

Substances of concern: Why and how to substitute?



1. Why substitute?

Benefits

There are many reasons why companies or other organisations may look to substitute a chemical, such as improving the environmental footprint of their products or manufacturing processes, providing a better technical functionality or responding to client demands or legal requirements. As part of these development efforts, it is important to look to reduce the potential risks caused by the substances that are used. Several substitution options should be considered: switching to a less hazardous chemical, using an alternative technique or creating a different product design. In practice, it is usually a combination of these actions that leads to success. Often, these actions improve production efficiency, drive innovation, help companies to gain a competitive advantage and save costs, and ultimately benefit human health and the environment.

1.1 Doing the right thing and thinking broadly

Many companies and other organisations see substitution as simply doing the right thing or as a critical component of their sustainability goals. Substitution to reduce the potential risk of your activities to your employees who work with the hazardous substance, to consumers using your products and to the environment can play a big part in making Europe a healthier place for all of us and for future generations.

When undertaking a substitution project, the easiest substitutes are often drop-in replacements with similar chemical structures. However, these are not always much safer.

The need to substitute presents an innovation opportunity. By focusing on the technical function served by the chemical of concern and what is really needed for the end product or service, a broader universe of substitution options becomes available. Thinking in wider terms by making your products safe-by-design and by using the concepts of sustainable chemistry and technology, can transform the initial goal of replacing a hazardous substance into creating a new, innovative product that is safe and sustainable along its life cycle – putting your company in a competitive position.

1.2. Innovation and efficiency

Assessing your substitution options requires you to look systematically at how the chemicals are being used in your own process or along your supply chain, what their functions are, and what options might exist for process or product innovation. You may even realise that the function performed by the substance or mixture you are using is no longer necessary if you change your process or the design of your product. This becomes a driver for innovation. Revisiting your materials and production process can also result in more efficiency, and can help to reduce the resources you use and the waste you generate during the life-cycle of your product.

1.3. Competitive advantage

As a company, replacing hazardous chemicals can give you a competitive advantage in the marketplace. Your customers will appreciate effective products that are also safer for workers and consumers and have fewer adverse impacts on the environment. Your substitution may even enable your customers to gain a market advantage and can reduce the costs they incur to comply with legislation on chemical safety. Market your product well and you will stand out from the competitors. And if the use of a hazardous substance is to be restricted by regulations or the market in the future, you will have made headway on the competition with your safer alternative.

1.4. Savings in regulatory costs

Hazardous chemicals are more tightly regulated to protect humans and the environment from their harmful effects. They consequently require higher levels of control in the workplace and down the supply chain. By replacing them with safer alternative chemicals, techniques, processes or product design, you will save time and effort in managing the risks related to their use.

Legal requirements

When gathering data on the impact of a chemical on human health and the environment, you may conclude that you could reduce the risk caused by your substance.

While that knowledge in itself may drive you to look for safer alternatives, for the most hazardous substances, the EU legislation can require you to substitute them.

Legal requirements bring new opportunities.

Over time, the most hazardous substances are being identified under REACH as substances of very high concern. Those substances are subsequently becoming subject to legal requirements to manage the risks they pose. It is essential to follow how your substances are being regulated, for example, whether they have been identified as substances of very high concern or whether there are proposals to restrict them or to require prior authorisation before they can be used. In that way, you can identify the likelihood of them being subject to more stringent legal requirements and this can give you a head start for preparing in time.

Anticipating legal requirements is a smart strategy. Better and safer alternatives may already be available, and they can open new opportunities for companies. Finding out the properties of potential alternatives is facilitated nowadays thanks to an access to more information. Data gathered on substances is available on ECHA's website to help you make informed choices.

1.5. Substitution in other legislation

Substituting hazardous chemicals is also part of the Biocidal Products Regulation. The BPR excludes the use of some hazardous substances. It also requires products containing substances that are candidates for substitution to be assessed in comparison with similar available products. This may lead to restriction in the authorisation of the biocidal products.

