

Properties criteria - BETA

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Introduction

ABOUT THE BASTA SYSTEM

The aim of the BASTA system is to phase out substances with particularly hazardous properties from building- and construction products. With products, BASTA refers to both articles and chemical products. The core of the BASTA systems is an transparent and scientifically based criteria and quality is ensured through follow-up audits. To achieve comparable and relevant requirement levels, BASTA's properties criteria are based on the European chemicals legislations REACH and CLP¹⁾. The BASTA system is founded on the legislation, to the extent that the limits of BASTAs criteria comply with specified classification limits. However, the BASTA system goes further than the legislation: where the legislation sets the limit for classifications, the BASTA system sets the limit for acceptable content. Where the legislation only covers chemical products, the BASTA system covers both chemical products and articles.

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THE BETA CRITERION

The BETA Property criteria are less stringent than the BASTA criteria¹⁾. This means that articles registered in the BETA register may be associated with risks. Therefore, registered companies must specify which BASTA criterion that the BETA registered article does not meet.

The supplier of products in the BETA register should provide information in the form of environmental and health and safety information, see template on <https://www.bastaonline.se/document/?lang=en>, for the assessment of risks during handling, usage, demolition and waste, as well as instructions for handling such risks. For chemical products, a safety data sheet is sufficient as environmental and health safety information provided that it complies with the REACH Regulation, Title IV (Information in the supply chain). Products that meet the BASTA criteria shall be registered in the BASTA register.¹⁾

Table 1 describes the substance properties covered by the BETA criterion. Products that are registered in the BETA register may not contain substances with the properties listed in the table, at concentrations equal to or above specified concentration limits. When a specific concentration limit is specified for a substance with regards to any property ⁴⁾, it applies instead of the one given in Table 1, the third column. All substances included in the so-called candidate list ⁶⁾ to REACH is subject to the criteria. The table contains footnotes that clarify or describe how the criteria should be interpreted and used. As the last entry to the document we find a list of the used hazard statements.

In addition to limiting the content of substances with specific properties, BETA also has information requirements. Table 2 describes the information requirements that apply to products registered in the BETA register.

Furthermore, the BASTA system has a requirement, entailing that registered companies must allow audits of the assessments that form the basis for the companies' article registration, as well as that suppliers can demonstrate that they have working methods, knowledge and documentation, which enable that the criteria can be followed over time. These requirements are stated in the agreement signed between the company and the BASTA system. A notification of any Criteria Changes that entails stricter criteria are announced at least 6 months before implementation.

BASIS FOR CALCULATIONS

The constituent substances content levels are to be calculated for the product in the form it is delivered to a building site or equivalent. Chemicals that have been used in manufacturing but are not present in the delivered product do not need to be considered.

If several substances have similar properties, their contents should be combined if it says "yes" in the fourth column in table 1, in order to obtain the total contribution in the assessment for the current hazard. More information on how the calculation is made can be found in footnote 10.

Continued from previous page...

If the classification of a chemical product that is a preparation²⁾, due to its properties differ from the included substances respective classification, it is the classification of the mixture that applies.

For complex articles³⁾ that consist of several parts, the basis for calculations should be the weight of the individual part that contains the substance, i.e the assessment should not be based on the content of the complex article. It is the individual concentration of each individual component that shall be evaluated against the BETA criterion concentration limits. See the definition of an “article” in **article 33 in the REACH regulation** ¹⁾.

Properties criteria in the BETA–register

Products that are registered in the BETA system may not contain substances with the properties listed in the table, at concentrations equal to or above specified concentration limits. In some cases, specific content limits must be considered⁴⁾.

Substance Properties	Definition	Concentration limit (by weight) (if specific limits not are specified) ⁴⁾	Summation ¹⁰⁾
1. Carcinogenic	Substances with properties according to hazard class of carcinogenic in category 1A and 1B (H350) ⁴⁾	0.1%	—
2. Mutagenic	Substances with properties according to hazard class of mutagenic in category 1A and 1B (H340) ⁴⁾	0.1%	—
3. Toxic to reproduction	Substances with properties according to hazard class of toxic to reproduction in category 1A and 1B (H360) ⁴⁾	0.3%	—
4. Effect during lactation	Substances that meet the hazard class Reproductive toxicity, category Effects on or via breastfeeding (H362) ⁴⁾	0.3%	—
5. Endocrine disrupting	a) Substances that are considered endocrine disrupters in accordance with the EU definition of endocrine disrupting substances ¹²⁾ . See BASTA's guide on restriction of endocrine disruptors ¹³⁾ .	0.1%	—
	b) Substances that receive the overall assessment Cat 1 or Cat 2 in EU's - EDS Database ⁵⁾	0.1%	—
6. Persistent, bio accumulative and toxic organic compound (PBT)	Substances with 1) a half-life > 60 days in marine water or >40 days in fresh- or estuarine water or > 180 days in marine sediment or >120 days in fresh- or estuarine sediment or >120 days in soil and 2) BCF (Bio Concentration Factor) >2000 l/kg (wet weight) and 3) Toxicity NOEC or EC10 < 0.01mg/l or CMR – Carcinogenic 1A, 1B (H350). Germcell Mutagenic 1A, 1B (H340). Toxic for reproduction 1A, 1B, 2 (H360 and H361) or classified H372 or H373	0.1%	—
7. Very persistent and very bio accumulative organic compound (vPvB)	Substances with 1) a half-life > 60 days in marine-, fresh- or estuarine water or > 180 days in marine-, fresh- or estuarine sediment or > 180 days in soil and 2) BCF (Bio Concentration Factor) >5000 l/kg (wet weight)	0.1%	—
8. Lead (Pb)	Lead or compounds of lead	0.1% ⁸⁾	Yes

