

A thought starter on how to better regulate professional users border-lining with industrial and consumer users under REACH restriction (Restriction Task Force¹)

1. Aim

The aim of this paper is to:

1. Help Dossier Submitters and RAC to define the approach for adequate protection of professional users from exposure to chemicals, in a restriction under REACH and
2. Reflect on the most appropriate risk management measures and operating conditions or best ways to deal with professional user (border-lining with industrial and consumer users) in Annex XV restriction proposals.

2. Background

When considering if a restriction under REACH is needed, Dossier Submitters (DSs) analyse the RMOs available to address the substance(s) of concern. This can involve questioning whether the OELs (European values) are protective enough for industrial and professional users or whether a REACH restriction is a more appropriate regulatory risk management measure. When the latter is the case, the DS can propose specific risk management measures to limit the exposure of employees and self-employees to the substance of concern. It is important for the DS to be able to distinguish professional, industrial and consumer uses from each other, so that the DS is able to define, in the conditions of a restriction proposal, whether for example different concentration limits of the substance/mixture or risk management measures or a combination of both should apply to those uses specifically.

The above has been noted during discussions of the Restriction Task Force (RTF). This paper was discussed at its meetings on the 30-31 January 2020 and on 29 September 2020 and also includes comments received from Competent Authorities and Stakeholders from the CARACAL-34 webex meeting.

3. Industrial and professional uses according to REACH

There is no definition of industrial and professional use in REACH i.e. in Title 1 chapter II, but there are references to the two types of use in its definitions 13, 25 and 35, as well as in section 6 of Annex VI. In Annex XVII, also, the terms "industrial installation" and activity of a "professional outside industrial installations" are mentioned.

The terms industrial, professional and domestic have been used in the restriction entries 46 and 59 of Annex XVII to REACH, in particular when the legislators wanted to make a

¹ This paper was developed by the Restriction Task Force, consisting of representatives from Member State Restriction Dossier Submitters, ECHA's Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC) members and secretariat, and the Commission (DG ENV and DG GROW). It was sent for information to the CARACAL-37 meeting on 17 November 2020.

differentiation between the exposure to chemicals during these different uses by addressing different activities.

When looking at the way the terms “industrial” and “professional” are used in REACH, two different contexts can be seen:

- Differentiating between lifecycle stages in the use of a substance;
- Defining the level of occupational health and safety management systems applied in companies.

4. Examples

ECHA’s Guidance on Information Requirements and Chemical Safety Assessment² and, specifically its chapter R.12 on use description, recommends understanding the concept “professional” as a characteristic to distinguish between use (i) at industrial sites and (ii) uses outside industrial sites (but not consumers or general public). This will lead to different lifecycle stages in terms of use description. A non-exhaustive list of characteristics associated with industrial sites and professional activities outside industrial sites is also provided and can also be used in a weight-of-evidence approach to determine whether a use is considered: as ‘use at industrial site’ or as a ‘widespread use by professional workers’.

4.1. Uses at industrial sites

Typical examples of “**uses at industrial site**”, the ECHA guidance mentions the following:

- Production of cars and other vehicles;
- Production of paper; and
- Production of semiconductors.

The following are some further examples:

- **Large sites for maintenance and repair:** related to public transport infrastructure (trains, airports/harbours). These cases should be considered as ‘uses at industrial sites’. The structure of the service for trains, ships and planes does not correlate with the municipal infrastructure. Sites for maintenance of buses and trams are more closely related to the municipal infrastructure. Nevertheless, usually their size is sufficiently big to treat them as an industrial site;
- **Industrial cleaning services:** carried out by small or large, well-trained or less trained service providers. This can include tank-cleaning, boiler cleaning, cleaning of machinery, etc. at industrial sites. This case should be regarded as a ‘use at industrial site’, regardless if the actual work is carried out by employees of the site or by external service providers. The resulting releases will be from the site where the cleaning operation takes place;

² <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

- **Process Cleaning:** Cleaning of interior surfaces of reaction vessels, process equipment, pipes, fittings etc. without disassembly in plants e.g. in food processing;
- **Surface Cleaning:** Multi Purpose Cleaner: Industrial cleaning services carried out by small or large, well-trained or less trained service providers. This can include tank-cleaning, boiler cleaning, cleaning of machinery, storage rooms, walls, floors etc. at industrial sites;
- **Large sites for water based washing/cleaning:** of textiles used in industry (cleaning wipes and work wear). These should be considered as 'uses at industrial sites'. The number does not correspond to the size of the municipality as few large sites normally serve a bigger region. Extensive and site-specific treatment infrastructure for wastewater and waste are normally present.