The EU Workers' protection legislation also places obligations on employers. As an example, employers must take measures to reduce the use of carcinogens or mutagens by replacing them with a substance, mixture or process that is not hazardous or less hazardous. If this is not feasible other measures should be used to lower the exposure as much as possible.

RELATED

- » [EU-OSHA - Dangerous substances section](#)
- » [Chemical Agents Directive](#)
- » [Carcinogens and Mutagens Directive](#)

Substitution of hazardous chemicals by safer alternatives should be seen in a broader context. The concepts of “safe-by-design” and sustainable chemistry put substitution in a bigger picture. Different definitions and approaches are linked with these notions, see for example:

- » [Safe-by-design](#)

[Safe Chemicals Innovation Agenda – Towards a research agenda for safe chemicals, materials and products, Wood Environment & Infrastructure Solutions UK Limited and Centre for Strategy and Evaluation Services, pp 8-9 – June 2018](#)

RELATED LINKS

- » [Sustainable chemistry](#)
- » [German Environment Agency](#)
- » [International Sustainable Chemistry Collaborative Centre \(ISC3\)](#)





2. How to substitute?

Substituting substances is not necessarily a simple replacement of one chemical with another. You need to do your homework and there is no «one size fits all». Methods that work in one company may not work for your product or process. One approach you can use to address your substitution challenge is functional substitution, where you consider the specific function of the substance and how it could be met by alternatives in a broad sense – covering not only the substance itself but also aspects such as production techniques and product design. You may also need to try several alternatives before you find the best one. In your assessment, beyond the consideration of hazard, exposure, technical performance and economic aspects, it is important to also look at wider effects, where these are relevant, such as energy and resource use, waste, and recycling and socio-economic impacts.

2.1. Identify your substance of concern

Identifying substances of concern in use is the first step in successfully implementing your plan for substitution.

- Make an inventory of the substances you use.
- Prioritise the substances that are candidates for substitution. These include substances that are considered the most hazardous, substances that may not be absolutely necessary for a product to function, and substances that may be subject to regulatory actions or market pressure in the near future.
- Identify the key functions that your substance of concern performs in the product or process.
- Inform and consult your supply chain, both clients and suppliers, to identify potential concerns and options.

Make sure you know your substances thoroughly, for example, their identity, the function they have in the mixture, product or process and their hazard profile. To this end, it is very important to create a full inventory of chemicals that are used in your process and assess the hazards and risks associated with these chemicals along the lifecycle of your product.

This is key for conducting an informed substitution project and avoiding 'regrettable substitution', which would not lead to any improvement in terms of risks for human

health or the environment. After careful scrutiny of your chemical inventory, you may proceed with the hazard and/or risk-based prioritisation of chemicals with a view to gradually replacing substances of concern with safer alternatives.

You should also understand what the key properties or functions that you actually need are. You might realise that you don't need to use hazardous chemicals at all. Your in-house knowledge and scientific and technical literature are probably the best sources of information at this stage.

Make a distinction between your end product and your process. You may have some requirements for your product and others for the process.

Inform your clients and suppliers if you are considering substituting a hazardous substance. They may have special requirements, or even better, ideas for promising alternatives. There may be specific supply chain certifications required for new alternatives or production modifications that need to be made and the timing for this should be taken into account.

Be proactive in supporting the substitution of hazardous chemicals used by your suppliers when they produce the mixtures or articles you purchase from them. Your company itself might not use substances of concern, but your suppliers may. As a client, you can ask these companies to inform you which hazardous substances are used for producing the goods they sell to you, why these substances are used and engage in a substitution process. Supply chain transparency on the use of hazardous chemicals and increased communication about supplier and customers' needs and opportunities, help safer substitutes to be identified and adopted.

Example: see the experience from Adidas group: https://newsletter.echa.europa.eu/home/-/newsletter/entry/1_16_innovation-transparency-and-collaboration

Create an inventory

Creating an up-to-date chemical inventory is an important step in clearly defining the range of chemicals that your company has to deal with. It also helps you to find out whether some of the chemicals in the inventory involve certain regulatory responsibilities for the company (e.g. under REACH or CLP). A chemical inventory usually includes all substances manufactured, imported or used by the given company. It should also contain information about the technical function, uses and volumes, as well as important life-cycle considerations such as manufacturing, handling, storing, transporting and disposing the chemical.

