

Implementation of REACH in a metalworking industry: a perspective from a downstream user

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ABSTRACT

REACH is a European Union's regulation regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH purpose is the improvement of environmental and human health protection, against risks originated by chemicals. The aim of this study is to present a practical perspective of the implementation and compliance of REACH requirements in a company which is a downstream user. This company manufactures articles, for decorative and utility purposes, coated by electroplating. The methodology followed started with the identification of the company's role under REACH, and an inventory of substances and their use in the production processes, were made. It was also applied a methodology to assess the amount of chemicals that are still present in the final products. The implementation of REACH with other related legislation is a complex and dynamic process that poses various challenges, including the full enrolment of the top management.

1. Introduction

Evidence shows, the risks of chemicals to human health and the environment have been often found of great concern. In fact, chemicals importance are due to their multiple effects (adverse and beneficial) and uses (Assmuth, Hilden, & Craye, 2010). Its importance reinforces the need to manage and assess the risks posed by them. In this sense, REACH regulation emerged in the European Union (EU), from the White paper on chemicals policy. REACH main purpose is to improve the protection of human health and the environment from the risks that can be posed by chemicals, while ensuring an effective functioning of the common EU market for chemical substances (Petry, Knowles, & Meads, 2006). It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals (ECHA, n.d.). This regulation came into force in June 2007, and is being implemented in a stepwise manner until 2018. The regulation applies "*without prejudice to Community workplace and environment legislation*" (UE, 2006) but many of its provisions impact chemicals risk management in the workplace. The four major elements of REACH (Registration, Evaluation, Authorization and Restriction) are summarized below according Hansen, Carlsen, & Tickner (2007):

1 - Registration: data collection on chemical use and toxicity

2 - Evaluation: examination by governments of the need for additional testing and regulation of chemicals

3 - Authorization: requirements for firms to seek permission to use chemicals of high concern; and

4 - Restrictions or complete ban of certain chemicals that cannot be used safely.

A company can have many different roles under REACH, as a role is tied to the company's activities related to a given substance. A downstream user has a specific role under REACH. It refers to using a substance, either on its own or in a mixture, in the course of his industrial or professional activities. Importers and manufacturers are examples of other roles under REACH. A downstream user role can be played by several and different types of companies, including mixtures' formulators, industrial users of chemicals, article producers, craftsmen, workshops and service providers or refillers (ECHA, 2014).

In Portugal, a campaign entitled "Support for Health and Safety and Environment (H&SE) Officers in the implementation of REACH by downstream users" was launched in 2014. This campaign result of a pilot project set by the European Chemicals Agency (ECHA), which present the follow general objectives: 1) Support the H&SE officers and to know and understand the obligations of downstream users (DUs) under the REACH Regulation; 2) Provide practical content of information on how to fulfil the obligations of DUs; and 3) Encourage H&SE to integrate the obligations of DUs under REACH, in everyday activities already working on other legal or regulatory requirements. Three Portuguese state agencies were involved: the Authority for Working Conditions (ACT) and the General Directorate of Economic Activities (DGAE) that coordinate the campaign and the General Inspection of Agriculture, Sea, Environment and Spatial Planning (IGAMAOT). The attributions of DGAE on REACH, especially the helpdesk are now in other Agency (IAPMEI).

This case study refers to a company that manufactures metal articles for decorative applications with functional aspects. With a total area of 2500 m², the company employs about fifty workers that work in one fixed shift (8am to 5pm), five days a week. The study intends to give a practical perspective of the implementation and compliance of REACH requirements together with other relevant legislation such as OHS legislation. It is focused on the finishing treatment given to metal articles, where a substance of very high concern (SVHC) was used. Environmental protection is also very important and considered in what concerns REACH implementation, but in this article such aspects will not be considered.

2. Method

The method followed in this case consisted in verifying for each chemical agent used in the company, REACH and OHS requirements. The implementation of REACH requirements was carried out in several phases, as described in the following subsections.

2.1. Identification of the role of the company under REACH

The first phase consisted in the identification of the company's role (or roles) under REACH, in order to know the specific obligations and to define specific actions. Guidance and information regarding the company's roles under REACH are available by ECHA. The determination of the roles under REACH followed its guidelines.

