Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 2dn)

What you need to know about UK-REACH



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Summary of Topics 1. Background of UK REACH, timeline, basic principles and competent authority 2. Actors affected by UK REACH 3. Which UK REACH procedure applies to your business? 4. DUIN under UK REACH 5. NRES under UK REACH 6. Registration under UK REACH 7. HSE registration fees 8. Take home message 9. How can GPC help you?



Background of UK REACH



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Background of UK REACH

- ➤ On 1st January 2021, at the end of the Brexit Transition period, UK REACH came into force and EU REACH ceased to apply in Great Britain. As a consequence, chemicals may not be manufactured or imported in Great Britain under an EU REACH registration.
- ➤ UK REACH applies in **Great Britain**, i.e.: England, Scotland and Wales.
- ➤ Please NOTE:

EU REACH still applies in **Northern Ireland**, as provided under the Northern Ireland Protocol agreed between the EU and the UK government.

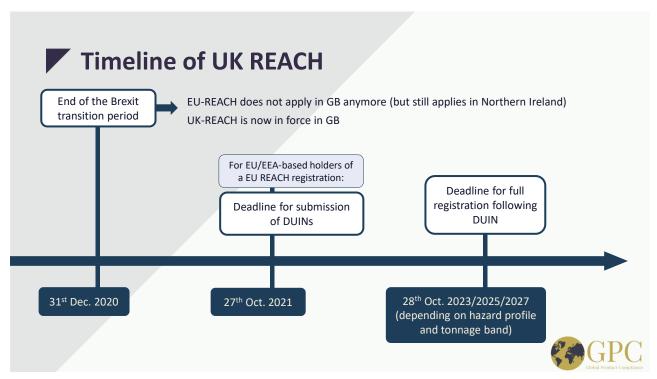


Background of UK REACH

- UK REACH is based on the EU REACH Regulation as amended by the REACH (EU Exit) Regulations 2019. UK REACH has been described as mirroring its EU counterpart.
- ➤ UK REACH contains **transitional provisions** for importers and exporters who were accessing the GB market with an EU REACH registrations prior to 1st January 2021. The purpose being to limit disruptions on the existing business.
 - Grandfathering (deadline expired)
 - DUIN (deadline: 27 October 2021)
- Transitional provisions do not apply to those who wish to place a substance on the UK market for the first time.



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Basic principles of UK REACH



The "no data no market" principle



The last resort principle on animal testing



Access to information for workers



The precaution principle







- The authority in charge of enforcing UK REACH is the Health and Safety Executive (HSE)
- Compliance with UK REACH is to be carried out through the IT platform <u>Comply with</u> <u>UK REACH</u>





Actors affected by UK REACH



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Who is concerned by UK-REACH?



Manufacturers (both GB and non-GB based)



Importers



Downstream users



Only representatives (OR)





The role of an OR

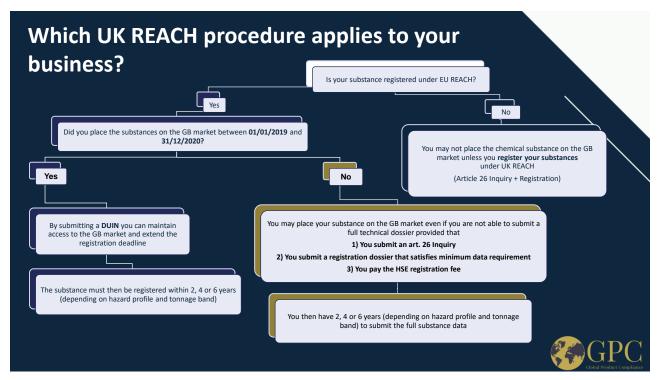
- Non-GB based manufacturers who wish to place chemical substances on the GB market may appoint a GB-based only representative (OR)
- An OR must be:
 - ✓ a natural or legal person established in Great Britain
 - ✓ equipped with sufficient background in the practical handling of substances and the information related to them
 - ✓ appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside Great Britain
 - ✓ responsible for complying with the legal requirements for importers under UK **REACH**

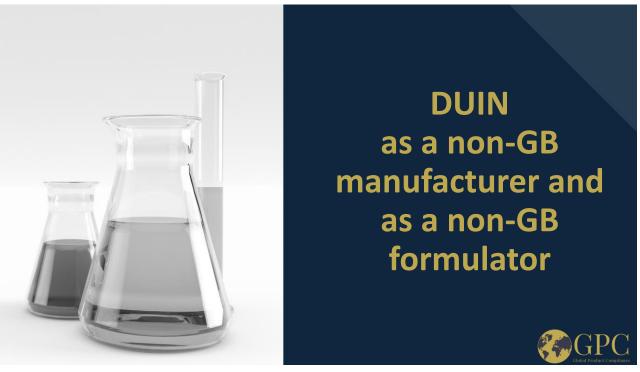
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Which UK REACH procedure applies to your business?







What is DUIN, how does it work?



Downstream User Import Notification (DUIN) is a process set out under the UK REACH transitional arrangements.

The notification allows EU/EEA based holders of an EU REACH registration to maintain access to the GB while postponing their UK REACH registration deadline.

EU/EEA based registration holders have 2 options:

- 1. They may let their GB-based downstream user(importer)/distributor/formulator submit the DUIN to HSE; or
- 2. They may appoint a GB-based OR to submit the DUIN to HSE

DUINs must be submitted **before October 27, 2021.** Once they have been notified, the substances must be fully registered under UK REACH, within 2, 4 or 6 years depending on tonnage band and hazard profile.



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What are the benefits of DUIN?

Maintaining access to the GB market while securing time to complete full registration of the substance within the deadline of 2, 4 or 6 years.

During these 2, 4 or 6 years, you can asses business opportunities in Great Britain while saving on the HSE registration fees.

Remarks:

- DUIN is not a pre-registration, as the concept does not exist under UK REACH.
- DUIN is conditional upon the substance being already registered under EU REACH
- The DUIN needs to be done only once per legal entity, and it must cover all the substances that you are dealing with.



What are the conditions to perform DUIN?

- 1. To be either:
 - A GB-based legal entity that was importing substances and mixtures into GB from the EU or from outside of the EU;
 - A non-GB based manufacturer, wishing to appoint a GB-based OR to perform the DUIN on behalf of the GB-based importer
- 2. The non-GB based manufacturer must hold a valid EU REACH Registration Number
- The GB-based importer or the non-GB based manufacturer must have placed the substance into the GB market during the period between January 1st, 2019 and December 31st, 2020.



