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Trade Union Priority List for REACH Authorisation

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Abstract

Background

The new EU REACH Regulation to control the trade and use of chemicals has a great potential to reduce worker exposure to hazardous substances and therefore reduce chemical related occupational diseases. REACH requires manufacturers of substances of very high concern (SVHC) to **request** an authorisation for each use of these substances in order to continue marketing them. There are between **1,500 and 2,000** SVHC on the European market; however, **to date**, the European Chemicals Agency has **published only 29** substances as candidates for the authorisation procedure. This work aims to contribute to the practical implementation of REACH by proposing a list of SVHC which from a union's perspective should have priority for inclusion in the authorisation procedure.

Methods

In a first stage SVHC for prioritisation were identified, following, prioritisation criteria were established and scores for each criterion were defined for finally developing the Trade Union List.

Results

Through previously presented criteria, the Trade Union List includes 305 high production volume chemicals that meet the requirements of the authorisation process under REACH. 190 of these substances are associated with recognised occupational diseases and 22 have been included in the REACH Candidate List.

Conclusions

In this paper, we present a precautionary but scientifically aligned process for identifying, scoring and ranking SVHC, including categories of substances not currently considered in other approaches to the REACH Regulation. This proposed methodology is advocated by Trade Unions to coherently prioritise SVHC in order to implement and enforce REACH in a way that will more effectively protect the health of the European working and general population.

BACKGROUND

On 1st June 2007, a new EU regulation for chemicals called REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) came into force in the 27 EU Member States and in the European Economic Area (EEA).[1] REACH establishes a process by which substances of very high concern (SVHC) will need an authorisation for being placed on the market. The aims of authorisation are to ensure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable safer alternative substances or technologies.

The list of substances subject to authorisation under REACH will be included in Annex XIV (Authorisation List) of the Regulation. Once a substance is included in Annex XIV, producers shall apply for an authorisation for each use of the substance within a set date. Substances will not be granted authorisation if they can not be adequately controlled and/or do not meet the required socio-economic criteria for ongoing use and suitable alternatives are available. The European Chemicals Agency (ECHA) -on request of the European Commission- and Member States suggest substances that fulfil the criteria of being a SVHC. This list is called the "Candidate List". ECHA must then draw up a recommendation of substances that will have priority in the authorisation process and the Commission makes the final decision on which of these substances will be included in Annex XIV, based upon ECHA's recommendations and taking into account the opinion of the Member State Committee. If a substance is included in the "Candidate List", suppliers of these substances or mixtures have the obligation to provide safety data sheets and distributors of articles containing these substances -in a concentration above 0,1 % weight by weight (w/w)- have the obligation to inform consumers of the presence of any authorised chemicals in the products they buy and how to use them safely.

REACH has the potential to reduce the number of diseases and deaths caused by occupational exposure to toxic chemicals as well as to promote the development of safer alternatives for substances included in the authorisation process. Better information on dangerous properties of products and articles and on adequate control measures will be available throughout the supply chain for substances included in the Authorisation List. [2]

On October 2008, ECHA published its first Candidate List, which included only 15 chemicals. The second Candidate List was published on January 2010, with only 14 additional substances.[3] On 14th January 2010, ECHA published its first draft recommendation for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) which included only 7 substances from the original Candidate List.[4] In order to help authorities identify the most urgent SVHC for inclusion in the Candidate List and establish a comprehensive prioritisation methodology for inclusion in the Authorisation List, the European Trade Union Institute developed the Trade Union Priority List (TU List).[5]

METHODOLOGY

The TU List was developed by chemists, health and safety consultants and environmental consultants from the Spanish Trade Union Institute for Work, Environment and Health (ISTAS) and the European Trade Union Institute (ETUI), with more than 20 years of experience in environmental and occupational chemical risk management.

To draw up the Trade Union Priority List these stages were followed:

1. Identification of SVHC for prioritisation.
2. Prioritisation criteria.
3. Definition of scores for each criterion.
4. Development of the list.

1. Identification of SVHC for prioritisation

SVHC included in the TU List were:

Carcinogenic substances

- Substances classified as category 1A, 1B and 2 in accordance with EU Regulation 1272/2008, so called CLP Regulation (categories 1, 2 and 3 in accordance with Directive 67/548/EEC) identified in Annex VI with hazard

statements H350 (may cause cancer) and H351 (suspected of causing cancer). Hazard statement is a phrase assigned to a hazard class and category that describes the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard.[6,7]

- Substances classified by the International Agency for Research on Cancer (IARC) as human carcinogens (IARC 1), that are probable human carcinogens (IARC 2A) and that are possible human carcinogens (IARC 2B).[8]

Mutagenic substances

- Substances classified as mutagenic category 1A, 1B and 2 in accordance with CLP Regulation (categories 1, 2 and 3 in accordance with Directive 67/548/EEC) identified in Annex VI with hazard statements H340 (may cause genetic defects) and H341 (suspected of causing genetic defects).