2.2. Inventory of chemical substances in use

In parallel, a chemical database (Microsoft Excel®) was developed in order to make easier the chemical management process. Despite the compilation of inventory lists of substances and volumes is not required by REACH regulation, it is a useful tool to meet their obligations (Neumann, Kotthoff, & Arnhold, 2013). Some of the topics of the database were: CAS and EINECS codes; supplier and country of origin; trade name; substance or mixture; safety data sheet (SDS) date (actual); chemical use in the production process; risk phrases; classification of substances of very high concern (SVHC); substances with restrictions; exposure sceneries (operating conditions (OCs), risk management measures (RMMs)); annual quantities purchased (in the last three years). After that, a survey was conducted in order to gather all the relevant information about the chemicals in use and stored, their applications, use conditions, among others. Then, with the

support of the accounting and purchasing department, it was possible to cross-data, obtain and analyse the SDS provided by suppliers. The main information was then organized and compiled. In addition, two other databases were developed. One to gather information regarding the imported chemicals and to determine the annual amount imported by chemical and the other, for chemicals with SVHC purchased in the UE.

2.3. Communication in the supply chain under REACH

After the role definition, it is important to know the specific communication flow, up and down the supply chain. The communication between the registrant and downstream user (DU) is crucial for the overall success. It is important that the downstream users should carefully check the information contained in the safety data sheet received before starting the communication with the supplier. The SDS checklist available in various languages on ECHA's website was used in this study.

2.4. Action Plan to accomplish with REACH

This phase consisted in the definition and development of an action plan containing the actions to take *per* role, deadline and status of the actions.

2.5. Identification of the amount of SVHC in the final product

This step consisted in gather and organize all the relevant information in a database about the articles produced in the company, containing the following topics:

- Sales code
- Final product
- Components
- Initial mass
- Surface finishing/treatment
- Exposure time
- Final mass
- SVHC included in the candidate list?
- SVHC identification
- % SVHC in the final product
- SVHC placed on the marked (ton/year)
- Report to ECHA needed¹?
- Substances intentionally released?
- Substances required for registration to ECHA²?
- Compliance with REACH Restrictions

The requirements of REACH define that in a final article, the amount of SVHC cannot represent more than 0.1% of the total mass. Otherwise, other actions must take place. In order to verify this in the final articles, forty-five articles were randomly selected. The analysis was made by the mass determination before and after the process of plating a sample of components of the final articles. The objective was to determine the component mass had not undergone a significant

¹ When verified simultaneously: - The substance is identified in the list of candidate substances; - The substance is present in articles above a concentration of 0.1% (m/m); - The total amount of the substance present in all produced and / or imported articles that contain a concentration greater than 0.1% (m/m) is greater than 1 ton/year per producer or importer.

² When verified simultaneously: - The substance intended to be released by the manufactured articles under normal or reasonably foreseeable conditions of use; - The substance is present in those articles in quantities above 1 ton/year per producer or importer. Exemptions to registration and notification are: - When there is no direct exposure to human beings or environment in normal or predictable conditions; - Substances have already been registered for that use.

increase and exceed the 0.1% (m/m), after the surface treatment. Since the electroplating process is automatic, and the exposure time to chemicals is constant, the components analysed in this phase are used as a reference for, in the future, justify the absence of dangerous quantities of SVHCs in articles entering in the market. If any change occurs into the electroplating process, such the concentrations of chemical substances used in the baths, or in commercial products itself, or even in the exposure times, among other abnormalities, all this analysis must be carried out again in order to verify the concentrations of SVHC in final articles.

2.6. Alignment of OHS obligations with REACH implementation

The production process of the company under study, may affect workers' health and safety and it is expected to have risks evaluated and communicated across the supply chain.

In the case of a mixture containing substances classified as dangerous substances, ECHA recommends that the SDS of that substance and its Annex with the exposure scenario (ES) should join the SDS of the mixture. It is the ES that evaluate and communicate risks across the supply chains.