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How to perform DUIN? (1/2)



- Appoint a GB-based OR if you are not going to let you GB-based importer perform the DUIN
- Open an account on HSE's IT system "Comply with UK REACH". A DUIN number will then be assigned to you
- Keep in mind that the deadline for DUIN is 27 October 2021

Past the deadline, substances will need to undergo full registration



How to perform DUIN? (2/2)



The DUIN takes the form of a standardised Excel spreadsheet, including (but not limited to) the following information: DUIN number, legal entity's name, CAS number, classification and labelling etc.



The spreadsheet then needs to be sent by email to HSE



For some of the information, it may be easier to add an attachment to the email (e.g. the Safety Data Sheet)



You must then **fully register** your substance within 2, 4 or 6 years



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DUIN as a formulator



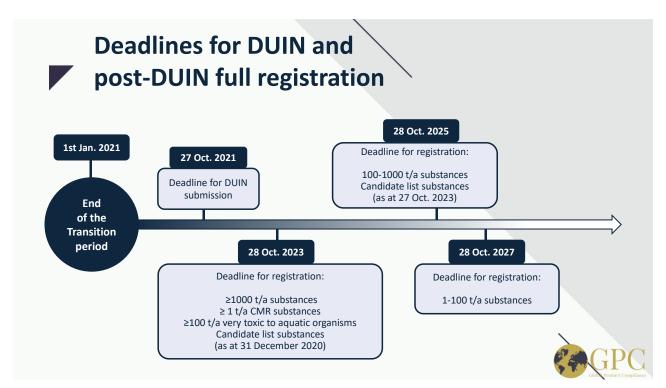
As a non-GB based formulator, you may also submit a DUIN via your GB-based OR if:

- 1. The individual substances within your mixture are registered under EU REACH, and
- 2. You have placed those mixtures into the GB-market during the period between 1st January 2019 and 31st December 2020.



In order to submit a DUIN via a GB-based OR, you will need to fill out the excel spreadsheet mentioned earlier.

<u>However</u>, the ECHA registration number of the substances does not need to be disclosed. In a private communication HSE has specified that the supply just needs to be covered by an EU REACH registration higher up the supply chain.







The New Registration of an Existing Substance (NRFS)

In order to provide parity between new registrants and DUIN beneficiaries, HSE recently introduced the concept of New Registration of an Existing Substance (NRES).

If you are a non-GB based manufacturer or a GB-based importer and you seek to place an EU REACH-registered substance in the GB-market for the first time, then your substance qualifies as a NRES.



Provided that you comply with a simplified registration process, you may place your substance on the GB-market and postpone the submission of the full data for your substance by 2, 4 or 6 years from 27 October 2021 (depending on tonnage band and hazard profile).

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The New Registration of an Existing Substance (NRES)

In accordance with the NRES procedure, you must:

- Submit an Article 26 Inquiry
- Submit the registration dossier, including a waiver explaining why you are not yet able to provide the full registration dossier (HSE is yet to issue a list of acceptable justifications)
- Pay the HSE authority fee



Once these steps have been completed, you are considered compliant with UK-REACH.

This means that you can start placing your substances on the GB market.

Please keep in mind that before the 2-, 4- or 6-years deadline, you will need to complete the full registration and pay the applicable LoA costs.





Full Registration process under UK REACH



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Registration under UK REACH

- The registration process applies to:
 - Non-GB based manufacturers (via an OR) and GB-based importers who wish to place a non-EU REACH registered substance on the GB market for the first time.

 Registration should be carried out as soon as possible.
 - ➤ Non-GB based manufacturers (via an OR) and GB-based importers who have previously submitted a DUIN.

 Registration must be carried out within 2, 4 or 6 years.
- The registration process consists of:
 - 1) Article 26 Inquiry
 - 2) Registration

Remarks:

- Registration is required prior to the manufacture or import into GB reaching 1 ton/year.
- Registration is per substance, per legal entity.
- Registration is not required for mixtures (formulations).
- Registrations must be accompanied by the appropriate registration fee



The Art. 26 Inquiry



- The first step to new registration is submission of Inquiry Dossier
- The process for compiling an inquiry dossier is analogous to the process under EU REACH and the requirements are the same.
- Inquiry dossiers must be submitted to The Agency via Comply with UK REACH.
- Upon receipt of inquiry number, your contact details will be shared with existing registrants, grandfathered registrants and other successful inquirers regarding that substance. This will enable you to engage in the data sharing process.



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The Registration (1/3)

Substance groups and joint registration



- Following the submission of an Inquiry, 'Comply with UK REACH' will organize the registrants according to substance groups (the UK REACH equivalent of SIEFs).
- Substance groups will be made up of multiple businesses that all want to submit a registration for the same substance.
- The group must then appoint a Lead Registrant (LR) to submit the joint registration dossier for that substance on behalf of all group members.
- The Lead Registrant role should be claimed on 'Comply with UK REACH' once the dossier is ready to be submitted.

The Registration (2/3)

Data sharing

 Sharing the data needed to submit a joint registration will be an important task for substance groups.



- ✓ Find out what studies are available
- ✓ Assess any data gaps within the group
- ✓ Consider other publicly available data

• A legal agreement or a **'Letter of Access' (LOA)** can formalize the data sharing agreement



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The Registration (3/3)

The Letter of Access (LoA)



- The LoA gives co-registrants and new members access rights to the data to be used in the lead dossier, for the purpose of completing their registration.
- If you seek to register under UK REACH a substance for which you had already purchased an EU REACH LoA, there is a good chance that you may not have to purchase the LoA again.
- To find out, we can contact your EU REACH Lead Registrant, and ask if they plan to claim the role of LR for UK REACH too.
- If so, they may decide not to charge you for a new LoA, or only charge some administrative fee.

Please keep in mind that even if you have already purchased an LoA for EU REACH purpose, the LR is under no obligation to grant you a free-of-charge LoA for UK REACH purpose





HSE Registration fees



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HSE registration fees

- UK REACH will apply fees to the same processes that were charged under EU REACH.
- The starting point for the UK REACH fees are the EU REACH fees and these have been converted from Euro to GBP, based on the average conversion rate for 2017.



