manageability	-2	1.00	-2
Broader Impacts	Additional human health or environmental impacts	-2.5	1.50	-3.75
	Socio-economic impacts	-1	1.50	-1.5
Regulatory Consistency	Consistency with existing EU legislation	-1	1.00	-1
	Consistency with other EU policy objectives	-2	0.50	-1
			Overall RMO score	**1.5**

Table 32. Scoring of the RMO 4

Criteria	Factor	Score	Weight Factor	Weighted Score
Effectiveness	Risk reduction capacity	2	2.00	4
	Measurability / Monitorability	3	1.25	3.75
	Timing to implementation	1	1.25	1.25
Practicability	Implementability	2.5	1.00	2.5
	Enforceability	2	1.00	2
	Manageability	-0.5	1.00	-0.5
Broader Impacts	Additional human health or environmental impacts	0	1.50	0
	Socio-economic impacts	-0.5	1.50	-0.75
Regulatory Consistency	Consistency with existing EU legislation	3	1.00	3
	Consistency with other EU policy objectives	3	0.50	1.5
			Overall RMO score	**16.75**

5.4. Selection of RMOs

Based on the evaluation of the different RMOs assessed for the selection of factors covered in the i-RMOA methodology and attending to the final scores assigned to each RMO, it appears evident that RMO 4 is the best suited overall to address potential concerns related to these chemicals.

Still, before establishing a final conclusion, it is recommended that a comparison should be done between RMOs. As outlined in the i-RMOA methodology described in Annex I, when evaluating a specific RMO, it is convenient to evaluate if this option is suitable, necessary, and proportionate, particularly in relation to whether any other alternative RMO would be available that would have a better performance. In the case of a possible inclusion of organotin substances in the REACH restriction process (RMOs 2 and 3) it could be concluded that, while the RMO may be efficient and suitable for the purpose of reducing risks, it would not provide a good balance between the risk reduction and potential negative impacts to society. The fact that there are other RMOs available that could bring an acceptable degree of risk reduction should lead to the conclusion that those other RMOs would have to be prioritised for regulatory purposes.

It needs to be noted that the scores obtained for the different RMOs need to be evaluated in relative terms, and with the objective of establishing a comparison between applicable options. The fact that one RMO yields a final positive score does not necessarily mean that it could be considered a favourable RMO (for example, in the case of RMO 3 – targeted restriction). What is relevant in this case is that there is another RMO (RMO 4 – Development of OELs under workplace regulation) which has obtained a significantly higher score. Therefore, the conclusion is that this option should be favoured, and the others disregarded.

The OEL route (RMO 4) appears to be much more balanced, with a good performance expected in terms of risk reduction while ensuring that critical products and processes for the European society would continue to be available.

5.5. Uncertainty

Different sources of uncertainty could influence the evaluation of the RMOs. In terms of items such as specific data on the substances evaluated (e.g., hazard profile, exposure, and uses) the most up to date sources of information have been used for the purpose of developing the i-RMOA, including information from literature and previous relevant work performed by industry, regulators and other parties. Efforts have been taken to try to refine and update this data, by performing a survey with the supply chain of these substances.

But beyond data accuracy, the most relevant sources of uncertainty come from the evaluation and assignment of scores to each RMO under the factors considered within the i-RMOA methodology. It is evident that, while the evaluation is performed in a rigorous and structured way, by trying to take all aspects into consideration that could impact the behaviour of one RMO under the analysed factors, the reasonings that lead to assigning scores are based on judgements undertaken by the evaluators. Ultimately, impact of the human factor on the evaluation cannot be neglected.

For this reason, the scores assigned to the different factors cannot be taken as absolute numbers, but as an orientation within the scale that has been used in the RMOA methodology. The indication of a range of values in some cases gives an idea of situations in which uncertainty has been identified, or in which a fixed answer to the question "how will the RMO perform under this factor" is simply not possible. A good example of this is, for example, the evaluation of factor Implementability under the Practicability criterion for RMO 4 (Development of OELs under workplace regulation). Although it is possible to provide generic assumptions that are likely to be reasonably accurate, such assumptions will have some degree of uncertainty, because it is not possible to perform a deep detailed analysis of impacts of the RMO depending on the specific OEL values that could be put forward by regulators. Ultimately, a full and exhaustive quantification of positive versus negative impacts, where multiple and diverse consequences can be derived from the implementation of an RMO, are not within the scope of the i-RMOA, which is limited to a reasoned qualitative comparison between the different options.