Whilst these uses could also look similar to typical professional uses, the exposure potential could be expected to be lower as there is more external control by site operators and the application of measures following the hierarchy of control. This should however be considered further by the DS on a case by case basis. A restriction for industrial uses could still be proposed if the exposure is not adequately controlled, despite it being lower than in a professional setting.

4.2. Professional users

What is also relevant in the ECHA guidance mentioned above, is the (non-exhaustive) list of typical examples of businesses where chemicals' use would be considered as "widespread use by **professional workers**":

- Building and construction business with a broad variety of activities (mostly micro companies);
- Maintenance services for office/household equipment;
- Indoor cleaning services for all kinds of buildings;
- Facade cleaning services;
- Hairdressing and other beauty services; and
- Health care services.

4.3. Borderline Industrial / professional use cases

There are also cases that are considered '**borderline**' i.e. it is more difficult to conclude on the lifecycle stage of the use. Some examples have been listed below including some possible approaches:

- **Textile dyeing and finishing:** This sector may have borderline uses between industrial and professional use depending on the setting. There may even be some related activities (e.g. home dyeing of cloth and even textile dyeing in textile cleaning shops) which may be considered borderline cases between professional and consumer use;

- **Workshops for car repair³ and finishing, car wash and other car care services:** The sites can be large and small. The predominant characteristic of these businesses is the huge number of small enterprises and the correlation to the municipal infrastructure (population density around the sites). Because of this, they should be reported as 'widespread use by professional workers'. In some cases, the workers' protection standards under which these businesses operate are similar to those of the car industry. This can be reflected when performing the human health exposure assessment by e.g. selecting the conditions of uses corresponding to 'industrial' settings;
- **Textile cleaning with solvents and other heavy duty or specialised chemicals in micro-workshops:** The predominant characteristic of the businesses is the small size of the enterprises and the correlation to the municipal infrastructure, so they should be considered as 'widespread use by professional workers', even though a high level of engineering control may be applied;
- **Construction:** The meaning is not that evident and in most of the cases does not depend on the size, large or small scale, or on the specific characteristics of the works. In most cases workers may not undertake an appropriate or suited training. In such cases it could be worth distinguishing professional from industrial use.

With regards to the use of the terms "industrial" and "professional" in the context of human health exposure assessment, the ECHA guidance flags the occupational conditions under which the workers use a substance or product. In general, it is assumed that 'industrial' conditions are usually associated with industrial settings to a certain degree of automation of the processing contributing to the reduction of the exposure and that it is easier to implement closed systems for example. Complementary to that additional conditions are the training of workers, proper work instructions and supervision.

The use of exposure assessment models can result in different exposure estimates depending on the type of conditions selected (industrial or professional), e.g. industrial conditions may assume a higher level of effectiveness for risk management measures, such as the use of closed systems, presence of local exhaust ventilation or supplementary use of personal protective equipment. Actually, a use can take place 'at industrial site', but for workers exposure assessment a lower effectiveness of risk management measures may be assumed (professional setting). There may also be uses where the opposite is the case, well trained, instructed and equipped mobile services with chemicals.

In the cases mentioned above, the professional use or user still needs to be protected with specific risk management measures that are equal to working in an industrial premises/installation.

Professional users often carry out their work outside a single base of operations (an industrial site) and are less likely to be able to use sophisticated RMM and exposure may be higher. In addition, often consumers can be co-exposed to the substances used (e.g. hairdressers,

³ Certain branches of car repair workshops can be very well organised with an implemented OSH system some industry sectors cannot comply with.

house painters etc). Many professional users may be self-employees⁴ and they are not covered by CAD/CMD or OELs as the legislation puts the responsibilities on employers. Lastly professional users are less likely to have access to specialist advice to help them decide on what risk management measures to implement – this explains their stated preference to be told through SDS and ES on what risk management to implement.

