

Review of EU REACH SVHC Candidate List for Authorization Based on Endocrine Disrupting Properties

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[EU Registration, Evaluation and Authorization of Chemicals \(REACH\) came into force in 2007.](#) It is a complex piece of legislation with many moving parts.

The first step in the REACH authorization process is to identify those substances that may have serious effects on human health or the environment and, therefore, the risks resulting from their use must be properly controlled and the substances progressively replaced when possible.

A Member State or the European Chemicals Agency (ECHA) at the request of the European Commission, can propose a substance to be identified as a Substance of Very High Concern (SVHC). If identified, the substance is added to the [Candidate List](#), which includes candidate substances for possible inclusion in the Authorization List (Annex XIV).

The inclusion of a substance in the Candidate List creates legal obligations to companies manufacturing, importing or using such substances, whether on their own, in preparations or in articles.

The intention to propose a substance to be identified as an SVHC is made public in the registry of intentions before the proposal is submitted so as to give advanced information to industry and other stakeholders.

The proposal is prepared according to Annex XV of REACH and includes two main parts. The first one provides the data and justification for identifying the substance as an SVHC. The second part, examined during the follow-up steps in the identification, includes information on volumes on the EU market and the uses of the substance, the resulting release and exposure, and possible alternatives to the substance.

After publication of the proposal, anyone can comment on it or add further information – for example, information related to the properties, uses, and risks of the proposed substance or its alternatives. If no comments are received, the substance is included in the Candidate List. The proposals and the comments are forwarded to the Member State Committee (MSC) to agree on the identification

as an SVHC. If the committee does not reach a unanimous agreement, the matter is referred to the European Commission.

Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorization List.

ECHA prioritizes the substances from the Candidate List to determine which ones should be included in the Authorization List (Annex XIV of REACH) and therefore, subject to authorization. ECHA regularly submits recommendations to the European Commission, which decides on the substances to be included in the Authorization List. Priority is normally given to substances with PBT or vPvB properties, wide dispersive use or high volumes.

The draft recommendation includes, amongst other things, the following information:

- Sunset Date from which the placing on the market and the use of a substance is prohibited, unless an authorization is granted or the use is exempt from authorization.
- Latest application date by which applications must be received if the applicant wishes to continue the placing on the market or use of the substance after the sunset date.
- Review periods for certain uses, if any.
- Uses exempted from the authorization requirement, if any.

Those who want to submit comments on the draft recommendation can do so within three months of the publication date. The Member State Committee prepares its opinion on the draft recommendation taking into account the received comments. The opinion of the Committee and the comments received during the public consultation will help ECHA finalize its recommendation, which will be submitted to the European Commission, for a decision on the substances to be included in the Authorization List.

As of this writing, there have been 173 chemicals nominated to the Candidate List, five of which were nominated based on their endocrine disrupting properties (Bis[2-ethyl]phthalate (DEHP), 4-(1,1,3,3-tetramethylbutyl)phenol, 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated, 4-Nonylphenol branched and linear, 4-Nonylphenol branched and linear ethoxylated).

What is the pool of chemicals considered for potential listing as EDCs?

EU REACH registration, evaluation and authorization applies to substances on their own; substances in mixtures; and certain cases of substances in articles. Chemical substances that are already regulated by other legislation such as medicines, biocides, pesticides, or radioactive substances are partially or completely exempted from REACH requirements.

There is a special transitional regime for substances which were already manufactured or placed on the market before REACH entered into force. Such substances are called phase-in substances.

Substances that fulfill at least one of the following criteria may be considered as phase-in substances in accordance with REACH:

- Substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- Substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992
- Substances that qualify as "no-longer polymer"

For these substances, the REACH Regulation sets the following registration deadlines:

30 November 2010

Deadline for registering substances manufactured or imported at 1 000 tonnes or more a year; substances that are carcinogenic, mutagenic or toxic to reproduction above 1 tonne a year; and substances dangerous to aquatic organisms or the environment above 100 tonnes a year.

31 May 2013

Deadline for registering substances manufactured or imported at 100-1 000 tonnes a year.

31 May 2018

Deadline for registering substances manufactured or imported at 1-100 tonnes a year.

How many chemicals are listed as EDCs?

The EU REACH Candidate List for Authorization currently lists five chemicals as having endocrine disrupting properties (Bis(2-ethyl)phthalate (DEHP), 4-(1,1,3,3-tetramethylbutyl)phenol, 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated, 4-Nonylphenol branched and linear, 4-Nonylphenol branched and linear ethoxylated).

Do the authors use the WHO/IPCS definition of an EDC?

Yes, they purport that they do use the WHO/IPCS definition, although it is difficult to confirm this from their website. The European Commission is [committed to using the WHO/IPCS definition](#).

Is the list homogeneous or does it classify different categories of EDCs?

The list is homogeneous and lists chemicals with endocrine disrupting properties.

What scientific expertise do the authors have?

ECHA employs more than 600 professionals with a wide range of expertise in chemistry, the biological and environmental sciences, including toxicologists and risk assessors.

Do the authors of the list engage other stakeholders?

Yes, the authorization phase of REACH is very open and transparent with multiple opportunities for stakeholders to submit information and to become engaged.

Is the list based on primary research or do they rely on other lists?

It is based on primary research.

Is the list updated on a regular basis with new information?

Yes, chemicals are nominated to ECHA for consideration to be added to the Candidate List of SVHCs on an ongoing basis.

Is there a process to appeal the listing of a chemical?

Yes.

What are the strengths of the list?

- The list is easily accessed and searched.
- The criteria for listing a chemical are fairly transparent.
- The process allows for multi-stakeholder input and for appeals.
- ECHA has a broad range of scientific expertise on staff and ample resources.
- The list is regularly updated.
- They employed the WHO/IPCS definition of an EDC. However, the criteria used to classify substances as EDCs are currently in a state of flux as the EU Commission has proposed criteria for use within the Crop Protection Products Legislation and the Biocidal Products Directive. Those criteria will also presumably be used for REACH.

What are the weaknesses of the list?

- The pool of chemicals evaluated excludes substances that are not covered by the REACH legislation (excludes medicines, pesticides and biocides).
- The Candidate List includes many chemicals that lack endocrine disrupting properties and so it is a bit misleading to describe it as a list of endocrine disruptors and confusion on this point is highly likely.
- The EU Commission has proposed criteria for classifying substances as EDCs based on the WHO/IPCS definition, but they have been roundly criticized and are undergoing further review and possible modification. It is likely that politics rather than science alone will play a large role in the final criteria.

What are the implications of the list for the Value Chain?

The current list of identified EDCs is small (N=5) and substitution has already occurred for most of the chemicals on the list. How the future list will impact the value chain will depend on the final criteria proposed by the EU Commission.