

Welcome

**Webinar: Assessing groups of
chemicals: what you need to know**

14 December 2021

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Jonathan Kuster
European Chemicals Agency



What you can expect from today

- Learn about our assessments of regulatory needs of groups of substances
- Learn what information you can find on our website
- Get advice on how to prepare if ECHA proposes regulatory actions for a substance you have registered
- Get answers to your questions



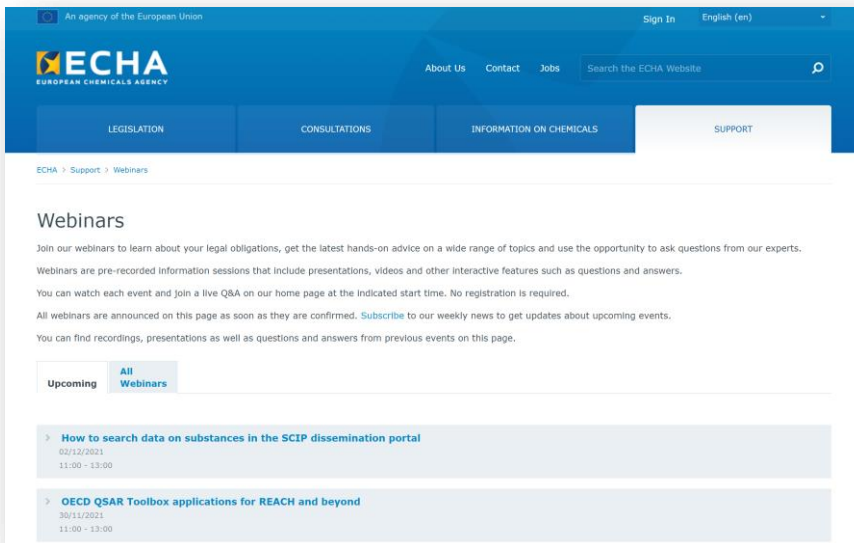
Questions

- Join Q&A at: slido.com
Event code:
- Send questions from
11:00 to 13:00 (EET, GMT +2)
- Only questions within scope
- Question not answered?
Contact us: echa.europa.eu/contact



Material available

- Video recording, presentations and Q&A:
echa.europa.eu/webinars



The screenshot shows the ECHA website's 'Webinars' page. The header includes the ECHA logo, navigation links for 'About Us', 'Contact', and 'Jobs', and a search bar. Below the header is a menu with categories: 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The main content area features a breadcrumb trail 'ECHA > Support > Webinars' and a heading 'Webinars'. The text explains that webinars are pre-recorded information sessions and provides instructions on how to watch and participate. It also mentions that recordings and Q&A are available on the page. At the bottom, there are two tabs: 'Upcoming' and 'All Webinars'. Two webinar events are listed:

Topic	Date	Time
> How to search data on substances in the SCIP dissemination portal	02/12/2021	11:00 - 13:00
> OECD QSAR Toolbox applications for REACH and beyond	30/11/2021	11:00 - 13:00