DUs have a legal obligation under REACH (under Article 37) in following the ES. The occupational exposure should be determined and if needed, exposure control (organizational or engineer control), should be considered in order to reduce the exposure to levels below the TWA.

Besides that, and according to European and national law, when in presence of a dangerous substance, as the SVHC substance previously referred, other legislation must be consulted to check if it is applicable, such as CAD and CAM Directives transposed into member states national law and also any other legislation related to it. If the worker is exposed to a carcinogenic and mutagenic substance it requires the implementation of control measures following a hierarchy. Other requirements to follow are health surveillance, training, keeping the workers and its representatives informed and take an action plan with adequate measures in accident, incident or emergency situation. The challenge that OHS professionals face is to fit measures determined by risk assessment and by risk management measures (RMMs) of the ES.

3. Results and Discussion

According to REACH the company undergoes the role of a downstream user, as a formulator and as an article producer. This means that the company acquires chemical substances from suppliers located within the UE for use in the production process as well as in supporting processes, including maintenance. The other role is as an article producer, placing on the market metal articles with different surface treatment.

The inventorying process allowed compiling information of fifty-seven chemicals agents from the SDS sent by the respective suppliers. Of these fifty-seven, three are SVHC in accordance with Article no. 57 of REACH (UE, 2006). The SVHCs are defined with at least one of the following toxicological properties:

- carcinogenic, mutagenic or toxic to reproduction, category 1 or 2 (GHS: Category 1A or 1B);
- persistent and bio accumulative and toxic (PBT);
- Very persistent and very bio accumulative (vPvB);
- Proven scientifically that are of high concern to humans or the environment (eg. endocrine disruptors).

One of them is a mixture containing hexavalent chromium (Cr VI) in the form of chromium trioxide used in the bath for surface treatment of metal articles. It is a substance of very high concern (SVHC) included in the Annex XIV of REACH, which is a substance that requires authorisation before being used. The reasons for inclusion of the chromium trioxide in this list on 15th of December of

2010 were the fact that the substance is carcinogenic (Article 57a) and mutagenic (Article 57b) (Table 1).

Table 1. Contents of the mixture SDS (section 3) containing chromium trioxide - classification according to part 3 of Annex VI (list of harmonized classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

International Chemical Identification	EC No	CAS No	Index No	%	Classification		
					Council Directive 67/548/EEC	Regulation (EC) No 1272/2008 (CLP)	
						Hazard Class and Category Code(s)	Hazard statement code(s)
chromium (VI) trioxide	215-607-8	1333-82-0	024-001-00-0	≥	O; R9 Carc. Cat. 1; R45 Muta. Cat. 2; R46 Repr. Cat. 3; R62 T+; R26 T; R24/25-48/23 C; R35 R42/43 N; R50-53	Ox. Sol. 1 Carc. 1A Muta. 1B Repr. 2 Acute Tox. 2 * Acute Tox. 3 * Acute Tox. 3 * STOT RE 1 STOT SE 3 Skin Corr. 1A Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H271 H350 H340 H361f *** H330 H311 H301 H372 ** H335 H314 H318 H334 H317 H400 H410

* explanation see chapter 1.2.1 of Annex VI of regulation 1272/2008 EC

** explanation see chapter 1.2.2 of Annex VI of regulation 1272/2008 EC

*** explanation see chapter 1.2.3 of Annex VI of regulation 1272/2008 EC

The remaining substances, despite being classified as toxic to reproduction 1B, do not require additional actions (such as registration or application for authorization) according to the REACH Regulation, since that safety instructions/standards both in storage and in handling are met, as described in SDS.

After the definition of the company's roles under REACH and the inventory of substances under use, an action plan was developed. Table 2 shows the defined action plan, showing also the requests made up the supply chain.

Table 2. Action plan by company's roles (adapted from Fernandes (2014)).

