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Materials and Articles: Requirements and criteria for the content of hazardous substances

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1. Introduction

This guideline is governing and includes requirements and criteria regarding hazardous substances contained in materials and articles in the Swedish Transport Administration's activities.

The Swedish Transport Administration uses large volumes of materials and goods in the construction and maintenance of infrastructure. Many materials and articles have a long lifespan, and the selection of new materials in a facility affects future environmental impact and costs significantly. Minimising the environmental impact of hazardous substances in materials and articles is part of the Swedish Transport Administration's work to create non-toxic and resource-efficient cycles and to achieve the environmental objective "A non-toxic environment". Such work is also part of minimising life-cycle costs through proactive prevention of the leakage and spread of hazardous substances, which eliminates costs for waste or remediation of contaminated soil. Non-toxic materials and articles are also necessary for enabling resource-efficient recycling and limiting our climate impact.

2. Aim

The aim of this guideline is to establish the Swedish Transport Administration's requirements and criteria regarding the content of hazardous substances in materials and articles.

This guideline will help the Swedish Transport Administration to:

- ensure compliance with the Swedish Environmental Code¹, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation² and the Construction Products Regulation (CPR)³.
- fulfil the environmental objectives "A non-toxic environment" and "Reduced climate impact".
- minimise life-cycle costs by preventing future soil, water and natural environment pollution and waste costs.
- ensure cost-effective management and waste disposal through access to documented knowledge and information.
- build and maintain sustainable infrastructure that minimises risks to health and the environment.

This guideline also aims to create consistency and clarity for manufacturers, materials suppliers and contractors in the construction sector by harmonising the requirements and criteria with:

- applicable parts of governing law such as REACH, the Swedish Environmental Code and CPR.

¹ Swedish Environmental Code (1998:808) Rules of consideration Chapter 2, especially the Substitution Principle and the Precautionary Principle

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council

³ Regulation (EU) No 305/2011 of the European Parliament and of the Council



 the National Agency for Public Procurement's ⁴ guidelines for materials requirements in construction contracts and guidelines for the use of sustainability criteria in public procurement.

- BASTA⁵, Byggsektorns avveckling av farliga ämnen.

- The Swedish Transport Administration's requirements and criteria for hazardous substances in chemical products⁶.

This harmonisation is expected to improve the efficiency of risk reduction and the phaseout of hazardous substances from materials and articles in the construction sector.

3. Scope

The requirements in this document cover materials and articles used in the construction of Swedish Transport Administration facilities as well as explosives which are defined as articles under REACH and used in construction of facilities. Chemical products which are subject to labelling requirements and used in articles (e.g., oil in a transformer or oil for surface treatment), are covered by the Swedish Transport Administration's requirements for chemical products, TDOK 2010:310.

These requirements shall apply in the context of:

- management of systems and component development, i.e., development/procurement of Technically Approved Materials (TGM) for materials supply under framework agreements⁷.
- planning, design, procurement, and construction of facilities.
- operations and maintenance.

These requirements are minimum and baseline requirements. If necessary, requirements exceeding these minimum requirements can be formulated as, e.g., technical and system requirements for specific groups of materials or articles.

Earth, rock and spoil⁸ used in construction of facilities is one group of materials where requirements exceeding the minimum requirements of this guideline are necessary⁹. Hazardous substances in earth, rock or spoil can occur naturally or as a contaminant;

⁴ www.upphandlingsmyndigheten.se

⁵ BASTA is a scientifically based system, with the aim of phasing out particularly dangerous substances from building and construction products. The BASTA system, which is owned by the Swedish construction industry, among others, is part of the environmental programme of the Swedish Construction Federation's Life-Cycle Council and has been financed by the EU's LIFE funding programme. (www.bastaonline.se)

⁶ The Swedish Transport Administration's requirements and criteria for the content of hazardous substances in chemical products are set out in TDOK 2010:310 *Kemiska produkter – granskningskriterier och krav för Trafikverket* . www.trafikverket.se/kemikaliehantering

⁷ This includes items acquired via purchase requisitions. Scarce items are not covered by the requirements.

⁸ This also includes granular materials, e.g., crushed concrete.

⁹ Miljöklassificering och bedömning av jordmassor, TDOK 2022:0063 (requirements) and TDOK 2022:0064 (advice).



they have not been actively added to serve a purpose. Their mobility, leachability and exposure to the surrounding environment differs from that of hazardous substances contained in manufactured materials and articles, justifying requirements that exceed those of this guideline. Earth, rock and spoil are exempt from the requirements of this guideline.

In addition to earth, rock and spoil, the following groups of articles are excluded from the requirements of this guideline:

- Fasteners¹⁰ consisting solely of metal, metal alloys or galvanised metal¹¹.
- Scarce items in Technically Approved Materials (TGM).
- Articles consisting solely of natural stone or rock materials, e.g., kerbstones.
- Articles manufactured exclusively from untreated wood.

Hazardous chemical substances may be present either in a chemical product or in articles or materials. The requirements and criteria for hazardous substances in chemical products are set out in TDOK 2010:310 *Kemiska produkter – Granskningskriterier och krav för Trafikverket* and TDOK 2010:311 *Kemiska produkter – granskning av märkningspliktiga kemiska produkter*. The REACH requirements are different for hazardous substances in chemical products and hazardous substances in materials and articles. Therefore, the Swedish Transport Administration has different requirement documents. However, the criteria (see section 6) are fully harmonised for chemical products and materials and articles.