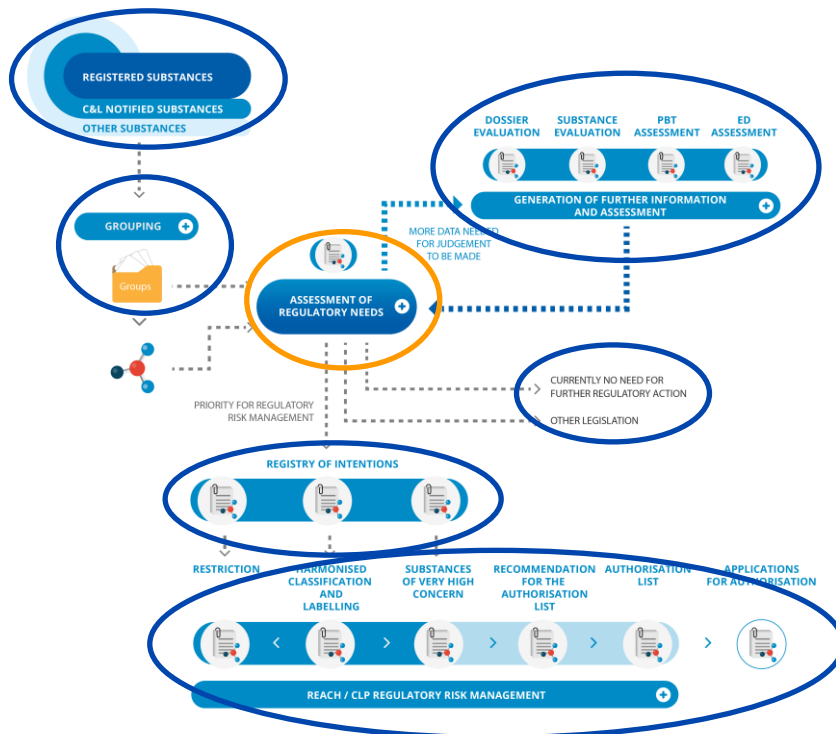
Agenda

Time	Topic	Speaker
11.00	Introduction	Jonathan Kuster
11.05	Assessments of regulatory needs: what you need to know about ECHA's work on groups	Jonathan Kuster
11.20	Assessments of regulatory needs in practice	Chrystele Tissier
11.45	Wrap-up	Chrystele Tissier
11.00 – 13.00	Webinar open for questions	

**Assessments of regulatory needs:
What you need to know about ECHA's
work on groups**

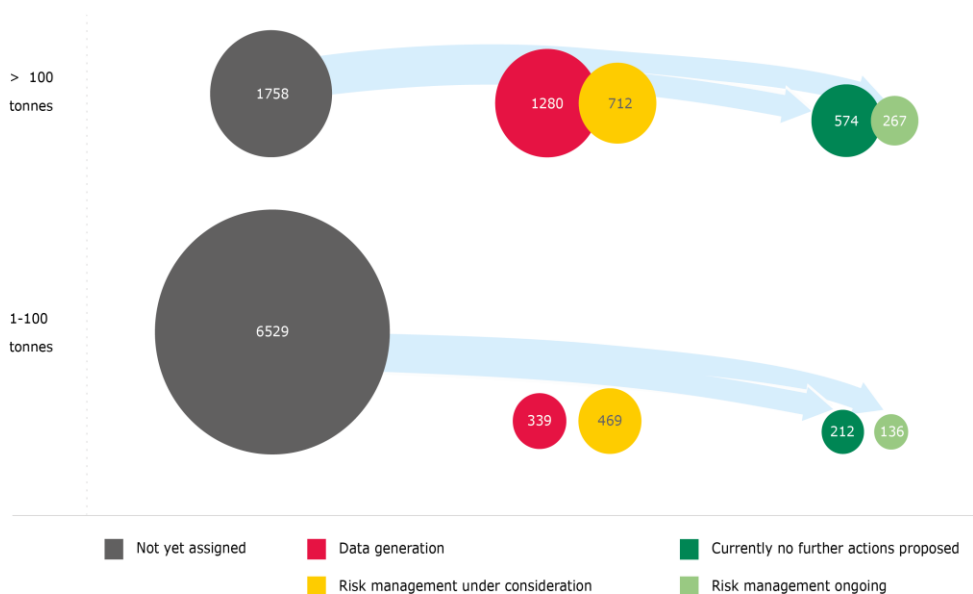


Integrated Regulatory Strategy



Chemical universe mapping

Every **registered** substance mapped to **one** regulatory 'pool' based on planned, ongoing or concluded **regulatory actions**



(Data: Dec. 2020)

Why we work on groups?

- For many substances of (potential) concern, relevant regulatory actions are already ongoing – on the substance itself or on related substances
- Benefits:
 - Treats related substances consistently
 - Targets the right substances at the right time
 - Pools information which may allow faster action – despite data gaps
 - Increases predictability of authorities' actions
 - Supports informed substitutions, or avoids regrettable substitutions

→ Preparatory work to support REACH & CLP processes

Making ECHA's work on groups more transparent



Communication to stakeholders so far

- Limited information publicly available so far on the work done by Authorities on groups of substances:
 - Generic information on website on “working with groups”
 - No information on the substances we assess together
 - No information on the outcome of the assessment
- Communication only via
 - Annual report on the Integrated Regulatory Strategy (IRS report): statistics, examples
 - Assignment of substances to pools in the chemical universe can be due to group assessment – but no further explanation available to public

Why more transparency? (1)

- Transparency is one core aim of the Chemical Strategy for Sustainability in particular in the context of “one substance – one assessment”

*“...to have **simpler and more transparent** processes, in order to reduce the burden on all stakeholders and to make decision-making faster as well as more consistent and predictable”*

- The first ECHA core value is transparency

Why more transparency? (2)

