

## REACH authorization

## Will the mountain give birth to a mouse?

In October 2008, the European Chemicals Agency published its first list of dangerous substances identified as candidates for authorization under the REACH rules. Just 15 chemicals are listed, when it could easily have been 800-plus. This article looks at the whys and wherefores of this very low-key start for REACH authorization.

The new EU Regulation to control the trade and use of chemical substances (REACH) came into effect in June 2007. It requires manufacturers and importers of chemicals to register them with the European Chemicals Agency (ECHA) as proof that they can be used safely. For chemicals of very high concern, industrialists must also get authorization for each use in order to continue marketing them. Authorization is a procedure designed to identify the most dangerous chemicals currently on the European market, control the risks arising from their uses and replace them with safer alternatives. There are thought to be between 1 500 and 2 000 substances of very high concern on the European market.

### Substances of very high concern

Substances of very high concern include substances which are:

- carcinogenic, mutagenic or toxic to reproduction (CMR) classified in category 1 or 2;
- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation;
- identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to humans or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters).

mends should be “prioritised” will be put on the list of substances subject to authorization (Annex XIV of REACH). Producers of these substances then face the choice of either stopping manufacturing them in favour of safer alternatives, or obtaining an authorization within the allowed time in order to continue using them. The Commission may grant or refuse authorizations in the particular case. The candidate list is also important in placing new obligations on the industrialists who manufacture and use these substances, especially duties to downstream users and consumers (see box, p. 25).

### A very low-key start

The REACH regulation requires the ECHA to publish its first recommendations on what it considers to be the priority substances for inclusion on the list of substances subject to authorization (Annex XIV) by June 2009 at the latest and to update this list at least every two years<sup>1</sup>. In readiness for this deadline, the Agency - which is based in Helsinki - busied itself up to June 2008 collecting proposals for substances that might feature on the candidate list. This involved the Member State Competent Authorities putting forward to the Agency 16 substances that could potentially be identified as being of very high concern<sup>2</sup>. After a period of public consultation, the ECHA Member State Committee<sup>3</sup> unanimously agreed on the identification of 15 substances of very high concern out of the 16 proposed<sup>4</sup>. The Agency therefore published in October 2008 a first list of 15 candidate substances for authorization (see table, p. 24).

### A long and complex procedure

The authorization procedure, and therefore the substitution principle's intended role in REACH, was hotly debated during the protracted negotiations leading up to the adoption of the Regulation. The outcome is a cumbersome and complicated procedure (see box, p. 27), which broadly runs as follows. Before actually being put forward for authorization, a substance of very high concern must first be identified as such. The production volume is irrelevant. Then, it may possibly be put on the list of substances that are “candidates” for authorization (the “candidate list”). Of all the candidate substances, only those that ECHA recom-

In the list of substances classified as dangerous in the European Union<sup>5</sup>, more than 800 are officially recognized as being category 1 or 2 carcinogenic, mutagenic or toxic to reproduction. This means they automatically meet the criteria for being identified as substances of very high concern. Furthermore, the Commission and Member States have already agreed on a further list of 27 persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances<sup>6</sup>. It might have been expected, therefore, that the Helsinki Agency's first list of candidate substances for authorization should include at least all these chemicals. A list of just 15 is a far cry from that.

<sup>1</sup> REACH regulation, article 58 (3).

<sup>2</sup> France proposed five substances, Norway three, Germany, Austria and Sweden two each, the Netherlands and the United Kingdom one each.

<sup>3</sup> See: Tony Musu, The European Chemicals Agency, keystone of REACH, *HESA Newsletter*, No. 34, June 2008, p. 8-12 (<http://hesa.etui.org> > Newsletter).

<sup>4</sup> Cyclododecane was left off for want of sufficient scientific evidence to identify it as a substance of very high concern.

<sup>5</sup> Annex I of Directive 67/548/EEC.