Construction products as defined in the Construction Products Regulation can be either chemical products or articles under REACH. Construction products which are articles under REACH are subject to the requirements of this guideline. CE marking under the Construction Products Regulation means that a construction product has been tested and certified according to a harmonised standard. CE marking does not include harmonised requirements or rules regarding content of hazardous substances, and the requirements of this guideline therefore apply to CE-marked construction products as well.

4. Definitions

A *chemical product* is a chemical substance or a preparation of chemical substances which is not an article. Definition according to the Swedish Environmental Code (1998:808) Chapter 14, Section 2.

Articles are objects which, in the course of production, acquire a specific shape, surface or design which determines their function to a greater extent than their chemical composition. Definition according to REACH, Chapter 2.

Composite articles are articles assembled from two or more articles. This principle is in line with the definition of an article in REACH (Article 3(3)), which reads: "after an object has become an article in its own right during the production process, it will remain an article until it finally becomes waste after use ends."

¹⁰ The term 'fasteners' refers, e.g., to Screws, nuts, washers, rivets, nails, hooks, loops, clamps and hardware such as hangers, brackets, angle irons and hose clamps.

¹¹ "Consisting solely of" means without surface treatment/coating with, e.g., plastic or rubber.

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A *chemical product subject to labelling* is a product with a hazard pictogram and/or statement according to the CLP Regulation (EC) No 1272/2008) under section 2 of the safety data sheet (in accordance with REACH, Regulation (EC) No 1907/2006 of the European Parliament and of the Council).

Materials are not defined in legislation. For the purposes of this guideline, materials means homogeneous materials from which articles might be made, e.g., wood, steel, plastic, etc.

Construction product is any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works. Definition according to Regulation (EU) No 305/2011, Article 2.

KemI The Swedish Chemicals Agency is the central regulatory authority responsible for chemical supervision in Sweden. KemI is the authority responsible for the environmental objective "A non-toxic environment" and works in Sweden as well as within the EU to promote legislation and regulations that contribute to achieving the environmental objective.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. På svenska: Registrering, utvärdering, godkännande och begränsning av kemikalier. REACH is the European Community legislation on chemicals. The rules are set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. REACH regulates chemical substances in both chemical products and articles.

ECHA stands for European Chemicals Agency.

BASTA (Byggsektorns avveckling av farliga ämnen) is a scientifically based system, with the aim of phasing out particularly dangerous substances from building and construction products. The BASTA system consists of criteria for the formulation of requirements as well as two registers, BASTA and BETA. BASTA is a self-declaration system in which suppliers register their own products which meet the requirements and do not contain substances with hazardous properties according to the BASTA or BETA criteria. IVL Swedish Environmental Research Institute and the Swedish Construction Federation are jointly developing BASTA, which is a non-profit company.

An *operator* is anyone who carries out or intends to carry out an activity or take a measure. The operator must, among other things, show that the obligations arising from Chapter 2 of the Swedish Environmental Code are met.

Substitution analysis An analysis describing how the Substitution Principle of the Swedish Environmental Code has been applied.

Risk analysis (environment and health) An analysis of the likelihood and extent of harm with regard to the application in question. The risk analysis is site-specific and must include measures to ensure that the impact on health and the environment is acceptable.

SVHC: Substances of Very High Concern. Particularly hazardous substances which can cause such serious and lasting effects on human health or the environment. Authorisation for use may be required from ECHA.

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5. Application

5.1 Application to different processes

The requirements and criteria in this guideline shall be applied to all processes in which the Swedish Transport Administration chooses and uses materials and articles. All main processes are affected by the requirements, and the following support processes have been identified as central to application and implementation:

- Planning and organising purchasing.
- Managing development of systems and components.
- Administering and developing the Swedish Transport Administration's infrastructure regulations.

The requirements apply to materials and articles supplied by Logistik as well as to materials and articles provided by contractors. For materials supplied via Logistik, the requirements must be implemented and applied in connection with the Swedish Transport Administration's procurement of goods and the signing of central framework agreements for Technically Approved Materials (TGM). For materials provided by contractors, the requirements must be implemented and applied when procuring contracts.

The requirements of this guideline are included in TDOK 2012:93 *Generella miljökrav vid entreprenadupphandling* and must also be applied in development and procurement according to TDOK 2014:0307 *Tekniskt godkänt järnvägsmaterial TGM-införande*.

The requirements also apply to materials and articles which are used or planned to be used in the construction of Swedish Transport Administration facilities as well as explosives which are defined as articles under REACH and used in construction of facilities.

5.2 Requirements for materials and articles

The Swedish Transport Administration's website <u>www.trafikverket.se</u> provides a guide that describes the procedure for the Swedish Transport Administration's requirements for materials and goods.

5.2.1 REQUIREMENTS FOR SUBSTITUTION

The Substitution Principle of the Environmental Code must be applied to the selection and use of materials and articles:

- 1. Materials and articles must primarily meet the Swedish Transport Administration's criteria for Group A.
- 2. If it is not possible to fulfil the Swedish Transport Administration's criteria for Group A, materials and articles that meet the criteria for Group B may be used.
- 3. If it is also not possible to meet the Swedish Transport Administration's criteria for Group B, materials and articles classified in Group C may be used. Materials and articles not meeting the criteria for Group B must fulfil the following specific conditions before use:

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 A documented substitution analysis and a risk analysis must be carried out before the material or article is used. If the substitution analysis shows no viable alternatives, and if risk analysis shows that use of the material/article poses acceptable risks, the material or article may be used.

The substitution and risk analyses must be documented in the TMALLs for substitution and risk analyses, available on the Swedish Transport Administration's website www.trafikverket.se or in another document that meets the minimum requirements of section 5.3.