Substances that are toxic for reproduction

- Substances classified as toxic for reproduction category 1A, 1B or 2 in accordance with CLP Regulation (categories 1, 2 and 3 in accordance with Directive 67/548/EEC) identified in Annex VI with hazard statements H360 (may damage fertility or the unborn child), H361 (suspected of damaging fertility or the unborn child).

Persistent, Bioaccumulative and Toxic substances (PBT) and very Persistent and very Bioaccumulative substances (vPvB).

- PBT list of the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic.[9]
- PBT/vPvB list of the Technical Committee on New and Existing Substances (TCNES).[10]

Endocrine disrupters (EDC)

- Substances included in the priority list developed within the EU-Strategy for Endocrine Disrupters classified as category 1 (evidence of endocrine disrupting activity in at least one species using intact animals) and category 2 (at least some in vitro evidence of biological activity related to endocrine disruption).[11-14]

Neurotoxicants

- Provisional list for occupational neurotoxicants included in the review published by Vela et al.[15]

Sensitizers

- Substances classified as skin or respiratory sensitizers by CLP Regulation, identified in Annex VI with hazard statements H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled) and H317 (may cause an allergic skin reaction).

The data source used to document the Trade Union list is the RISCTOX database that contains (eco) toxicological information for more than 100,000 substances and includes substances that have been identified as carcinogenic, mutagenic, toxic for reproduction, endocrine disrupters, neurotoxicants, etc. by European legislation and different national and international organizations.[16]

2. Prioritisation criteria

Criteria used for prioritisation in the TU List were:

- Known health effects on exposed workers;
- Environmental toxicity, persistence and potential to bioaccumulate; and
- Prevalence of exposure, estimated through production volume data. High Production Volume Chemicals (HPVC), are substances that are produced in, or imported into, the EU in quantities greater than 1,000 tonnes per year.[17]

3. Definition of scores for each criterion.

The European Union Risk Ranking Method (EURAM) was followed to score health effects, in a scale ranking from 1 (lowest score) to 10 (highest score).[18]

EURAM scores were applied for known CMR (10 points), for suspected CMR (9 points) and for sensitizers by inhalation (7 points). Health and environmental effects not included in EURAM have been given a score in accordance with the level of concern that REACH confers on them. For instance, known endocrine disrupters and PBTs are given a high score (9 points) as they are clearly established in REACH as substances of very high concern, whereas suspected endocrine disrupters and neurotoxicants are given a lower but still precautionary score (7 points), as shown in Table 1.

Table 1. Health and environmental effect scores, used by European Union Risk Ranking Method (EURAM) and the Trade Union Priority List.

SUBSTANCES	EURAM score	TU List score
EU Carcinogens cat. 1A or 1B	10	10
IARC Carcinogens 1 or 2A group		10
EU Mutagens cat.1A or 1B	10	10
EU Reprotoxicants cat.1A or 1B	10	10
EU known Endocrine Disrupters		9
PBT		9
EU Carcinogens cat.2	9	9
IARC Carcinogens 2B group		9
EU Mutagens cat. 2	9	9
EU Reprotoxicants cat.2	9	9
Sensitizers by skin contact	6	7
Sensitizers by inhalation	7	7
Neurotoxicants		7
EU suspected Endocrine Disrupters		7

Scores were applied by effect. Hence one substance that is a carcinogen according to CLP Regulation and also according to IARC, will be given the score associated with the most conservative (and maximum) designation. The scores of all the effects were added. Substances with several health effects score higher as a total of all the scores added together.

4. Development of the list

The High Production Volume Chemicals list (step 2) was combined with the selected lists of substances with hazardous properties (step 1) and given a score (step 3). Substances exempted by REACH Regulation (speisses, mattes, sludge, slimes, drosses, skims, calcines and residues; substances that only have pesticide or biocide use; and some complex hydrocarbon distillates) or already banned by other means (EU Regulation 850/2004 on POPs) were removed from the list. [19] However, naphthas (petroleum derivatives) have not been removed as they are widely used as solvents, which are within the scope of REACH authorisation and Refractory Ceramic Fibres (RCF) were also included in the TU list.