<sup>6</sup> “OSPAR List of Chemicals for Priority Action” on [www.ospar.org](http://www.ospar.org)

## Candidate list of substances for authorization (at 28/10/2008)

Substance name	EC No. (CAS No.)	Reason for inclusion	Function and examples of use
1 Triethyl arsenate	427-700-2	Carcinogenic	Intermediate used in the manufacture of semi-conductors
2 Anthracene	204-371-1	PBT	Intermediate used in the synthesis of other chemicals. Also used in pyrotechnic articles
3 4,4'- Diaminodiphenylmethane (MDA)	202-974-4	Carcinogenic	Hardener used in epoxy resins and adhesives
4 Dibutyl phthalate (DBP)	201-557-4	Toxic to reproduction	Plasticizer used in PVC products
5 Cobalt dichloride	231-589-4	Carcinogenic	Intermediate used in the synthesis of other cobalt compounds
6 Diarsenic pentaoxide	215-116-9	Carcinogenic	Used for special glass production
7 Diarsenic trioxide	215-481-4	Carcinogenic	Used in lead-acid batteries
8 Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	Carcinogenic, mutagenic and toxic to reproduction	Intermediate used in the synthesis of other chromium compounds
9 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	vPvB	Fragrance used in detergents and toiletries
10 (a) (2-ethylhexyl) phthalate (DEHP)	204-211-0	Toxic to reproduction	Plasticizer, used in PVC products
11 Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9  (134237-50-6) (134237-51-7) (134237-52-8)	PBT	Flame retardant, used in plastics, textiles and electronic devices
12 Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB	Used in rubber articles, textiles, adhesives
13 Bis(tributyltin)oxide (TBTO)	200-268-0	PBT	Anti-mold used in textiles, leathers
14 Lead hydrogen arsenate	232-064-2	Carcinogenic and toxic to reproduction	Biocide used for the treatment of wood
15 Benzyl butyl phthalate (BBP)	201-622-7	Toxic to reproduction	Plasticizer, used in PVC products

Source: information taken from the ECHA website: [http://echa.europa.eu/chem\\_data/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/candidate_list_table_en.asp)

Greyed-out substances are classified as priority for authorization in the ECHA Member State Committee's draft Recommendation (published on 14 January 2009)

### Why such a short list?

There may be several reasons why the first candidate list is so short. One is certainly political. Consumers and industrialists themselves might see the candidate list as a black list of undesirable substances. There was therefore wide support among the Commission and Member States for keeping the first list short in order to test the system.

Also, the REACH Regulation now gives European consumers the right to ask manufacturers of goods (e.g., toothbrushes or household electrical appliances) whether their products contain a substance included on the candidate list, and manufacturers must reply within 45 days. The advantage of a small number of substances for industrialists, but also the policing and enforcement authorities, is clear to see.

Another reason is the crowded schedule for the time within which Member State Competent Authorities had to put up their first proposals for candidate substances: June 2008 was both when the REACH Regulation came into operation and the start of the six-month pre-registration period for substances. This was a difficult time in which the authorities had to juggle many tasks to get the system up and running, often with limited resources.

Finally, the fact of REACH being a brand new system, the complexity of the authorization procedure generally, and a possible lack of expertise in some Member States may be other reasons why only 16 substances were proposed by a total of just seven countries.

## The candidate list puts new obligations on firms

**Article 7(2)** EU and European Economic Area (EEA) producers or importers of articles have to notify ECHA if their article contains a substance on the Candidate List. This obligation applies if the substance is present above 0.1% (w/w) and its quantities in the produced/imported articles are above 1 tonne in total per year per company.

Notifications of substances included in the Candidate List before 1 December, 2010 must be submitted by 1 June 2011 at the latest.

Notifications of substances included in the Candidate List after 1 December 2010 must be submitted 6 months after inclusion at the latest.

**Article 31(1.c)** The supplier of a substance included in the Candidate List must provide the professional user of the substance with a Safety data sheet.

**Article 31(3.b)** The supplier of a non-classified preparation which contains a substance included in the Candidate List in a concentration above 0.1% (w/w) must provide the professional user at his request with a Safety data sheet.

**Article 33(1)** Producers or importers of articles containing a candidate list substance in a concentration above 0.1% (w/w) must provide sufficient information to their customers to allow safe use of the article.

**Article 33(2)** Producers or importers of articles containing a candidate list substance in a concentration above 0.1% (w/w) must provide to any consumers who request it sufficient information to allow safe use of the article. The information must be provided within 45 days of receipt of the request and contain at least the name of the substance.