- Important share of our work not visible to the public
 - Ca. 3400 substances assessed by ECHA, but no substance-specific information published (except chemical universe, annual IRS report - see previous slide)
 - 7 December 2021: first assessments published
 - Aim: gradually publish all of ECHA's assessments of regulatory needs
- Very difficult to communicate at a general level on the work done on groups (e.g., in the IRS report)
 - Beyond examples: Concrete assessments of groups / substances need to be published

Why more transparency? (3)

- Support informed substitution, avoid regrettable substitution
 - Enable stakeholders to use structural similarity and related assessment when searching for alternative substances
- Predictability for industry is limited
 - No time for industry to update their registration dossiers and plan for the upcoming regulatory work
 - No possibility for authorities to refer to the fact that industry had time to prepare
 - Industry and authorities can prepare: faster action, no “surprises”

Steps towards more transparency

- Update of the general information available on our website (summer 2021)
 - Update of the [IRS infographic](#) to better reflect the work we are currently doing with groups of substances
 - New page on [assessment of regulatory needs](#) (replacing the RMOA page)
 - General page to explain the [grouping approach](#)
- Publication of ECHA's reports (7 December 2021)
 - Update of [PACT](#) with information on assessment of regulatory needs
 - New [list: assessments of regulatory needs](#) (including also RMOAs)
- Today – 14 December 2021:
 - New [Q&A](#) on assessments of regulatory needs
 - Webinar to introduce the changes after publication

**What's new on our website:
PACT and assessments of regulatory
needs list**





LEGISLATION

CONSULTATIONS

INFORMATION ON CHEMICALS

SUPPORT

Search our data

I have read and I accept the legal notice

Search for chemicals / regulated substances

e.g. Formaldehyde, or 200-001-8 or 50-00-0, or 605-001-00-5

Search for chemicals

COVID-19 information



Some of our IT applications and systems are due to undergo maintenance.

LEGISLATION

- › REACH
- › CLP
- › BPR
- › PIC
- › POPs
- › CAD/CMO (OELs)
- › WFD
- › DWD

CONSULTATIONS

- › Consultations in the authorisation process
- › Substances of very high concern identification
- › Draft recommendation for inclusion in the Authorisation List and consultation
- › Applications for authorisation consultations
- › Submitted restrictions under consideration
- › Consultations on new scientific evidence
- › Current calls for comments and evidence
- › Testing proposals consultation
- › Harmonised classification and labelling consultations
- › Harmonised classification and labelling targeted consultations
- › ECHA Executive Director's requests related to the CLH process

INFORMATION ON CHEMICALS

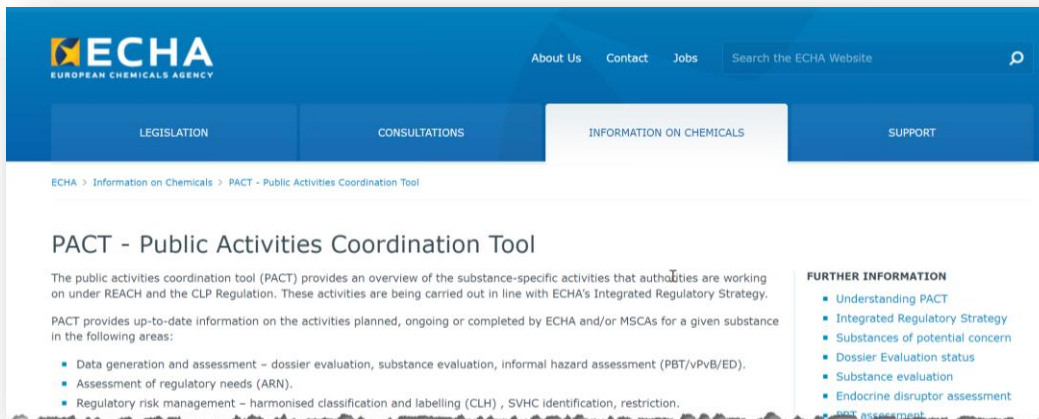
- › Registry of CLH intentions until outcome
- › Registry of restriction intentions until outcome
- › Registry of SVHC intentions until outcome
- › Registered substances
- › Annex III inventory
- › Pre-registered substances
- › EC Inventory
- › Dossier Evaluation status
- › PACT - Public Activities Coordination Tool
- › Assessment of regulatory needs list
- › PBT assessment list
- › Endocrine disruptor assessment list
- › Substance evaluation - CoRAP
- › Information on Candidate List substances in