Substances considered or suspected to cause occupational diseases in the EU have been highlighted.[20]

RESULTS

The resulting TU List includes 305 HPVC entries with at least one of the selected dangerous properties represented by its score. From this listing, 190 of these entries are substances or groups of substances associated with recognised occupational diseases and 52 entries are substances that cause diseases suspected of being occupational in origin. Table 2 includes an example of how substances are scored in the list and subsequently ranked.

Table 2. Examples of the scoring system used in the Trade Union Priority List for REACH Authorisation: selected substances from a total of 305 entries in the List.

Name	C 1A,1B	IARC 1, 2A	M 1A,1B	R 1A, 1B	ED 1	PBT / vPvB	C 2, IARC 2B	M 2	R 2	S	N	ED 2	TOTAL
acrylamide	10	0	10						9	7	7		43
nitrotoluene *	10		10		9				9				38
diphenyl ether, octabromo derivative				10	9	9	9						37
sodium chromates *	10	0	10	10						7			37
bisphenol A					9	9			9	7			34
styrene					9		9			7			25

* : several isomers of this group might have different extent (or lack) of available test data. In those cases, most hazardous substance was taken as a reference for the whole group.

C 1A, 1B: Carcinogen Category 1A or 1B according to EU Regulation 1272/2008 classification criteria

C2: Carcinogen Category 2 according to EU Regulation 1272/2008 classification criteria

IARC 1: Human carcinogen according to IARC criteria

IARC 2A: Probable human carcinogen according to IARC criteria

IARC 2B: Possible human carcinogen according to IARC criteria

M 1A, 1B: Mutagen category 1A or 1B according to EU Regulation 1272/2008 classification criteria

M2: Mutagen category 2 according to EU Regulation 1272/2008 classification criteria

R 1A, 1B: Reprotoxic category 1A, 1B according to EU Regulation 1272/2008 classification criteria

R2: Reprotoxic category 2 according to EU Regulation 1272/2008 classification criteria

ED1: Known to be endocrine disrupter according with Community Strategy for Endocrine Disrupters

ED2: Suspected to be endocrine disrupter according with Community Strategy for Endocrine Disrupters

PBT: Toxic, Persistent and Bioaccumulative

N: neurotoxicant

S: sensitizer

The complete TU list of 305 substances can be [consulted in the electronic version of this paper at JECH website.](#)

LIMITATIONS OF THE TU LIST

Prioritising substances of high concern has become a need for many governments or supra-governmental organizations which aim to implement legislative actions that will limit or prohibit the use of certain chemicals considered particularly dangerous to human health or to the environment. [21]

Several lists of extremely hazardous chemicals have been developed by governmental agencies or non governmental organizations with the common denominator of containing large lists of substances that are considered of special concern due to their negative effects on human health or the environment. Some examples are the Extremely Hazardous Substance List of the United States Environmental Protection Agency (US-EPA); the List of Undesirable Substances of the Danish Environmental Protection Agency (EPA); the Priority Substances List of Environment Canada; the PRIO database of the Swedish Chemicals Inspectorate and the Substitute It Now! List (SIN List) developed by ChemSec together with a group of European NGOs. [22-26]

The Candidate List of 29 SVHC published by ECHA and the resultant Authorisation List (that may include 7 SVHC by mid 2010) are clearly insufficient to effectively and quickly fulfil the goals of REACH to protect the health and environment from highly hazardous chemicals. Many other substances which also meet the required criteria could have been included in the initial Candidate List, such as the 1,000 CMR substances on the official list of hazardous substances with a harmonised classification and labelling at the European Community level, .

Millions of European workers are exposed to chemical substances on a daily basis, not only during the production of these chemicals but also in the many downstream sectors where these substances are used. The European Trade Union Institute (ETUI) estimates that around one in three of all occupational diseases recognised in Europe each year is due to exposure to

hazardous chemicals based on European Occupational Diseases Statistics and occupational disease prevalence data.[27] Furthermore, it is estimated that each year among 35,000 and 45,000 workers die in Europe due to their exposure to carcinogens in the workplace.[28]

The aim of the TU List is to urgently contribute to the debate about the number and choice of substances of very high concern for inclusion in the REACH authorisation procedure. However, the TU List has several limitations that should be considered.