Turnover/Balance sheet ceilings for SMEs for UK REACH

Enterprise category	Headcount	Turnover or Balance sheet total	
Medium-sized	< 250	≤ £43.650 million	≤ £37.539 million
Small	< 50	≤ £8.730 million	≤ £8.730 million
Micro	< 10	≤ £1.746 million	≤ £1.746 million



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Reduced fees for SMEs

Enterprise and Tonnage Bands	Large enterprise	Medium enterprise	Small enterprise	Micro enterprise
1 to 10	£1,138	£740	£399	£57
10 to 100	£3,061	£1,990	£1,071	£153
100 to 1000	£8,185	£5,320	£2,865	£409
above 1 000 tonnes	£22,064	£14,342	£7,723	£1,103





Take home message



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Take home message (1/3)

- ✓ Identify the substances to be placed in the GB market in qty. ≥ 1 tpa apart from your EU exports earlier
- ✓ Check- if the substance is already registered in EU-REACH as EU Registered substances may make you eligible for DUIN
- ✓ Check- if the substance will be placed in the GB for the first time Submit inquiry and registration dossier as soon as possible
- ✓ Early submission means possibility to be a part of substance group so prioritise substances for inquiry submission immediately after DUIN

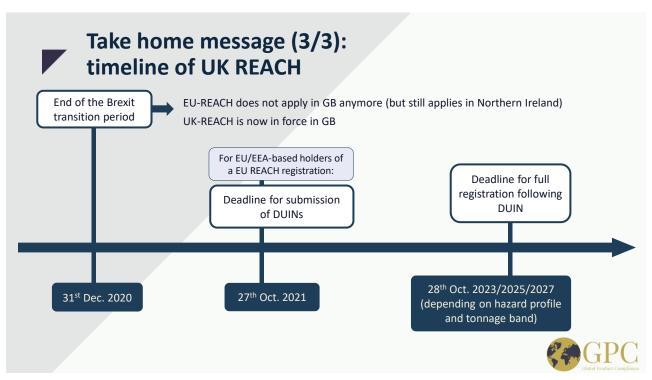




- ✓ Check- if the SDS is updated or not the substance classification should be as per the new GB CLP
- ✓ Identify the competent OR to take responsibilities towards your UK-REACH compliances.
- ✓ Be transparent to your OR and give complete information to avoid any non compliances
- ✓ Keep yourself updated on UK REACH developments gpcgateway.com.



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How can GPC help you?

- Registrations and DUIN Notifications
- Only Representative services
- Study Management
- Safety Data Sheet (SDS)
- Communication with Authorities
- UK-REACH Compliance Advisor (DU communications and certificates)



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Contact us for global regulatory services



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Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 2nd)

Understanding AICIS (Australian Industrial Chemical Introduction Scheme)



Speaker
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Panelist
Mrs. Ketki Kulkarni
Sr. Manager (Regulatory & Client Account)
Global Product Compliance Europe AB

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Summary of Topics Regulation overview Key terminology Australian Chemical Inventory – AICS Who can comply or being affected? Authorized Representative Categorization Authority Fee and Charges Steps towards Compliance Take home message

Introduction - AICIS

- AICIS Australian Industrial Chemical Introduction Scheme
- Regulates the introduction of industrial chemicals in Australia.
- Protection of human health and the environment through restriction, regulation, assessment, evaluation and by managing risks arising due to introduction.
- Safe use of industrial chemical.
- · Maintain a Register of Industrial Chemical Introducers

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Transition from NICNAS to AICIS

The Australia's 30-year-old National Industrial Chemicals Notification and Assessment Scheme (NICNAS) became the Australian Industrial Chemical Introduction Scheme (AICIS) from 1st July 2020.

NICNAS registration will carry over to the AICIS, with same registration id.

NICNAS	AICIS
Permits	Certificates
Secondary notification obligations	specific information requirements
NICNAS assessment permits	AICIS assessment certificates
Current commercial evaluation permits (CECs)	Commercial evaluation authorisation (CEA)

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GHS in Australia

- On 1 January 2021, Australia began a two-year transition from GHS 3 to GHS 7.
- GHS 3 was adapted by Australia on 1st January 2012.
- During the transition, manufacturers and importers may use either GHS 3 or GHS 7 to prepare classifications, labels and SDS for hazardous chemicals.
- From 1 January 2023, only GHS 7 shall be used for classification and SDS & Label preparation.

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Key Terms in AICIS

INTRODUCE: means import, or manufacture of an industrial chemical in Australia

INDUSTRIAL CHEMICAL: this covers a broad range of chemicals used in inks, plastics, adhesives, paints, glues, solvents, cosmetics, soaps and many other products.

- ✓ Any chemical element, compounds or complexes of chemical elements, UVCBs with an industrial use
- ✓ Chemicals released by an article, where the article has an industrial use
- ✓ Naturally-occurring chemicals with an industrial use
- ✓ Polymers with industrial use

- Agricultural chemical product.
- Veterinary chemical product.
- Therapeutic good.
- · Use as food for humans or animals.

Industrial chemicals do not include radioactive chemicals.

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Basic principles of AICIS

- The AICIS regulates chemicals with industrial uses by considering their hazard and risk.
- Business Registration
- No Substance registration
- No direct tonnage/volume criteria
- Annual Reporting for all chemicals

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Australian Inventory of Industrial Chemicals - AICS

- · Currently around 40000 chemicals are included
- list of all industrial chemicals in use in Australia between 1 January 1977 to 28 February 1990. In addition, it includes new assessed chemicals and corrections as required.
- Divided into 2 parts Public Inventory and Confidential Inventory
- It is important to check all the components of product (including impurities) in the inventory

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AICS - Contd.

These can be introduced (import or manufacture) into Australia without telling the authority about it provided that:

- > Business is registered
- Comply with any conditions and obligations (set out in the chemical's terms of listing) Example - Importation volumes of up to 10 tonnes per year or Use in industrial surface coatings not available for public use, including for coating pipes not intended for potable water sources

(apply for vary the terms of the Inventory listing if conditions can not be met)

Substance not listed in public list:

- 1. a naturally occurring chemical
- 2. an alloy or hydrate
- 3. on comparable chemicals list (16 substances)

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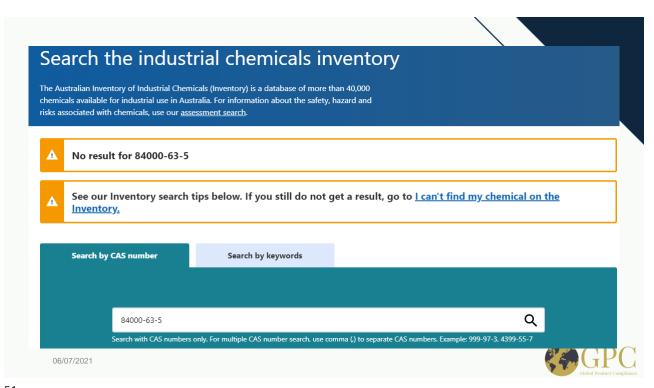
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Australian Inventory of Industrial Chemicals - AICS

	Public Inventory	Confidential Inventory
List	Not downloadable	Not accessible
Substances on Inventory	Listed Introductions	Listed Introductions
Annual Reporting	√	√
Record Keeping	V	V
How to Search	By using • CAS Number • Name • Molecular formula	 Apply through AICIS Business Services Need submit proof of Public Inventory search
Authority Fee	No fee	No fee

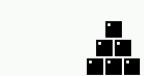
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Australian Importers



Non-Australian Exporters/Authorized Representatives

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Australian Agent/Authorized Representative

- Foreign companies who directly export to Australia are referred as Introducers.
- · Business registration is mandatory before any chemical is exported to Australia. Fee is applicable for the same.
- Australian Registered Business Number (ARBN) is mandatory to provide for business registration.
- · Australian agent or distributor need to be used if any foreign company is unable to obtain ARBN.
- In that case Australian Agent will be an Introducer and Foreign company will be termed as Chemical Data provider.