SUPPORT

- › Getting started
- › Guidance
- › Q&As Support
- › Testing methods and alternatives
- › Webinars
- › Dossier Submission Tools
- › National Helpdesks
- › Practical examples of exposure scenarios
- › Practical examples of chemical safety reports
- › Small and Medium-sized Enterprises (SMEs)
- › Recommendations to registrants
- › Registration phases
- › Substance identification
- › Restriction

Public Activities Coordination Tool

- Planned, ongoing and past activities
- Substance-by-substance
- Under REACH and CLP
- By ECHA and MSCAs



The screenshot shows the ECHA website interface. At the top, there is a blue navigation bar with the ECHA logo on the left and links for 'About Us', 'Contact', 'Jobs', and a search bar on the right. Below the navigation bar is a secondary menu with four tabs: 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS' (which is highlighted), and 'SUPPORT'. The main content area has a breadcrumb trail: 'ECHA > Information on Chemicals > PACT - Public Activities Coordination Tool'. The title 'PACT - Public Activities Coordination Tool' is prominently displayed. Below the title, there is a paragraph explaining that the tool provides an overview of substance-specific activities under REACH and CLP. A section titled 'PACT provides up-to-date information on the activities planned, ongoing or completed by ECHA and/or MSCAs for a given substance in the following areas:' is followed by a bulleted list of activities: 'Data generation and assessment – dossier evaluation, substance evaluation, informal hazard assessment (PBT/vPvB/ED)', 'Assessment of regulatory needs (ARN)', and 'Regulatory risk management – harmonised classification and labelling (CLH), SVHC identification, restriction.' To the right of the main text, there is a 'FURTHER INFORMATION' section with a bulleted list of links: 'Understanding PACT', 'Integrated Regulatory Strategy', 'Substances of potential concern', 'Dossier Evaluation status', 'Substance evaluation', 'Endocrine disruptor assessment', and 'PBT assessment'.

echa.europa.eu/pact

Public Activities Coordination Tool

Substance name	EC / List no	CAS no	Data generation and assessment				ARN	Regulatory risk management			
			SEv	PBT	DEV	ED	ARN	CLH	SVHC	Restriction	
1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	272-013-1	68648-93-1	-	-	-	-	1	-	-	-	
1,2-Cyclohexanedicarboxylic acid, 1,2-dilisononyl ester	431-890-2	166412-78-8	-	-	1	-	1	-	-	-	
1,2-dibromoethane	203-444-5	106-93-4	-	-	-	-	1	-	-	-	
1,2-dichloropropane	201-152-2	78-87-5	-	-	2	-	1	1	-	-	
1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran	214-946-9	1222-05-5	-	1	3	1	1	-	-	-	
1,3,5-trioxane	203-812-5	110-88-3	1	-	2	-	1	-	-	-	
1,3-benzodioxolane	205-992-0	274-09-9	-	-	-	-	1	-	-	-	
1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	-	-	4	-	1	1	-	-	
1,3-dimethyl-1H-pyrazole	689-662-5	694-48-4	-	-	-	-	1	-	-	-	

- Activities per substance
- ARN = Assessment of regulatory needs

Assessment of regulatory needs list

- Substance-by-substance (also for substances included in a group assessment)
- Extended filter / search options

The screenshot displays the ECHA website interface for the 'Assessment of regulatory needs list'. The top navigation bar includes 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The breadcrumb trail reads 'ECHA > Information on Chemicals > Assessment of regulatory needs list'. The main heading is 'Assessment of regulatory needs list', followed by a descriptive paragraph: 'The assessment of regulatory needs list includes substances for which an assessment either is under development or has been completed.' A 'Further information' button is visible to the right. Below this, a section titled 'Filter the list' contains a search bar with the placeholder text 'e.g. Formaldehyde, or 200-001-8 or 50-00-0, or 605-001-00-5'. The filter form includes several fields: 'Status' (dropdown menu), 'Authority' (dropdown menu), 'Concern' (dropdown menu), 'Date of intention' (date range selector), 'Follow-up' (dropdown menu), 'Date of assessment' (date range selector), 'Foreseen regulatory need' (button labeled 'Select'), and 'Latest update' (date range selector). A 'Group name' text input field is located at the bottom left of the filter section. At the bottom right of the filter area, there are 'Filter' and 'Clear all' buttons.

echa.europa.eu/assessment-regulatory-needs

Assessment of regulatory needs list

- Assessment of regulatory needs = RMOAs and group assessments
- By MSCAs and ECHA