Main resources

Example of tools/sectors chemicals inventories and manufacturing restricted regulatory lists:

- » [PRIO Inventory tool](#): PRIO is a web-based tool that can help you to preventively reduce health and environmental risks from chemical substances.
- » [Global Automotive Declarable Substance List \(GADSL\)](#): The global standard list for declaring the composition of parts within the automotive industry.
- » [IMDS](#): Automobile industry's material data system.
- » [Textile sector](#): Zero discharge of hazardous chemicals programme (ZDHC): The ZDHC Manufacturing Restricted Substances List (MRSL) is a list of chemical substances banned from intentional use in facilities that process textile materials and trim parts in apparel, leather and footwear.

Information on hazard of substances

- » [ECHA's web pages on chemicals](#): Information on the hazard and use of substances
- » [OECD eChemPortal](#): Information on the properties of chemicals
- » [RISCTOX](#): A database on risks and hazards of substances.

Prioritisation

Once you have made a full inventory of your chemicals, you can proceed with prioritising substances to substitute. Prioritisation is of utmost importance when considering resource constraints to which many SMEs are particularly susceptible. You can select the substances you want to substitute first on the basis of hazard, exposure and risk assessment. This selection is generally influenced by regulatory and business considerations as well. A lot of resources exist which can help you in this regard.

Main resources

1. Guidance documents on prioritisation

- » [Guide on minimising chemical risk to workers' health and safety through substitution](#)
- » [PRIO priority setting guide](#): Step -by- step guide on how to prioritise chemical substance risks in articles and products.

2. Specific lists of hazardous substances (non-exhaustive)

Lists of substances under REACH and Water Framework Directive

- » [ECHA's Candidate List](#): Lists substances of very high concern that may be included in the Authorisation List.
- » [ECHA's Authorisation List](#): List of substances of very high concern for which you need authorisation to use under REACH.
- » [ECHA's list of recommendations for inclusion in the Authorisation List](#): ECHA's recommendations on which substances from the Candidate List to include in the Authorisation List.
- » [List of Restrictions](#): Substances restricted under REACH.
- » [ECHA's Registry of intentions](#): Lists substances that have been proposed for harmonised classification, restriction or as substances of very high concern.
- » [ECHA's public activities coordination tool \(PACT\)](#): The public activities coordination tool (PACT) gives advance notice of the substances that are on an authority's radar for exploring the potential need for regulatory risk management.
- » [The Community rolling action plan \(CoRAP\)](#): Specifies the substances that will be evaluated under REACH over the next three years.
- » [Water Framework Directive - priority and priority hazardous substances](#): Substances or groups of substances are on the list of priority substances for which environmental quality standards were set under the Water Framework Directive.

Other lists

- » [OSH Wiki - Dangerous substances](#): Examples of dangerous substances listed by EU OSHA.

- » [Trade Union Priority List for REACH Authorisation](#): Priority list of chemical substances of very high concern set up by EU trade union association.
- » [TEDX](#): List of potential endocrine disruptors set up by TEDX, a science based, nonprofit research institute.
- » [Safer Chemicals Ingredients List](#): List of chemical ingredients that the Safer Choice Program has evaluated and determined to be safer than traditional chemical ingredients used for the same function.
- » [SIN List](#): The “Substitute it now” list of substances set up by the NGO ChemSec.
- » [SINimilarity](#): Database set up by the NGO ChemSec for checking if your chemical bears structural resemblance to that from the SIN List.

3. Tools to support prioritisation

- » [GreenScreen® List Translator \(GLST\)](#): Screen assessment tool for identifying chemicals of high concern. It attributes scores to chemicals based on information obtained from over 40 hazard lists. GLST can be an effective tool for prioritising chemicals for a more in-depth scrutiny and assessment.
- » [PRIO – Prioritisation tool](#): PRIO is a web-based tool that can help you to preventively reduce health and environmental risks from chemical substances.