Uncertainties are unavoidable when developing an i-RMOA, and they need to be taken into account when evaluating the results. Indeed, the margins established in the overall scores for the different RMOs, with minimum and maximum values derived from the assignment of individual scores to factors and application of weights as per the RMOA methodology, reflect those uncertainties. **Table 33** through **Table 36** provide further description of the score ranges obtained per factor under each RMO, as well as overall RMO score ranges.

Table 33. Uncertainty: score ranges of RMO 1

Criteria	Factor	Score Range	Weight Factor	Weighted Score Range
Effectiveness	Risk reduction capacity	2 / 3	2.00	4 / 6
	Measurability / Monitorability	-3 / -2	1.25	-3.75 / -2.5
	Timing to implementation	1 / 2	1.25	1.25 / 2.5
Practicability	Implementability	-3 / -2	1.00	-3 / -2
	Enforceability	-2	1.00	-2
	Manageability	-3 / -2	1.00	-3 / -2
Broader Impacts	Additional human health or environmental impacts	-2	1.50	-3
	Socio-economic impacts	-2	1.50	-3
Regulatory Consistency	Consistency with existing EU legislation	-2	1.00	-2
	Consistency with other EU policy objectives	-1	0.50	-0.5
	Overall RMO score range			**-15 / -8.5**

Table 34. Uncertainty: score ranges of RMO 2

Criteria	Factor	Score Range	Weight Factor	Weighted Score Range
Effectiveness	Risk reduction capacity	3	2.00	6
	Measurability / Monitorability	1 / 2	1.25	1.25 / 2.5
	Timing to implementation	3	1.25	3.75
Practicability	Implementability	1	1.00	1
	Enforceability	-3 / -2	1.00	-3 / -2
	Manageability	-3	1.00	-3
Broader Impacts	Additional human health or environmental impacts	-3	1.50	-4.5
	Socio-economic impacts	-3	1.50	-4.5
Regulatory Consistency	Consistency with existing EU legislation	-1 / 1	1.00	-1 / 1
	Consistency with other EU policy objectives	-3	0.50	-1.5
	Overall RMO score range			**-5.5 / -1.25**

Table 35. Uncertainty: score ranges of RMO 3

Criteria	Factor	Score Range	Weight Factor	Weighted Score Range
Effectiveness	Risk reduction capacity	2 / 3	2.00	4 / 6
	Measurability / Monitorability	2	1.25	2.5
	Timing to implementation	3	1.25	3.75
Practicability	Implementability	1 / 2	1.00	1 / 2
	Enforceability	-2	1.00	-2
	Manageability	-2	1.00	-2
Broader Impacts	Additional human health or environmental impacts	-3 / -2	1.50	-4.5 / -3
	Socio-economic impacts	-1	1.50	-1.5
Regulatory Consistency	Consistency with existing EU legislation	-1	1.00	-1
	Consistency with other EU policy objectives	-2	0.50	-1
	Overall RMO score range			**-0.75 / 3.75**

Table 36. Uncertainty: score ranges of RMO 4

Criteria	Factor	Score Range	Weight Factor	Weighted Score Range
Effectiveness	Risk reduction capacity	2	2.00	4
	Measurability / Monitorability	3	1.25	3.75
	Timing to implementation	1	1.25	1.25
Practicability	Implementability	2 / 3	1.00	2 / 3
	Enforceability	2	1.00	2
	Manageability	-2 / 1	1.00	-2 / 1
Broader Impacts	Additional human health or environmental impacts	0	1.50	0
	Socio-economic impacts	-1 / 0	1.50	-1.5 / 0
Regulatory Consistency	Consistency with existing EU legislation	3	1.00	3
	Consistency with other EU policy objectives	3	0.50	1.5
	Overall RMO score range			**14 / 19.5**

