REACH Implementation Projects (RIPs)

Introduction of RIP 3.8

Agenda

- Introduction of REACH Implementation Projects (RIPs)
- Introduction of RIP 3.8
  - Guidance on requirements for substances in articles
- ECHA news

Introduction of REACH Implementation Projects (RIPs)

- What is RIPS?
- RIPs are a REACH guidance documents
  - to provide supplementary information to the legal text
  - to cover all technical aspects of REACH
  - to be produced with the assistance and endorsement of the Member States authorities, the European Commission, NGOs and industry
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- Hence, companies and authorities should use the guidance documents as the primary source of information when they need advice on how to fulfill their REACH duties.

- Where can I get it?
- Download: http://reach.jrc.it/guidance_en.htm

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- The following Guidance Documents have been developed within RIPs:
  - Guidance mainly for Industry Use:
    - Guidance on registration (Updated on May 2008)
      - to describe when and how to register a substance under REACH
    - Guidance on pre-registration (Published on Sept. 2007)
      - to describe how to identify the substances that can be pre-registered

- Guidance for intermediates (updated on Feb. 2008)
  - to describe when and how the specific provisions for the registration of intermediates under REACH can be used
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- Guidance for monomers and polymers (Updated on May 2008)
  - to describe the specific provisions for polymers and monomers under REACH.

- Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD) (Updated on Feb. 2008)
  - to describe specific provisions under REACH for substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)

- Guidance on Classification and Labeling notification (Not available)
  - to describe when and how to notify a classification and labeling for a substance under REACH

- Guidance on requirements for substances in articles (Updated on May 2008)
  - to assist producers and importers of articles in identifying whether they have obligations under REACH; in particular in relation to registration and notification according to Article 7, and in relation to article supply chain communication according to Article 33.

- Guidance for Downstream Users (Updated Jan 2008)
  - to describe the roles and obligations of downstream users

- Guidance on the preparation of an application for authorization (Not available)
  - to describe how to prepare an application for authorization and also provides guidance on analysis of the alternatives and substitution plan

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• Legal Notice

This document contains guidance on REACH explaining the REACH obligations and how to fulfill them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.
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- Legal Notice
- RIPs are still an extremely useful and reliable information.
  - But...
  - ECHA can update it when they need
  - Guidance reference, but not a legal reference!!

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- No longer “RIP 3.8”
  - Guidance on requirements for substances in articles
- Published on 26 May 2008
- 118 pages

Who is this guidance for?

- This guidance document is addressed to producers, importers & suppliers of articles located in the EU as well as only representative of non-EU suppliers of articles.

Main Objectives:

- Assist article suppliers to fulfill
  1. registration,
  2. notification and/or
  3. communication requirements related to substances in their articles
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- Articles in REACH
- Pre-Registration

Do you remember?

Registration (for articles)

- Intended to be released?
  - Yes
  - Substance >= 1t/yr
    - Registration
  - Registration

- A Big Question!!
- How to define what substance is the “intended to be released”

Registration

- Articles
- Pre-Registration

Intended to be released under normal or reasonably foreseeable conditions of use (Art. 7) and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year.

Substances/preparations

- In a special containers or carriers
- Already a integral part of an article
Golden Rule to determine whether “Intentionally released”

- Is the function mainly to deliver a substance / preparation?

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Example 1 – Toner Cartridge

1. Would the cartridge be work if the toner was moved from it?
   - it would still be possible to bring it to paper, although with a loss of quality and convenience

2. What is the function of the cartridge?
   - its function is to hold the toner in place inside a printer and it controls the speed and mode of release

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Example 1 – Toner Cartridge

3. The cartridge is disposed of without the toner, which is consumed during the useful life of the cartridge

Conclusion:
- a toner cartridge is a special container containing a preparation
Example 2 – Firecracker

1. Would the chemicals (powder) still be capable in principle of carrying out the intended purpose if they were removed from the article?
   • It would still be possible to explode and make light effects, although with a loss of quality.

2. What is the function of the firecracker?
   • Its function is to bring the substances (chemicals) or their reaction products into the air.

Conclusion:
• A firecracker is a special container containing a preparation.

Example 3 – Wet wipes
Example 3 – Wet wipes

- Its function is to remove dirt from surfaces
  - the cleaning effect could generally be achieved by using the detergent (preparation)
  - However, if in doubt, the wipe alone would achieve the same result
- In this case it is considered that it would be easier to achieve the desired result with the preparation (e.g. water only)

Conclusion:
- cleaning wipes should in general be considered as a special carrier material containing a preparation.

Golden Rule to determine whether “Intentionally released”

- Is the function mainly to deliver a substance / preparation?
  - YES
  - Hence, it is substance/preparation in a container / carrier

Golden Rule to determine whether “Intended to be released”

- Is the chemical composition more relevant for the function than shape, surface and design?
  - OR
- Does the chemical content of the object contribute to an accessory function?
Example 4 – Scented eraser

- an rubber eraser consists of an elastic material and additive agents
- fragrance substances can also be added to provide an accessory function of a good smell.

Conclusion:
- the fragrance substances only fulfill their function if they can be inhaled and thus it is intended that they are released.

Example 5 – Fragranced T-shirt
Example 5 - Fragranced T-shirt

• an fragranced T-shirt consists of cotton material and fragrance substances can also be added to provide an accessory function.
• E.g. Screening for organic compound could be perform using e.g. GC-MS.

Conclusion:
- the fragrance substances only fulfill their function if they can be inhaled and thus it is intended to be released.