2.2. Scope the issue and identify potential alternatives

Once you have prioritised your substances and selected some of them as candidates for substitution, it is time to look for potential alternatives. Setting the scope of the substitution project is critical given that this is the step where you determine:

- (a) the level of stakeholder engagement you intend to undertake;
- (b) the goals and principles underlying the project; and
- (c) decision criteria on which alternative to choose.

Setting the scope of the substitution project also involves establishing boundaries for the assessment. This helps to focus resources and outline a plan to assess alternatives, including planning which health effects, exposure pathways, life cycle segments, and technical functionality/performance attributes need to be considered.

As a first step, you should carefully consider if there is a real need for the technical functionality provided by the substance of concern and/or if there are other ways of achieving the same goal. For example, do you really need to provide your customers with a printed receipt that may contain hazardous ink developers, or would an electronic receipt be a suitable alternative? As you think of possible safer alternatives, look into your options more widely, such as the substances, techniques and product designs that you could use.

Elimination and substitution: first options of the STOP principle

The Chemical Agents Directive (CAD) of the EU recommends following a hierarchy or 'order of priority' of control measures to prevent or reduce exposure to dangerous substances, known as the "STOP" principle, the complete elimination of the substance being at the top:

- S = Substitution = complete elimination of the dangerous substance or substitution with a safer alternative;
- T = Technological measures = minimising the concentration of dangerous substance in the exposure zone;
- O = Organisational measures = minimising the number of exposed workers and/or the duration and intensity of exposure;
- P = Personal protective equipment = wearing protective clothing or equipment such as goggles and gloves as a barrier to exposure.

Source: [EU-OSHA](#)

See also the hierarchy of controls described by The National Institute for Occupational Safety and Health (NIOSH) in the US where 'elimination' comes first, followed by 'substitution', 'engineering controls', 'administrative controls' and finally 'personal protective equipment'.

[CDC/The National Institute for Occupational Safety and Health \(NIOSH\)](#)

Follow this principle when you address the use of hazardous chemicals and keep in mind that elimination and substitution are the preferred options.

The function is the focal point

Starting from the technical function of the substance rather than its chemical structure and the associated risks is key to allowing a wider range of substitution solutions. Rather than focusing on similar chemical drop-in substitutes, which often have similar toxicity profiles, this approach – known as 'functional substitution' – helps to avoid regrettable substitution and can lead to process and product innovation opportunities.

Different conceptual levels can be considered when deciding whether to undertake a substitution project: the level of chemical function, the end use function, and function as service.

See e.g. Tickner J. et al. Advancing Safer Alternatives Through Functional Substitution, *Environ. Sci. Technol.* 2015, 49, 742–749. Available at <http://pubs.acs.org/doi/abs/10.1021/es503328m>

Alternatives may range from a basic chemical substitution to the complete elimination of the use of substances of concern thanks to a redesign of the production process, the material used, the end product or even the way the ultimate service is provided ("system change"). All these options should be considered, aiming to find the best way to substitute chemicals of concern in a sustainable manner.

A number of resources are available to help identify a range of potential alternatives for further evaluation. Internet searches give you access to scientific and technical literature. The analysis of alternatives submitted as part of applications for authorisation to use substances of very high concern as well as those prepared for REACH restrictions can also be helpful. Ask your suppliers and clients, your industry association, trade union, and organisations who are promoting safer chemicals or techniques, including NGOs, technological institutes and academia. All of these stakeholders may help you find the most suitable alternatives to your substance use.

If the number of alternatives is simply large to fully evaluate given existing resources, reduce the number by screening the alternatives further using your substitution project goals, principles, decision rules, and performance criteria. It is important to identify a reasonable range of viable alternatives and then comparatively assess them using the steps further described (hazard/risk assessment; performance assessment; economic viability and other impacts).