4.4. Borderline professional / consumer use cases

There may be professional activities as mentioned in the examples above, where professional users use chemicals without sufficient safety precautions due to the reasons mentioned, without receiving an appropriate training (e.g. on hazard, on exposure, on risk management measures), without sufficient knowledge of the hazard (e.g. through the labelling) and risk from the exposure to chemicals. In such cases, the behaviour of such professionals in terms of handling hazardous chemicals could be considered closer to the use made by consumers using cleaning agents, hair dyes or glues in activities that are mainly conducted at home, indoors or outdoors. In these cases, professionals are usually exposed to higher concentrations of chemicals due to higher frequency of exposure and longer duration than consumers.

Other examples are the following:

- **Do-it-yourself (DIY) activities:** A typical example of borderline activity with similarity consumer use/professional use is a DIY activity which closely matches the risk for consumers to the one for the professional workers (repairs, painting, small carpentry, cleaning and maintenance services, etc.);
- **Specific uses of a chemical:** An example of similarity between professional use and industrial use already tackled through a restriction is the case of dichloromethane in paint strippers where a license for professional users is foreseen to be granted by Member States. In that case, professional users were treated more like consumers, in that the license system which was set up by Member States in their national law to control the professional uses of DCM was stricter than the risk management measure put in place in the restriction for industrial uses. This was due to the fact that the exposure of professional users was difficult to control in the same way as it was for consumer users.

When hazardous chemicals pose a risk to consumers, the regulatory approach that is often proposed in a restriction under REACH is to set up a concentration limit for the presence of the substance as such or contained in a mixture or in an article, that is placed in the EU market and used by consumers. The concentration limit, that is sometimes proposed, is often the lowest detection limit, the CLP concentration limit for the relevant substance or the limit at which a chemical does not perform any function, e.g. as a paint stripper, as an adhesive, or as an insulation material. The reason to choose such a limit is to ensure maximum protection from the exposure to that chemical and to prevent any adverse effect to health, taking into account the socio-economic impact of such measure when applicable.

⁴ 32.6 million persons aged 15 to 74 in the European Union (EU) were self-employed in 2018⁴. They accounted for 14% of total employment. 15% of self-employed list their work as 'Craft and related trades workers', 14% were skilled agricultural, forestry and fishery workers, a smaller proportion (<5%) were plant and machine operators.

Based on the explanations above, for cases where the professional use of hazardous substances is expected to be similar to the use by consumers, the appropriate protection level should be considered; normally this could be expected to be a restriction with concentration limits or specific risk management levels. This type of restriction may need a definition of professional user to be agreed (or professional use outside an industrial site). As an alternative the restriction could specify which exact professional uses a restriction applies to or to specify the industrial uses excluded from the restriction⁵.

5. Conclusions

As mentioned earlier, in order to select the most appropriate risk management measure it is important for the DS to be able to distinguish professional, industrial and consumer uses from each other, and define, in the conditions of a restriction proposal, whether different concentration limits of the substance/mixture or risk management measures should apply to those uses specifically. If during the DSs analysis the available information shows that professional users have difficulties to implement the OELs, there are (at least) two options available:

- 1) Propose risk management measures under the REACH restriction which can reduce/minimise the exposure level, if the professional user operates in a setting similar to the industrial use.
- 2) Set up of concentration limits for the substance on its own or in a mixture, if the professional use is similar in terms of operational conditions and exposure to the consumer use. Where possible, the concentration limits should lead to a safe exposure level similar to underlying scientific value (DNEL, mode of action limit, DMEL etc.) for the substance. Where this is not the case, it should be justified.

A combination of the two options may also be considered. Also complementary measures such as specific workplace conditions, training of workers, proper work instructions and supervision as set up under OSH should be considered

This analysis should be conducted on a case-by-case basis taking into account the different situations of exposure for the different categories of use and it should take into account the specific hazard profile of the substances and the threshold/non threshold effects.

⁵ This was the approach taken in the D4-D6 restriction where the industrial uses exempted were specified. By way of derogation, paragraph 1 shall not apply to: a) Placing on the market of D4, D5 and D6 for the following uses: Industrial use as a monomer in the production of silicone polymer; Industrial use as an intermediate in the production of other organosilicon substances; Industrial use as a monomer in emulsion polymerisation; Industrial use in formulation and/or (re-)packing of mixtures; Industrial production of articles; Industrial use in non-metal surface treatment; Industrial use as laboratory reagent in Research & Development activities.