Example 6 - Panty Hose with Lotion

• Its function is to provide clothing.
  • Thus, panty hose is an Article whose main function is unrelated to the lotion.
  • In this case, lotion (i.e. skincare) is only an accessory
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Example 6 – Panty Hose with Lotion

• Conclusion:
  ➢ The Panty Hose with a Lotion should be regarded as an article with an intended released.

Golden Rule to determine whether “Intended to be released”

➢ Is the chemical composition more relevant for the function than shape, surface and design?
  ➢ Or
  ➢ Does the chemical content of the object contribute to an accessory function?
    • YES
    • Hence, it is an article with an intended released.

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BESIDE of Registration...

Notification is also very important!!

➢ If the Article is not listed under “Intended to be released”, Notification may be required for the substances contain in the articles.
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**Notification (for articles)**

- Intended to be released?
  - No
  - SVHC\(\geq 0.1\%\) w/w & substance\(\geq 10\) yr
  - Notification

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**Definition of SVHC (Substance of Very High Concern):**

- **CMR**
- **PBT**
  - Persistent, Bio-accumulative and Toxic
- **vPvB**
  - very Persistent and very Bio-accumulative

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**Example 7**

- **Thermometer**
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Example 7 – Thermometer

• Conclusion:
  ➢ thermometer (including the liquid it contains) should in general be considered as an Article containing with substance as integral parts (no intentionally release).

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Example 8 – Batteries

➢ Its function is to provide electric current.
  • The voltage is produced through a chemical reaction between two unlike materials, occurring simultaneously at two different electrodes.

• In this case, the electrolyte and the electrode active materials as such cannot provide any electric current outside the battery, thus, the container does not have a function of “delivering” it and does not control its release.

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Example 8 – Batteries

➢ Different types of batteries and some of them may not fulfill all criteria in the same way (i.e car batteries)
  • Shape and design can vary to a very large extent.

• However, the principle of functioning is the same, thus, Conclusion:
  ➢ The battery is an Article containing a preparation as an integral part (no intentionally release).
Example 9 – Automotive Tyres

- Tyres are polycyclic aromatic hydrocarbons (PAHs) contained in high aromatic (HA)
- It is a mixture of synthetic and natural rubbers, textile and metal reinforcing materials.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Persistent</th>
<th>Bioaccumulative</th>
<th>Carcinogenic (Cat. 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antanthrene</td>
<td>+</td>
<td>+</td>
<td>(+)</td>
</tr>
<tr>
<td>Benzo(a)anthracene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Benzo(a)pyrene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Benzo(b)fluoranthene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Benzo(e)pyrene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Benzo(g,h,i)perylene</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Dibenzo(a,h)anthracene</td>
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<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluoranthene</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Indeno (1,2,3-c,d)pyrene</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Pyrene</td>
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<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Benzo[j]fluoranthene</td>
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<td>+</td>
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<tr>
<td>Benzo[k]fluoranthene</td>
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<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Chrysene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

PAHs are complex “group” of substances and many of them are harmful to health and the environment.

Several of the individual PAHs contained in HA oils are classified as Category 2 carcinogens in the Community wide classification list.
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Example 9 – Automotive Tyres

• Conclusion

• Case 1: If the substance in the articles are listed as SVHC (> 0.1% (w/w)) and the total amount is over 1 tonne per year
  ➢ Notification and Communication is Needed

• Case 2: If the substance in the articles are listed as SVHC (> 0.1% (w/w)) but the total amount of articles produced or imported are NOT over 1 tonne per year
  ➢ Communication is Needed Only

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  ➢ Guidance on requirements for substances in articles

• ECHA news

ECHA News

22/07/2008
REACH-IT Bulk Pre-Registration

Functionality now available

The bulk pre-registration functionality is now available in REACH-IT. It allows companies to submit pre-registration files for substances listed in EINECS. Companies may take preparatory steps outside the REACH-IT system and submit the files in an XML format specified by ECHA. Full compliance with the specified format is essential for all submitted bulk files to ensure their correct processing in the REACH-IT system.

• The bulk pre-registration functionality is now available in REACH-IT. It allows companies to submit pre-registration files for substances listed in EINECS.
  • The new functionality was launched and it will allow companies pre-registering substances to submit a file covering up to 500 substances listed in EINECS.
ECHA News

• Data Submission Manual 6: Submission of Bulk Pre-registrations

July 22, 2008

ECHA News

• ECHA announced that the correction of Annex IV and V has been made. Additional substances had added in the list for exemptions from the Obligation to register in accordance with article 2(7)(a) and 2(7)(b).

ECHA News

01/09/2008
First ECHA newsletter is available

ECHA Newsletter, the bimonthly newsletter of the European Chemicals Agency, provides regular information on the Agency’s activities as well as lively stories and pictures of daily life within ECHA. The newsletter aims at developing yet another channel of dialogue with the stakeholders and providing information for the general public. It also plays an important role in supporting the Agency’s overall quest for openness and transparency.

• Pre-registration
  – 4,627 Companies signed up in REACH-IT
  – 32,191 pre-registrations had created
  – 13,883 substances was listed

• ECHA Helpdesk
  – 3,733 questions received at the ECHA Helpdesk

Conclusion

➢ Guidance on Requirements for Substances in Articles

• Clear definition/identification and examples of:
  1. substance/preparations in special containers / on special carrier materials
  2. substances intended to be released from articles
  3. substances/preparations being (integral) parts of an articles. (Notification and Communication)
Conclusion

- Determination and Calculation on SVHC and volume of substances/preparations in articles per year
- Checking whether a substance in an article has been Registered: IUCLID 5, Only Representative, Substance Information Exchange Forum (SIEF)