Role	Actions	Deadline	Status
Downstream user	Ask the suppliers the SDS updated according to REACH	Immediately, and if any FDS is outdated	They have been requested to all suppliers
	Evaluate with suppliers if the substances have been registered and/or pre-registered in the legally prescribed deadlines. This analysis should be carried out for all chemicals used in the company	Immediately	They have been requested the registration status to all suppliers
	Transmit to the supplier's information on its uses, if the substance is not yet registered. This allows registrants include these uses in the chemical safety assessment	Until May 31, 2017, since the registration deadline is May 31, 2018	It was provided all the information on the use given to the substance and conditions of use in the company. For chemicals already registered, the company must make sure that the SDS provides for the use given to the substance in its facilities

Role	Actions	Deadline	Status
			and associated conditions of use.
	Implement the measures specified by the suppliers to ensure the safe use of the substance (as SDS)	12 months from the reception of the SDS date regarding to the registered substance	The company must analyse the FDS, identify and take the necessary measures to control the risks in its facilities
	Implement the measures communicated in the exposure scenario or take alternative measures. When a DU receive an exposure scenario with a SDS, you should check if the exposure scenario covers their own use of the substance and its conditions of use	When applicable	Ongoing
	Evaluate if any of the substances used has any type of restriction and, if applicable, accomplish with the imposed restrictions (Annex XVII of REACH)	When applicable	Ongoing
	Assess whether any of the substances used, is in the list of substances subjected to application for authorization (Annex XIV of REACH)	When applicable	Currently the company uses the following substances listed in Annex XIV: chromium trioxide (VI)
	Ask suppliers / manufacturers of chemical substances subjected to authorization request if they intend to request authorization for the substance, including its use	The deadline for the submission of the request for authorization by the Consortium was February 2016	In May 2015 it was submitted to ECHA the request for authorization for the use of chromium trioxide after the use of the deadline in August 2017 (after this date cannot be used without permission from ECHA). It is under review and public consultation
Article Producer	Assess whether any of the substances used in the manufacture of the article is on the list of candidate substances, available on the ECHA website	Prior to the acquisition of a new chemical and, in the case of existing products, provided that the Candidate List is updated	Ongoing. Need to keep updated.
	Determine the concentration of SVHC of each component present in the final article (action on suppliers)	Prior to the acquisition of components	Ongoing
	Determine the concentration of SVHC in the article. Set a consistent methodology based on experience and knowledge of the production process, suppliers and managers of surface treatment line or laboratory analysis of items for determining the amount of the existing SVHC	Immediately	Ongoing
	If the amount of the SVHC in the article is greater than 0.1% (m/m), the company will have to provide sufficient information to consumers to ensure its safe use	Immediately (this obligation shall take effect as soon as the substance is included in the list of candidate substances to authorization)	Ongoing

Despite it was requested the update SDS according to REACH to all suppliers (by e-mail and letter) as indicated in table 1, a first look at the SDS of the mixture that contained chromium trioxide showed that: 1- the mixture SDS did not indicated its use on section 1.2; 2- the SDS must be reviewed since mixture was classified according to the Directive 1999/45/CE, but its components (substances) had been classified according to the CLP; 3- SDS of dangerous substances did not come along with the mixture SDS nor does the mixture SDS included all relevant dangerous substance information, both ECHA's recommendation.

Whenever DUs have certain obligations relating to adopting the control conditions and risk management measures, which is the case, actualized SDSs are essential to REACH implementation and for risk assessment, that must be communicated to the company workers and down the supply chain.

In case of the mixture of chromium trioxide, should be considered other factor which is the fact that after a period of public consultation on applications for authorisation, DU must have, in 2017, to communicate if they are using this chemical agent registered for that use, otherwise they have to substitute the chemical agent which is rather difficult since is commonly used in the metallurgic industry.

As an article producer the concern about the concentration of the previously identified SVHC is real and its determination should be taken with rigour. Results show that none of the articles analysed had SVHC concentrations above the recommended.

As confirmed on the SDS, chromium trioxide is classified as a dangerous substance for health or environment due to its toxicological properties like acute and chronic toxicity, corrosivity as well as skin and respiratory sensitization. Furthermore, chromium trioxide is a reproductive toxicant, a germ cell toxicant and in particular, a carcinogenic substance.