 The purchaser must be informed if a material or article in Group C will be used. The purchaser must also be informed of the results of the risk analysis before work starts.

Materials and articles may not be used if they contain substances on the Swedish Transport Administration's Prohibition List (section 6, Table 2) in concentrations equal to or exceeding the criteria of the substance in question. These materials and articles are classified in Group D.

When products classified in Group D, with authorised uses listed in Table 2, are to be used, the specific conditions for Group C must be met (item 3 above).

When using materials and articles for which no information on contents is available, the content of candidate substances must be checked 12. Materials and articles containing candidate substances must also be checked against the Prohibition List. If the candidate substance is prohibited, the product is classified in Group D, otherwise in Group C. Materials and articles not containing a candidate substance are classified in Group E. For products in Group E, a documented substitution analysis must be carried out before the material or article can be used.

It must be possible to verify that the criteria are met through BASTA/BETA registration, assessment from an assessment provider (Byggvarubvedömningen or SundaHus)¹³ or a certificate from the supplier¹⁴.

For materials and articles supplied via Trafikverket Logistik (TGM, Technically Approved Material), Trafikverket Logistik is responsible for substitution and the provision of information as well as any documentation regarding the Swedish Transport

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¹² Candidate substances are subject to the information requirement under REACH, Article 33. Suppliers are responsible for informing the supply chain about the content of candidate substances. However, this requirement does not specify *how* the information must be provided. The information can therefore be obtained directly from the supplier or be publicly available on their website. Users/contractors must ensure that they have accessed the information as directed by the supplier.

¹³ A key for translating other assessments to the Swedish Transport Administration's criteria can be found under www.trafikverket.se/materialkrav and Mallar riktlinjer och dokument.

¹⁴ The Swedish Transport Administration's TMALL 0194 "*Intyg från material- och varuleverantör*" or another template with equivalent content must be used. TMALL 0194 can be found under www.trafikverket.se/materialkrav and Mallar riktlinjer och dokument.



Administration's classification in Groups A, B, C or E. Trafikverket Logistik is responsible for ensuring that substitution analyses (for Groups C and E) and risk analyses (for Group C) are available in the Material Catalogue, which can be found on the Swedish Transport Administration's website. The Substitution Principle has already been applied for such products when the framework contract is signed.

5.2.2 ENVIRONMENTAL PERFORMANCE REQUIREMENTS

For incorporated materials and articles selected and purchased by the contractor pursuant to:

- Road contracts: at least 80 percent must meet the Swedish Transport Administration's criteria for Group A.
- Railway contracts: at least 50 percent must meet the Swedish Transport Administration's criteria for Group A.

Electrical and electronic products are excluded from the calculation of environmental performance requirements.

5.2.3 REQUIREMENTS FOR REPORTING AND DOCUMENTATION

Materials and articles designed and/or incorporated in a facility must be documented in a bill of materials. The bill of materials must be recorded in TMALL 0558 or in an Excel template that meets the Swedish Transport Administration's minimum requirements as stated in section 5.4. The requirement to use TMALL 0558 or Excel template applies to all incorporated materials and articles, except materials and articles that are provided by the Inköp och Logistik department or registered in Maximo via template TMALL 0742. When materials and articles are stored in IVAR (inventory database), replacement of materials and articles must also be registered directly in IVAR rather than via TMALL 0558.

Updated bill of materials including substitution analyses, risk analyses and any supplier certificates, must be available during the project and regularly reported to the purchaser¹⁵. Reporting must also show how the current bill of materials fulfils the environmental performance requirements in 5.2.2.

The bill of materials and related annexes must be included in the final documentation. The bill of materials must include all incorporated materials and articles purchased by the contractor. ¹⁶ Material and articles delivered by Inköp och Logistik will be declared in the report "Materialförteckning for TGM". The report is provided by Inköp och Logistik and include all materials and articles delivered within the specific contract. The contractor must supplement the report with geographical location for materials and articles in group C and group E.

¹⁵ Regularity is determined by the size and scope of the project. For projects shorter than 3 years, the appropriate time interval is considered to be between 3 and 6 months. In projects longer than 3 years, or for maintenance contracts, the minimum is deemed to be once annually. The purchaser in this case is the Swedish Transport Administration's project group.

¹⁶ Incorporated materials and goods are those residing in the Transport Agency's facility, such as geotextile, guide posts, culverts, storm drains, asphalt, and railway-specific materials.

The following must be attached to the bill of materials:

- Substitution analyses for materials and articles in Groups C and E.
- Risk analyses for materials and articles in Group C.
- The report "Materialförteckning för TGM" provided by Inköp och Logistik.

Information on the content of hazardous substances, and verification of criteria for articles from Inköp och Logistik, can be found in the Swedish Transport Administration's Material Catalogue. Documentation provided by Inköp och Logistik, i.e., substitution and risk analyses, need not be attached to the bill of materials. Any necessary site-specific risk analyses must be attached to the bill of materials. ¹⁷ The contractor must always make an assessment whether the risk analysis is sufficient or whether a site-specific analysis should be created. In cases where the contractor assess that a site-specific risk analysis is not necessary, the decision must be documented in the bill of materials.

Compliance with the environmental performance requirements under 5.2.2 must be verified by the bill of materials submitted in the final documentation. The environmental performance requirement includes all incorporated materials and articles purchased by the contractor themself as well as all incorporated materials and articles registered in Maximo. The bill of materials must clearly show that the requirement is fulfilled.