Finally, **Table 37** summarises the minimum, maximum and average scores obtained for each RMO, along with calculated standard deviations and standard error values. It needs to be highlighted that these values are not intended to provide statistical significance to the scores and calculations performed, but simply to give an overview of the degree of uncertainty and variability when evaluating the expected outcome of each different RMO. This is also reflected

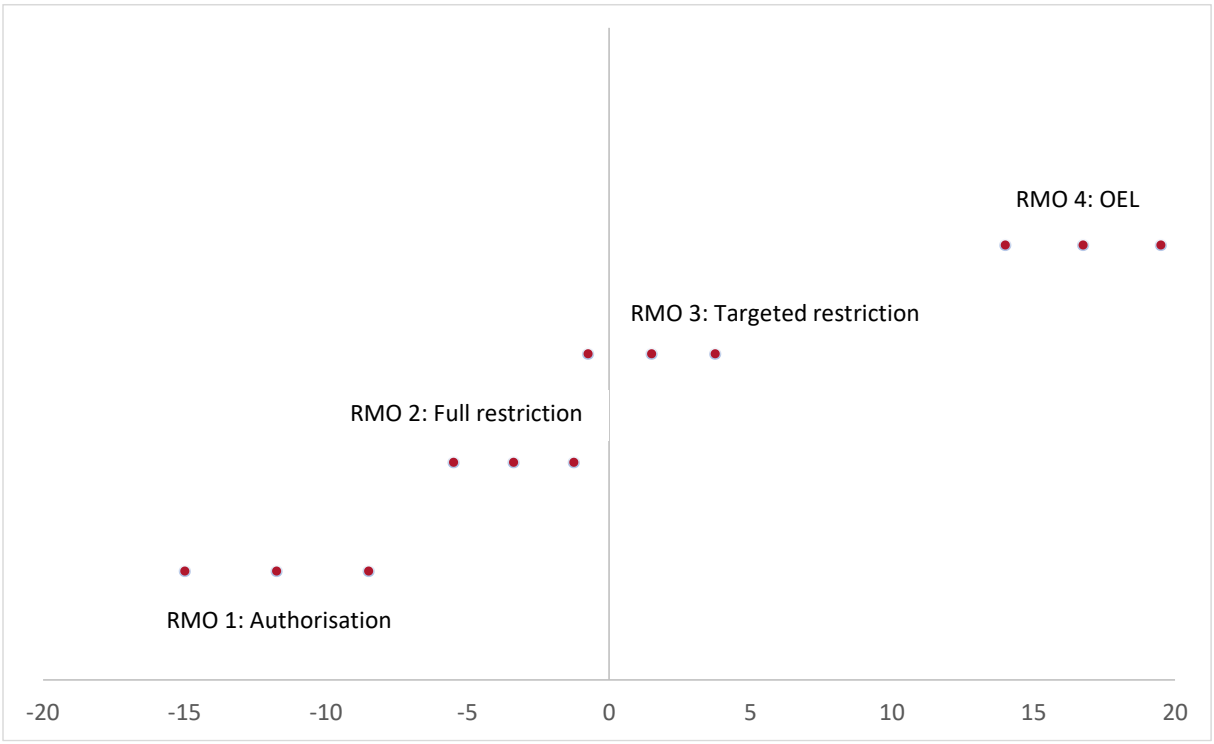
in **Figure 1**, where the scores are displayed for each RMO. Separation between the values in the graph gives an idea of potential uncertainty related to each RMO.

It is relevant to underline that no overlaps have been identified between minimum and maximum scores between different RMOs (i.e., the maximum possible score of any of the RMOs evaluated is lower than the minimum possible score of the following RMO as ranked in **Table 37**). This suggests that uncertainty is in general minimised in terms of whether one RMO would be preferable in comparison to the others

Table 37. Summary of scores, standard deviation, and error for each RMO, ranked by highest average score

	Min. Score	Average Score	Max. Score	Std. Dev.	Std. Err.
RMO 4: Development of OELs under workplace regulation (CMRD)	14	**16.75**	19.5	3.89	2.75
RMO 3: Targeted restrictions under REACH	-0.75	**1.5**	3.75	3.18	2.25
RMO 2: Full restriction under REACH	-5.5	**-3.38**	-1.25	3.01	2.13
RMO 1: Authorisation under REACH	-15	**-11.75**	-8.5	4.6	3.25

Figure 1. Graphical indication of minimum, maximum and average scores for each RMO



6. CONCLUSIONS

The i-RMOA performed on the organotin substances classified as Repr. 1B has been based on a thorough analysis of the properties of these additives and their current situation in the EU market, which allows to establish the following conclusions.

