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International Chemical Regulatory and Law Review

Editorial

Back in December 2019, the European Union (EU) unveiled the Green Deal which aims to work towards creating a carbon-neutral economy by 2050. The Chemicals Strategy for Sustainability is central to this vision, emphasising safer practices in the industry. However, integrating these measures into existing regulation, such as REACH (EC No 1907/2006), remains a challenge. In 'Is the EU Shooting Itself in the Foot With Its Chemical Regulations Scheme?' Jaime Sales examines the current impact and argues for collaborative solutions to work towards a greener future.

Dandan Ge's article, 'Recent Developments in Chinese Chemical Legislation: China's New Chemical Substances Registration (MEE Order No. 12) and HazChem Registration', explores the impact of these changes for chemical management in China. Ge details how this update imposes new registration requirements for chemical substances and distinguishes between substances listed in the Inventory of Existing Chemical Substances of China (IECSC) and those used for unauthorised industrial applications.

'Strictly Controlled Closed Systems: A Heat Transfer Restriction Proposal Case Study' introduces the Strictly Controlled Closed Systems (SCCS) operating principle, which is based on an ECHA restriction proposal on heat transfer fluids. SCCS aims to standardise safe operation across the EU, minimising worker exposure and environmental release. Joshua Baptist, Matthias Schopft, and Francisco Hernandez detail how by amalgamating safety standards, SCCS provides an inspection checklist for industry compliance and regulatory oversight by bringing safety standards together, ensuring standardised management to reduce environmental and human risks.

We hope you enjoy this issue of ICRL and encourage you to consider contributing to future issues of the journal.

Dieter Drohmann
Managing Editor

Is the EU Shooting Itself in the Foot with Its Chemical Regulations Scheme?

*Jaime Sales**

The European Union has developed an ambitious plan to become the first climate-neutral continent in the world. The European Green deal lays out a set of policy actions aimed at achieving such goal. However, while the validity of the final aspiration is unquestionable, a full deployment of all the foreseen activities could have a boomerang effect that may prevent from such objective being achieved. Initiatives such as the Chemicals Strategy for Sustainability foresee the ban or limitation of uses of chemicals that are critical not only to ensure the green transition in Europe, but also for highly technological sectors for which Europe intends to obtain market independence from other regions. Together with the full development of the REACH Regulation (authorisation and restriction processes), the self-assigned leadership of the EU in the control of chemicals may result in increased uncertainty for investments (certainly not alleviated by the introduction of the essential use concept) that could move to other continents. While Europe continues to place the regulatory focus on chemical hazard instead of adequate control of risk, an adequate balance between protection of safety and the environment and an adequate functioning of society will be hard to achieve.

I. Introduction

On December 2019, the European Union (EU) disclosed the so-called Green Deal, with the objective to achieve a sustainable and carbon neutral (net zero) economy for the year 2050.[1] In order to guarantee the green transition for the European industry, this Pact includes a set of legislative initiatives that add on to the already saturated regulatory landscape of chemicals in Europe.

Some of these initiatives aim at strengthening the control over the use of chemical substances in the EU territory. Of relevance is the Chemicals Strategy for Sustainability, with the objective to better protect citizens and the environment from harmful chemicals, and boost innovation by promoting the use of safer and more sustainable chemicals.[2] In this regard, the initiative to develop the concept Safe and Sustainable by Design (SSbD) plays a key role.[3] This is an approach to support the design, development, production, and use of chemicals and materials that focuses on providing a desirable function (or service), while avoiding or minimising harmful impacts to human health and the environment, in line with, and beyond existing and upcoming regulatory obligations.

In summary, another 'layer of complexity' for the European chemical industry, which for more than 15 years now has been focused on the compliance of the requirements established in the REACH Regulation (EC No 1907/2006) on registration, evaluation, authorisation, and restriction of chemical substances.[4] This Regulation, one of the most complex pieces of legislation in the chemicals landscape, already sets the objective to contribute to the protection of human health and the environment, in front of risks related to the manufacture and use of chemicals, highlighting the need to substitute substances of very high concern by safer alternatives.

In parallel, and in the context of an increasingly complex economic and geopolitical scenario, the EU

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1 See <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en>

2 See <https://environment.ec.europa.eu/strategy/chemicals-strategy_en--gt-

3 See <https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design_en>

4 See <https://environment.ec.europa.eu/topics/chemicals/reach-regulation_en>

has developed different initiatives, yet equally ambitious, which in some cases are closely related to the objectives of the Green Deal. For example, the European Chips Act is designed to bolster Europe's competitiveness and resilience in semiconductor technologies and applications, helping to achieve both the digital and green transition.[5] From the point of view of energy, initiatives such as the EU hydrogen strategy and REPowerEU establish a framework for supporting the adoption of renewable energies to help decarbonization of the EU in a profitable way, reducing its dependency on imported fossil fuels.[6] It is also worth referring to the upcoming Batteries Regulation, approved in 2023. The demand for batteries, which are critical technologies to ensure sustainable mobility, is expected to grow significantly over the coming years.[7] The new Regulation aims at minimising the environmental impact of the batteries life cycle and to promote circularity.

In order to be prepared for these initiatives, the EU needs to ensure access to safe, diverse and sustainable supply of a set of raw materials, which are essential in a wide variety of strategic technological sectors. For this reason, the EU is currently working on a Critical Raw Materials (CRM) Act, expected to be approved in Spring 2024, which grants these objectives and promotes Europe's independence from third countries in the access to this kind of raw materials.[8]

II. Conflicting Objectives

Unfortunately, too often the objectives from certain European regulations come into conflict with those established by other pieces of legislation. Even more, an excessive lack of flexibility in certain regulatory procedures tends to generate uncertainties that may lead to situations of loss of investment from industrial stakeholders. As an example, different metals defined as strategic materials in the new CRM Act (e.g., nickel, cobalt, lithium, or boron) are substances that exhibit certain hazardous properties. Nickel is a known carcinogen for the human respiratory tract;[9] cobalt may impact the reproductive system, induce mutations in cells or lead to the development of certain types of cancer.[10] And currently, there is a strong debate around the possible classification of lithium salts as toxic to the reproduction of humans.[11] As per boron, this element deserves a separate discussion which will be provided in detail in a future publication due its classification as reprotoxic and its multiple uses. Therefore, technologies based on these materials would not qualify as SSbD as previously described. Moreover, raw materials containing these elements may be considered as substances of very high concern and based on dispositions in the REACH Regulation, their uses could be eventually banned in the EU.

But those elements are currently irreplaceable in the production of batteries that must support the transition to a decarbonized economy, as well as in multiple critical uses for society (production of steel, development of other renewable energies, catalysts to reduce sulphur and nitrogen emissions...).[12] Therefore, on one side Europe promotes the development of highly innovative technologies that must take us to a 'net zero' emissions scenario, as well as the assurance of a sustainable sourcing of the materials that are necessary to develop such technologies. But, on the other side, barriers continue to be imposed on those materials, over which frequently 'swords of Damocles' are placed in the form of long and uncertain procedures related to potential restrictions or authorisations, which may be a threat to their availability on the market following an increasingly stringent regulatory framework.

5 See <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-chips-act_en>

6 See <https://energy.ec.europa.eu/topics/energy-systems-integration/hydrogen_en; https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/repowereu-affordable-secure-and-sustainable-energy-europe_es>

7 See <https://environment.ec.europa.eu/news/new-law-more-sustainable-circular-and-safe-batteries-enters-force-2023-08-17_en>

8 See <https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1661>

9 See <https://nickelinstitute.org/en/science/human-health-fact-sheets/fact-sheet-2-nickel-nickel-compounds-carcinogenicity/>

10 See <https://www.cdc.gov/niosh/topics/cobalt/default.html#:~:text=It%20can%20harm%20the%20eyes, duration%2C%20and%20work%20being%20done>

11 See <https://www.europarl.europa.eu/doceo/document/P-9-2022-002788_EN.html#:~:text=The%20proposal%20of%20the%20European,decarbonisation%20of%20the%20European%20economy.>

12 See <https://nickelinstitute.org/en/about-nickel-and-its-applications/#:~:text=Nickel%20has%20outstanding%20physical%20and,stainless%20and%20heat%2Dresisting%20steels; https://www.cobaltinstitute.org/about-cobalt/#:~:text=Cobalt%20is%20essential&text=Cobalt%20can%20be%20magnetized%20and,high%2Dtemperature%20strength%20is%20important; https://rechargebatteries.org/>

Other materials that may be highlighted in this 'two-sided coin' that is the European legislation on chemicals are fluoropolymers.[13] These high value plastics provide essential properties in key technological sectors such as hydrogen production, battery components, water filtration and food processing, medical devices, heat and refrigeration systems, chemical industry, transport (automotive and aerospace) and production of semiconductors.[14] Such a wide range of applications is possible thanks to the properties that fluoropolymers exhibit, including (but not limited to) chemical and temperature resistance, durability, non-permeability, fire resistance, low coefficient of friction, or dielectric properties. At the same time, fluoropolymers are non-hazardous materials acknowledged as polymers of low concern.[15] However, due to their chemical structure they are part of a broad group of chemicals (per- and polyfluoroalkyl substances, PFAS) which does include certain substances that are highly toxic for humans and the environment. Unfortunately, fluoropolymers are included in the universal PFAS restriction proposal that is under evaluation by EU regulators.[16] If approved as proposed, this restriction may lead to the ban of many of the high value applications of fluoropolymers, which will inevitably put the development of critical technologies at risk. It is relevant to note that the United Kingdom (no longer a member of the EU) has announced that in their future restriction of PFAS, fluoropolymers will be excluded due to their high importance and acknowledged low toxicity.[17]

III. Risk-Based Over Hazard-Based Regulation

The situation described previously has been highlighted by different stakeholders. One of the 'solutions' that is being discussed is the development of the so-called Essential Use Concept, which should be incorporated to regulatory decisions in the context of banning, restricting or authorizing uses of chemicals of concern.[18] Under this scheme, the use of those chemicals will only be allowed if it is considered to be necessary to ensure the health and safety of people or the environment, or to guarantee an adequate functioning of society, as long as no safer alternatives are available. Again, there are conflicting views when deciding if uses of substances of concern should be allowed to continue if the previous conditions are not met, even if safe use can be demonstrated.