## When will the first authorizations filter through?

There is still a long way to go between this candidate list and the first authorizations being granted (or refused). ECHA's publication of the list of candidate substances for authorization is only the end of the first stage. The Agency's Member State Committee now has to recommend priority substances for authorization (1 June 2009 at the latest), after which the Commission will have to decide which substances to include in Annex XIV (autumn 2009). Manufacturers of these substances will then have to submit their authorization applications (no earlier than spring 2011). The ECHA's Risk Assessment Committee and Socio-Economic Analysis Committee then have to draft their opinion on the dossiers submitted by industrialists (over a year if applicants want to comment on the draft opinion) before the Commission can give a final decision. In net terms, the first decisions to authorize any of the candidate substances published in October 2008 might not be taken until early 2013!

Meanwhile, the candidate list has to be updated with additional substances of very high concern proposed by the Member States or Commission. The Commission has been heavily criticized for not having proposed any of these in the first list, and so hastily asked ECHA to draw up for it identification dossiers for five substances of very high concern (so-called "Annex XV dossiers", see box p. 27). The Agency is planning a first update of the candidate list in October 2009. It has also put on its website a register of intentions enabling interested parties (Member States, NGOs, industrialists, trade unions,

etc.) to find out which substances the authorities are considering preparing an Annex XV dossier for<sup>7</sup>.

## How many substances will there actually be?

No-one can say for sure before the end of 2009. In any event, the Commission is not bound by whatever selection of priority substances the Agency recommends this June, and some substances could well languish on the candidate list forever. Whatever "prioritisation" the Helsinki Agency proposes, however, will give a pointer to the maximum number of substances that the Commission is apt to include in Annex XIV of REACH.

ECHA published a first draft recommendation by the Member State Committee on 14 January 2009. Only 7 of the 15 candidate substances are proposed as priority<sup>8</sup>. This may yet change if the Committee takes account of whatever comments come in during the three month consultation period provided for interested parties. For the reasons cited earlier, however, and the fact that the Regulation specifies that the number of substances subject to authorization cannot exceed the Agency's capacity to handle applications within the time provided, the final number of substances will likely struggle to get into double figures.

## The union view

The European Trade Union Confederation (ETUC), through its representatives and observers in the ECHA, has repeatedly complained that too few

<sup>7</sup> [http://echa.europa.eu/chem\\_data/reg\\_intentions\\_en.asp](http://echa.europa.eu/chem_data/reg_intentions_en.asp).

<sup>8</sup> See substances highlighted in the table.

substances of very high concern were proposed and finally included in the first candidate list. It argues that this very shaky start could put the entire authorization procedure's credibility on the line and undermine REACH's substitution aims. Also, the small number of substances on the candidate list severely restricts consumers' right to know.

The ETUC has therefore called on the Member State Competent Authorities, the Commission and the ECHA to put on the candidate list all the substances already classified as category 1 or 2 carcinogens, mutagens and reprotoxins in the EU. Drawing up identification dossiers for these should not put a drain on official resources as the Regulation provides a simplified Annex XV for substances already classified in Annex I of Dangerous Substances Directive 67/548/EEC.

Chemical hazards are responsible for a third of occupational diseases in the EU<sup>9</sup>. The ETUC also wants priority given to substances of very high concern to which workers are most exposed. Taking its cue from the SIN List<sup>10</sup>, put forward by an alliance of environmental NGOs, the ETUC recently published a list of priority substances for workers, in the hope that the authorities will take a lead from it.

## Conclusions

Authorization in REACH has often been touted as the best way of eliminating or replacing by safer alternatives the 1500 to 2000-odd most dangerous substances currently found on the European market. As the Regulation's measures get rolled out in practice, it is becoming clear that authorization is a long and winding road which will lead to no more than 10 to 15 substances being processed a year. At this rate, it will take more than a century to rid ourselves of the manufactured chemicals that pose most health concerns for workers, the public and the

### ETUC earmarks priority chemicals for REACH authorisation

On 31 March 2009, the European Trade Union Confederation (ETUC) presented a list of priority chemicals for authorisation under REACH to the European Parliament. ETUC is calling on the Member States and European Commission for the 306 substances of very high concern on its list – especially the 191 that cause recognised occupational diseases – to be included on the candidate list of substances for authorisation under the REACH rules.