These organotin substances show a hazard profile (Repr. 1B) that renders them as substances of concern. This situation has been known for many years now and has led to the following situations:

- A number of legislative initiatives have been launched in Europe to limit or ban their use.
- The industry has made significant efforts to substitute them when this is technically possible. Indeed, today these substances are no longer used in some applications where they have traditionally been

However, no specific risks have been identified for their use, since the results of the risk assessment are within safe limits in all cases. For this reason, regulatory options that would lead to bans or limitations on the use of these organotin substances are not justified. Indeed, such ban would create significant challenges, as organotin substances cannot be substituted in certain applications (they have already been replaced to the maximum possible extent with other materials), which would result in certain valuable products being lost to society, with very limited gain (if any) related to improvement of risk situations.

In addition, a ban on the use of organotin stabilisers in the production of PVC articles would make recycling of those articles impracticable. In addition to the direct negative impacts on the industry, this would have negative consequences for the environment, as these waste streams would have to be managed through landfill or incineration, which would hinder the goal of moving towards a circular economy.

Taking all available information into consideration and following the use of a pre-defined methodology for this study, the conclusion from the i-RMOA is that the best regulatory action would be to define and implement harmonised OELs across the European industry, which would need to ensure compliance with the values to be defined.

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ANNEX I – Description of the Chemservice RMOA methodology

Introduction.

The purpose of a Regulatory Management Option Analysis (RMOA) is to help authorities clarify whether regulatory action is necessary for a given substance[6] having the potential to cause harm, and to identify the most appropriate measures to address a risk. By establishing a systematic, coherent, and transparent approach, the RMOA allows for an objective analysis of all the possible regulatory initiatives that could be undertaken on a given chemical. An RMOA can be developed by ECHA or by a Member State, however industry can also decide to carry out an Industry RMOA (i-RMOA).

Companies or industry sectors that take the initiative to prepare an i-RMOA may use its conclusions to anticipate and assist during regulatory reviews and challenges; it may also help industry to contribute credibly to the RMOAs developed by authorities, and to any subsequent decision processes at EU level.

An RMOA consists of different technical actions, that can be summarized as follows:

- Identification, discussion, and prioritization of risks related to a substance.
- Identification of all potential regulatory management options (RMOs) that could be proposed to eliminate, minimize, monitor, and control the probability and/or impact of the risks.
- Analysis of all the potential RMOs against a set of proportionality criteria and factors for their ability to reduce the risk.
- Identification of the most suited RMO or combination of RMOs.

While there is no official RMOA guidance or template established, different approaches have been used by authorities and industry to develop RMOAs in the context of the REACH and CLP Regulations. The present RMOA methodology has been developed using the following guidance documents as reference:

- ECHA Guidance for the preparation of an Annex XV dossier for restrictions (2007).
- Eurometaux Guidelines for an Industry Risk Management Option Analysis v3 (2017).
- ECHA Integrated Regulatory Strategy Report (2019).

Different criteria are evaluated in the RMOA; each criterion includes a set of independent yet related factors that help to frame the analysis, focusing on specific impacts that each one of the RMOs identified may trigger in relation to the specific factor under evaluation. The list of criteria and factors used in this RMOA methodology are described next:

[6] An RMOA may be developed for a single substance, a group of substances or any other chemical linked to a specific potential concern.

Criteria and factors to be evaluated.

The different factors that will be analysed are grouped into 4 different criteria: Effectiveness, Practicability, Broader Impacts and Regulatory Consistency. The following indications aim at describing those criteria and factors, including a (non-exhaustive) list of questions that will be used to guide the developers through the RMO evaluation process.