The problem comes with the need to adequately fix the criteria that will allow establishing when the use of a substance can be regarded as 'essential'. In fact, the approval of a clear definition of the concept, and of guidance that may support its application, have been delayed by European authorities, with significant controversy on efforts performed in this field.[19] It is surprising to see that on-going restriction procedures (e.g., PFAS) are making references to this (still not approved) concept. Indeed, it will always be controversial to establish who must decide, and under what specific circumstances, that the use of a chemical is 'necessary for an adequate functioning of society', considering as well that a use identified as 'not essential' today may become essential in the future, when the substance may no longer be available on the market (concepts such as economies of scale and industry willingness to keep production in Europe should also be brought to the discussion).

As previously discussed, in order to grant the continued use of a substance of concern, it will be necessary to demonstrate that there is no safer alternative for the use. It is unquestionable that there is a need to promote innovation and the continued development of safer materials. However, certain stakeholders (including some regulators) do not seem to acknowledge that science itself imposes certain limits to what innovation, applied to the development of new materials, may provide. This is due to the fact

13 Jaime Sales, Francisco Hernández, Deepak Kapoor, Marcel van den Noort, 'Fluoropolymers: The Safe Science That Society Needs' (2022) International Chemical Regulatory and Law Review 1, 13-23.

14 Jaime Sales, Michael Schlipf, Deepak Kapoor, 'Critical Use of Fluoropolymers in the Functioning of Modern Society' (2023) International Chemical Regulatory and Law Review 1, 29-36.

15 Barbara J. Henry et al., 'A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers' (2018). Integrated Environmental Assessment and Management. Volume 14, Number3, 316–334; Stephen H. Korzeniowski et al., 'A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers' (2022) Integrated Environmental Assessment and Management, Voume 19, Number 2, 326-354.

16 See <https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

17 See <https://www.hse.gov.uk/REACH/assets/docs/pfas-rmoa.pdf>

18 See <https://cefic.org/media-corner/newsroom/defining-essential-use-of-chemicals-what-is-at-stake/>

19 See <https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf>

that frequently, the natural causes that make a substance hazardous (such as reactivity or persistence in the environment) are the same ones that provide useful properties that cannot be obtained with other materials. Or, *vice versa*, materials that may offer comparable performance to that obtained from a substance of concern will frequently share the same hazardous characteristics. Furthermore, the evaluations required to verify that an alternative offers an equivalent performance compared to the original substance may lead to rushed and incorrect conclusions with significant damage to the impacted value chains. Therefore, establishing time limited authorisations (or derogations) for certain uses, based on usually overoptimistic expectations on the development of alternatives that will work at industrial scale (not just at the laboratory) does not appear to be a good system to provide certainty to those that have to invest in the development of highly complex technological processes.

In reality, the solution to this dilemma could be quite simple. It would require the EU to move towards a risk-based approach rather than a hazard-based approach for the management of chemicals. This would be a complete swift in the regulatory strategy that the EU is currently following, and while it has already been contested by certain stakeholders, voices have been raised suggesting that Europe is pushing too much its focus on hazard as the key driver for decision-making, to a point where it is questionable that certain decisions are based on balanced and consistent scientific assessments. [20] Indeed, despite the fact that, as previously discussed, elements such as lithium, cobalt or nickel are (or may in the future be classified as) toxic chemicals, efficient technologies to ensure adequate control of risk have been developed and are currently available (fluoropolymers being a good example for this, even if they are not toxic chemicals themselves).[21] It is the case that some substances used in industrial settings are classified as toxic due to effects observed in studies where animals were exposed via oral ingestion, typically at doses that are much higher than those to be expected for workers in industrial settings. Rules and mechanisms established to derive conclusions on classification of chemicals are not under question; however, basing regulatory decisions on extrapolations from such studies to real life situations, which are likely not realistic of the use, do not appear to be reasonable. In this regard, perhaps the on-going discussions around classification of lithium salts may be one of the most obvious examples.

Lithium-based treatments have been known for many years to be the most effective therapy for dealing with symptoms of certain psychiatric disorders.[22] Studies are available that evaluated conditions of women suffering from such disorders, who at the same time faced trouble during pregnancy (e.g., miscarriage or malformations). Some regulators conclude that there is a direct link between lithium exposure and negative health effects and are using those studies to recommend classification of lithium compounds under the CLP Regulation (EC No 1272/2008) as Toxic to Reproduction Category 1A (known to be reprotoxic for humans).[23] There are certain facts that make such conclusions questionable, for example: 1) those studies have significant flaws in terms of reliability, 2) top quality, GLP compliant (2 generation) studies performed with animals showed no effects, and 3) relevant human studies that may challenge the preliminary conclusions from regulators have not been considered in the assessment. Still, leaving those facts aside, it does not seem reasonable to base regulatory options (e.g., potential bans vi REACH for substances with a classification as Toxic to Reproduction Category 1A) for uses of lithium at industrial settings where no ingestion is expected on (doubtful) results based on oral exposure of a very specific population cohort. Particularly, when such regulatory options may impact heavily on a key technological sector such as the manufacture of batteries.

IV. Conclusions

The path towards a society that will ensure a high level of protection for people and the environment, in what concerns the exposure to hazardous chemi-

20 See 'The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? Archives of Toxicology (2021), Matthias Heizler, et al.; also see <https://chemsec.org/reports/hazard-vs-risk/>

21 Bruno Ameduri, Jaime Sales, Michael Schlipf, 'Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerisation Aids' (2023) International Chemical Regulatory and Law Review 1, 18-28.

22 See <https://www.nhs.uk/mental-health/conditions/bipolar-disorder/treatment/>

23 See <https://echa.europa.eu/es/regulations/clp/legislation>

cals, is an inalienable goal that must be clearly fixed in the European political agenda. There are tools available that allow to evaluate and adequately establish the risk related to uses of chemical substances. When such risk is deemed to be unacceptable, it must be avoided, removing the use if there is no other option. But, when it is possible to guarantee an adequate control of risk, care should be taken to raise barriers on technological progress in the name of an unnecessary regulatory over protectionism, especially when this may lead to the loss of leadership of the EU in critical sectors for society. Unfortunately, the pressure to claim a global leadership in the field of regulations on chemical products is taking Europe towards maximum positions that are not always supported by the best available scientific data, and which could be counterproductive by limiting technological developments that are necessary to ensure the objectives fixed in different European policies on decarbonization or technological progress. Indeed, regulatory certainty and predictability are necessary for industry to be able to view Europe as an attractive target to undertake the considerable investments that those technologies will require.

Recent Developments in Chinese Chemical Legislation: China's New Chemical Substances Registration (MEE Order No. 12) and HazChem Registration

*Dandan Ge**

In 2020, the Chinese Ministry of Ecology and Environment (MEE) issued Order No. 12, replacing MEP Order No. 7. New measures for environmental management registration of chemical substances require different registration types for new substances not listed in the Inventory of Existing Chemical Substances of China (IECSC) and for substances listed in the IECSC but used for industrial applications other than permitted uses in order to be researched, manufactured, imported, processed and used in the territory of the People's Republic of China (PRC). Registration is not mandatory for mixtures (formulations). However, if the substances that make up a mixture are considered new substances, they must be registered. This also applies to variable component substances and complex reaction products without unique and definite molecular structures. Polymers are not exempt from registration.

I. Updates on China New Chemical Substances Registration (MEE Order No. 12)

1. Background

On 15th October 2010 the Chinese Ministry of Environmental Protection (MEP) released the revised version of the Measures on Environmental Administration of New Chemical Substance (MEP Order No.7). In 2020 the Chinese Ministry of Ecology and Environment (MEE) issued Order No. 12, which replaced MEP Order No. 7 and has already come into force on 1st January 2021.[1]

Under MEE Order No. 12 chemical substances are divided into existing and new substances. These new measures for the environmental management registration of new chemical substances require different registration types for (i) new substances, which are not listed in the Inventory of Existing Chemical Substances of China (IECSC); and (ii) substances, which have been listed in the IECSC but are used for industrial applications other than permitted uses, irrespective of their annual quantities, before they can be researched, manufactured, imported, processed and used in the territory of the People's Republic of China (PRC). The registration shall be submitted to the Chinese competent authority, Solid Waste and Chemical Management Centre (SCC) of MEE.