The bill of materials must be stored in the systems which 'TDOK 2012:139 Överlämnande av ny eller förändrad infrastruktur" mentions regarding administration data. Materials documentation regarding aspects of the facility for which clear guidelines are lacking in TDOK 2012:139 must be saved together with blueprints for these parts of the facility. Information regarding hazardous substances must be documented and made available in the Swedish Transport Administration's administrative data during the life cycle of the material/article until disposal.

5.3 Specific conditions

If a Group A or B material or article can not be substituted per the Swedish Transport Administration's criteria, specific conditions must be fulfilled before use according to the requirements in section 5.2.1.

5.3.1 SUBSTITUTION ANALYSIS

According to Chapter 2, Section 4 of the Swedish Environmental Code, operators must avoid using chemical products or articles which can be expected to pose a risk to human health or the environment if they can be substituted by products that can be assumed less hazardous. This Substitution Principle is a cornerstone of the general rules of consideration of the Swedish Environmental Code.

The substitution analysis must describe how the Substitution Principle of the Swedish Environmental Code has been applied in the selection of a material or article. The substitution analysis must also present the reasonableness assessment, pursuant to Chapter 2, Section 7 of the Swedish Environmental Code, which justifies the choice.

The substitution analysis aims to demonstrate how substitutes have been considered and evaluated and that no viable substitutes which are better for health and the environment have been found.

¹⁷ The contractor must always assess whether Trafikverket Logistik's risk analysis is sufficient or whether a site-specific risk analysis is necessary.



The substitution analysis must be documented and at least describe:

- The need for the material or article.
- Can another method with less impact on health and environment be substituted?
- Are alternative materials or articles available?
- Do any of the alternative materials or articles have less environmental and health impact?
- How the operator has searched for substitutes.
- Reasonableness assessment and product choice justification.
- If information regarding the content of materials or articles is missing, it must be verified that the user has contacted the supplier to seek information on the content.

The substitution analysis must consider the construction, operations/maintenance and waste phases.

Substitution analyses for materials and articles regarding which information on content is missing can be reported and documented in aggregate¹⁸.

TMALL 1168¹⁹ indicates how to fulfil the minimum requirements for substitution analysis.

The substitution analysis must be carried out by a person with the necessary competence.

Substitution analysis in the procurement of Technically Approved Material (TGM) When procuring TGM, i.e., when the Swedish Transport Administration signs a framework agreement for a certain article, a substitution analysis must be produced. This analysis must follow the procedure for support processes, *Hantera system-och komponentutveckling*, TDOK 2014:0307. Substitution analysis must be carried out in the pilot-study phase²⁰

5.3.2 RISK ANALYSIS

The purpose of the risk analysis is to assess whether use poses acceptable risks. If the risks are deemed acceptable, a material or article may be used when measures to manage the risks have been adopted pursuant to the risk analysis. If the risks are deemed unacceptable, substitution and risk reduction measures must be investigated further to achieve an acceptable level of risk.

Risk analysis must be documented and describe at least:

¹⁸ The aggregation of substitution analyses means that one substitution analysis can be created for several materials/articles. This document must then describe the methodology used to search for substitutes, e.g., by stating that substitutes were searched for in the BASTA/BETA register, Byggvarubedömningen and SundaHus.

¹⁹ The Swedish Transport Administration's TMALL 1168 can be found under www.trafikverket.se/materialkray and Mallar, riktlinjer och dokument.

²⁰ In procurement of framework agreements, the pilot study's substitution analysis can be used as a basis for environmental requirements in the technical statement of requirements.

• Intended use of the material/article (function, area of use, handling, working methods and procedures).

- Name of the hazardous substance, CAS number and classification according to CLP²¹.
- The quantity of the hazardous substance and the total quantity of the goods/articles.
- Potential risks from use and their management.
- Need for protective measures or risk reduction measures
- Requirements for waste disposal.
- Assessment of impact on health and environment.

TMALL 1167^{22} indicates how to fulfil the minimum requirements for risk analysis. The risk analysis must be carried out by a person with the necessary competence.

Risk analysis in procurement of Technically Approved Material (TGM)

If risk analysis for procurement of TGM is carried out in the pilot study, its results may impose requirements for the inclusion of risk reduction measures in the technical statement of requirements.

5.4 Bill of Materials

The purpose of the Bill of Materials is to store product information on the materials and articles incorporated into the facility. The Bill of Materials ensures better traceability of hazardous content and enables management and waste disposal which is cost-effective and safe for the environment as well as the working environment. The Bill of Materials is also used to verify the performance requirements of section 5.2.2.

The Bill of Materials must include at least the following:

- Contractor
- Contract number
- Date
- Article number (where applicable)
- SCIP number²³
- Product name:
- Supplier or manufacturer (company name)²⁴

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²¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

²² The Swedish Transport Administration's TMALL 1167 can be found under www.trafikverket.se/materialkrav and Mallar, riktlinjer och dokument.

²³ The SCIP number is provided where applicable, i.e., when the item has a SCIP number in the SCIP database. Information on SCIP and its legal requirements can be found on the website of the Swedish Chemicals Agency (see www.kemi.se).

²⁴ The supplier/manufacturer must verify that the criteria are fulfilled, e.g., through registration in BASTA, Sunda Hus or BVB or through self-assessment (supplier certificate). Suppliers and manufacturers not registering products in the assessment system must indicate the registration number of the assessment system in the Bill of Materials.

- Geographical location²⁵
- Purpose or use
- Total quantity of the material/goods in the facility²⁶
- Whether the product meets the Swedish Transport Administration's criteria for Group A or Group B
- Whether the product meets the Swedish Transport Administration's criteria for Group A or Group B, and which phase-out substance violates the criteria. Name, CAS number and content in % by weight must be stated.
- Whether information on product content is lacking
- · How compliance with the requirements was verified

The Bill of Materials can be provided in TMALL 0558 or in another Excel template that fulfils the minimum requirements.