All of the chemicals listed by ETUC are considered to meet the REACH criteria for classification as “substances of very high concern”. However, the trade union list goes further as it ranks chemicals by reference to their intrinsic toxicological properties and identifies those that cause occupational diseases which are recognised at EU level.

ETUC believes that including the union-listed chemicals in the candidate list for REACH authorisation would cut the incidence of chemical-related occupational diseases and the inherent costs for the community, workers and industry.

The ETUC Priority List: <http://hesa.etui.org>

environment. The Member State Competent Authorities, Commission and ECHA must sort things out now if the high hopes workers and consumers have pinned on the REACH authorization procedure are not to be betrayed. For that would inevitably bring the whole reform into disrepute as a huge con-trick. ■

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<sup>9</sup>Tony Musu, *REACHing the workplace, How workers stand to benefit from the new European policy on chemical agents*, ETUI, 2006.

<sup>10</sup>“Substitute It Now!” campaign ([www.sinlist.org](http://www.sinlist.org)).

## How does the authorization procedure go in practice?

The authorisation process comprises four steps. Industry has obligations in the third step, but interested parties (Member States, industrialists, NGOs, trade unions, etc.) can submit their comments in steps 1 and 2.

### Step 1 Identifying substances of very high concern and including them in the candidate list

Substances of very high concern are identified by the Member State Competent Authorities or the Helsinki Agency (on behalf of the European Commission) by preparing a dossier – known as an “Annex XV dossier”<sup>\*</sup> – for each substance proposed. Interested parties can comment on substances for which a dossier has been prepared. This procedure results in the Agency’s Member State Committee drawing up a list of substances identified as of “very high concern”, and therefore potentially subject to authorization (the “candidate list”). There must be unanimous agreement in the Member State Committee for a proposed substance to be put on the candidate list. In the event of disagreement over a substance, the European Commission will decide by the Comitology procedure. The candidate list must be published and periodically updated by the Agency.

### Step 2 “Prioritising” substances in the candidate list and including Annex XIV substances

The Agency (via its Member State Committee) then has to adopt an opinion to recommend to the Commission which of the substances of very high concern on the candidate list should be regarded as priority for authorization. The Regulation however requires priority to be given to substances that are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), those that have wide dispersive uses or that are produced in high volumes. The number of “prioritized” substances – i.e., included in the list of substances that should be subject to authorization (Annex XIV of REACH) – may not exceed the Agency’s capacity to handle applications within the time provided.

The interested parties can submit comments during this procedure. The Commission then takes the following final decisions through a Comitology procedure:

- whether or not a substance recommended by the Agency will be subject to authorization;
- which uses of the substances included in Annex XIV will not need authorisation (e.g. because sufficient controls established by other legislation are already in place);
- the “sunset date” by when a substance can no longer be used without authorisation.

### Step 3 Applications for authorisation by industry

Applications for authorisation need to be made within the deadlines set for each use not exempted from the authorisation requirement. They must include among other information:

- a chemical safety report covering risks related to those properties that caused the substance to be included in the authorisation system (unless already submitted as part of the registration);
- an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.

If this analysis reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative. The suitability of available alternatives is assessed taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible.

An applicant can include a socio-economic analysis in his application. He must do so if he is unable to demonstrate adequate control of risks and where no suitable alternative exists. A fee is payable for each application, which may amount to as much as 50 000 euros.

The Agency provides expert opinions for all applications via its Risk Assessment Committee and its Socio-Economic Analysis Committee tasked with preparing opinions. The applicant can comment on these opinions.

### Step 4 Granting of authorizations by the European Commission

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled, even where there is a safer alternative substance or technology. The “adequate control route” does not apply to substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.

If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

Downstream users may only use such substances for uses which have been authorised. For this they must either:

- obtain the substance from a company that was granted an authorisation for that use. In this case, they must stay within the conditions of that authorisation, and notify the Agency that they are using an authorised substance; or
- apply themselves for authorisations for their own uses.

All authorisations will be reviewed after a certain time-limit, set on a case-by-case basis.

<sup>\*</sup> There are three kinds of “Annex XV dossier” in the REACH Regulation: for the identification of a substance of very high concern; for proposing the harmonized classification and labelling of a substance; for proposing the restriction of a substance.