Though registration is not required for mixtures (formulations), the substances that comprise a mixture must be registered if they are defined as new substances. Variable component substances, complex reaction products which have no unique and uncertain molecular structures, once they are new substances, also fall within the scope of registration. Polymers are not exempt from registration. Even if all monomers are listed in the IECSC, registration for polymers is required, when the polymer itself is a new substance.

Subject to different purposes and quantities of the substance, there are three registration types under MEE Order No.12:

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1 MEE Order No. 12 full legal text (in Chinese) <https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202005/t20200507_777913.html>

- Regular registration: For new substances manufactured or imported in PRC at or above 10 tonnes per year;
- Simplified registration: For new substances manufactured or imported in PRC between 1 and 10 tonnes per year;
- Record notification: For new substances manufactured or imported in PRC at less than 1 tonne per year (even if a new substance is used as a sample for some testing in a Chinese laboratory); Polymers with new monomer or reactant concentration ≤ 2% or Polymer of Low Concern (no tonnage limit).

2. China's Existing Chemical Substance Inventory: IECSC and its Supplements (2013-2023)

IECSC contains all existing substances manufactured, processed, sold, used or imported in China between 1st January 1992 and 15th October 2003 as well as new substances which were registered according to SEPA Order No. 17 or MEP Order No. 7 previously and five years have passed since their first production or import. By the end of 2023 IECSC contains 46,970 substances in total, in which more than 3,500 substances are marked as confidential.

In order to avoid unnecessary registration, before a substance is registered, it is recommended for the companies to check whether the substance is in the public part of IECSC; check whether the substance can be exempted from registration; and submit a formal inquiry to SCC of MEE for a full IECSC search under uncertainty.

At present, SCC solely accepts the inquiry submission through its own inquiry software, so it is necessary for the companies to download the specified software and submit the information as required. SCC charges 3,000 CNY (ca. 390 EUR) per substance for verifying whether a substance is identified as new substance. Once all required data for an inquiry is available, such as substance name, CAS number, molecular formula, structural formula etc., and the inquiry fee is paid, a confirmation letter will be usually issued by SCC within 14 days.

It should be noted that for inquiry SCC requires the companies to provide the molecular and structural formula of the inquired substance. 'When identifying a substance, it is necessary to refer to the molecular formula and structural formula to accurately determine whether the substance is the same as the substance in the IECSC, so as to determine whether the substance is a new chemical substance. In addition, SCC has taken strict confidentiality measures for each material submitted by the entrusting unit, and every member of SCC also strictly abides by the confidentiality regulations of SCC, so the entrusting unit does not have to worry about leaking secrets'.[2]

Public and supplementary substance information can be found on the MEE official website.[3] On 22nd January 2024 MEE published additional 7 substances, which are to be added in the IECSC.[4] Substances which are added to the IECSC are:

- Regular registration according to MEE Order No. 12: the substance will be added to the IECSC after five years from the date of first registration;
- Regular registration according MEP Order No. 7: as of 1st January 2021 - the implementation date of MEE Order No. 12 - , if the actual production or import of the substance is less than five years, it shall be added to the IECSC after five years from the date of the first production/import; if there is no actual production/import, the substance shall be added to the IECSC after five years from the implementation date of MEE Order No. 12;
- Regular registration according to SEPA Order No. 17: the substance shall be added to the IECSC within six months from the implementation date of MEE Order No. 12.

Only regularly registered substances can be added to the IECSC. Substances that have been registered in the form of simplified registration and record notification cannot be included in the inventory.

Recommendation: regularly track regulatory changes, guidance and IECSC updates to find out

2 See <https://www.meescc.cn/ggzc/bszn/hxwzjspb/201404/t20140403_594914.shtml>

3 IECSC (2013) <https://www.mee.gov.cn/gkml/hbb/bgg/201301/t20130131_245810.htm>, IECSC (supplemental summary, 2016-2022) <https://www.meescc.cn/ggzc/bszn/xhxwzgl_20061/zgxy-hxwzml/202305/W020230508642542676612.pdf>, IECSC (supplements 2023) <https://www.mee.gov.cn/ywgz/gtfwyhxpgl/hx-phjgl/wzml/index.shtml>

4 See <https://www.mee.gov.cn/ywgz/gtfwyhxpgl/hx-phjgl/wzml/202401/W020240122357169692500.pdf>

Table 1: IECSC and its supplements (2013-2023)

Supplements	Publication Date	Number of the Substances
	Jan. 2013	45,612
1	Mar. 2016	31
2	Nov. 2018	45
3	Jan. 2019	28
4	Jan. 2020	47
5	May 2020	156
6	Oct. 2020	28
7	Dec. 2020	238
8	Apr. 2021	204
9	Apr. 2021	115
10	Jun. 2021	255
11	Jul. 2021	8
12	Aug. 2021	15
13	Oct. 2021	23
14	Dec. 2021	11
15	Mar. 2022	18
16	Jul. 2022	22
17	Dec. 2022	42
18	Jun. 2023	43
19	Dec. 2023	29
Supplement 1-19		1,358
Total (2013-2023)		46,970

Table 1 illustrates IECSC and its supplements between 2013 and 2023.

which obligations a substance is expected to comply with MEE Order No. 12.

3. Applicants for the Registration and CBI Concerns for Non-Chinese Companies

Applicants for registration are: manufacturers or importers of new substances in PRC, i.e. enterprises or public institutions registered within the territory of PRC who bear independent legal liabilities; oversea companies (incl. companies from Hong Kong, Macao and Taiwan) who directly export new substances to PRC. They can be manufacturer, formulator, or distributor; and companies (processing user) who intend to apply for new uses registration or to change the registered uses of the products managed by other laws and regulations to other industrial uses. A non-Chinese company that intends to export a new substance to PRC has two options to complete the registration:

(a) request a Chinese importer to register the substance; or
(b) entrust a qualified Chinese agent by mutual agreement to register the substance. The role of the Chinese agent is similar to the role of 'Only Representative' under EU REACH. Non-Chinese company shall jointly perform the registration and obligations after registration, as well as bear liabilities according to MEE Order No.12.

Only an applicant can be the holder of a registration certificate. In case that a non-Chinese company entrusts a Chinese agent to register a new substance, the non-Chinese company holds the registration certificate.

It needs to be emphasised that only non-Chinese companies that directly export new substances to PRC can entrust qualified Chinese agents, even if they are non-Chinese distributors. In the event that a new substance will be involved in indirect export into PRC, which means the new substance as such or in mixture will be sold by non-Chinese manufacturer or non-Chinese formulator to non-Chinese distributor first and subsequently be exported by the latter to Chinese importer, only the non-Chinese distributor can entrust a Chinese agent to submit a registration for the new substance, not the non-Chinese manufacturer or formulator.

How can non-Chinese manufacturer/formulator keep Confidential Business Information (CBI) of their new substances in case that non-Chinese distributor and its Chinese agent, or Chinese importer

Table 2: Results of CBI protection requests for chemical name

Registration Type	Results of CBI Protection Requests	
	Rejection	Approval
Regular Registration	It is possible that CBI application will be rejected by the authority.	CBI application is approved by the authority: Generic name will be displayed on the registration certificate; Instead of chemical name, generic name will be disclosed on the official website.
Simplified Registration	It is possible that CBI application will be rejected by the authority.	CBI application is approved by the authority: Generic name will be displayed on the registration certificate; Instead of chemical name, generic name will be disclosed on the official website.
Record Notification	CBI application won't be rejected.	Generic name will be displayed on the receipt. Chemical name will not be disclosed on the official website (even without CBI application).

will be the registrant? Acting as Third Party non-Chinese manufacturer/formulator can submit confidential data of the new substance to SCC via official system directly, after they sign a Non-Disclosure Agreement (NDA) with SCC for third party data submission separately.

a. CBI protection requests

In general, the guidance document of MEE Order No. 12 describes the following information protection applications: Where applicants request CBI protection for trade secrets, they shall do so when they are applying for the simplified/regulator registration or record notification accordingly. The columns in the registration application or record notification forms which allow the applicants' information protection are provided with corresponding check boxes. When information protection is required, applicants should check the corresponding fields. Fields that do not tick the box must not be required for information protection. If applicants submit the application materials but do not submit a column for the application for information protection, they cannot apply for information protection in the future.

If information of a chemical name is applied for protection, applicants shall provide alternative information, such as the class name of the chemical substance. The compilation of class names should refer to the requirements of the Guidelines for the Preparation of Class Names for the Declaration of New Chemical Substances; be based on the names of new chemical substances; should not violate the chemical categories reflected in the names of new chemical substances; should not cover up the chemical characteristics or basic structure reflected in the names of new chemical substances as much as possible.

The term of protection of identification information such as the name of a chemical substance shall not exceed five years from the date of first registration or record notification. The validity period of other information protection shall be from the date on which the application for information protection is approved to the date on which the applicant applies to withdraw the information protection request, or the relevant information is disclosed by the competent department of ecology and environment under the State Council in accordance with law, because it may have a major impact on the environment or health and public interests. The extension application shall not exceed another five years.

If applicants for simplified/regular registration intend to apply for the protection of chemical substance identification information (including Chinese and English names, CAS numbers, molecular and structural formulas, etc.), they shall submit materials explaining the necessity of information protection. Ap-

plicants for record notification are exempted from submitting materials explaining the necessity of information protection.