Substance name	EC / List no	CAS no	Authority	Concern	Status	Follow-up	Latest update
1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	84777-06-0	ECHA		Under development	CLH	07/12/2021
1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran	214-946-9	1222-05-5	France	Endocrine disruption	Concluded	Other	24/11/2021
1,3,5-trioxane	203-812-5	110-88-3	ECHA		Under development	CCH	07/12/2021
1,3-benzodioxolane	205-992-0	274-09-9	ECHA		Under development	No action	07/12/2021
1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	Germany	<input type="checkbox"/> Respiratory sensitiser <input type="checkbox"/> Skin sensitiser	Concluded	Restriction	24/11/2021

1,3,5-trioxane



EC / List no: 203-812-5 CAS no: 110-88-3

Concern

Status

Under development

Follow-up

CCH

Foreseen regulatory need

Currently no EU RRM action needed

Date of intention

25/09/2020

Date of assessment

27/09/2021

Summary document

 [GMT_214_Cyclic_acetals_from_aldehydes_Report_public.pdf](#)

Full document

Group name

Cyclic acetals from aldehydes

Remarks

Authority

ECHA

Submitter organisation

ECHA

Submitter email

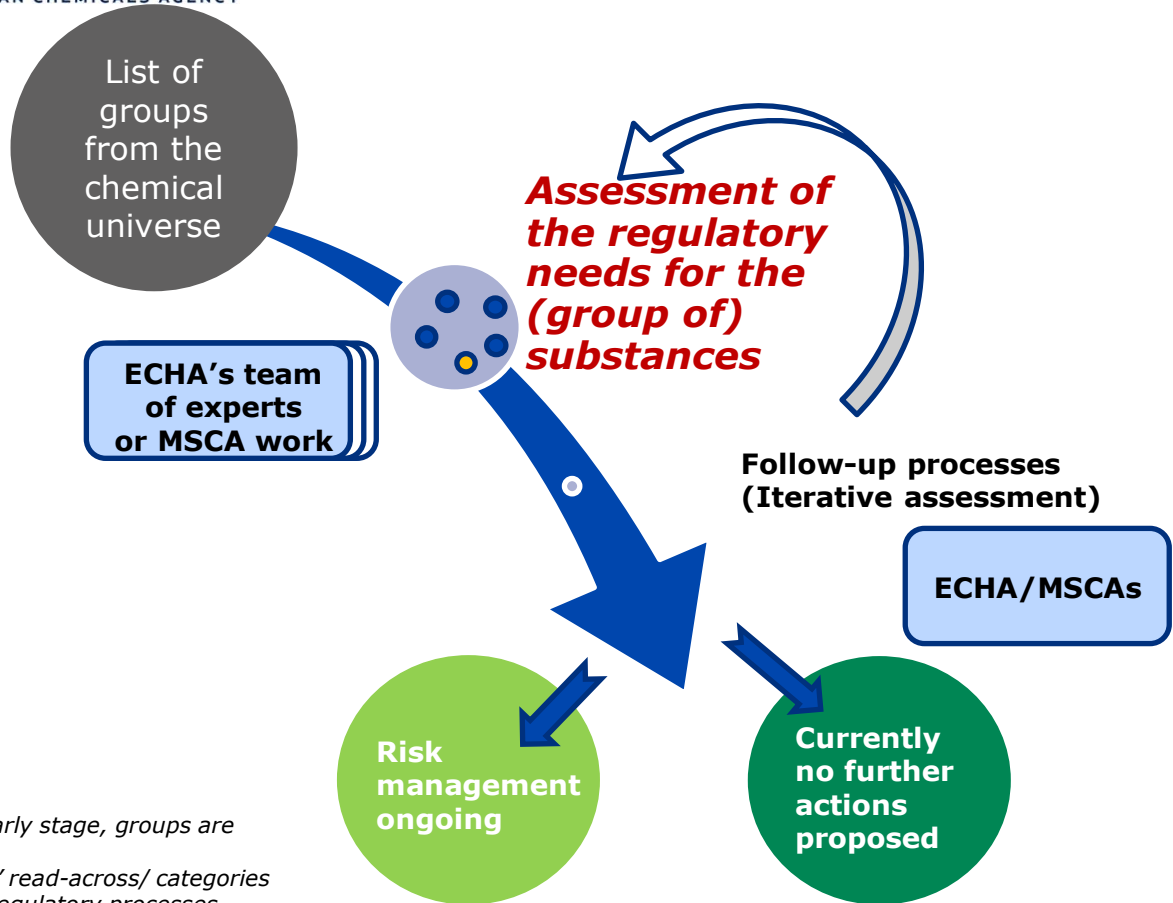
screening@echa.europa.eu

Submitter phone

Assessments of regulatory needs in practice



Work on groups



* At this early stage, groups are **not:**
registrants' read-across/ categories
groups in regulatory processes