To conduct a substitution project in an adequate way, we recommend you choose and follow a recognised methodology. Several frameworks have been proposed and they vary in terms of approach, scope and complexity. We suggest you start with a review of available frameworks listed in the OECD substitution toolbox, which include, among others, the following:

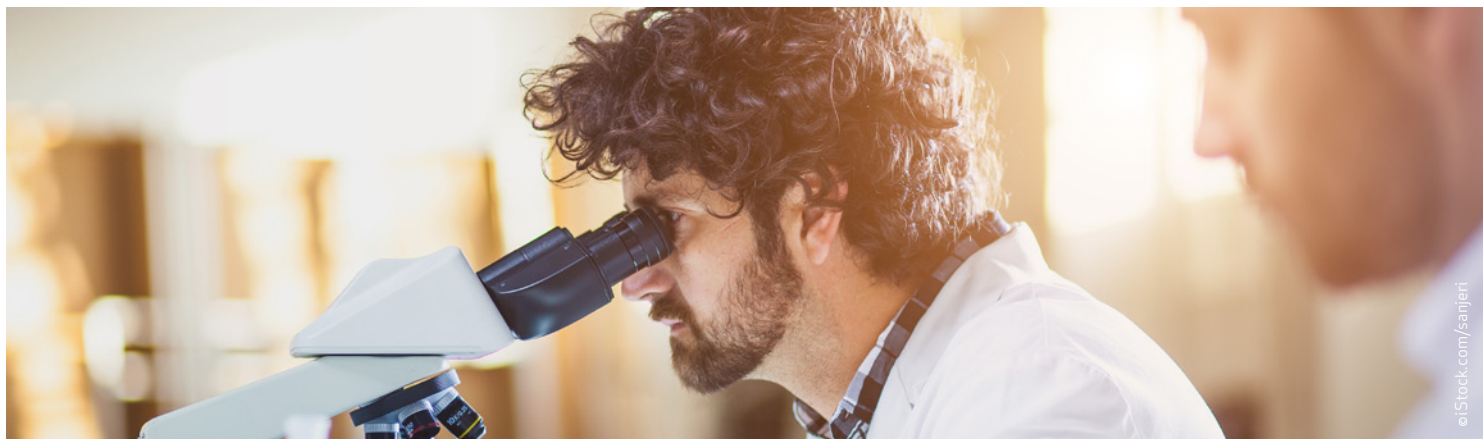
- ECHA guidance on the preparation of an application for authorisation.
- Stockholm Convention Alternatives Guidance (for persistent organic pollutants).
- The Lowell Center for Sustainable Production's Alternatives Assessment Framework.
- US National Research Council's Framework to Guide Selection of Chemical Alternatives.
- BizNGO's Chemical Alternatives Assessment Protocol.
- The Interstate Chemicals Clearinghouse Guidance for Alternatives Assessment and Risk Reduction.
- US EPA Design for the Environment's Alternatives Assessment Methodology.
- Alternatives Analysis Guide – California Department of Toxic Substances Control's Safer Consumer Products program.
- Guide on sustainable chemicals – German Environment Agency.
- SUBSPORT – guidance material.

General resources on substitution and analysis of alternatives

- » [OECD Substitution toolbox](#): A compilation of resources relevant to chemical substitution and alternatives assessments.
- » [SUBSPORT](#): Alternative substances and technologies, with tools and guidance for substance evaluation and substitution management.
- » [Toxics Use Reduction Institute \(TURI\)](#): The Toxics Use Reduction Institute (TURI) at the University of Massachusetts Lowell provides resources and tools to help businesses, municipalities, and communities in Massachusetts find safer alternatives to toxic chemicals.
- » [European Agency for Safety and Health at Work \(EU-OSHA\)](#): EU-OSHA provides a number of resources in relation to chemicals at the workplace, including on their substitution.

Online platform for looking for safer alternatives

- » [Chemsec Marketplace](#): Online platform enabling buyers and sellers of alternatives to hazardous chemicals to interact.
- » [CORDIS database of projects under the EU Research and Innovation funding programmes](#): CORDIS provides information on all EU-supported R&D activities, including programmes (H2020, FP7 and older), projects, results, and publications.