- Criterion 1. Effectiveness: Degree to which the RMO is capable to produce the desired effect in terms of risk reduction, including possibility to measure effects. It is related to the efficacy of the RMO.
    - *Factor 1.1. Risk reduction capacity.*
        - Does the RMO reduce exposure to a level that allows adequate control of the identified risk?
    - *Factor 1.2. Measurability / monitorability.*
        - Can the necessary parameters required to evaluate or quantify the efficacy (amount of substance used, emission or exposure levels) of the RMO be easily identified and monitored?
    - *Factor 1.3. Time until implementation.*
        - What will be the expected time to implementation?
- Criterion 2. Practicability: Degree to which the RMO can be implemented, managed, and enforced. This is related to the efficiency of the RMO.
    - *Factor 2.1. Implementability.*
        - Can the involved actors understand, and implement the RMO easily?
        - Is it likely that the involved actors will be fully aware of implications in terms of obligations and responsibilities from implementation of the RMO?
        - Are the necessary techniques, technology, and alternatives available and economically feasible in the timeframe to implement the RMO?
    - *Factor 2.2. Enforceability.*
        - Will the authorities responsible for enforcement be able to verify compliance of relevant actors with the RMO?
        - Will the RMO allow the enforcement authorities to set up efficient supervision mechanisms?
    - *Factor 2.3. Manageability.*
        - Will the involved actors be capable of managing the progress of the RMO in terms of ensuring its effectiveness?
        - How complex are the supply chains that will be impacted, and will this influence the capacity to manage the RMO?
        - Is the administrative burden for actors concerned and authorities proportional to the risk to be avoided?

- Criterion 3. Broader Impacts: Degree to which the RMO brings balance between the expected effect (risk reduction) and any other impact on the supply chain and society. This will measure the potential effects that the RMO will have beyond the directly impacted stakeholders.
    - *Factor 3.1. Additional human health or environmental impacts.*
        - Is the use of the substance contributing to key applications to protect human health or the environment that would be put at risk by the implementation of the RMO?
    - *Factor 3.2. Socio-economic impacts.*
        - What impacts will the RMO bring at company and sectorial level, also on unsuspected value chains through product impacts (e.g., loss of functionality) and market impacts?
        - Are the efforts needed to implement the RMO and their impact adequately balanced with the adverse effects that are being avoided?
- Criterion 4. Regulatory consistency: Degree to which the RMO is in line with other EU existing or future initiatives, and how could implementation of the RMO impact those.
    - *Factor 4.1. Consistency with existing EU legislation.*
        - Is the RMO consistent with legal requirements already in place?
    - *Factor. 4.2. Consistency with other EU policy objectives.*
        - Would the implementation of the RMO lead to any unexpected impacts on other EU policy goals of the EU?

Scoring, weighting, and rating.

Each one of the factors listed above is analysed according to a scoring system, which is based on the expected positive or negative impact that the RMO may bring to each factor, compared with the baseline situation, or state of the art at the moment of conducting the RMOA. The scoring system used in this RMOA methodology is described next:

+3	High positive impact on the factor is expected from the implementation of the RMO
+2	Medium positive impact on the factor is expected from the implementation of the RMO
+1	Low positive impact on the factor is expected from the implementation of the RMO
0	Neutral impact on the factor is expected from the implementation of the RMO
-1	Low negative impact on the factor is expected from the implementation of the RMO
-2	Medium negative impact on the factor is expected from the implementation of the RMO
-3	High negative impact on the factor is expected from the implementation of the RMO

It is relevant to underline that not all the factors evaluated should be regarded as being of equal importance. For this reason, a weighting mechanism is introduced, that establishes

specific weights for each relevant factor. In order to assign weights to factors, the general principle of any regulatory action at EU level, which is to ensure a high degree of protection of human health and the environment while enhancing the competitiveness of the EU industry, needs to be kept in mind. Taking this into consideration, the assumption is that factors within the 'Effectiveness' and 'Broader Impacts' criteria have to receive higher weights than those under 'Practicability' and 'Regulatory Consistency'. In a second step of the process to assign weights to factors, it is also considered that the 'Risk reduction capacity' should be the factor to receive the highest weight, which is set at twice the value of the baseline. Next, the two factors dealing with the 'Broader impacts' ('Additional human health or environmental impacts' and 'Socio-economic impacts') are assigned with a 50% stronger weight than the standard factors, in order to reflect the importance of the additional societal impacts that each RMO may bring. Finally, the remaining factors under 'Effectiveness' ('Measurability / Monitorability' and 'Expected time until implementation') are considered to be more important than the baseline factors, but of slightly lower relevance than the factors that have been previously discussed for the establishment of weights; therefore, they are assigned with a 25% increase compared to the baseline.