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Annual Reporting

All importers and manufacturers (introducers) of industrial chemicals must submit an annual declaration after the end of our registration year regardless of their category.

> August 2021 - 30 1 July 2020 - 31 November 2021

August 2021

When you must submit your annual declaration

The period that your annual declaration covers



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New Chemicals - Categorization

Chemicals not on AICS - NEW CHEMICALS - Categorization Required

Categories

- 1. Listed introductions substances present in AICS
- 2. Exempted introductions very low risk
- 3. Reported introductions low risk
- 4. Assessed introductions medium to high risk
- 5. Commercial evaluation introductions
- 6. Exceptional circumstance's introductions

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1. Listed introductions

- Chemical introduction that is it is available on Inventory
- Must meet any terms of Inventory listing for that chemical.



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2. Exempted introductions

Poses a very low risk to human health and the environment.

- · Polymers of Low Concern.
- Industrial chemicals that are imported and subsequently exported.
- · Industrial chemicals that are solely for use in research and development
- · Non-functionalised surface treatment chemicals
- Low concern biopolymer
- · Polymers that are comparable with a listed polymer
- · Chemicals that are comparable with listed chemicals

Comparable list

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Exempted Introduction contd.

- It is possible to introduce such substance without informing to authority provided business registration is done
- Business registration could be done by Authorized Representative or by Australian importer or by Foreign introducers (having ARBN number)
- · Obligations-
 - Record keeping
 - Annual reporting
 - some types of chemicals, once-off exempted introduction declaration is required to be submitted before 30 November 2021

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3. Reported introductions

Low risk to human health and the environment.

- Industrial chemicals at nanoscale that are solely for use in R&D (volume of introduction in registration year is between10-100kg/year).
- Industrial chemicals (other than at the nanoscale) that are solely for use in R&D(volume of introduction in registration year >250kg).
- · Low-risk flavours
- · Fragrance blend introductions.
- · Introduction of UV filters

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Reported Introductions - Contd.

- Once-off pre-introduction report is mandatory to be submitted before introduction
- · Details of Australian agent also needs to be submitted if appointed
- · Introducers must keep records about the chemical and its use
- · Submit an annual declaration.
- · Application for CBI protection can also be made.

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4. Assessed introductions

Poses medium to high risk to human health and the environment.

- Chemicals that contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and polyfluorinated alkyl substances, known as PFAS)
- · Industrial chemical at nanoscale, that are not soluble.
- Polyhalogenated organic chemicals that are persistent or have environmental degradation.
- Polyhalogenated organic chemicals products known to be persistent (greater than 100 kg/year.)
- Persistent gases (greater than 100 kg/year.)
- Organotin chemicals (more than 10kg/year)
- · End use as a biocidal active

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Assessed Introductions – Contd.

- Mandatory to get the introduction accessed by the authority and get the assessment certificate
 before the chemical (or product containing or releasing the chemical) can be exported, imported or
 manufactured.
- Fees apply for these applications and must be paid before the start of assessment
- After assessment Chemical will be listed on the inventory after 5 years of assessment (if not applied for early listing)
- · Information on chemical will be published on the website as assessment/evaluation statement

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5. Commercial Evaluation Introductions

- CEA Commercial Evaluation Authorization is to evaluate the commercial potential of a chemical.
- This authorization can be granted by the authority for 4 years for a maximum volume of 10 tonnes over 4 years
- · Application needs to be submitted through online Business Registration service.
- · Renewal/extension of CEA is not possible
- · Industrial chemical will not be,
 - 1. available to general public,
 - 2. release into environment prior treatment,
 - 3. uncontrolled use at any workplace

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6. Exceptional Circumstances Introductions

Federal Minister of Health may issue an exceptional circumstances authorisation for an introduction of industrial chemical.

 Introduction of the industrial chemical is in the public interest to address significant risks to human health or the environment.

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Authority	Fee and	Charges
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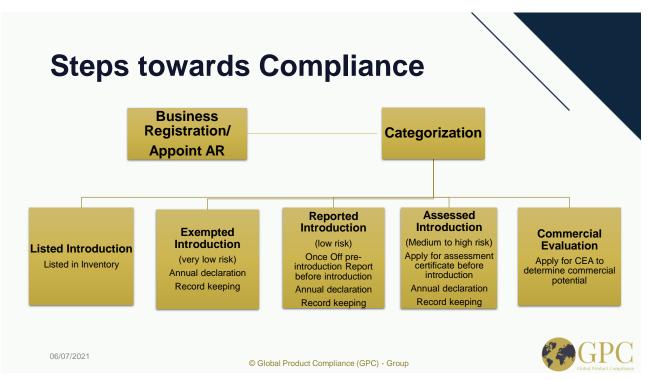
Particular	AUD (20-21)	Y- 21-22
Inventory – Early Listing	1,499	1,490
Apply for an assessment certificate - health and environment focus	34,967	34,965
Apply for an assessment certificate - health focus	23,643	23,675
Apply for an assessment certificate - environment focus	23,643	23,675
Apply for an assessment certificate - very low to low risk	7,599	7,435
Apply for an assessment certificate (consolidated application) - additional chemical that has the same end use as the first chemical and meets the similarity criteria	5,385	7,015
Apply for a commercial evaluation authorization	6,280	6,490

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Take Home Message

- Identify the substances expected to export to Australia
- Check the status of the inventory
- Identify the competent person within the organization/consultant
- Perform substance assessment for identifying hazard nature to categorize
- · Plan your activities in advance
- Keep up to date information available for any further requirements from the authority

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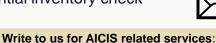


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How GPC can help

GPC has a legal entity in Australia

- Authorized Representative services
- Review and Interpret Regulatory applicability AICS
- · Prepare and submit application for confidential inventory check



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- Annual Reporting
- Substance assessment
- Categorization of new chemicals
- · Application preparation & submission for relevant introductions

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Chemical Regulations and Management in Thailand



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Introduction - Hazardous Substance Act

The Ministry of Industry (MOI) in Thailand published a new regulation Hazardous Substance Act B.E. 2535 for the notification of the production and import of hazardous substances.