For this substance exists an Occupational Exposure Level (OEL) in the workplace. That can be observed on Section 8 of the mixture's SDS - Control of individual protection/exposure. For chromium trioxide the Portuguese standard NP 1796 (2014) indicates a TWA: 0,01mg/m³ (expressed in Cr). So in what refers to human health effects, risk assessment might require monitoring of workers, workplace atmosphere or biological monitoring to determinate the ventilation efficiency or other control measures and or the necessity to use respirators protection. The Portuguese standard NP EN 689 should be consulted in order to choose the method to evaluate the exposure to chemical agents inhalation.

4. Conclusions

It is required from the DU, a heavy bureaucratic paper and it is rather difficult to accomplish with complex and extent regulations such as REACH and CLP along with OHS obligations.

The implementation of REACH requirements is a time consuming and continuous process that requires knowledge on REACH. One of the main challenges is to get the full enrolment and support of the top management.

It was also found that despite all the information and guidance documents available on the ECHA agency website, the stakeholders (especially small companies such as DU) that are part of the supply chain, have lack of knowledge regarding REACH, its requirements, and how implement it and articulate its obligations and good practices with OHS legislation. This must be seen with great concern, especially because the communication among the supply chain is fundamental for REACH and OHS purposes. One may also conclude that SDS quality is generally poor and there is lack of information on PPE and RMMs for identified ES.

Considering all the questions raised all along this study, it was found very important that official agencies with responsibilities in monitoring safety and environmental conditions of organizations, develop systematic and periodical actions to promote training and awareness in this vast subject that is REACH. This topic is rarely approached during the initial training for OHS professionals or

during academic degrees and that must also change. Therefore, it is seen with great expectation the contribution of Authority for Working Conditions (ACT) for the Portuguese Campaign to help OHS and other professionals in implementing REACH, particularly after the recent free electronic publications related to personal protective equipment (PPE) and control exposure to chemicals, product of a joint project between ACT, the Sectorial Standard Organism for Health and Safety (APSEI) and the Portuguese Quality Institute (IPQ).

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References

- [1] Assmuth, T., Hilden, M., & Craye, M. (2010). Beyond REACH: roadblocks and shortcuts en route to integrated risk assessment and management of chemicals. *The Science of the Total Environment*, 408(18), 3954-3963. doi:10.1016/j.scitotenv.2010.02.010
- [2] ECHA. (n.d.). REACH. Retrieved June 21, 2016, from <http://echa.europa.eu/regulations/reach>
- [3] ECHA. (2014). *Guidance for downstream users* (Version 2.). Helsinki: European Chemicals Agency.
- [4] Fernandes, E. (2014) *Caso prático: Aplicação do Regulamento REACH em empresas de tratamentos de superfície, Conferência de lançamento da Campanha "Apoio aos Técnicos de Segurança no Trabalho e Ambiente na implementação do REACH pelos utilizadores a jusante"* Lisbon, ACT. Available in: [http://www.act.gov.pt/\(pt-PT\)/Campanhas/Campanhas%20a%20decorrer/REACH/Documents/17.15_Eduarda%20Fernandes_20141030.pdf](http://www.act.gov.pt/(pt-PT)/Campanhas/Campanhas%20a%20decorrer/REACH/Documents/17.15_Eduarda%20Fernandes_20141030.pdf) [last access 2016.05.01]
- [5] UE. (2006). *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) No 1907/2006*. European Parliament and of the Council.
- [6] Hansen, S. F., Carlsen, L., & Tickner, J. A. (2007). Chemicals regulation and precaution: does REACH really incorporate the precautionary principle. *Environmental Science & Policy*, 10(5), 395-404. doi:<http://dx.doi.org/10.1016/j.envsci.2007.01.001>
- [7] Neumann, B., Kotthoff, G., & Arnhold, V. (2013). REACH: risks, challenges and opportunities for sintered parts manufacturers. *Powder Metallurgy*, 56(3), 174-183. doi:10.1179/0032589913Z.000000000110
- [8] Petry, T., Knowles, R., & Meads, R. (2006). An analysis of the proposed REACH regulation. *Regulatory Toxicology and Pharmacology: RTP*, 44(1), 24-32. doi:10.1016/j.yrtph.2005.07.007