5.5 Supplier certificate

The purpose of the supplier certificate is to allow suppliers to verify how criteria are met. Certificates can be issued when the material or article is unavailable in the assessment systems or the assessment of the material/article cannot be translated to the Swedish Transport Administration's Groups A or B.

Technically Approved Material (TGM)

Supplier certificates regarding hazardous content in the procurement of TGM materials²⁷ are sent to the Swedish Transport Administration's purchaser using TMALL 0194. The purchaser, in turn, sends the supplier certificate to the organisation mailbox miljostodmaterial@trafikverket.se for review and categorisation. Certificates and information regarding how various items meet the Swedish Transport Administration's requirements will then be available to contractors in the Material Catalogue.

Contracts

Supplier certificates regarding hazardous content can be provided in TMALL 0194 or in another document containing equivalent information.

5.6 Classification of materials and articles

Similar to chemical products, materials and articles can be classified into four groups using the Prohibition List and the Swedish Transport Administration's criteria. Materials and articles lacking information cannot be classified, and form a fifth group.

Group A - Authorised

Group B - Risk-reduction

Group C - Phase-out

Group D - Prohibited

Group E - No information on content

²⁵ For articles that meet the criteria of Group A or B, geographical location is indicated with a precision consistent with the requirements for other final documentation. For articles that do not meet the criteria, the geographical location shall be indicated in coordinates or kilometres in accordance with TMALL 0558

²⁶ Quantity to be expressed in number, area or weight.

²⁷ The requirements are specified either in the statement of requirements or in the appropriate procurement template.

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The Swedish Transport Administration's criteria are harmonised with the BASTA criteria. The criteria and the Prohibition List are found in section 6.

5.6.1 GROUP A - AUTHORISED

Materials and articles classified in Group A under this classification procedure are best from an environmental and working environment perspective.

Materials and articles in this group do not contain any risk-reduction or phase-out substances, i.e., no substances with properties H1 to H10 (white *and* grey boxes) in excess of the specified content limits according to section 6, Table 1.

The criteria for classification in Group A are the same as the criteria for inclusion in the BASTA register.

5.6.2 GROUP B - RISK-REDUCTION

Materials and articles in Group B are better from an environmental and working environment perspective than products classified in Group C and worse than products classified in Group A. The risks associated with the use of risk-reduction substances must be limited in accordance with the environmental objective "A non-toxic environment". Risk-reduction substances have less severe health and environmental properties than phase-out substances.

Materials and articles in this group do not contain any phase-out substances, i.e., substances with properties H1 (a,c,e,g); H2 (a); H3 (a,b,d,e,f); H4; H5; H6; or H7 (a,b,c) in excess of the specified content limits according to section 6, Table 1 (white fields).

However, materials and articles classified in Group B contain risk-reduction substances, i.e., substances with one or more of the properties H1 (b,d,f); H2 (d); H7 (d); H8; H9; H10 in excess of the specified content limits in section 6, Table 1 (grey boxes).

The criteria for classification in Group B are the same as the criteria for inclusion in the BETA register.

5.6.3 GROUP C - PHASE-OUT

Materials and articles in Group C are less favourable from an environmental and working environment perspective than products classified in Groups A and B. The products in this group will be gradually phased out from use in Swedish Transport Administration activities and replaced by less environmentally and health hazardous products.

Materials and articles classified in this group contain phase-out substances with one or more of the properties H1 (a,c,e,g); H2 (a); H3 (a,b, d, e, f); H4; H5; H6; or H7 (a,b,c) in excess of the specified content limits in according to section 6, Table 1 (white boxes). These criteria are harmonised with criteria under REACH Article 57, Substances of Very High Concern and criteria for inclusion in the Candidate List. The criteria are also harmonised with the criteria for phase-out substances according to the Swedish Chemicals Agency's PRIO database and the environmental objective "A non-toxic environment".

Materials and articles classified in Group C fulfil neither the criteria for registration in BASTA nor the criteria for registration in BETA.

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5.6.4 GROUP D - PROHIBITED

Materials and articles classified in Group D may not be used in the activities of the Swedish Transport Administration. This prohibition may include all uses or only certain applications or uses. The Prohibition List of the Swedish Transport Administration includes substances which are prohibited by law as well as other hazardous substances which the Swedish Transport Administration has decided to phase out and replace with products that are less hazardous to health and the environment.

Materials and articles containing chemical substances on the Swedish Transport Administration's Prohibition List²⁸ in a concentration equal to or in excess of the limit for each criterion²⁹ are classified in Group D - Prohibited.

For the Swedish Transport Administration's Prohibition List, see section 6, Table 2.

5.6.5 GROUP E - NO INFORMATION ON CONTENT

Materials and articles classified in Group E are worse from an environmental and work environment perspective than products classified in Groups A, B or C because there is no available information on their content. Therefore, these products cannot be classified in Groups A, B, C or D. Products in Group E pose a risk to human health and the environment, as there is no information to assess the need for risk reduction measures.

The content of materials and articles in Group E must be checked for substances covered by the information requirement of REACH Article 33. Materials/articles which are not checked cannot be used, i.e., are classified in Group D.

6. Criteria and Prohibition List

The Swedish Transport Administration's review criteria are harmonised with BASTA's criteria. This harmonisation aims to simplify the process and avoid multiple parallel and similar systems, ensuring efficiency in the phase-out of hazardous substances. The criteria are based on European chemicals legislation: REACH and CLP.

