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Implementation of the chemicals regulation REACH – Exploring the impact on occupational health and safety management among Swedish downstream users

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ABSTRACT

In the present study we have examined how the European chemicals regulation Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) has influenced occupational risk management of chemicals at Swedish downstream user companies. The data were collected through interviews with occupational health and safety professionals, safety representatives and authority employees. The results show that most of the informants had scarce knowledge about REACH and that REACH implementation has not had any major impacts on downstream users' occupational risk management, but the impacts the regulation has had were perceived as positive. For instance, clear substance identification and increased hazard information were appreciated improvements of safety data sheets (SDS). However, with regards to identifying how to safely use a substance or product neither the SDSs nor the attached exposure scenarios were perceived as sufficient. REACH was not perceived as a major driver for substitution but has had some impact on substitution, either by requiring it for certain substances as through the authorisation procedure or facilitating the identification of relevant substances to substitute as more information on hazards has become available. The obstacles to REACH implementation are similar to those of occupational health and safety legislation; lack of awareness, understanding and/or incentives to take action. Especially smaller companies with their limited resources lag behind. Reaching the full potential of REACH requires more work on motivating and supporting downstream users to fulfil their REACH obligations.

1. Introduction

In the present study we have examined the influence of the European chemicals regulation Registration, Evaluation, Authorisation and Restriction of Chemicals substances (REACH) on chemical risk management at Swedish workplaces. This regulation came into force in June 2007, and is being implemented in a stepwise manner until 2018. REACH is aimed to improve the protection of human health and environment from hazardous chemicals as well as to enhance innovation and competitiveness of the EU chemicals industry (EU, 2006). The regulation applies "without prejudice to Community workplace and environment legislation" (EU, 2006, preamble), but many of its provisions impact chemicals risk management in the workplace.

Swedish occupational health and safety (OHS) legislation places the main responsibility for preventing ill health and accidents resulting from working conditions on the employer (Swedish Parliament, 1977), through e.g. requirements on performing risk assessments and work systematically with OHS. Similar requirements are found in the EU frame work directive on occupational safety and health (EU, 1989) and its daughter directive the Chemical Agents Directive (EU, 1998). Risk assessment of chemical exposures is today incorporated in the Swedish Work Environment Authority (SWEA) provisions on chemical safety in the work environment (SWEA, 2011a). These provisions also connect to the requirements on systematic work environment management (SWEM) first developed in the 1990s (SWEA, 2001). Amongst other requirements, the SWEM and chemical safety provisions state that the employer is responsible for giving the employees the

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information necessary for preventing ill-health and accidents at work. Safety data sheets (SDS) are important tools for communication of health risks and safety measures along the supply chain as well as within companies. The information in the SDS makes up the basis for workplace risk assessments of hazardous chemicals and SDSs for these chemicals are to be made available to employees (SWEA, 2011a).

SWEA also issues the provisions on occupational exposure limits (OELs, SWEA, 2011b). In Sweden, OELs have been set since the late 1960s and the list is updated with a few years' intervals. Swedish OELs are binding and pragmatic, i.e. they are set taking socioeconomic and technical feasibility into account as well as the scientific evaluation of health effects. The scientific evaluation of health effects is performed by an independent expert group while the extrapolation from data to OEL and corresponding consequence analyses are performed by desk officers at SWEA.

Enforcement of Swedish OHS legislation is performed by a division of SWEA, which is also responsible for enforcement of several REACH obligations connected to work environment (REACH articles: 14.6, 34b, 35, 37.4, 37.5, 38, 60.9, 60.10, 67.1; as listed in §17 of the Swedish work environment ordinance). In general terms SWEA's REACH enforcement aims to ensure that manufacturers and users apply the OHS risk management measures (RMMs) resulting from REACH procedures and that downstream users, when required, provide information to the European Chemicals Agency (ECHA) and/or their supplier. Other REACH obligations are enforced mainly by the Swedish Chemicals Agency which is the Swedish competent authority for REACH. ECHA has no enforcement responsibilities but acts as a central point in the REACH system as it manages the IT-infrastructure and co-ordinates member states' competent authorities.