Assessment of regulatory needs

- Support authorities conclude on the **most appropriate way to address the identified concerns** for a group of substances or single substances
- Elements looked at
 - Hazards
 - Uses/potential for exposure
 - Group boundaries (and need for subgrouping)
 - Potential for substitution
- Main source of information: registration dossiers
- Consultation with Member States before publication on PACT to:
 - Provide input/suggestions to the way proposed for the (group of) substance (s)
 - Raise awareness early on of possible candidates for RRM actions

An iterative assessment

- **First assessment at screening level** (focused on registration information)
- **Then, usually data generation or “currently no action” is proposed as first step – in some cases, risk management is already possible**
 - Assessment of read-across/category approach is only done during official processes (e.g. compliance check)
- **Depth of assessment and knowledge on substances will increase in further iterations**

Benefits

- **Benefits of grouping (as highlighted earlier)**
 - Treats related substances consistently
 - Targets the right substances at the right time
 - Pools information which may allow faster action – despite data gaps
 - Increases predictability of authorities' actions
 - Supports informed substitutions, or avoids regrettable substitutions
- **In addition**
 - Early identification of the most appropriate regulatory tools to address the concern identified
 - Immediate action possible after the first assessment (e.g. CLH)
 - Action in the future if hazard confirmed (e.g. CLH, restriction)
 - Focus the generation of data to those endpoints/substances where we have identified a concern and need for regulatory risk management action
 - Speed up RRM action after generation of hazard data
 - Ensure early identification and communication of potential RRM cases to MSs

Expectations on industry

- Improved quality of the registration dossiers will provide authorities a more solid basis for deciding on the need for further actions.
- Opportunity for industry to clarify the potential hazard and use profile of their substances early on before any RRM actions is initiated focusing resources of both industry and authority to the right substances
- If RRM foreseen, consider alternatives – the group may give indications whether similar substances are safer or will be subject to RRM as well

Main aim of the reports publication

- Make clear what will be the next actions on a group of substances
- focussing not only on the immediate next action (CCH for many substances) but on the end goal i.e. Need for EU RRM or no need currently for EU RRM (if hazard/lack of hazard clarified)
- Document includes actions identified and which substances have been assessed together
- NB! Grouping done by ECHA different from read across

Content of the reports

- Cover page (group name, structure, versioning, overview of substances)
- Disclaimer
- Foreword explaining what is the purpose of the document
- 1 • Overview of the group
- 2 • Justification for the (no) need for regulatory risk management action at EU level
- 3 • Summary of conclusions and actions (including overview table)
- Annexes
 - Overview of registrants self and harmonised classification table
 - Overview of the uses
 - Overview of relevant past and ongoing activities (when needed)
 - C&L notifications

Example/case study



Assessment of regulatory needs

Authority: ECHA

Date: 27 September 2021



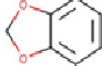


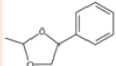
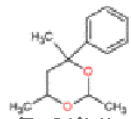
Group Name: Cyclic acetals from aldehydes

General structure: -

Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	27 September 2021	

Substances within this group:

EC number	CAS number	Substance name	Chemical structure	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Subgroup 1: Cyclic acetals from formaldehyde and acetaldehyde				
203-812-5	110-88-3	1,3,5-trioxane		Full, >1000
204-639-8	123-63-7	2,4,6-trimethyl-1,3,5-trioxane		OSII or TII
205-992-0	274-09-9	1,3-benzodioxolane		OSII or TII
208-015-6	505-65-7	1,3-dioxepane		Full, not (publicly) available
211-463-5	646-06-0	1,3-dioxolane		Full, >1000
251-752-3	33941-99-0	2-methyl-4-phenyl-1,3-dioxolane		Full, not (publicly) available
945-924-3		Reaction mass of 2,4,6-trimethyl-4-phenyl-1,3-dioxane isomer 1 and 2,4,6-trimethyl-4-phenyl-1,3-dioxane isomer 2		Full, not (publicly) available

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2 Justification for the need for regulatory risk management action at EU level	9
3 Conclusions and actions	12
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Annex 2: Overview of uses based on information available in registration dossiers	17
Annex 3: Overview of completed or ongoing regulatory risk management activities	18
Annex 4: Non exhaustive list of substances in the C&L inventory that may fall into the group definition (optional)	19

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA's website.²

Information on
the group



Overview of
uses, potential
for exposure

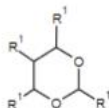


1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the cyclic acetal moiety shown in the figure below.