If BASTA updates its criteria before a revision of the criteria is made in this guideline, BASTA's changes will apply in a transitional period until the guideline is revised.

Materials and articles are assessed according to the criteria in Table 1, which is based on hazard statements (CLP Regulation, EC No. 1272/2008).

The criteria apply to each part of a composite article, i.e., the content limits are calculated as the ratio of substance weight to the weight of each individual article or material in a composite article. For a composite article to fulfil the Swedish Transport Administration's criteria for Group A or B, none of the constituent sub-components (including constituent chemical products) may contain substances with hazardous properties in concentrations that exceed the specified limits in the criteria.

Phase-out substances are substances with properties as indicated in the white fields in Table 1. These criteria are harmonised with criteria under REACH Article 57,

²⁸ For the Swedish Transport Administration's Prohibition List, see Table 2 and www.trafikverket.se

²⁹ This limit is based on the properties of the chemical substance/group of substances according to CLP or specific lists (e.g., SIN list for endocrine-disrupting chemicals) and the limit of the corresponding criterion in Table 1.

Substances of Very High Concern and criteria for inclusion in the Candidate List. The criteria are also harmonised with the criteria for phase-out substances according to the Swedish Chemicals Agency's PRIO database and the environmental objective "A nontoxic environment".

Risk-reduction substances are substances with properties as indicated in the grey fields in Table 1. The risks associated with use of risk-reduction substances must be minimised in accordance with the environmental objective "A non-toxic environment". Risk-reduction substances have less severe health and environmental properties than phase-out substances.

Table 1. Health and environmental hazards

Properties / substances	Definition	Limit (% by weight)
H1: Carcinogenic, Mutagenic, Reproductive toxicity (CMR)	(a) Substances meeting the criteria for Carcinogenicity, Category 1A or 1B (H350)	0.1% For each substance, levels not to be totalled
	b) Substances meeting the criteria for Carcinogenicity, Category 2 (H351)	1% For each substance, levels not to be totalled
	(c) Substances meeting the criteria for Germ Cell Mutagenicity, Category 1A or 1B (H340)	0.1% For each substance, levels not to be totalled
	(d) Substances meeting the criteria for Germ Cell Mutagenicity, Category 2 (H341)	1% For each substance, levels not to be totalled
	(e) Substances meeting the criteria for Reproductive toxicity, Category 1A or 1B (H360)	0.3% For each substance, levels not to be totalled
	(f) Substances meeting the criteria for Carcinogenicity, Category 2 (H361)	3% For each substance, levels not to be totalled
	(g) Substances meeting the hazard class for Reproductive toxicity, Category Effects on or via lactation (H362)	0.3% For each substance, levels not to be totalled
H2: Endocrine Disruptor ³⁰	a) Substances meeting the criteria for being endocrine disrupting for human health or endocrine disrupting for the environment (EUH380 and EUH430) or substances assessed as endocrine disrupting according to one of the following: - EU definition for endocrine disruptors - REACH Candidate list, Article 57(f) - ChemSec SIN list	0.1% For each substance, levels not to be totalled
	d) ³¹ Substances meeting the criteria for suspected of causing endocrine disruption in human, category 2, or the environment, category 2 (EUH381 and EUH 431)	1%

³⁰ Criterion H2 for endocrine disruptors differs from the BASTA criteria. The Swedish Transport Administration's criteria do not include substances that appear on CoRAP and the "List of EDCs" from the Danish Centre for Endocrine Disruptors.

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³¹ The order of letters in the sub-criteria follows BASTA's criteria, where each sub-requirement retains its letter, even though the requirement has ceased to apply. New partial requirements get new letters. The reason is that there must be traceability for each sub-criteria.

Properties / substances	perties / substances Definition	
Н3: РВТ	a) Persistent, bioaccumulative and toxic organic substances (PBTs) meeting the criteria to accumulates in the enviroinment and living organisms, including humans (EUH440).	0.1% For each substance, levels not to be totalled
	b) Very persistent and very bioaccumulative organic substances (vPvB) meeting the criterias to strongly accumulates in environemt and living organisms, including humans (EUH441)	0.1% For each substance, levels not to be totalled
	d) PFAS (defined as fluorinated substances containing at least one complete fluorinated methylor methylene carbon atom, without any H/Cl/Br/I-atom attached to it ³²	0.1%
	e) Persistent, mobile and toxic substances (PMT) meeting the criteria for long-lasting and diffuse contamination of water resources (EUH450)	0.1%
	f) Very persistent and very mobile substances (vPvM) meeting the criteria for very long-lasting and diffuse contamination of water resources (EUH451)	0.1%
H4: Particularly hazardous metals	a) Lead or lead compounds (Pb)	0.1% ³³
	b) Lead or lead compounds (Pb), machine steel moving parts ³⁴	0.35%
	(c) Mercury or mercury compounds (Hg)	Total prohibition ³⁵
	d) Cadmium or cadmium compounds (Cd)	$0.01\%^{36}$
H5: Ozone-depleting	a) Substances meeting the criteria for Hazard Class Hazardous for the ozone layer (EUH059, H420)	0.1% For each substance, levels not to be totalled

³² Definition according to OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris

³³ Lead is included in the Swedish Transport Administration's Prohibition List, see Table 2.

³⁴ Applies to machine steel moving parts where fatigue strength is required, e.g., shute bolts.

³⁵ Low levels of mercury not intentionally added at any stage are not prohibited. Low levels means a presence of 2.5 mg or less per kg. Deviations in excess of 2.5 mg/kg are permitted where they result from natural occurrence in carbon, ore or ore concentrates.