Identification of SVHC for prioritisation

From a Trade Union point of view, several aspects should be considered when prioritising substances subject to the REACH authorisation process, such as intrinsic hazardous properties, relationship to occupational diseases, and human or environmental exposure. However, there is little or incomplete information on most of these factors. For example, EU Member States have completed only 138 risk assessment reports on individual substances with a wide set of toxicity and ecotoxicity data; EU registers on occupational diseases offer data on only a limited number of substances related to occupational diseases and data on environmental exposure is based mainly on estimations and do not cover all European countries.[29-32] Taking into account the above limitations, the most reliable information that could be used to set up the priority list, was information on the intrinsic hazard properties of substances but this in itself is often incomplete for many endpoints such as disruption of the immune system, acute toxicity, depletion of ozone layer, and ecotoxicity, as examples.

Therefore, the list may not include substances of high toxicity or ecotoxicity that deserve attention from authorities and perhaps should also be eliminated from the market through the REACH authorisation process. However, only substances included in official EU and international publications or regulations have been taken into account and these documents are not regularly updated with available knowledge on toxicity.

REACH considers substances of very high concern (SVHC) as those meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with CLP regulation. However, the TU List has also included substances identified by IARC as human carcinogens (IARC 1) and probable human carcinogens (IARC 2A). This is because the scientific evidence behind IARC reports is internationally recognized and strong enough to raise a level of concern equivalent to those substances classified as carcinogenic category 1A or 1B in CLP Regulation.

Taking a precautionary approach, the TU list also includes CMR substances category 2 according to the EU Regulation 1272/2008 as there is partial evidence (although not conclusive) of carcinogenicity, mutagenicity and toxicity for reproduction from appropriate human and animal studies. Other EU legislations have included restriction to these substances along the same reasoning. For example, Directive 76/768/EEC includes a provision in Article 4b that prohibits the use in cosmetic products of carcinogenic, mutagenic and substances that are toxic for reproduction (CMR) with category 1A, 1B and 2 as classified by CLP Regulation.[33, 34]

Another limitation of the TU List is the number of neurotoxicants considered, since there is no available official data on substances that cause major permanent functional changes in the central or peripheral nervous system. CLP regulation only includes narcotic effects; therefore it does not have a classification for neurotoxicity itself nor specific hazardous statements. For that reason, literature review was used to identify occupational neurotoxicants and add them to the list.

The TU List also includes the PBT list of the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic. These substances do not meet all the PBT/vPvB criteria established in Annex XIII of REACH. However, scientific evidence behind the OSPAR list of PBT substances is strong enough to be considered as being of an equivalent level of concern to substances classified as PBT or vPvB by REACH.[35]

Because there is little or no publicly available toxicity data for 75.000 substances on the European market the 138 substances for which complete risk assessment reports have been published - and therefore have more complete available data - might be over-represented at the top of the Trade Union List.[36] Other substances that have not gone through the EU risk assessment program may not be included in the TU List.

Errors leading to an underestimation of toxicity of certain substances might be introduced into the prioritisation scheme due to these data gaps.

Prioritisation criteria.

Because of the large number of chemicals produced annually, and their lack of fully comprehensive assessments of human exposure and possible health effects, it would be prudent to calculate an acceptable estimation of exposure with the available data. From a Trade Union point of view, it is important to choose substances widely used in the workplace, and, or, in different sectors. To find out which substances are widely used, we explored occupational exposure databases. However, it is complicated to find updated occupational exposure databases that cover all EU countries, and most of the existing databases are private.[37, 38] An additional source to obtain workers' exposure data is the European list of occupational diseases. These substances have been marked in the list as stated previously.

The high production volume data used for this project was obtained from the Ex-European Chemicals Bureau and was published in 1999. This high production chemicals database was established by the Council Regulation 793/93, for substances produced in the European market between 1971 and 1981.[39] Thus this information may not be properly updated and it is clear that many substances currently produced in high production volumes in Europe, are not considered in the TU List. For instance, triethyl arsenate, has been identified as a SVHC in the REACH Candidate list published by ECHA, but it is not in the TU List because it was registered after 1981 and it is not included in the Ex-ECB HPVC database. Another example of a substance not updated is musk xylene which is recommended by ECHA for inclusion in Annex XIV, although is registered as Low Production Volume Chemical (LPVC) in the Ex-ECB database.

Definition of scores for each criterion.

Confirmed PBTs and EDs were given the same rank (9) than possible CMRs (CMR 2) in the TU List although PBTs, CMRs and EDs are equally identified as SVHC under REACH. This decision was taken due to the high impact of cancer and reproductive disorders due to occupational exposure to CMR.

Development of the list.