The group contains 13 registered substances (10 full registrations, 1 NONS, 2 OSII or TII) and consists of mono- and multi-constituent substances. The main chemical feature of the group is more than one cyclic ether functionality with other varied structures e.g. alkyl chain or aromatic ring. The main type of chemical structure of these substances is the ether functionality.

Generic structure of the group members:



R¹: H, Me, Alkyl, Aryl,

The ring can be 5-, 6- or 7-membered and can contain 3 oxygen atoms as well.

Two subgroups were defined: (1) cyclic acetals from formaldehyde and acetaldehyde and (2) cyclic acetals from other aldehydes. In both subgroups there are quite a lot of differences in the chemical structures (e.g. number of atoms in ether ring, presence of aromatic ring, number, position and nature of substituents) however there are also substances that are structurally similar.

For one substance in the group (EC 211-463-5) there is an ongoing substance evaluation (studies clarifying skin irritation and serious eye damage have been requested), an intention from Germany for regulatory management option analysis (RMOA) and a harmonised classification proposal submitted by industry proposing to add Repr. 1B and Eye Irrit. 2 to the existing harmonised classification as Flam. Liq. 2.

Based on information reported in the REACH registration dossiers, most substances are used as a fragrance/odour agent in a variety of applications including washing and cleaning products, polishes and wax blends, cosmetics. The substances are used at industrial sites (including the formulation stage), by professional workers and consumers. High exposure potential for professional workers and consumers as well as high potential for releases to the environment cannot be excluded.

Two substances (EC 203-812-5 and 208-015-6) are used only as monomer/intermediate in polymer production by industrial workers. Even though there may be potential for releases to the environment and exposure for workers it is generically assumed that these are properly controlled in industrial settings.

Many substances in the group have been registered as intermediates where use under strictly controlled conditions (SCC) has been reported by the registrants.

Note clarifying
the scope of the
assessment,
present in all
reports



Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

Last action foreseen on the group/ subgroup/ selected substances and identified concern



Short summary of the hazard assessment and potential for exposure



Different steps needed and their impact



2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction combined with authorisation for Repr. 1 B hazard due to the potential for release/ exposure of the substance 1,3-dioxolane (EC 211-463-5).

Substance EC 211-463-5 is self-classified for Repr. 1B by the lead registrant, fulfils the screening criteria for being P/vP and is expected to be mobile in the environment. The substance is used as monomer/intermediate in polymer production and as solvent in many applications (laboratories, washing and cleaning products, coatings, lubricants and metal working fluids/rolling oils) and therefore there is a high potential for exposure for both workers and consumers as well as high potential for releases to the environment.

The results from a pending extended one-generation reproductive toxicity study (EOGRTS) and an ongoing substance evaluation (SEv) will give clarification on the hazard. Furthermore, compliance check (CCH) will be initiated in order to clarify the persistency potential.

The first step of the regulatory risk management (RRM) action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH³) as Repr. 1B.

CLH will trigger company level risk management measures (RMM) under the occupational safety and health (OSH) legislation for workers, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30 of REACH Annex XVII.

CLH will also support regulatory action under other regulations. For instance, in this specific case harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as fragrance, since CMR cat. 1 are restricted by this regulation.

Justifications and discussion on the regulatory instrument proposed

Reported use descriptors (e.g. rolling, brushing, spraying) suggest that there is high potential for exposure, particularly via dermal absorption and inhalation for both industrial and professional workers.

Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not fully covered by the OSH legislation. Consumers may be co-exposed to the substances used by professionals. Therefore, a restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals is suggested after CLH. If after generation of data, P/vP and mobility properties of the substance exist, those properties should be considered when developing the restriction as releases to the environment are expected.



Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability (CSS) which aims to extend to professional users under REACH the level of protection granted to consumers.

For the remaining industrial uses where potential for exposure cannot be excluded, **it is suggested to use authorisation**. After being classified as repr. 1B SVHC identification could be initiated followed by inclusion in the Authorisation list. SVHC identification could also consider P/vP and mobility properties of the substance. Although, SVHC identification alone would likely send a message to Industry to seek alternatives, inclusion in Annex XIV would ensure that suitable substitutes are sought and that health risks in industrial settings are minimised.