The material on the necessity of information protection should include:

- A statement of the application for information protection, stating whether the information for protection is the applicant's trade secret, and whether the information does not belong to the content required by other laws and regulations of the People's Republic of China for information disclosure;
- The specific information column for which information protection is applied and the corresponding protection period;
- An indication of whether it is known to the public;
- A statement of whether the information for protection is of commercial value;
- Whether the applicant has taken and will continue to implement relevant measures to prevent the information applied for protection from being leaked and provides the specific content of the relevant measures.

The possible results after applicants submitted their CBI protection requests for chemical name of a new substance in simplified/regular registration or record notification can be seen in Table 2.

Recommendation: before submitting registration, applicants should evaluate the necessities of CBI protection request: which information needs to be kept confidential and what is the CBI value? What to do if an application for CBI protection request is denied by the authority and whether there are alternatives?

4. Special Provisions for Polymers: Polymer Record Notification

Polymer record notification is applicable to two types of polymers: (a) Polymer containing ≤ 2% monomer or reactant which is identified as new substance and (b) Polymer of Low Concern (PLC). For the purposes of this definition, such polymer (a) shall refer to:

- Polymer itself is not in the IECSC, but the percentage of all monomers or reactants identified as new substances is less than or equal to 2%; or
- Polymer itself is not in the IECSC, but all monomers/reactants are included in the IECSC.

Polymers of low concern are those that meet one of the following conditions:

- The average molecular weight of the polymer is between 1,000 and 10,000. The molecular weight is less than 500 of oligomers containing less than 10% and oligomers with molecular weights less than 1,000 containing less than 25%. At the same time, it shall not contain highly concerned or highly reactive functional groups, such as heavy metals, cyano (except non-conjugated), acrylates, aziridine, isocyanates (except for the end-capped isocyanates), thioisocyanates, vinyl sulfones, alkoxysilanes (alkyl is methyl or ethyl base), amines, spiroleamines, halosilanes, hydrazine, α/β lactones, methacrylates, etc.;
- The numerically average molecular weight of the polymer is greater than or equal to 10,000. The molecular weight is less than 500. The oligomer content is less than 2% and the oligomer content is less than 5% with a molecular weight of less than 1,000;
- It is a polyester polymer. Polyester polymer refers to a polymer whose backbone is a monomer bonded by ester bonds, or a polymer whose backbone presents the characteristics of ester bond linkage.

Once the conditions above are met, applicants can submit SCC record notifications for their polymers (no tonnage limit!).

a. Material requirements for polymer record notification

For polymer record notification, except the material specified in Table 3, the following information should be provided by the applicant for the polymer characterisation:

- List of monomers/reactants, including the chemical name of the monomer/reactant, CAS number, content (feed weight ratio/weight percentage), and indication whether the monomer/reactant has been included in the IECSC; and
- Molecular weight profiles, including Gel Permeation Chromatograms (GPC) or other results to characterize the molecular weight of polymers and their distribution, such as weight-average molecu-

Tabel 3: Registration type and application materials

Registration Type	Record Notification	Simplified Registration	Regular Registration
Scope of Application	Q < 1 t/a; Polymer containing ≤ 2% of monomer/reactant which is identified as new substance or polymer of low concern (PLC), no tonnage limit	1 t/a ≤ Q <10 t/a	Q ≥ 10 t/a
Application Materials			
Application form	x	x	x
Appendixes to the application form	x	x	x
Legal person certificate/business license, representation contract/agreement, authorisation letter	x	x	x
List of monomers/reactants, plot of molecular weight distribution, mechanism of polymerisation, materials illustrating that substances in question are not polymers which are subject to regular or simplified registration	x (for Polymer containing ≤ 2% monomer/reactant which is identified as new substance; PLC)		
Other known information on the characteristics of environmental and health hazards and environmental risks of new substances	x	x	x
Testing report or data/materials		x	x
Qualification certificate of the testing institutions		x	x
Materials stating the necessity of information protection		x	x
Letter of commitment for implementing/transmitting risk control measures and environmental management requirements		x	x
Conclusions incl. basis on the persistence, bioaccumulation and toxicity of new substance		x	
Environmental risk assessment report			x
Socio-economic benefit analysis report (for highly hazardous new chemicals–fnref:6–)			x

Summary of the approximate registration time required for different registration types.

lar weight, number-average molecular weight, molecular weight distribution, etc. Molecular weight and molecular weight profiles are essential information to determine whether a substance

Table 4: Estimated registration timeline

Type	Regular Registration (Q ≥ 10 t/a)	Simplified Registration (1 t/a ≤ Q <10 t/a)	Record Notification (Q < 1 t/a)
Test	Physicochemical properties, toxicity and ecotoxicity will be required, depending on the hazardous properties of the substance. Test: ca. 7-36 months	Applicants need to provide physicochemical properties and data for ecotoxicity, based on persistent, bioaccumulative and toxic (PBT) properties of the substance. Toxicity data is not required. Test: ca. 4-16 months	Only known risk/ hazard data need to be submitted. No test is required.
Registration	ca. 7-12 months	ca. 3-6 months	ca. 2-4 weeks
SCC review	5 working days	5 working days	Random check
Technical Review by Expert Committee	60 days	30 days	-
Correction, if required	6 months (one submission)	6 months (one submission)	Not specified
MEE Approval	30 working days	30 working days	-
Public Consultation	at least 3 working days	at least 3 working days	-
Public Notice	20 working days	20 working days	Periodically

Summary of the approximate registration time required for different registration types.

meets the definition of a polymer or whether it is a polymer of low concern; and
- The mechanism of polymerisation reaction includes a general description of the monomer, process, conditions and mechanism of polymerisation reaction in words or diagrams; and
- Materials indicating that the substance does not fall under the cases where polymer record notification does not apply.

b. Cases where polymer record notification does not apply

Polymers that meet one of the following conditions shall be registered in regular or simplified form. A polymer record notification in such cases is not possible:

- Cationic polymers or those that are expected to become cationic polymers (e.g., polymers containing amine groups, isocyanates, etc.) in a natural aqueous environment;
- Degraded or unstable polymers, including those that are easily degraded, decomposed, depolymerised, and those that decompose after production or use. Degradation, decomposition, or depolymerisation refers to the chemical changes that cause polymers to be broken down into simpler, smaller molecular weight substances by the effects of oxidation, hydrolysis, heat, light, solvents, or microorganisms;
- Absorbent polymers with an average molecular weight of 10,000 or more. Absorbent polymers are polymers that are capable of absorbing their own weight of water, excluding polymers that are soluble in water and polymers that are dispersed in water (including self-dispersed or dispersed);
- Fluoropolymers containing perfluoroalkyl sulfonic acid, perfluoroalkyl carboxylic acid or fluorotelomer structural fragments in their structure,

Table 5: Statistics on registration (2021-03.2024)

Registration Type	New Substance Registration Amount according to MEE Order No. 12			
	2021	2022	2023	2024
Regular registration	1	18	42	25 (29.02)
Simplified registration	38	179	199	37 (19.03)
Record notification	7,010	5,473	Jan.-Jun.: 3,069 Jul.-Dec.: still being counted	still being counted

Registration amount between 2021 and March 2024.

and fluoropolymers containing perfluoroalkyl structural fragments covalently bonded to carbon or sulfur atoms in the polymer molecule;
- In addition to impurities, polymer contains elements other than the following permissible elements: The polymer component must contain at least two elements of carbon, hydrogen, nitrogen, oxygen, sulfur, or silicon (C, H, N, O, S, or Si). Additional elements: fluorine, chlorine, bromine and iodine covalently bound to carbon (F, Cl, Br and I), as well as chloride, bromide and iodide in single-ion form (Cl-, Br- and I-). Other permissible single-ionic elements are sodium, magnesium, aluminum, potassium and calcium (Na+, Mg+2, Al+3, K+ and Ca+2), as well as elements such as lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin and zirconium (Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn and Zr) with less than 0.20% by weight.

Nevertheless, if a polymer meets the following three conditions at the same time, health toxicology, ecotoxicology data and environmental risk assessment reports are not required for simplified and regular registration:

- The structure of the polymer does not contain metals other than sodium, magnesium, potassium, calcium; and
- The polymer is insoluble in water, lipophilic solvents (n-octanol, n-heptane) and general solvents (tetrahydrofuran, dimethylformamide); and
- The polymer is stable under acid-base conditions, i.e. stability tests at pH 4.0, 7.0, 9.0 and 1.2 (if physiologically important) show stability.

II. Updates on Hazardous Chemicals (HazChem) Registration in China

1. Overview of HazChem Registration

The Measures for the Administration of Registration of Hazardous Chemicals were promulgated by Order No. 53 of the State Administration of Work Safety (SAWS) on 1st July 2012 and have been in force since 1st August 2012. According to the new measures – China SAWS Order No. 53[5] – manufacturers and importers in China shall register their hazardous chemicals with the National Registration Center of Chemicals (NRCC) of SAWS prior to their manufacturing and importation.

a. Scope of HazChem registration

According to Articles 2 and Article 21 of SAWS Order No. 53, there are two types of chemicals that need to be registered:

- Chemicals listed in the 'Catalogue of Hazardous Chemicals (2015)';
- Chemicals that are not listed in the 'Catalogue of Hazardous Chemicals (2015)' but have been identified as hazardous chemicals according to China GHS.[6]

5 SAWS Order No. 53 full legal text (Chinese) under <https://www.gov.cn/gongbao/content/2012/content_2251664.htm>

6 The Catalogue of Hazardous Chemicals (2015) can be found on the official website: <https://www.mem.gov.cn/gk/gwgg/xgxywj/wxhxp_228/201503/W020200317436190600087.pdf>

b. What needs to be registered is the chemicals as a whole: both substances and mixtures are subject to registration

In the case that a chemical product (formulation) contains some ingredient listed in the 'Catalogue of Hazardous Chemicals (2015)' but the product itself is not classified as hazardous according to China GHS (concentration of the ingredient in the product is below cut-off value), a registration is not required for the product (formulation).