The following table gives an overview of the weights assigned to each factor, and their relevant contribution to the overall RMO scoring, based on the assumption of all factors being scored +1; the contribution of the criteria (which is a result of adding the individual contribution of each factor considered under each criteria) is also displayed.

Criteria	Factors	Weight Factor	Factor contribution	Criteria contribution
Effectiveness	Risk reduction capacity	2	16%	36%
	Measurability / monitorability	1.25	10%	
	Expected time until implementation	1.25	10%	
Practicability	Implementability	1	8%	24%
	Enforceability	1	8%	
	Manageability	1	8%	
Broader Impacts	Additional human health or environmental impacts	1.5	12%	24%
	Socio-economic impacts	1.5	12%	
Regulatory Consistency	Consistency with existing EU legislation	1	8%	16%
	Consistency with other EU policy objectives	1	8%	

In the final step, the scores for the different factors are added after application of the corresponding weight conversions, and the total scores for each one of the RMOs evaluated are compared. The RMO with the highest score should be selected as the most effective and

proportionate regulatory route for the substance. In certain cases where different RMOs would be non-exclusive, or which would cover clearly differentiated stages of the lifecycle of a substance, combinations of RMOs could be selected.

With the result of the RMOA at hand, and as a final overview of the process, the following three questions to establish the overall proportionality of the RMO selected should be valuated:

a) Suitability: Is the RMO appropriate to achieve the objective that is pursued?

b) Necessity: Is there no other RMO considered suitable to achieve the objective that is less cumbersome, costly, or restrictive whilst equally effective in achieving the objective?

c) Proportionality *stricto sensu*: Is the RMO considered suitable and necessary, while not too excessive? Here, the balance between the different interests at stake (e.g., industry & society) need to be considered.

Data gathering and uncertainty.

Information used for developing the RMOA may come from many sources. In an i-RMOA, the sponsor industry (either a company or an association) should provide as much data as possible to the team in charge of building the RMOA. Moreover, information from regulatory sources (e.g., ECHA website) will be useful to adequately describe potential concerns for regulators. Ultimately, surveys established through the value chain should be put in place to collect as much information as possible, especially for evaluation of impacts downstream to the users of a substance. All these data sources will contribute to the uncertainty, which will have to be adequately considered in the RMOA.

The development of the RMOA, including scoring of the different factors, is subject to the interpretation of the developers and dependent on the accuracy and reliability of the data used for the analysis (it is not always possible for the developers to ensure that the data used is fully accurate, as this will frequently be provided by the sponsor of the RMOA or other interested parties). For this reason, the outcome of the RMOA will inevitably be subject to interpretation. In order to reflect this, it is possible for the developers to provide combined or non-fixed scores for a given factor (e.g., +1/+2), depending on the level of uncertainty. This needs to be adequately documented by the developers.

The use of non-fixed scores per factor will lead to variable overall scores, resulting in minimum, maximum and average values for the different RMOs. The use of weights, most of which are greater than one, will increase the variability. In principle, average values should be used for comparison, however the different ranges obtained for each RMO should be compared as well. Overlaps for different RMOs (e.g., the average of RMO1 is higher than the average of RMO2, but the maximum score of RMO2 is higher than the minimum score of

RMO1) need to be evaluated carefully. If these overlaps are significant, or if they may rise question on why one RMO should be preferred over another, then it may be concluded that the assessment is not robust enough, and further refinement of the data used for the evaluation could be required, for example, by improving the socio-economic impact evaluation of the different possible RMOs to be considered, to allow for a more accurate score to be assigned.

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