Alternatively, to SVHC and authorisation, setting an EU-wide exposure limit for workers under OSH or REACH for industrial uses was also considered. Several national occupational exposure limits (OELs) are already in place⁴. However, the main use of the substance is as solvent and therefore it is assumed likely that viable (less toxic) alternatives are available and that it would actually be beneficial to rather push for substituting the substance to safer alternatives which authorisation would support. Therefore, for the time being, authorisation is suggested as the next regulatory risk management option to address potential exposure to workers on industrial sites. This proposal will be revisited, preferably based on further assessment when developing further the restriction on mixtures used by professionals which should also support clarifying what are those industrial uses in need for EU RRM action.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
211-463-5	Known or potential hazard for reproductive toxicity	Known or potential hazard for persistence, mobility and toxicity	Several widespread uses reported including use in washing and cleaning products, lubricants, coatings, high potential for exposure for both workers and consumers	<p>Need for EU RRM: Restriction combined with authorisation</p> <p><u>Justification:</u> The harmonised classification as Repr. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with low</p>	<p>First step: CCH</p> <p>Next steps (if hazard confirmed):</p> <ul style="list-style-type: none"> • CLH • Restriction for professional uses • SVHC identification followed by authorisation for industrial uses

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data extracted on 29 September 2020.

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
203-812-5	1,3,5-trioxane	Flam. Solid 1, H228 STOT SE 3, H335 (resp. Irrit.) Eye Irrit. 2, H319*	Flam. Solid 1, H228 Repr. 2, H361d STOT SE 3, H335 (resp. Irrit.)	
208-015-6	1,3-dioxepane		Flam. Liquid 2, H225 Eye Irrit. 2, H319	Not classified
211-463-5	1,3-dioxolane	Flam. Liquid 2, H225 Repr. 1B, H360d *		
204-639-8	2,4,6-trimethyl-1,3,5-trioxane	Flam. Liquid 3, H226	Flam. Liquid 3, H226	Flam. Liq. 2, H225 Acute Tox. 4, H302 (oral)
205-992-0	1,3-benzodioxolane		Flam. Liquid 3, H226 Acute Tox. 4, H302 (oral) Eye Irrit. 2, H319 **	Acute Tox. 4, H332 (inhal) Acute Tox. 4, H312 (dermal)
251-752-3	2-methyl-4-phenyl-1,3-dioxolane			
945-924-3	Reaction mass of 2,4,6-trimethyl-1,3,5-trioxane			

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 29 September 2020.

EC/List number	RMOA	Authorisation		Restriction *	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV			
203-812-5						Cosmetics (prohibited); FCM (authorised)
208-015-6						FCM (authorised)
211-463-5	YES				YES	FCM (authorised)
426-130-1						NONs

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 29 September 2020.

Main types of applications structured by product or article types	Use in polymer preparations and compounds (plastic articles)	Use in laboratories	Use in coatings	Use in lubricants	Use in metal working fluids/rolling oils	Use in de-icing agents	Use in metal surface treatment products	Use in washing and cleaning products	Use in cosmetics	Use in polishes and wax blends, biocidal products, air care products
203-812-5	I	I								
208-015-6	I									
211-463-5	I	I	F, I, P, C	F, I, P, C	F, I, P	F, P		F, I, P, C	F, C	
251-752-3								F, I, P, C	F, P, C	F, P, C
945-924-3								F, I, P, C	F, P, C	F, P, C
224-436-8								F, I, P, C	F, P, C	F, P, C
259-210-8								F, I, P, C	F, C	F, P, C
266-795-3								F, I, P, C	F, P, C	F, P, C
279-482-1								F, P, C	F, C	F, P, C
426-130-1								F, I, P, C	F, P, C	F, P, C
815-031-2							F, I	F, I, P, C	F, P, C	F, P, C

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release**includes only substances with a full registration; substances not included in this table have either (only) an intermediate registration or C&L notification

Wrap-up





Take-home messages

- Keep your registrations up-to-date
- Follow PACT regularly to see whether there is an assessment of regulatory needs for your substance
- Follow the updates of the annual IRS report and the chemical universe
- There's plenty of information on PACT but also on our websites available now (Q&A, work on groups website,...)

Q&A panel

- Webinar open until 13:00 Helsinki time (EET, GMT+2) to answer questions
- If your question is not answered by the end of the webinar, send it via our contact form:
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