In the case that a Chinese company intends to manufacture or import diverse hazards chemicals (formulations) contain some same hazardous substance, the manufacturer/importer needs to register each hazardous chemical (formulation) separately.

c. Who shall register hazardous chemicals under SAWS Order No. 53?

Companies in China who manufacture or import hazardous chemicals shall register. Non-Chinese companies who export hazardous chemicals to China cannot register but can complete the registration through their Chinese importers. For protection of CBI of hazardous chemicals (e.g. recipe information), non-Chinese companies can let an independent third party in China submit a HazChem registration, on behalf of their Chinese importers, if the Chinese importers agree.

d. Materials required for HazChem registration

- Legal entity information: Registrant shall upload a scanned copy of the registration form of the hazardous chemicals manufacturer (or importer) in the "Enterprise Information - Electronic File" in the hazardous chemicals registration system. Registrant shall be responsible for the legality, authenticity and validity of the information reported;
- Composition information of hazardous chemicals: name, CAS number, content etc.;
- Classification and labeling information according to China GHS: hazard categories, pictograms, warning words, hazard descriptions, precautionary instructions of hazardous chemicals;
- Physical and chemical properties: appearance, solubility, melting point, boiling point, flash point, explosion limit, auto-ignition temperature, decomposition temperature etc.;
- Main uses: lawful uses, prohibited or restricted uses of the products recommended by the enterprise;
- Hazard properties: physical hazards, environmental hazards and toxicological characteristics of hazardous chemicals;
- Safety requirements for storage, use and transportation: safety requirements for storage include the requirements for building conditions, warehouse conditions, safety conditions, environmental sanitation conditions, temperature and humidity conditions, the safety requirements for use include the operating conditions during use, protective measures for operators, hazard control measures at the use site, etc., and the safety requirements for transportation include requirements for transportation or transportation methods, means of transmission of hazard information to relevant transportation personnel, safety measures in the process of loading and unloading and transportation;
- Emergency responses: measures for dangerous situations including emergency treatment methods for chemical accidents such as fire, explosion, leakage, poisoning, suffocation, and burns in the process of production, use, storage, and transportation of hazardous chemicals. 24h emergency contact number is required;
- Safety Data Sheet (SDS) and labels according to China GHS.

All materials need to be submitted online and no paper materials are required.[7]

2. QR Code for Hazardous Chemicals

The hazardous chemicals safety information code (hereinafter referred to as QR code) is a two-dimensional code symbol composed of the registration number or serial number of hazardous chemicals, unit identification code, query URL, information of the hazard characteristics and safe disposal of hazardous chemicals. Each hazardous chemical produced and imported by each enterprise corresponds to a unique safety information code.

7 HazChem registration system login: <https://whpdj.mem.gov.cn/#/login>

China introduced 'one enterprise, one chemical product, one QR code' rule for hazardous chemicals in 2021 and launched therefore new Hazardous Chemicals Registration Comprehensive Service System on 16th February 2022 to enable the automatic generation of QR code for registered hazardous chemicals. After HazChem registration, the system will automatically generate a QR code for produced and imported hazardous chemicals. If necessary, registrant can edit the content of QR code and generate a new one. The purpose of implementing the management of "one enterprise, one product, one code" is to strengthen the identification and control of safety risks and strictly prevent accidents.

This QR code system will be successively implemented nationwide. The first pilot project regarding QR code system started in Guangdong province in 2021, subsequently in 2022 in Jiangsu and Shangdong provinces, later in different provinces/municipalities such as Shanghai, Zhejiang, Fujian, Beijing, Hebei, Sichuan, Shanxi, Shaanxi, Yunnan etc., and it is expected to be rolled out nationwide. The current implementation varies from region to region, which is related to the requirements of local customs and authorities.

a. Requirements for QR code:

- The QR code composes of registration number or serial number of hazardous chemicals, unit identification code, query URL and information of the hazard characteristics as well as safe disposal of hazardous chemicals;
- Each hazardous chemical produced and imported by each enterprise corresponds to a unique safety information code;
- The QR Code should be set in the blank space in the lower right corner of the chemical safety label. If there is no space to affix the QR code in the blank space in the lower right corner of the chemical safety label, during the pilot period, the enterprise can choose to add it in the blank space of the chemical safety label;
- The QR code on the chemical safety label of the same product of the same company should be fixed in the same place;
- The quality level of QR code printing should at least meet the requirements of GB/T 23704-2017 level 2.0. The printed QR code symbol should not be easy to deform and be damaged, and can follow the chemical safety label to achieve the whole process of circulation;
- The size of the QR code symbol should be determined according to the size of the chemical safety label, which is generally not less than the size of the pictogram in the chemical safety label. In general, the short side of the QR code symbol should not be less than 1 cm;
- Imported hazardous chemical products should be printed with a QR code in the blank space in the lower right corner of the chemical safety label or after integrating the QR code into the chemical safety label before the product enters China customs. If there are special circumstances that cannot be completed before entering customs, the QR code should be added before the product enters the Chinese market.

Recommendation: companies shall focus on the notice of the region where they are located on the implementation of QR code and keep in touch with parties within the supply chain for the latest information.

Strictly Controlled Closed Systems: A Heat Transfer Restriction Proposal Case Study

*Joshua Baptist, Mathias Schopf and Francisco Hernandez**

The purpose of this paper is to introduce a newly proposed operating principle for the heat transfer use sector, which originates in an ECHA restriction proposal on partially hydrogenated terphenyls.[1] *Heat transfer fluids are substances that enable processes to maintain desired temperature ranges accurately and are used in nearly every manufacturing sector. Heat transfer fluids achieve this through their thermal stability properties, and when operated in a closed system, can provide manufacturing processes with years of function with little maintenance. A new operating principle focused on this theme of closed system operation is called Strictly Controlled Closed Systems (SCCS). The SCCS will serve to standardise safe operation of heat transfer systems in the European Union by limiting exposures to workers and releases to the environment. The SCCS is a combination of several safety standards, principles, and guidelines from inside and outside the heat transfer use sector. This combination of resources has resulted in a novel inspection checklist that should aid in industrial compliance and review of enforcement agencies. In addition, SCCS should provide a regulatory path for hazardous heat transfer fluids to follow as a class. SCCS will allow even hazardous heat transfer fluids to have cradle-to-the-grave standardised management aimed at minimisation of environmental and human exposures. It is our expectation that adoption of this standard will be a role model to ensure the continued use of important chemistries in applications and manufacturing that drive the EU economy.*

I. Motivation

This new operating principle is an adapted approach from the combination of various industrial sector's legislations, guidelines, and standards that aim to ensure safe and tightly operated heat transfer systems. This combination of rules, with existing operating principles in the heat transfer industry, has produced the Strictly Controlled Closed Systems (SCCS) approach. Compliance with this concept is important to protect employees and the environment from exposure to hazardous substances. SCCS may become an integral part of future restriction proposals and will likely be mandatory for the uses addressed by these restrictions. It is important to consider that SCCS could find broader applications in other substances to ensure achievement of high safety standards in other industrial applications.

II. Regulatory Background

According to the REACH guidance for identification of substances, Terphenyl, hydrogenated (PHT)

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1 Available at <https://echa.europa.eu/documents/10162/8445876d-1fc6-dac4-7b12-d798c2afea43> accessed 12 March 2024.

is an Unknown or Variable composition, Complex reaction product or Biological origin (UVCB) substance that is not manufactured within the EU, but imported into the EU as a substance, substance in mixtures and articles. The main use of this substance is as a Heat Transfer Fluid (HTF), involving around 90% of the imported volume. The remaining 10% of its use is in other applications, such as an additive in plastics, sealants, adhesives, and coatings, solvent/process medium, and laboratory chemicals.

PHT has been under regulatory scrutiny by European authorities since 2017, when the Finnish Member State Competent Authority (MSCA), the Finnish Safety and Chemicals Agency (Tukes), published a Risk Management Option Analysis (RMOA) on this substance.[2] According to Tukes, the substance fulfils the REACH Annex XIII criteria based on its Persistent, Bioaccumulative, and Toxic (PBT) as well as its very Persistent and very Bioaccumulative (vPvB) properties. However, because it was not treated as a PBT/vPvB substance, further environmental Risk Management Measures (RMM) were determined to be necessary.

As a result, Tukes recommended the inclusion of PHT as a Substance of Very High Concern (SVHC) in the REACH Candidate List[3] followed by the inclusion of the substance in REACH Annex XIV, or the Authorisation List. PHT was included on the Candidate List for authorisation in 2018 following Tukes' recommendation.

Tukes conducted another RMOA[4] on the two alternatives for PHT in the heat transfer use, dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene. During the development of this RMOA, a functional grouping concept for high temperature, non-pressurised heat transfer fluids was presented at the EU's Risk Management and Evaluation platform (RiME+) meeting in February 2019. Consultation with other Member States and Registrant(s) was arranged in December 2019 and January 2020, respectively.