Substance Properties	Definition	Concentration limit (by weight) (if specific limits not are specified) ⁴⁾	Sammanräkning ¹⁰⁾
9. Mercury (Hg)	Mercury or compounds of mercury	Ban ⁷⁾	Yes
10 Cadmium (Cd)	Cadmium or compounds of cadmium	0.01%	Yes
11. Dangerous to the ozone layer	Substances meeting the criteria for the hazard class Hazardous to the ozone layer (EUH 059, H420) and all substances listed in the Annex to Regulation (EC) No 1005/2009 ⁹⁾	0.1%	—

Table 2. Information requirements in the BASTA-register

Information requirements	Definition	Informations-limits (weight-%)
A. Substances on the Candidates list⁶⁾	The chemical name, CAS number and substance level shall be stated for substances found on the Candidates List. Enter the information into the description field in the system registration view. The text must contain the phrase "Contains substances on the Candidate list."	0,1 % ¹¹⁾
B. Information requirement linked to Criteria 5 Endocrine disrupters¹⁴⁾	The chemical name, CAS number and substance level shall be stated for substances covered by the information requirement in step C. The information is entered into the designated field in the registration view. See current substances covered by the information requirement at https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en .	0,1 % ¹⁴⁾

NOTES

- 1) CLP, Regulation (EC) no 1272/2008 on the classification, labeling and packaging of substances and mixtures, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20181201&rid=2>

REACH, Regulation (EC) no 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (Reach), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20150601&from=EN>

- 2) Chemical element and its compounds in natural or prepared form, including additives necessary to product stability and any impurities from the production process, but excluding solvents which may be separated without affecting the stability of the substance or changing its composition.

Preparations: means mixtures or solutions composed of two or more substances.

- 3) For more information regarding the definition of an "article", or "complex article", see KEMI's fact sheet on substances in articles. <https://www.kemi.se/global/broschyrrer/guidance-for-suppliers-of-articles.pdf>

To determine if the article meets the BETA criterion need the substance content in the article needs to be checked against the criteria limits. For complex articles that consist of several parts, the basis for calculations should be the weight of the individual part that contains the substance, not the total weight of the complex article. The concentration, which is compared to the BETA defined concentration limit, should therefore be calculated on each part of a complex article which itself meets the definition of an "article" in **article 3.3 in the REACH regulation:**



To determine if the article meets the BETA criterion need the substance content in the article needs to be checked against the criteria limits. For complex articles that consist of several parts, the basis for calculations should be the weight of the individual part that contains the substance, not the total weight of the complex article. The concentration, which is compared to the BETA defined concentration limit, should therefore be calculated on each part of a complex article which itself meets the definition of an “article” in **article 3.3 in the REACH regulation**:

“Article: An article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition”. An object that in a certain step in its life cycle has become an article, will normally remain an article until it eventually becomes waste after end use (“once an article, always an article”).

- 4) For information about H-phrases, concentration limits and specific classification limits: see ECHA’s classification database “C & L Inventory,” <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>. In those cases where there are specific classification limits for individual substance content, that is, higher or lower than the content limits specified under each criterion, these apply. This applies to both substances with harmonized classification and non-harmonized (self-classification).

For PAHs in plastic or rubber components covered by Commission Regulation (EC) No 1272/2013 and where exposure can be by skin or mouth, the content limits apply in accordance with EC 1907/2006 (Annex XVII, paragraph 50 of the REACH Regulation).