1st issued in B.E. 2535, the 4th revision of Hazardous Substance Act

Two key goals are meant to be realized with the implementation of **Hazardous Substance Act B.E. 2535** (1st issue) (HSCA):

- To ensure hazardous substances are only handled by authorized operators and appropriately handled, transported and disposed.
- Supervision over the entire supply chain to prevent misuse and abuse of hazardous substances.



Regulatory Agencies

Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC)

Department of Fisheries (DOF), MOAC

Department of Livestock Development (DLD), MOAC

Food and Drug Administration (FDA), Ministry of Public Health (MOPH)

Department of Industrial Works (DIW), Ministry of Industry (MOI)

Department of Energy Business (DOEB), Ministry of Energy (ENERGY)

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MOI Notifications: List of Hazardous Substances

List of Hazardous Substances w.r.t year List of Hazardous Substances No. 1 B.E. 2556 (2013) Link - http://reg3.diw.go.th/haz/wp-content/uploads/2016/12/announce56.pdf

List of Hazardous Substances No. 2 ————— B.E. 2558 (2015) Link - http://reg3.diw.go.th/haz/wp-content/uploads/2016/12/announce58.pdf

List of Hazardous Substances No. 5 ————— B.E. 2562 (2019) Link - http://reg3.diw.go.th/haz/wp-content/uploads/2019/09/Notification161062.pdf

List of Hazardous Substances No. 6 B.E. 2563 (2020) Link - http://reg3.diw.go.th/haz/wp-content/uploads/2020/06/List-of-Hazardous-Substances_Vol_6862020.pdf

Link: http://reg3.diw.go.th/haz/?page_id=1231



Thailand Existing Chemicals Inventory (TECI)

- Currently 11,479 Chemicals are included in Thailand Existing Chemicals Inventory (TECI)
- > From DIW online consultation results with actual production/ import data will include in the chemical inventory for Chemical information data but the DIW will verify the data before input in the inventory (criteria is under consideration)
- ➤ If the substance/mixture is not classified as Type 1,2, 3,or 4,and if it has any of the GHS hazard properties, then the company shall apply for the declaration of the hazardous substance **List 5.6**
 - But it will not allow nomination process for new substance.
- Link: http://inventory.diw.go.th/hazardous61/

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Thailand Existing Chemicals Inventory (TECI) 🕋 หน้าหลัก 🍰 เข้าสู่ระบบ 🔾 ขึ้นพอนการค้นหาสารเหมี 风 วัดอุอันคราชชนิดที่ 4 วารณาพิมพ์ เงื่อนไขการค้นหาข้อมูล สูตรโมเลกุล **Chemical Code:** (1) Select the year in which chemical is ซนิดวัตถุอันตราย listed to the inventory (2) Type of chemicals (Organic, กลุ่มสารเคมี Inorganic, Polymer) (3) Select type of chemical: CAS-Number Low concerned chemical LCC, รหัสสารเคมี General chemicals GC. Chemicals of Concern CoC, Chemical of High Concern CHC ล้างข้อมูล (Search) © Global Product Compliance (GPC) - Group



Hazardous Substance & Classification Import Procedure Notification Type I (Wo.Ao./Ao.Ko.6 form **Notification** Hazard Degree (Wo.Ao./Ao.Ko.5 form) Type II Registration Operational (Wo.Ao./Ao.Ko.1 form) Personnel **GHS** Notification Registration Type III (Wo.Ao./Ao.Ko.1 &Wo.Ao.3 or 5 or 7 forms License Type VI Prohibited Registration License: valid for 6 years License Permit: valid for 1-3 years © Global Product Compliance (GPC) - Group

Notification, Registration & Licensing Procedures

All producers, importers, carriers and persons in possession of listed HS must notify, register or submit application of a license at the **Hazardous Substances Control Bureau**, **DIW**.

HS Type1

- Notification of product information and import of >1t/y hazardous chemicals (e.g. Menthol)
- · It can be done within 1 day

HS Type 2 & 3

- · Check status of substance via online system and discuss with DIW authorities
- · Submission of application and related documents: 100% composition, MSDS, etc.
- · Checking of application and its information by DIW officers
- · Evaluation process
- Registration required (Type 2) (e.g. Styrene) It may take 17 days for certificate.
- · Registration & license required; (Type 3) (e.g. Acetone) to approve & appeal to Ministery in 30 days

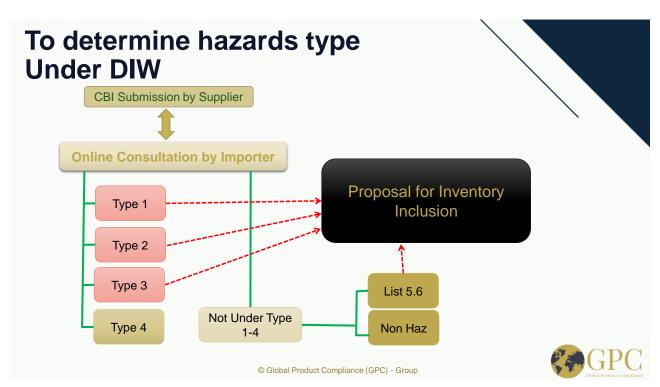
HS Type 4

- Totally banned (import, export and possession) (e.g. Phenyl hydrazine)
- · Exemption : R& D purpose chemicals

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Notification to list 5.6

 Notification to Department of Industrial Works (DIW) via the online system

https://www.diw.go.th/hawk/en/content.php?mode=procedure

- Once within 60 days from the date of manufacture or import
- Only required for hazardous substances listed in annex 5.6

Information required:

- □ Legal entity
- ☐ Type of activity: production or imports
- ☐ Type of hazardous substances: substance or mixture
- □ Trade name and HS code
- ☐ Transport information: UN number, class
- □ Composition
- Type of packaging
- Manufacturer name and country of origin
- ☐ GHS classification
- Physico-chemical properties, toxicological, ecotox and disposal information (from SDS)
- ☐ Copy of GHS SDS prepared in Thai



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HS List 5.6: Controlled Substances based on Hazard Properties