The RMOA was consequently published in 2020 and concluded a few things. First, that these alternative substances could have similar PBT/vPvB properties as PHT. Therefore, to avoid regrettable substitution of PHT, the PBT/vPvB properties of the alternatives should be clarified via additional testing and evaluation. If the alternative fluids were determined to be PBT/vPvB substances, then for consistency reasons, SVHC identification would be the first RMM option to be considered. Second, the likelihood of the alternative's exposure to the environment cannot be overruled.[5] This fact, combined with the PBT/vPvB status of these substances, could be considered as an unacceptable risk to the environment. This determination resulted in a need to have input from all stakeholders. Following the stakeholder input, Tukes proposed that restriction was an adequate RMM, not only for the alternative substances, but for PHT as well.[6]

Considering these conclusions, PHT was included in the Restrictions Roadmap under the Chemicals Strategy for Sustainability, issued by the European Commission in 2022. The drafting of the restriction proposal was assigned to the Italian MSCA. The restriction proposal was submitted in April 2022 and a public consultation was opened for six months.

The input received from manufacturers and downstream users of the substance was considered by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), which published its draft opinion in March 2023.

The public consultation on the draft opinion of the Committee for Socio-Economic Analysis (SEAC) of ECHA, also published in March 2023, was consequently launched. The compiled final opinion of both committees was published in June 2023, and it is now under discussion in the European Commission. The main point of the restriction proposal is the following:

> Terphenyl, hydrogenated will be restricted to heat transfer use. Only systems that operate according to the new guidance document, Strictly Controlled Closed Systems (SCCS), will be allowed to use ter-

2 Available at <https://echa.europa.eu/documents/10162/1df6cc6a-8065-041d-bdc2-8204434e3d3d> accessed 12 March 2024.

3 Available at <https://echa.europa.eu/documents/10162/fb7a9167-7d65-dd4c-2aa2-b8182d4a8e37> accessed 12 March 2024.

4 Available at <https://echa.europa.eu/documents/10162/333ab3aef376-1fb2-3cd7-25836138b020> accessed 12 March 2024.

5 Although the main use of these alternative substances as an HTF takes place in a closed-loop manufacturing system with limited discharges, exposure to the environment cannot be overruled, especially during loading operations, renewal, and disposal phases of HTFs.

6 Furthermore, a restriction has the advantage that it can be targeted at the uses posing a risk, something that cannot be managed through the authorisation process.

phenyl, hydrogenated.[7]

Under ECHA's Final Opinion[8], heat transfer systems operated in the EU will be obligated to abide by the new operational standards laid out in *Appendix 5 How to reach the Strictly Controlled Closed System (SCCS) condition in heat transfer systems using Terphenyl, hydrogenated as HTF*. In general, SCCS harmonises already established approaches for the safe operation of heat transfer systems and provide regulators with the comfort and knowledge that facilities using PHT will be protective of human and environmental health. The rest of this article will aim to provide high-level understanding of the implications of the proposed operational standard by detailing each of the included rules, standards, and guidelines that comprise the SCCS.

III. Legal and Technical Basis of the SCCS

The concept of SCCS was introduced by regulatory bodies into the discussion of the restriction proposal for PHT. Until this introduction, the term SCCS was not defined in the heat transfer sector. However, other existing industrial guidelines and standards (e.g. German DIN 4754) already refer to permanently technically tight systems when operating a HTF system and were combined with other standards to develop the SCCS. The following paragraphs will provide a quick overview on the different regulations, standards and guidelines referenced in SCCS. A summary of the standards discussed in this section are included in Table 1: Referenced Standards for SCCS.

1. Federal Institute for Occupational Safety and Health's Technical Rules for Hazardous Substances, Avoidance or Minimising Dangerous Explosive Mixtures

The Technical Rules for Hazardous Substances (TRGS) describe state-of-the-art technology as well as occupational procedures for working with hazardous substances in several industrial sectors. For example, while TRGS 722 deals specifically with measures to avoid or minimise the occurrence of explosive mixtures, the standard also highlights the importance of operations being conducted via a closed system. A distinction on emission likelihood is made for systems operating with hazardous substances. The systems are described as having permanent technical tightness, technical tightness, and system parts with emissions of combustible substances due to operational implications. For the concept of SCCS, the requirements of a permanently tight system are essential as they stipulate that no emissions are expected if the conditions of the TRGS are met.

2. German Social Accident Insurance Institution for Chemical Industry's Safety Considerations When Operating Heat Transfer Plants with Organic Heat Transfer Media

This document, published by the BG RCI, describes basic considerations for the design and inspection of a heat transfer system. It also includes a questionnaire to prompt operators on how to mitigate risks. The questionnaire is divided into sections to check for the location, equipment, HTF, fire hazard, and occupational safety and working procedures.

3. European Commission's Reference Document on Best Available Techniques (BREF) in the Production of Polymers

The Directive 2010/75/EU on industrial emissions, known as IPPC (Integrated Pollution Prevention and Control) Directive, aims to ensure a high level of protection for the environment by improving the management and control of industrial processes. To achieve this, operators should apply Best Available Practices (BAT) to take appropriate preventative measures against pollution. BATs are defined as '*the most effective and advanced stage in the development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing the basis for emission limit values and other permit conditions designed to prevent and, where that is not practicable, to reduce emissions and the impact on the environment as a whole*'. BATs are compiled in BAT Reference Documents (BREF) spe-

7 Terphenyl, hydrogenated is also derogated for 10 years for aerospace and defense applications in spare parts, maintenance, and repairs.

8 Available at <https://echa.europa.eu/documents/10162/d2bd9817-102b-f9b3-8023-a913678e849f> accessed 12 March 2024.

cific for each industrial sector. For example, the BREF to produce polymers, published by the European Commission in 2007, includes some BATs that have been considered by regulatory bodies in the definition of the SCCS.

4. DIN 4754-1:2015-03. Heat Transfer Installations Working with Organic Heat Transfer Fluids – Part 1: Safety Requirements, Test

The first editions of this German Standard date back to the 1980s. Because this is an essential industry standard that informs heat transfer operators on design, operation, and maintenance procedures, it has received regular reviews and updates. The most recent version, DIN 2015, includes additions around flow protection devices and level controllers. It is worth noting that the basic operating principles of a permanent technically tight system have not changed since the first editions of this standard. As such, it is reasonable to conclude that many heat transfer systems in the EU, and other regions, may already be operating within SCCS parameters.

5. NFPA 87, Standard for Fluid Heaters

This US standard describes minimum requirements for fluid heaters aimed at minimising the fire and explosion risk of the system. This standard includes requirements for design, material selection, location, inspections, and operation. An overarching goal of this standard is to ensure the minimisation of fluid loss from the heat transfer system.

6. European Union's Annex XVII to REACH – Conditions of restriction – Entry 74 - Diisocyanates, O =C=N-R-N = C=O, with R an Aliphatic or Aromatic Hydrocarbon Unit of Unspecified Length

This document was issued by ECHA in August 2020. It has been considered by regulatory bodies as a good example of how training requirements for workers managing a substance of concern are considered and detailed in a restriction. A non-exhaustive list of specific requirements for the training on HTFs has been defined in the SCCS and questions about training have been included in the checklist. The main reason for including this organisational measure in this new operating principle is to reinforce the training of workers to ensure that the production plant is permanently tight.

7. How to Comply with European Union's REACH Restriction 71, Guideline for Users of NMP (1-methyl-2-pyrrolidone)

This document, issued in July 2019, is very important in determining the scope of the SCCS. This document outlines a general RMM approach that can be applied to other different aprotic solvents in case similar REACH restrictions are introduced for them. Considering that the heat transfer system installations are similar across industry sectors, the SCCS approach should be considered in the restriction of other different HTFs.

8. European Chemicals Agency's Guidance on Intermediates & How to Assess Whether a Substance is Used as an Intermediate Under Strictly Controlled Conditions and How to Report the Information for the Intermediate Registration in IUCLID

While the SCCS concept is novel to the heat transfer sector, there are already similar concepts developed in European legislation. One example is the Strictly Controlled Conditions (SCC) concept that has been developed within the REACH Regulation for the management of intermediate substances. The concepts referenced for SCCS include the design of the heat transfer system installations (Guidance on intermediates) and the use of the substance (Practical Guide 16). Both concepts, SCC and SCCS, are because technical design is the key factor at achieving rigorous containment.

9. FM Global's Property Loss Prevention Data Sheets 7-99 – Heat Transfer Fluid Systems

FM Global is an insurance company offering their services world-wide. Based on their long history and engineering expertise they provide insights to help their customers to enhance the reliability and efficiency of their equipment. Their published engineering guidelines – called FM Global Property Loss Prevention Data Sheets – will help engineers to reduce the risk of property loss due to fire or failure of equipment. Like other standards and guidelines already mentioned, the underlying concept is to avoid releas-

es of combustible substances thereby mitigating fire risk and environmental exposure. Specific guidance to minimise these risks describes containment measures, functional testing of interlocks, operational procedures, training of operators, and HTF fluid testing.