RCF, or aluminium silicate wools, were included in the TU List although they were not included in the HPVC list. However 25,000 tonnes of these materials was used in Europe in 2005. About 25,000 workers are exposed annually in Europe to these types of high temperature wools. RCF have been also proposed by the Commission as candidate substances for which an Occupational Exposure Limit Value might be defined at EU level, signalling that they are recognized to be highly relevant for workers health.[40,41] Recently, in January 2010, Zirconia Aluminosilicate Refractory Ceramic Fibres have been included in the REACH Candidate List.

Inclusion of substances linked to occupational diseases in REACH candidate and authorisation lists is crucial for the improvement of workers health. The list of substances considered or suspected to cause occupational diseases in the EU was used as a baseline since these substances are involved in scientifically recognised occupational diseases liable for compensation in most EU countries. Nevertheless, it is very difficult to relate with certainty an occupational disease to a particular substance. On the other hand, the procedure to include substances related with occupational diseases is long and complicated. Therefore, some widely used substances that are related with occupational diseases might not be included in our project. No specific scoring was applied to the substances capable of producing an occupational disease, since this approach would not have been consistent with the other criteria based on human and environmental endpoints.

CONCLUSIONS

Workers are exposed to substances of very high concern (SVHC) in their workplaces and for longer periods of time than the general population. Therefore, from a Trade Union point of view these SVHC must be targeted for priority action.

Experience with the ongoing pre-registration procedure in REACH now reveals that more chemicals are being pre-registered than anticipated. The list of pre-registered substances published in the ECHA Website contains more than 143,000 different substances (this is more than 2 times the 70,000 chemical substances and intermediates substances expected by the Commission when drawing up the REACH Regulation). These substances are being pre-registered as required based on their production volume and the hazardous properties of the substance. Approximately 50,000 different substances are envisaged

to be registered by the 30 November 2010 deadline. These substances are thus being produced in more than 1,000 t/y, and are carcinogenic, mutagenic or toxic for reproduction (CMR) in categories 1A or 1B produced in more than 1 t/y; or very toxic to aquatic life and very toxic to aquatic life with long lasting effects (H400/H410) produced in more than 100 t/y. Based on such criteria, these substances are directly related to workers' exposure or can be considered as substances of very high concern. Of this total, 38,500 substances are estimated to be produced in more than 1,000 tonnes per year. If this new data is compared with the 2,782 substances previously covered by the Ex-European Chemicals Bureau (Ex-ECB) HPVC database, it becomes clear that the number and the amount of highly produced substances are dramatically increasing in Europe. This signals that a revision of the TU List should be the list of substances registered under REACH and published by ECHA. The REACH registration process will potentially deliver information on uses and exposure scenarios for substances produced or imported in more than 10 t/y and this information will begin to be accessible by the end of 2010.

At the time the TU List was developed it had 88 substances in common with the SIN List 1.0, the other list also developed to influence the REACH authorisation process. [26] The SIN List 1.0 included 267 chemicals of high concern and used commonly in consumer goods (which has now expanded to 356 substances and substance groups in the revised version updated in October 2009). The main difference between the two lists is that the TU List takes into account the specific issues concerning workers' health in the workplace, applies a precautionary approach towards chemicals 'suspected' of certain harmful effects, and includes a proposal for ranking SVHC. Both lists however, combined together to total 484 substances, consist of substances that present well known risks to human health and the environment, and should consequently be included in the REACH candidate lists and substituted as soon as possible with safer alternatives. It is noteworthy that 66 of these common substances are linked to occupational diseases.

Including the TU List into the REACH Candidate List will improve information on the risks of these substances and how to control them throughout the supply chain, as suppliers of these substances or mixtures have the obligation to provide safety data sheets and distributors of articles containing these substances have the obligation to inform consumers of the presence of any authorised chemicals in the products they buy and how to use them safely. Substances that already have a harmonised classification would not need a complete Annex XV authorisation dossier. Therefore, including them in the Candidate List would have an important impact on the protection of human health and the environment and would not excessively impact ECHA's limited resources.

Furthermore, 74,000 workers die each year from exposure to pollutants at work in EU-27.[42] Including the TU list into both the REACH candidate and authorisation lists would promote the development of safer alternatives and reduce the incidence of chemical-related occupational diseases and the attendant costs for communities, workers and industry itself.

In this paper, we present a precautionary but scientifically aligned process for identifying, scoring and ranking Substances of Very High Concern including categories of substances not currently considered in other approaches to the REACH regulation. This proposed methodology is advocated by Trade Unions to coherently prioritise SVHC in order to implement and enforce REACH in a way that will more effectively protect the health of the European working and general population.[43]

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