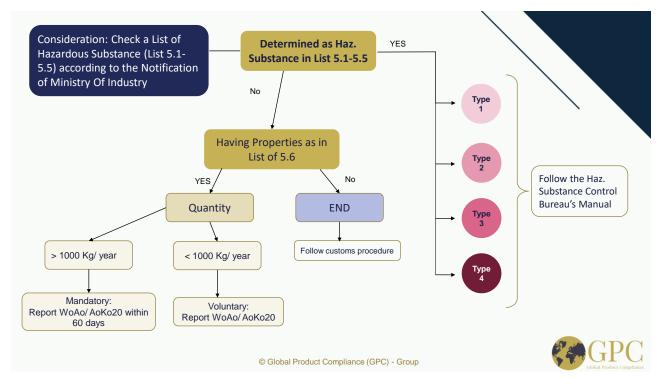
No.	Hazard Properties		
1	Explosive		
2	Flammable substance		
3	Oxidizing agent or Peroxide		
4	Toxic Substance		
5	Mutagen		
6	Corrosive		
7	Irritant		
8	Carcinogen		
9	Toxic substance to reproductive organ		
10	Environmentally hazardous substance		

ເລ່ນ ດຫໄກ	ตอนพิเศษ	രേ 1	หน้า ๑๕ ราชกิจจานเบกษา	๑๙ กมภาพันธ์ ๒๕๕
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		on cookle	ะกาศไว้ ดังต่อไปนี้	

Hazardous Substance Type1 under the condition "...only substances or mixtures not having responsible agency for production or import. They shall be compiled with criteria and method prescribed by MOI..."

https://www.diw.go.th/hawk/news/haz/%E0%B8%9A%E0%B8%8A%205.6.pdf







The MOI Notification on the declaration of the List 5.6 hazardous substances (Draft)

The change is about the repeal of the MOI Notification Re: the declaration of the List 5.6 hazardous substances under the responsibility of DIW B.E. 2558 (2015)

According to this draft, manufacturers or importers of substances or mixtures which have the **total amount of the single substance in all products** >1,000 kg/year must provide the information in compliance with the WoAo/AoKo20 Form.

The criteria shall follow the GHS system Note: this is a draft expected to come into force this year.

Link: http://php.diw.go.th/rubfung/upload1/file1_108.pdf

Key Changes includes:

- Import of manufacture
 Volume must be < 1 kg
- The R&D also for education, testing, and analysis
- For Type 2, no notification and registration required
- For Type 3, no licensing and registration required
- It must comply with the GHS classification & labeling
- Valid might be 6 months & renewal is not possible



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The MOI Notification on the declaration of the List 5.6 hazardous substances (Draft)

วอ./อก. ๒๐ หมายเลขรับแจ้ง. Notifier Information:Company Name, Address ใบแจ้งข้อเท็จจริงเกี่ยวกับการผลิตหรือการนำเข้า ซึ่งวัตถุอันตรายตามบัญชี ๕.๖ .ปี สัญชาติ... เลขประจำตัวผู้เสียภาษีอากร (บุคคลธรรมดา / นิติบุคคล) สถานที่ทำการหรือที่อยู่เลขที่_____ หมู่ที่____ ตรอก/ซอย_____ ถนน_____ ตำบล/แขวง____ จังหวัด รหัสไปรษณีย์ โทรศัพท์ โทรสาร ขอแจ้งข้อเท็จจริง เกี่ยวกับ 🛮 การผลิต 🗖 การนำเข้า ซึ่งวัตถุอันตราย ตามบัญชี ๕.๖ ต่อกองบริหารจัดการวัตถุอันตราย กรมโรงงานอุตสาหกรรม ตามรายละเอียดดังต่อไปนี้ **GHS Classification** Application/Use Amount (tons/year) รายการที่ ชื่อสารเคมี CAS No. คุณสมบัติความเป็นอันตราย รูปแบบการนำไปใช้ ปริมาณรวม (เมตริกตัน/ปี) □ จำแนกตามระบบ GHS 🗖 ใช้โดยบุคคลทั่วไป Consum 🛮 > ๑ ถึง <๑๐ >1-<10 □ >= ๑๐ ถึง < ๑๐๐ >=10 -<10 เ∎□ >= ๑๐๐ ถึง < ๑๐๐๐ ประเภทย่อย (Category)..... 🗖 ใช้เชิงพาณิชย์ Commercial ■ ใช้ในเชิงอุตสาหกรรม Indust ประเภทย่อย (Category)..... Sr.No. Chemical Name CAS No. □ >= sooo >1000 >=100-<10 ประเภทย่อย (Category)...... ■ใช้เป็น intermediate หรือ Non-isolated Intermediate □ นอกเหนือจากที่จำแนกตามระบบ GHS 🗖 ใช้โดยบุคคลทั่วไป □ จำแนกตามระบบ GHS ่ □ > ๑ ถึง <๑๐ ใช้เชิงพาณิชย์ ประเภทย่อย (Category)..... 🗆 >= ๑๐ ถึง < ๑๐๐ 🗖 ใช้ในเชิงอุตสาหกรรม ประเภทย่อย (Category)...... 🗆 >= ๑๐๐ ถึง < ๑๐๐๐ 🗖 ใช้เป็น intermediate หรือ □ >= sooo ประเภทย่อย (Category)..... นอกเหนือจากที่จำแนกตามระบบ GHS Non-isolated Intermediate © Global Product Compliance (GPC) - Group

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R&D Exemption

Import, export or possession of the hazardous substances found under List No. 5 which are used in Research and Development (R&D) and the volume does not exceed 1 kg are exempted from the following:

Register for hazardous substance **Type 2 & 3**Notify for hazardous substance **Type 2**, OR
Obtain a license for hazardous substance **Type 3**

Notification to the MOI Re: "A Specialized Personnel Responsible for Safe Storage of Hazardous Substances under the Responsibility of the DIW" for hazardous substance Type 1, 2 and 3

Prior to import or manufacture, those who are qualified should submit supporting dossiers as outlined in form WoAo/AoKo24 which is annexed to this notification. When officially signed by a competent authorized officer, the form and the dossiers will to be used as evidence for concerned authorities.

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R&D Exemption

Basic information on the substance to be submitted include:

- WoAo/AoKo24 form: Importer name, address and commercial license
- Chemical identification trade name, formula name, quantity to import/export, country of origin, producer company and means of transportation.
- Warehouse address, location, protective and preventive measures on warehouse structure and occupational health and safety
- GHS-SDS: Material safety data sheet (in the case of industrial chemicals) or the results of efficacy trial, residue trial, quality analysis, toxicological data assessment (in the case of pesticides)

- Education certificate/science work certificate.
- Details of R&D project including the research objectives
- Method of the research
- Disposal information

Link: http://php.diw.go.th/rubfung/upload1/file1_109.pdfand http://php.diw.go.th/rubfung/upload1/file2_109.pdf





Submission and Certificate

- Single window submission
- Certificate
- CBI

06/07/2021



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The Hazardous Substance Single Submission (HSSS)

- ☐ HSSS is a web-based hazardous substance registration system
- ☐ For the registration of hazardous substance Type 2,3 and licensing of Type 3
- □ Operations related to each hazardous substance with a quantity from 100 kg or more During January June or July December Of each year, inform the facts according to the form Wor. / Kor. 7 (form Wor. / Kor. 7.1 and Form Wor./or. 7.2)
- ☐ Link: http://hazdiw.diw.go.th/singlesubmit/#/login





The Hazardous Substance Single Submission (HSSS)

After Submitting all information in Prescribe Form, Valid certificate has been generated.