10. Global Assess Protection Service's Guidelines on Organic & Synthetic Heat Transfer Fluids and Equipment

Global Asset Protection Services publishes guidelines to support their clients in constructing and operating a safe HTF system. Their guidelines focus on minimising the chances for unintentional release of potentially hazardous substances. Special emphasis is given to hazard analysis in relation to design and installation, operation and inspection, and maintenance requirements of a heat transfer system.

11. HDI Risk Consulting's Risk Engineering Guideline – Heat Transfer Oil Systems

This guideline describes preventive measures which minimise the risk of fire by eliminating potential sources for combustible fluid releases. While the specific recommendations are in-line with other standards and guidelines, such as DIN 4754 and NFPA 87, an important remark in the guideline is 'Safety does not last forever' and regular inspection, maintenance, and training is required to ensure rigorous containment.

12. Association of German Engineer's Heat Transfer Systems with Organic Heat Transfer Media – Operation, Maintenance, and Repair

The Association of German Engineers (VDI) publishes guidelines on various technical topics. These guidelines provide engineers with insight on the current standard of technology to support them in their day-to-day work. VDI 3033 has sections about HTF with details on chemical and physical properties as well as what role they play in safe operation of a heat transfer system. In addition, information about fundamental considerations for design and operation of HTF systems, maintenance, and repairs are detailed. There are also useful checklists to plan inspections and maintenance to ensure continued safe operation of the heat transfer system.

13. European Union's Directive 2014/68/EU – Pressure Equipment Directive

This European Directive covers pressure equipment placed on the EU market. Given this directive is applicable to all equipment with a maximum allowable pressure greater than 0,5 bar, and nearly all HTF systems have a forced fluid flow, any HTF system in the region must comply with the requirements. Depending on the fluid group – most HTFs are categorised as group 1 media as their maximum operating temperature is above the flash point of the fluid – more rigorous requirements are made to the testing of the suitability of the equipment. Testing has not only been done at construction and commissioning of the equipment but also as repetitive inspection, where the time interval depends on volume and pressure. In most cases, inspections must be done by an accredited inspection body.

14. European Union's Directive 2012/18/EU (Seveso) - Control of Major-accident Hazards Involving Dangerous Substances: European Parliament and Council

The Seveso directive aims to prevent and limit the consequences of industrial accidental releases for human health and the environment. The Seveso classification is based on two criteria: the presence of hazardous substances and their quantity. Hazardous substances under the Seveso Directive are identified in two ways: as a named list of specific substances, and more generally by hazard classifications under the CLP Regulation. Facilities covered by Seveso are also split into two categories: Lower and Upper tier. Lower-tier facilities have dangerous substances above a certain threshold set out in Annex I of the Directive, while Upper-tier facilities have dangerous substances above an even higher defined threshold. Upper-tier establishments have more obligations than Lower-tier ones, such as preparing a safety report and an internal emergency plan.

This Directive was enacted to prevent major accidents in chemical industrial sites, and to ensure appropriate preparedness and response should such accidents nevertheless happen. Therefore, it has been considered as a reference for the definition of the SCCS concept, especially concerning operational controls of the plants.

IV. Strictly Closed Controlled Operation of a Heat Transfer System

The SCCS principle defines the design, technical, and operational conditions to be met by an HTF system to ensure a high level of protection against emissions into the environment. According to the proposal for the PHT restriction, compliance with the SCCS principle will be mandatory for all existing and future heat transfer systems using PHT. This will be the only way to meet the derogation condition of the HTF use defined in that restriction.

These requirements are included in the current version of the restriction proposal under *Appendix V How to reach the Strictly Controlled Closed System (SCCS) condition in heat transfer systems using Terphenyl, hydrogenated.* The requirements of *Appendix V* are addressed to HTF users of PHT to provide practical advice and assist them in complying with their obligations under the HTF derogation of PHT. In addition, it is addressed to enforcement authorities to aid in their verification of compliance during inspections at sites operating heat transfer systems with PHT. New installations shall be designed and constructed, existing installations adapted, and all facilities operated following the technical requirements and operating procedures laid out in SCCS to ensure rigorous containment is achieved.

It is worth noting that this document does not define any exhaustive list of equipment or technical requirements. As stated in *Appendix V*, it is possible to deviate from the requirements if it can be demonstrated that the rigorous containment is otherwise fulfilled. Therefore, the technical procedures and equipment cited in the document should be considered as examples only. Appendix V defines conditions and requirements related to:

- Design and construction of:
  - The installation area
  - Vessels and tanks
  - Piping and piping parts
  - Pumps
  - Thermal insulation
  - Sampling points
  - Other technically leak-tight plant components
  - Control equipment and safety devices
- Fill and start-up (unloading and loading of the HTF)
- Operation and maintenance, including storage and top-up
- Dismantling, decommissioning and waste treatment
- Inspections and training

It is important to note that the SCCS principle does not only introduce technical conditions and requirements but also introduces operational and procedural requirements, such as training or inspection. This wide scope of the approach aims to ensure the technical tightness of the installation.

Appendix V also contains an inspection check list. This checklist informs the design of heat transfer systems as well as increase regulators ability to enforce the standard. The inspection checklist will be an extremely useful tool to audit compliance on-site, for both HTF users and enforcement authorities.

V. Conclusion

The purpose of proactively detailing this new standard to the broader market is to ensure that the heat transfer sector remains proactive in its designs and updates as the SCCS is eventually adopted. It is important to understand that expectations of all industry are increasing, and having measures in place to remain compliant now, and in the future, will be a critical component in remaining competitive. With the adoption of SCCS, it will be possible to have hazardous heat transfer fluids remain on the market and minimise exposure and release potential. It is our expectation that adoption of this standard will ensure the continued use of important chemistries in applications and manufacturing uses that drive the EU economy.

Appendix

Table 1: Referenced Standards for SCCS	
Referenced Standard or Guidance	Summary of Relevance to SCCS
BAUA 2022. TRGS 722. Technical Rules for Hazardous Substances, Avoidance or Minimizing dangerous explosive mixtures. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAUA),2022:	In general, the Technical Rules for Hazardous Substances (TRGS) describes state of the art technology as well as occupational procedures for working with hazardous substances in several industrial sectors. A distinction is made between permanently technical tightness, technical tightness, and system parts with emissions of combustible substances due to operational implications from the use of hazardous substances. For the concept of SCCS, the requirements of a permanently tight system are essential as they stipulate that no emissions are expected if the conditions of the TRGS are met.
BG RCI, 2022. Safety considerations when operating heat transfer plants with organic heat transfer media. German Social Accident Insurance Institution for Chemical Industry (BG RCI):	This document published by the BG RCI describes basic considerations for design and inspection as well as includes a questionnaire to mitigate risks associated with the operation of HTF systems.
COM 2007. Reference Document on Best Available Techniques (BREF) in the Production of Polymers. European Commission, August 2007.	The Directive 2010/75/EU on industrial emissions, known as IPPC (Integrated Pollution Prevention and Control) Directive, aims to ensure a high level of protection for the environment by improving the management and control of industrial processes.
DIN 2015. DIN 4754-1 Heat transfer installations working with organic heat transfer fluids –Part 1: Safety requirements, test. DIN, 2015:	This is an essential industry standard that informs heat transfer operators on design, operation, and maintenance procedures.
ECHA 2020. Annex XVII to REACH – Conditions of restriction – Entry 74 - Diisocyanates, O =C=N-R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length. European Chemicals Agency (ECHA), August 2020	The main reason for including this organizational measure in this new operating principle is to reinforce the technical (constructive and design) measures to ensure that the production plant is permanently tight.
ECHA 2019. How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl-2-pyrrolidone). European Chemicals Agency (ECHA), July 2019	Considering that the heat transfer system installations are similar across industry sectors, even if using other types of HTF different from PHT, the SCCS approach could be considered in the restriction of other different HTFs.
ECHA 2014. How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID. Practical Guide 16; European Chemicals Agency (ECHA), June 2014. & ECHA 2010. Guidance on intermediates. Version 2. European Chemicals Agency (ECHA),December 2010	An example of the Strictly Controlled Conditions (SCC) concept that has been developed within REACH Regulation for the management (manufacture and/or use) of intermediate substances. Although the intermediate substance definition is not applicable to HTFs, regulatory bodies have considered some of the SCC requirements regarding the design of the heat transfer system

	installations (Guidance on intermediates) and the use of the substance (Practical Guide 16) in the development of the SCCS concept.
FM Global 2022. Property Loss Prevention Data Sheets 7-99 Heat Transfer fluid systems. FM Global 2022:	FM Global engineering guidelines – called FM Global Property Loss Prevention Data Sheets – will help engineers to reduce the risk of property loss due to fire or failure of equipment. Specific guidance to minimize the risk describes containment measures, functional testing of interlocks, operational procedures, training of operators, and HTF fluid testing.
NFPA 87 - NFPA 87, Standard for Fluid Heaters, 2018:	This US standard describes minimum design, material selection, and inspection requirements for heater transfer systems to minimize fire and explosion risk.
GAP 2013. Guidelines Organic & Synthetic Heat Transfer Fluids and Equipment. Global Asset Protection Services, 2013:	Global Asset Protection Services publishes engineering guidelines to support operating a safe HTF system. Special emphasis is given to hazard analysis in relation to design, installation, operation, inspection, and maintenance requirements.
HDI 2016. Risk Engineering Guideline – Heat Transfer Oil Systems. HDI Risk Consulting GmbH, 2016:	The HDI guideline describes preventive measures which minimize the risk of fire by eliminating potential sources for combustible fluid releases. In particular, the guide is referring to DIN 4754 and NFPA 87.
VDI, 1995. VDI 3033. Heat transfer systems with organic heat transfer media – Operation, Maintenance, and repair. Verein Deutscher Ingenieure e.V. (VDI), 1995:	The VDI 3033 has sections about HTF discussing thermal stability, oxidation, and physical properties like viscosity and vapor pressure and their role in safe operation. There are also useful checklists to plan inspections and maintenance to operate the system safely.
European Directive 2014/68/EU – Pressure Equipment Directive:	The directive aims to prevent and limit the consequences of such accidents for human health and the environment. Some of the requirements defined in Directive 2012/18/EU (Seveso) have been considered by the regulatory bodies for the operation, storage, and maintenance of heat transfer system installations under SCCS conditions.