³⁶ Cadmium is included in the Swedish Transport Administration's Prohibition List, see Table 2.

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Properties / substances	Definition	Limit (% by weight)
H6: Fluorinated greenhouse gases	a) Fluorinated greenhouse gases (F-gases) ³⁷	0.1% For each substance, levels not to be totalled
H7: Allergenic	a) Substances meeting the criteria for Respiratory sensitiser (H334), Category 1A.	0.1% (solid/liquid/gas) For each substance, levels not to be totalled
	b) Substances meeting the criteria for Respiratory sensitiser (H334), Category 1 or 1b	0.2% (gases) 1% (solid/liquid) For each substance, levels not to be totalled
	c) Substances meeting the criteria for Skin sensitiser (H317), Category 1A	0.1% For each substance, levels not to be totalled
	d) Substances meeting the criteria for Skin sensitiser (H317), Category 1 or 1B	1% For each substance, levels not to be totalled
H8: Toxicity	(a) substances meeting the criteria for Hazard Class Acute Toxic Category 1, 2 or 3:	The minimum ATE values ³⁸ classifying a product as Acute Toxic, Category 3. Summarised per exposure route:
	Oral: H300, H301	ATE≤ 300
	Dermal: H310, H311	ATE≤ 1000
	Inhalation: H330 or H331	Gases ATE \leq 2500 Vapours ATE \leq 10 Dust/mist ATE \leq 1.0
	(b) Substances fulfilling the criteria for Hazard Class Specific Target Organ Toxicity from Single Exposure (STOT-SE) Category 1 (H370)	1% For each substance, levels not to be totalled
	(c) Substances fulfilling the criteria for Hazard Class Specific Target Organ Toxicity from Single Exposure (STOT-SE) Category 2 (H371)	10% For each substance, levels not to be totalled
	(d) Chemical products meeting the criteria for Aspiration Toxic, Category 1 (H304)	This criterion applies to the chemical product rather than the substance
	(e) Substances meeting the criteria for Hazard Class Specific Target Organ Toxicity from Repeated Exposure (STOT-RE) Category 1 (H372)	1% For each substance, levels not to be totalled
	(f) Substances meeting the criteria for Hazard Class Specific Target Organ Toxicity from Repeated Exposure (STOT-RE) Category 2 (H373)	10% For each substance, levels not to be totalled

³⁷ Applies to F-gases listed in Annex I to Regulation (EU) No 517/2014, e.g., hydrofluorocarbons (HFCs), which are included in the Swedish Transport Administration's Prohibition List, see Table 2.

³⁸ ATE= Acute Toxic Estimate. The varying ATE values for different exposure routes are presented in the BASTA Methods of Calculation (www.bastaonline.se).



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Properties / substances	roperties / substances Definition	
H9: Volatile Organic Compounds (VOC)	(a) substances with an initial boiling point < 250°C measured at a standard pressure of 101.3 kPa, and which fulfil the criteria for any of the hazard labels: Lethal, Toxic or Harmful by inhalation (H330, H331, H332), May cause drowsiness or dizziness (H336), May cause damage to organs (H371) or May cause damage to organs through prolonged or repeated exposure (H373)	10%
H10: Environmental hazard	(a) Substances meeting the criteria for Hazard Class Hazardous to the aquatic environment, Category Acute 1 (H400)	25% if M= 1 ^{39,40}
	(b) Substances meeting Hazard Class Hazardous to the aquatic environment, Category Chronic 1 and 2 (H410) and (H411)	2.5% for H410 substances with M=1 25% for H411 substances
	c) Substances meeting the criteria for Hazard Class Hazardous to the aquatic environment, Category Chronic 4 (H413). Calculated for mixtures which do not fulfil the criteria for Chronic 1, 2 or 3. Calculation includes substances classified as Chronic 1 (H410), 2 (H411), 3 (H412), or 4 (H413)	25%

Table 2. Swedish Transport Administration Prohibition List: Substances in articles, materials and chemical products

Substance	CAS	Authorised uses of materials and articles	Authorised uses of chemical products
Acrylamide	79-06-01		
Anthracene	120-12-7		
Anthracene oil	90640–80-5, 90640–81-6, 91995–15-2	Creosote grindstones and poles Asphalt paving	Creosote for wood impregnation Bitumen for asphalt paving
Arsenic and its compounds	All included in the Candidate list, REACH Annex XIV or Annex XVII*.		
Benzene	71-43-2		Environmental Class 1 fuels may contain concentrations of this substance according to the Swedish Fuel Quality Act 2011:319
Bisphenol A	80-05-7	Residues from manufacturing of electrical and electronic products	

³⁹ Applies when no substance has a specific lower limit listed in the Classification List (Annex VI, Table 3.2 of Regulation (EC) No 1272/2008).

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 $^{^{40}}$ M = The multiplication factor according to Regulation (EC) No 1272/2008 (CLP) and depends on the L(E)C50 value. The BASTA Methods of Calculation can be used (www.bastaonline.se).