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Confidential business information (CBI) 100% Composition Disclosure:

- ➤ DIW would require 100% composition disclosure for evaluation.
- Companies may choose to keep some composition information to themselves due to CBI concern.
- Under such circumstances, the company has to take its own risk since the DIW could only evaluate the chemicals are hazardous or not based on the information provided.
- Earlier, to avoid disclosing this information, the consultant recommends using a third-party representative to deal directly with the DIW on substance identity.



Confidential business information (CBI) 100% Composition Disclosure:

- Companies may provide 100 % composition to the authority directly via email at: director.cbi@diw.mail.go.th within 3 months and the consultation result must align with the SDS.
- Authority will make an evaluation and if product has any hazardous components, company (supplier) needs to agree to disclose hazardous ingredients and percentage. The CBI procedure may take around 8-12 months (minimum).
- Activities need to be reported to the competent authority within the corresponding deadline

☐ Period during which Activities are Conducted	☐ Declaration Deadline
☐ Jan to Jun	☐ Jul of the same year
☐ Jul to Dec	☐ Jan of the next year

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Future actions in chemical Management in Thailand (1)

- > The new Hazardous Substance Act (the latest amendment) will need to enacted by parliament
- Amendment of the declaration of the List 5.6 hazardous substances (from Product to Single substance)
- Review the classification of hazardous substances (update List of Hazardous Substances No._ (B.E. 256X))
- > Prioritization system of chemicals and hazardous substances

National Center for Chemical Data and Hazardous Substances

Chemical database

- Usage purpose
- Hazard property
- Quantity (average)

Chemical inventory

- Characteristic: chemical name/ CAS No. DIW No.
- Include both of hazardous substances and nonhazardous substance



Future actions in chemical Management in Thailand (2)

➤ The National Committee on Strategy Development for Chemical Management in conjunction with the academic sector, private sector, and people sector, has prepared the Master Plan on Chemical Management (2019-2037)

Strategy 1: to enhance efficiency in monitoring and management of chemicals

Strategy 2: to develop big data management, risk assessment, and chemical standard

Strategy 3: to build awareness and change consumption and production behaviors.

Strategy 4: to reduce risks of chemicals throughout their life cycle.

Strategy 5: to conduct research and development, create knowledge and innovation in substitution for hazardous chemicals.





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GHS Implementation in Thailand:

Thailand has implemented GHS through the Hazardous Substance Act and Hazard Classification and Communication System of Hazardous Substances B.E. 2555 (2012). GHS SDSs and labels are required for hazardous substances from 13th March 2013 and for mixtures from 13th March 2017.

Classification

- Adopted all building blocks of GHS Rev. 5;
- Concentration limit for reproductive toxicant: 0.3%/3%;
- Classification list by Department of Industrial Works

Labelling

- A UN proper shipping name (if available);
- Small package & label size: Not specified.

Safety Data

Standard 16-section SDSs;

Sheet

Language: Thai



Take Home Message

- Identify the substances that already export or plan to be exported to Thailand
- Check the status of substance in the inventory (TECI)
- Identify the competent person within the organization/consultant to perform Substance Assessment (Identifying hazard nature of substances)
- Plan your activities in advance and stay update on compliance requirements from the authority.
- Follow GPC Thailand to see the latest updates: https://gpcgateway.com/Common/home.php?country_id=11&country_name=Thailand

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How can GPC help you?



Regulatory Compliance SDS Authoring, review, translation



Prepare and submit application for inventory check: hazardous substance List 5.6 and CBI



Authorized Representative services



Product and Substance: **Notification** and **Registration**





Contact us for global regulatory services









https://gpcgateway.com/

Global Product Compliance (GPC)

compliance@gpcregulatory.com





IDEON, Beta 5, Scheelevägen 17, 22363 LUND. SWEDEN



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Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 2nd)

SCIP Database: Implications on Substances in Articles



Speaker
Ms. Elena Kondryukova,
Regulatory Researcher & Business Developer
Global Product Compliance (GPC) Group
Email: elena@ru.gpcregulatory.com

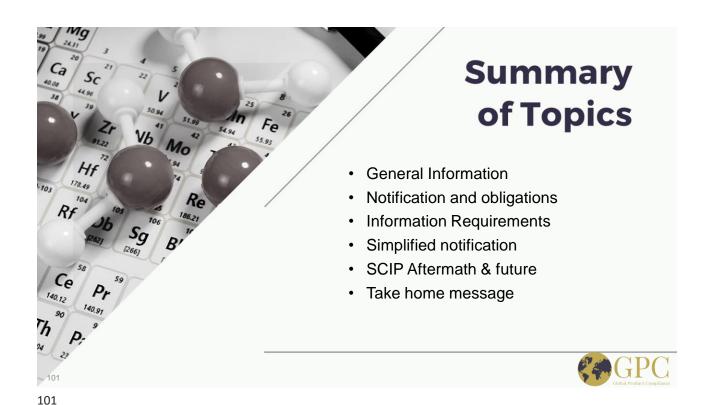


Panelist Mr. Shrirang Bhoot CTO, Global Product Compliance Europe AB

06/07/2021







General information on the SCIP

Introduction:

- Substances of Concern In articles as such or in complex objects (Products).
- Established under Waste Framework Directive (WFD).
- · Valid for the entire EU market

Definitions:

- · Article (ex: Brakes, wheel etc.).
- · Complex Object (ex: Bikes, Cars etc).
- Candidate List.
- Substance of Very High Concern (SVHC).







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Objective

 The SCIP database ensures that the information on articles containing Candidate List substances is available throughout the whole lifecycle of products and materials, including at the waste stage. The information in the database is then made available to waste operators and consumers.

The main aims:

- to support circular economy
- prevent waste being generated,
- reduce hazardous substances in materials and products





04

Users of the Database

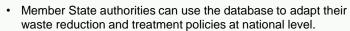
 The primary users - waste treatment operators and consumers. It will ultimately help waste operators to improve their waste separation and recycling processes.



 The database should increase knowledge on which substances are used in which articles.



 Consumers can use this information to find out more about the SVHCs in the products they buy and make informed choices.