Inspection List

Table 2: Inspection Check List for Heat Transfer Systems designed to achieve the SCCS Condition

Requirements	Response		Remarks
	OK	Action required	

A. Installation and equipment			
Is the whole heat transfer system installed on a concrete (or equivalent) surface?			
Is the area under the heat transfer system designed to divert potential leakage and runoff to a safe location?			
Suitable equipment has been installed for this purpose (sloped floors, curbs, dikes, drainage systems, etc.)?			
Is potential leakage and runoff diverted to a closed containment system?			
Is potential leakage and runoff diverted to a waste treatment facility?			
Are vessels and tanks equipped with vents and/or expansion lines?			
Are vents and/or expansion lines routed into collection systems?			
Are vents and/or expansion lines connected to air pollution control equipment?			
Does the installation have calamity basin/tanks to control large accidental spills of PHT?			
Has the number of flanges in the piping lines been minimized to minimum technical requirements?			
Are there stop valves installed in the flow and return pipes?			
Has the suitability of the stop valves been proved (by manufacturer tests or an accredited expert)?			
Are the installed pumps prepared to contain leakages by themselves (magnetically driven, canned motor, double seals, liquid barrier, etc.)?			
If not, is it guaranteed that any leakage from the pumps will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Have the pump housings designed to withstand at least a maximum pressure of 16 bar?			
Has the suitability of the shaft seals been proved (by manufacturer tests or an accredited expert)?			
Is thermal insulation installed in such a way that leaks can be detected?			

Is the equipment for sampling points of PHT specially designed to contain leakages?			
Are all the other installed components (valves, flanges, seals, connections, etc.) prepared to contain leakages by themselves?			
If not, is it guaranteed that any leakage from them will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Are there control equipment and safety devices in place to ensure the safety of the system and the process?			

Requirements	Response		Remarks
	OK	Action Required	
B. Filling, start-up, shutdown, and drain of PHT			
Has the heat transfer system been provided with accessories to ensure the safe performance of these operations?			
Have start-ups and shutdowns been minimized according to the site-specific operations?			
Please, provide the number of start-ups and shutdowns from the last inspection.			
Are there operating instructions for start-up and shutdown?			
Are start-up and shutdown performed by qualified persons?			
Has the PHT completely drained (due to degradation) and filled from the last inspection?			
If so, were all the components (pumps, piping, connections, etc.) of the heat transfer system continuously monitored for leakages during these operations?			
Are there operating instructions for the complete drain and filling of PHT?			
Is the complete drain and filling of PHT performed by qualified persons?			
C. Operation of the heat transfer system			
Has an operating limit for pressure been established?			
Has any deviation from the pressure limit been detected since the last inspection?			

If yes, please specify how many pressure limit deviations have been detected and which values were reached.			
Has an operating limit for temperature been established?			
Has any deviation from the temperature limit been detected since the last inspection?			
If yes, please specify how many temperature limit deviations have been detected and which values were reached.			
Has an operating limit for PHT level been established?			
Has any deviation from the PHT level limit been detected since the last inspection?			
If yes, please specify how many PHT level limit deviations have been detected and which values were reached.			
Has an operating limit for flow rate been established?			
Has any deviation from the flow rate limit been detected since the last inspection?			
If yes, please specify how many flow rate limit deviations have been detected and which values were reached.			
Is there an operating manual for the heat transfer system?			
Are there operating instructions for the heat transfer system?			
Are there operating instructions for handling PHT?			
Are operating manual and operating instructions always available to the workers in a form and language they can understand?			
Requirements	Response		Remarks
	OK	Action Required	
D. Maintenance of the heat transfer system			
Is there a preventive maintenance plan in place?			
Are there operating instructions for maintenance and repair work?			
Is maintenance performed by qualified persons?			
Are control and safety devices checked for their effectiveness?			

Are all the openings in the installation (e.g., maintenance holes, instrument ports, etc.) included in the maintenance plan?			
Is the heat transfer system or parts of it tested for leakage detection?			
How is the heat transfer system or parts of it tested for leakage detection? Which tests are conducted (e.g., use of foaming agents, acoustic test, etc.)?			
Installation area			
Heater			
Vessels and tanks			
Vents and relief devices			
Piping and piping parts			
Pumps			
Thermal insulation			
Sampling points			
Valves			
Flanges			
Seals			
Connections			
Control equipment			
Safety devices			
Is the heat transfer system or parts of it checked visually during operation for leakage detection?			
Are these tests performed according to the procedures defined by the manufacturer or other accepted standards?			
If so, which ones are used?			
What are the time intervals of the tests for leakage detection?			
Is there a test book or written records about these tests?			
Is the heat transfer system or parts of it tested for leakage detection before the start-up, during the filling and drain of PHT, and after the shutdown of the operation?			

Is the heat transfer system or parts of it checked visually during these activities to detect leakages?			
Is the painting with wetting agents test (e.g., soap solution) performed during these activities to detect leakages?			
Is thermal insulation removed during these activities to facilitate the detection of leakages?			
Is the plant or parts of the plant tested for leakage detection after adaptations, maintenance, and repair?			
Are there operating instructions for the detection of leakages?			

Requirements	Response		Remarks
	OK	Action Required	
E. Maintenance of the heat transfer system (cont.)			
Are tests for leakage detection performed by qualified persons?			
Are leakages corrected promptly (regardless of how small they may be)?			
Are the leakages corrections of a permanent nature?			
Are leakages cleaned up immediately?			
Are there operating instructions for the elimination and cleaning of leakages?			
Is the elimination and cleaning of leakages performed by qualified persons?			
Is the oil-soaked thermal insulation promptly replaced and the cause of the leak corrected?			
Is PHT sampled and its quality controlled a minimum of once a year?			
Are there operating instructions for sampling of PHT?			
Is PHT sampling performed by qualified persons?			
Are there operating instructions for top-up of PHT?			
Is top-up of PHT performed by qualified persons?			
F. Dismantling/decommissioning and waste disposal			

How are the low boiling fractions disposed of?			
Vented, condensed, collected, and externally disposed of.			
Vented and internally incinerated.			
Is the drained PHT from the heat transfer fluid collected (vessels/tanks)?			
Is the sampled PHT collected (little containers)?			
Are spills removed using absorbent material?			
Has the heat transfer system or parts of it been dismantled after the last inspection?			
If so, was the heat transfer system emptied, flushed, rinsed, and cleaned prior to dismantling?			
Are the above-mentioned materials disposed of internally?			
If so, is the company officially authorized, holding a license for waste collection?			
Are the above-mentioned materials recycled as energy by internal incineration?			
Are the above-mentioned materials disposed of by external companies?			
If so, are these external companies officially authorized, holding a license for waste collection and transportation?			
Do the vehicles used for transportation meet the requirements laid down in ADR?			
Are the above-mentioned materials recycled as energy by authorized external incinerators?			
Is intermediate waste storage necessary?			
If so, are all the relevant legal provisions observed?			
Are there operating instructions for dismantling and waste disposal?			
Are dismantling and waste disposal performed by qualified persons?			

Requirements	Response		Remarks
	OK	Action Required	

G. Training			
Is there a general training plan in place?			
Are there specific training plans per job position/activity?			
Are the training needs of each job position evaluated and documented?			
Does the content of each specific training include adequate information about the hazards associated with the use of PHT?			
Does the content of each specific training include adequate information about the hazards associated with the use of the equipment?			
Does the content of each specific training include adequate information to avoid the release of PHT into the environment?			
Does each specific training comply with the provisions set by all the Legislation applicable to the job position/activity?			
Are the contents of each specific training recorded?			
Do the participants confirm by signature their participation in each specific training?			
Is the completion of each specific training documented?			
Is the effectiveness of each specific training evaluated?			
Has the periodicity of each specific training been defined?			
Has the training level of the subcontractors been evaluated?			
H. Inspection			
Has an inspection plan been defined for the heat transfer system?			
Are external inspections by third-party accredited inspectors required prior to start-up of the heat transfer system or parts of it?			
Are external inspections by third-party accredited inspectors required during operation of the heat transfer system or parts of it?			
If so, how often are these inspections conducted?			
Are internal inspections by trained and instructed site personnel performed on the heat transfer system or parts of it?			

If so, how often are these inspections conducted?			
Are the results of these inspections documented?			
Are the identified observations and deficiencies recorded and addressed?			
Result of the inspection			
After this inspection, can be considered the heat transfer system permanently technically tight (system achieving SCCS condition)?			
Members of the inspection team			
Date of the inspection			

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