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Lead and its compounds	All included in the Candidate list, REACH Annex XIV or	**According to Directive 2011/65/EU and Directive	Sludge-based paint in contexts with special cultural
	Annex XVII*.	2006/66/EC, Detonators	environment requirements
Boric acid	10043–35-3, 11113–50-1		
Phthalates			
-Benzyl butyl phthalate (BBP)	85-68-7	**According to Directive 2011/65/EU	
-Dibutyl phthalate (DBP)	84-74-2	**According to Directive 2011/65/EU	
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	**According to Directive 2011/65/EU	
-Diisobutyl phthalate (DIBP)	84-69-5	**According to Directive 2011/65/EU	
Hexabromocyclododecane (HBCDD)	25637–99-4, 3194-55-6, 134237-51-7, 134237-50-6, 134237-52-8		
Hexachlorobenzene (HCB)	118-74-1		
Cadmium and its compounds	All included in the Candidate list, REACH Annex XIV or Annex XVII*.	**According to Directive 2011/65/EU and Directive 2006/66/EC	
Short-chain chlorinated paraffins (SCCP)	85535–84-8	2000/100/120	
Hexavalent chromium compounds	All included in the Candidate list, REACH Annex XIV or Annex XVII*.	**According to Directive 2011/65/EU	
Mercury and its compounds	All included in the Candidate list, REACH Annex XIV or Annex XVII*.	**According to Directive 2011/65/EU	
Sodium borates	1303-96-4, 12179-04-3, 1330-43-4		
Nonylphenol and Nonylphenol ethoxylates	All included in the Candidate list, REACH Annex XIV or Annex XVII*.		
Organophosphates			
-Tris(2-chloroethyl) phosphate (TCEP)	115-96-8		
Pentachlorophenol (PCP)	87-86-5, 131-52-2		
Perfluorinated substances (E.g., PFOA and PFOS)	All included in the Candidate list, REACH Annex XIV or Annex XVII* or POPs Regulation.		
Polybrominated diphenyl ethers (PBDEs)	All included in the Candidate list, REACH Annex XIV or Annex XVII* or POPs Regulation.		
Organotin compounds	All included in the Candidate list, REACH Annex XIV or Annex XVII*.		
Chemical pesticides			
-Biocidal products	All	May be used in impregnated wood and building materials that are NTR certified***	May be used: -in small-scale pest control, e.g., rats or wasps -as wood preservatives -for slime prevention -in anti-fouling products -as a preservative in water-based products -as a disinfectant for human hygiene

-Plant protection products	All		May be used in railways in the
			national vegetation programme
			"Nationell
			vegetationsreglering" and in the
			control of giant hogweed and
			Persian hogweed.
			May also be used for the control
			of Japanese knotweed, giant
			knotweed and bohemian
			knotweed 41
Chlorofluorocarbons	All regulated by Regulation		
(CFCs),	(EC) No 1005/2009 of the		
Hydrochlorofluorocarbons	European Parliament and of		
(HCFCs),	the Council of 16 September		
Halon compounds	2009 on substances that		
	deplete the ozone layer.		
2,4-Dinitrotoluene	All included in the Candidate		
	list, REACH Annex XIV or		
	Annex XVII*.		
Glycol ethers			
-2-Etoxyethanol	110-80-5		
-2-Methoxyethanol	109-86-4		
-2-Etoxyethyl acetate	111-15-9		
Benzo(a)pyrene	50-32-8	Creosote grindstones and	
		poles	
		Asphalt paving	

^{*} Substances listed in Annex XVII prohibited only for uses specified in the restriction.

7. Related documents

Guideline TDOK 2010:310 Kemiska produkter – granskningskriterier och krav för Trafikverket.

Procedure TDOK 2010:311 Kemiska produkter - granskning av märkningspliktiga kemiska produkter.

Guideline TDOK 2012:93 Generella miljökrav vid entreprenadupphandling

 $\label{thm:condition} \mbox{Procedure TDOK 2014:0307} \ \textit{Tekniskt godkänt järnvägsmateriel TGM - införande}$

TMALL 0558 Materialförteckning TMALL 1168 Produktvalsanalys

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^{**}In products covered by the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) (RoHS, 2011/65/EU) or batteries (2006/66/EC), substances may be used in Swedish Transport Administration activities for applications which are exempt from the directives according to a decision of the EU.

^{***}NTR-certified wood and building materials must be classified according to the criteria in Table 1, i.e., according to their chemical content.

⁴¹ Giant hogweed and Persian hogweed are on the EU list of invasive species (Implementing Regulation (EU) 2016/1141). The invasive species Japanese knotweed, giant knotweed and bohemian knotweed are not subject to legal requirements, but are problematic for the Swedish Transport Administration. Eradication of these species may be carried out with approved methods according to the conditions of the Swedish Chemicals Agency's product approval for the pesticide.

GUIDELINE

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TMALL 1167 Riskanalys TMALL 0194 Intyg från material- och varuleverantör om material eller varans innehåll av farliga ämnen

Key for translating other assessments to the Swedish Transport Administration's criteria for hazardous substances at www.trafikverket.se

Guide: *Arbetsgång materialkraven* TDOK 2012:22, available at <u>www.trafikverket.se</u>

8. Version log

Adopted version	Documentdate	Change	Name
1.0	18/04/2012		Malin Kotake
2.0	01/02/2013	Ch. 5.4 och 5.6	Karin Andersson
3.0	30/01/2014	Ch. 5 and 6	Anna Reuithe
4.0	25/08/2015	Ch. 1, 2, 3, 4, 5, 7,	Anna Reuithe
		8	
5.0	30/01/2017	Ch. 2, 4, 5, 6, 7, 8	Anna Reuithe
6.0	11/04/2018	Ch. 4, 5, 6,	Jenny Fredriksson
7.0	01/01/2020	Ch. 3, 4, 5, 6	Jenny Fredriksson
8.0	28/03/2021	Ch. 3, 5, 6,	Jenny Fredriksson
9.0	01/04/2022	Ch. 3, 5, 6,	Jenny Fredriksson
10.0	01/08/2023	Ch. 3, 5, 6, 7	Lina Ejenstam
11.0	01/08/2024	Ch. 5, 6	Lina Ejenstam