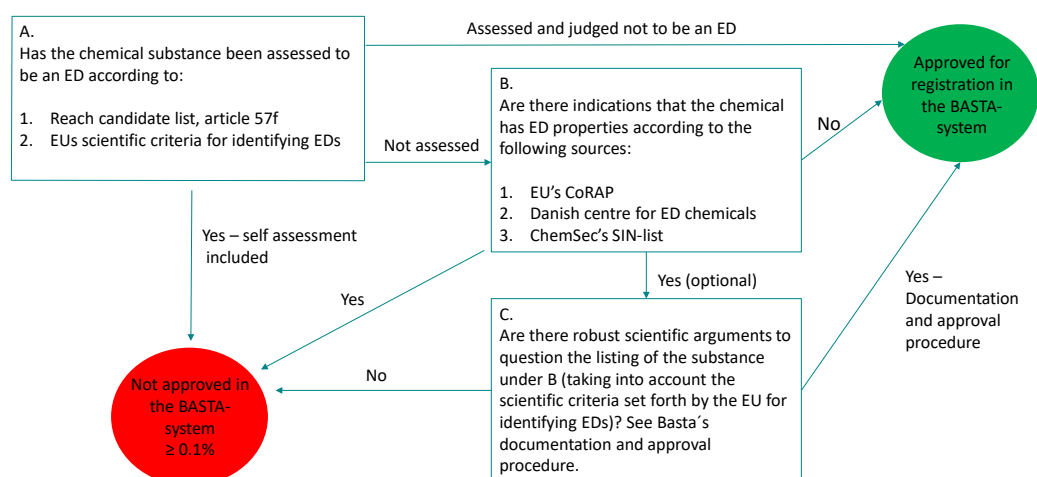
- 5) An extract of the EDS database in its entirety can be found at <https://www.bastaonline.se/document/?lang=en>
- 6) Substances listed on the Candidate List: <https://www.echa.europa.eu/web/guest/candidate-list-table>
- 7) In accordance with criteria 9 there is a ban on mercury. The ban applies to articles where mercury has been used or added. **Low concentrations of mercury that are not intentionally added in any stage thus fall outside the prohibition, but such traces/contamination of mercury should not exceed 2.5 mg/kg. Deviations exceeding 2.5 mg/kg are permitted in cases where they stem from natural occurrence in coal, ore or ore concentrate. The BETA register allows for exemptions according to the RoHS directive (2011/65 / EU)**
- 8) The intention is that the concentration of these substances shall be close to zero. The BETA registry allows exceptions to the concentration limit 0.1% in accordance with the RoHS Directive (2011/65/EU).
- 9) According to “Guidance on the Application of the CLP Criteria”, a substance is defined as ozone depleting if ODP (Ozone Depletion Potential) is equal to or greater than 0.005. These known substances are listed in **Annex I** to Regulation (EC) No 1005/2009. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1005>
- 10) In criteria 8-10 the summation shall include the total concentration levels of lead, mercury and cadmium.
- 11) The information limit applies even if the specific classification limit differs.
- 12) Basta’s criterion for endocrine disruptors is based on the scientific criteria applied under EU chemicals legislation: “Commission delegated regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012” as well as the “Commission regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties”.

The criteria means that substances should be considered to have endocrine disrupting properties if they meet all of the following criteria:

- a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
- b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
- c) the adverse effect is a consequence of the endocrine mode of action.

- 13) For the assessment of which substances that are covered by the above definition, apply Basta's methodology described in the document "Guidance document for handling criteria for endocrine disruptors in the construction industry" (IVL rapport B2369, 2020).

For application in Basta, see the document "Guidance - limitation of endocrine disruptors in Basta Criterion 5", which is available in its entirety on the website <https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en>. The guide gives practical instructions on which substances are considered endocrine disruptors in the BASTA system by applying the following decision tree:



- 14) Information requirements linked to criterion 5 - Endocrine disruptors. Substances evaluated as permitted in Basta in accordance with Step C of Basta's decision-making tree for the limitation of endocrine disruptors (see note 13) are subject to the information requirement. Substances listed on CoRAP, Danish Center for Endocrine Disruptors or the Chemsecs SIN list are generally not allowed in Basta. An exception is if an evaluation has been carried out which shows that the scientific basis for the list of substances are not compatible with the EU criteria for endocrine disruptors. A current list of assessed and evaluated topics can be found on the page <https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en>.

Risk phrases used in these criteria

H 340	May cause genetic defects
H 350	May cause cancer
H 360	May damage fertility or the unborn child
H 361	Suspected of damaging fertility or the unborn child
H 362	May cause harm to breastfed children
H 372	Causes damage to organs through prolonged or repeated exposure
H 373	May cause damage to organs through prolonged or repeated exposure
H 420	Harms public health and the environment by destroying ozone in the upper atmosphere
EUH 059	Hazardous to the ozone layer

The links contained in the document are updated outside of BASTA's control. BASTA is not responsible ensuring that the links are updated at all times but refer to the relevant website. The criteria are continuously reviewed to conform and adapt to new legislation, knowledge and objectives in the chemicals field. New versions of the criteria will enter into force on January 1st or alternatively on July the 1st.

Information about construction products that meet the properties criteria are found on the web-site www.bastaonline.se.

E-mail address is bastaonline@ivl.se You can also contact BASTAonline AB, Box 21060, SE-100 31 Stockholm, Sweden.

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