1.1. Obligations and tasks under REACH

REACH replaces a large number of different EU (non-occupational) chemical regulations. A major change to these old regulations is that REACH places greater responsibility on manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use substances in such a way that they do not adversely affect human health. There are several different procedures under REACH. *Registration* is the procedure under which manufacturers and importers need to register a substance if they manufacture or import more than 1 tonne per year. With increasing tonnage the information required about the substances' properties and safe uses increases. *Evaluation* designates the procedure under which ECHA controls the completeness of registration dossiers but also substance evaluation, under which competent authorities in the member states may perform in depth evaluations assessing the need for additional regulatory action. *Authorisation* is the procedure under which certain substances of very high concern, listed in Annex XIV of REACH, are banned for any use unless an authorisation is granted by the European Commission. *Restriction* is the procedure under which specific uses of certain substances are prohibited; restrictions are listed in Annex XVII of REACH.

Industry's responsibility to produce information about risks and safe uses is thus introduced with the registration procedure. For most substances that were already manufactured or placed on the market before REACH's entry into force registration is being implemented stepwise. Registration deadlines have been set according to tonnage imported or manufactured per registrant and year as well as hazardous properties. The first REACH registration deadline was on November 30th 2010 (>1000 tonnes, substances that are carcinogenic, mutagenic or toxic to reproduction substances > 1 tonne, and substances dangerous to aquatic organisms or the environment > 100 tonnes), the second May 31st 2013 (100–1000 tonnes) and the third and final deadline will be on May 31st 2018 (1–100 tonnes).

Registrants have to perform a chemical safety assessment for any substance they manufacture or import in amounts greater than 10 tonnes per year. The chemical safety assessment includes hazard assessments and assessments of exposure for all supported uses along the supply chain. A chemical safety assessment may also be performed by downstream users if their uses are not supported by any upstream registrant. The supported uses and required RMMs are to be determined using derived *no-effect levels (DNELs)* as benchmarks. DNELs are delineated in Annex I of REACH as a value to represent an exposure level below which humans are not expected to experience adverse health effects. In the chemical safety assessment DNELs are to be derived for each relevant exposure route (dermal, oral, inhalation), exposure duration (acute/short-term and long-term), effect (local and systemic) and population (workers and the general population). The resulting information about supported uses and required RMMs, including any DNELs for the worker population, is to be submitted to ECHA but also communicated down the supply chain with an SDS.

While the registration requirements apply to single substances, requirements on SDSs apply to both substances and mixtures. In the SDS a supplier, be it a registrant or a downstream user, describes the properties of the substance (or mixture), its hazards and instructions for handling, disposal and transport and also first-aid, fire-fighting and exposure control measures. The requirements for the compilation of the SDS are now specified in Article 32 and Annex II of REACH. Mostly these requirements are the same as in previous regulations concerning SDSs (major changes for SDSs for substances have been summarised for instance by ECHA (2014)).

A new concept introduced by REACH is the *extended SDS* which includes the so called *exposure scenarios*. Exposure scenarios are attachments to the SDS that provide information on how the exposure of workers, consumers and the environment to a substance can be controlled in order to ensure its safe use. Companies have to compile exposure scenarios for any substance for which they have performed a chemical safety assessment under REACH. Attached exposure scenarios must be consistent with the information in the main body of the SDS. Exposure scenarios may be compiled also for mixtures containing substances that have a chemical safety assessment, but this is not mandatory under REACH. Upon having received an exposure scenario downstream users have to consult it and within 12 months take appropriate action to ensure safe use (REACH Article 37 and 39).

REACH thus entails much work and responsibility for registrants but also for the different kinds of downstream users. Downstream users' tasks and obligations under the different REACH procedures to some degree depend on the kind of downstream use (e.g. formulation, production of articles or end use). Among these tasks and obligations are to:

- Provide information regarding their uses to suppliers of substances, so that registrants may include these uses in their chemical safety assessment.
- Implement measures specified by their supplier to ensure the safe use of the substance.
  - In case the downstream user's use is not supported (and will not become by current or other supplier), if exemptions do not apply and if substitution is unfeasible: prepare a downstream user chemical safety report.
- Inform their supplier if they have new information on the hazards of the substance or the risk management advice is not appropriate.
- Comply with any authorisation and/or restriction requirements as well as requirements regarding substances in articles.