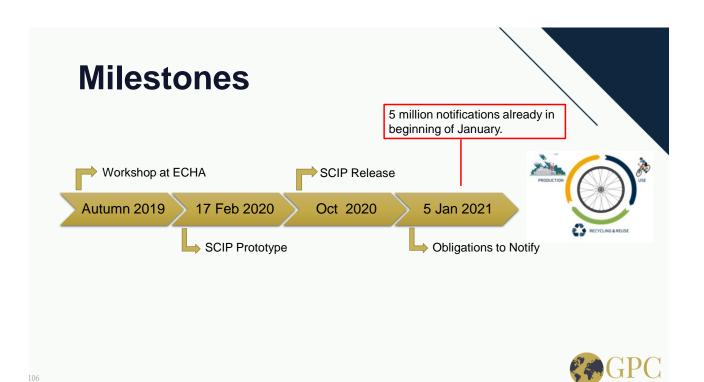




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Notification and Obligation



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Notification and Obligation

- SCIP notification covers all articles placed on the EU market containing a substance of very high concern on the Candidate List in a concentration above 0.1 % w/w. (irrespective of tonnage)
- 5 January 2021 information on article should be communicated
- ✓ EU producers and assemblers,
- ✓ EU importers,
- ✓ EU distributors of articles
- Other actors in the supply chain placing articles on the market (Assemblers)
- ✓ It also allows third parties to submit data on your company's behalf, based on intra-party arrangements – the 'foreign user' concept



Retailers,

 Other supply chain actors supplying articles directly and exclusively to consumers



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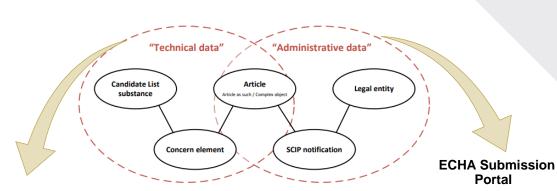


Information requrements



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Information Requirement



IUCLID 6 (Server or Desktop)

S2S = Companies own system to prepare notification dossiers and submit automatically to ECHA.



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Article information requirement – Article identification

- Identifiers
 - Article name
 - Other names (brand, model)
 - Primary article identifier (EAN, GTIN, catalogue number, part number,...)
 - Other identifiers (EAN, GTIN, catalogue number, part number,...)
- Categorisation
 - Article category (CN/TARIC code)
 - · Production in the EU
- Characteristics (picture, dimensions, colour, weight, ...)

Red = mandatory (no data will fail submission)
Yellow = required (input needed, but can be waived/no additional information) for a successful submission
Black = optional



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Article information requirement— Safe use instructions



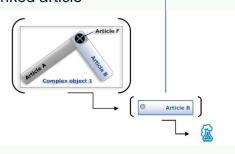
- Option 1: Provide safe use instruction(s) (free text)
- Option 2: Select 'No need to provide safe use information beyond the identification of the Candidate List substance'
- Disassembling instructions



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Article information requirement – Complex object component(s)

- · If applicable
- Number of units
- · Linked article



- · Identifiers
 - o Article name
 - o Other names (brand, model)
 - o Primary article identifier (EAN, GTIN, catalogue number, part number,...)
 - o Other identifiers (EAN, GTIN, catalogue
 - number, part number,...)
- Categorisation
 - o Article category (CN/TARIC code)
 - o Production in the EU
- Characteristics (picture, dimensions, colour, weight, ...)
- Safe use instruction(s)
 - o Disassembling instructions



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Information on the Concern Element – Concern element(s)



- · Candidate list substance -Name, EC, CAS
- · Concentration range, incl.
 - > 0.1% w/w and \leq 100% w/w
- Material category and/or Mixture category (EUPCS)
- Additional material characteristics





Simplified submissions



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Simplifying data submission

- Defining how to re-use data submitted by a supplier to ECHA:
 - "Simplified notifications" (e.g. useful for distributors): if an article is not changed, the duty holder can benefit from a simplified notification referring to the data submitted by his supplier without preparing a dossier.
 - "Referencing" (for assemblers of complex objects): if an article (already notified by a supplier) is incorporated into a complex object, the duty holder can refer to the submitted data without re-entering it.

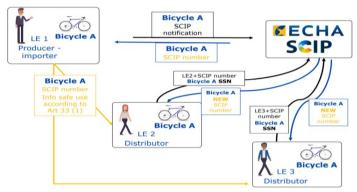


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Simplified notification

For distributors

- 1. The product received = product supplied
- 2. No dossier needed in the submission
- 3. The distributor links to the notification of the supplier and does not need to submit updates





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"Referencing"

Referencing overview Wheel A SCIP notification Wheel A SCIP number Into safe use according to Art 33 (1) Wheel A SCIP number Wheel A SCIP number Into safe use information + concern element) Wheel A SCIP number



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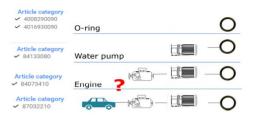
'Grouping' and 'Hierarchy'

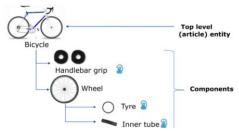
 Identical or quasi-identical articles as such and complex objects (products) can be submitted in one notification: ('grouping')





 Many layers of components and subcomponents of a complex object have to be reported in order to allow the identification and 'location' of the article containing a Candidate List substance: ('hierarchy')







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SCIP Aftermath & future plans

clobal Pro

SCIP aftermath



93% of all submission were approved (December 2020).

10 Million submission in March from 3600 companies.

· Partially thanks to the video guidance provided by ECHA on how to notify substances.



The TARIC code – hard to obtain information on material category or components in complex articles, especially for EU importers.



Complex objects: the notification is more time-consuming because of additional information.



Supply chain communication is important in order to become compliant.

A pilot study has identified that many companies didn't succeed to communicate necessary information regarding candidate list substances in concentrations above 0.1% w/w, which resulted in inability to comply (Chemical Watch, 09.04.21).



Submissions only though the SCIP system, all applications submitted through Article 33 REACH system will not be reviewed.



>1000 components nominated after 26th of March submissions will automatically be failed. MAX 1000 components per one submission.

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Future of the SCIP

- Not all EU countries have yet applied WFD on the national level, e.g. The SCIP obligation is not yet binding in these countries.
- The SCIP Dissemenation Portal will be published on ECHA's website for public access in the near future.
- · Possibility to update the dossier.
- Only essential information will be provided in the database, things considered as "optional" (e.g. The description of the product) will be shown only if filled in.



Take home message

- Start preparing your dossiers in time! The more complex the object the longer it might take to collect all necessary information.
- Make sure to have MAX 1000 components in one submission dossier – group your articles if possible.
- Check with your supplier if they have done the SCIP notification for the article you have – if yes, then "Simplified Notification" or "Referencing" will simplify the process for you.
- Prepare and submit through the SCIP submission system.



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https://gpcgateway.com/

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