2.3. Assess, compare and select alternatives

Once you have a shortlist of alternatives compiled, continue by comparing the options and decide which one would be the most promising for your use. You will need to carry out the following assessments:

- Hazard and risk assessment.
- Performance assessment.
- Economic viability assessment.
- Assessment of other impacts.

When comparing, you should also consider wider effects such as energy and resource use, waste, recycling or social impact.

Keep in mind that a substitution project is best approached in a stepwise and iterative process. You need to prioritise which elements you will assess first and in which level of detail – deciding this upfront when setting the scope for the substitution project.

After a first high-level analysis, come back to the criteria that appear to be key for the decision-making and carry out a more thorough analysis.

For chemical alternatives, make sure you evaluate their risks (hazard and exposure). Check whether ECHA or the EU Member States have them on a list for closer examination – they may be subject to future regulatory measures and you would not want to substitute to a substance that may soon become flagged as of concern. Use different toxicology databases and exposure models to make sure you get the full picture.

In addition to assessing the hazards and risks associated with the use of the alternative substances, it is also important that you assess performance and economic viability. You may want to make use of experimental design methods, which allow you to study several variables simultaneously. Finally, taking a lifecycle perspective, you might need to consider potential trade-offs between the different alternatives options (e.g. hazard vs greenhouse gas emissions).

Hazard and risk assessment

After selecting a few promising alternatives based on their perceived substitution potential, it is important that each alternative is carefully assessed in terms of the hazards and risks associated with it. For chemical alternatives, apart from clearly defining physical and chemical characteristics of the substance, it is critical that environmental and human health properties are properly established, too. The resources listed below can help you compare the hazard properties of different substances.

Related methods, tools and materials for comparative hazard assessment

- » [GreenScreen® for Safer Chemicals](#): A comparative hazard assessment tool developed by Clean Production Action. It helps evaluate alternatives to chemicals of concern based on 18 hazard endpoints.
- » [The Quick Chemical Assessment Tool \(QCAT\)](#): A simplified version of the GreenScreen® for Safer Chemicals hazard assessment methodology, to allow SMEs to perform a quick alternatives assessment for chemicals of concern. QCAT also provides detailed information on where to find data and how to interpret the data needed to complete a hazard assessment using the tool.
- » [GHS Column Model](#): On the basis of just a small amount of information on the products in question, substitute substances can be assessed with the aid of this table.
- » [Pollution Prevention Options Analysis System \(P2OASys\)](#): The tool was designed by the Toxic Use Reduction Institute of Massachusetts (TURI). It aims to help companies conduct a comparative analysis of the hazard profile of alternatives. It can be used to analyse technological processes, individual chemicals or chemical mixtures. The tool requires certain expertise which may render it unsuitable for SMEs.

See also the resources listed for under “Identify your substance of concern” page in relation with hazard assessment

Performance assessment

To ensure that the selected alternatives have a substitution potential, it has to be assessed whether they meet your performance criteria. The extent of performance assessment will vary depending on various conditions such as the application, the availability of the technical data and the availability of the alternative on the market.

Assessing economic viability

Understanding the full economic impact of adopting an alternative is key to determining the fate of a substitution project. Assessing economic viability would typically include a detailed cost assessment, cost-benefit analysis and market assessment. The cost assessment would quantify direct and indirect costs derived from the use of current chemicals and the selected alternatives. The cost-benefit analysis, on the other hand, would help quantify the benefits conferred by the use of the alternative against the costs incurred. The market assessment, in addition to collating pricing information,

would help you in terms of better understanding the market trends with respect to the manufacturing and use of the alternatives. It would also help you understand the impact that adopting the alternatives would have on the supply chain.

Related tools/materials

- » ECHA [Guidance document on socio-economic analysis in authorisation](#)

Assessing the other impacts

It can be valuable to assess some additional impacts of switching to an alternative such as greenhouse potential, resource use, waste generation or social impacts along the product lifecycle. This refined assessment would help ensure that the chosen alternative is sustainable. Several methodologies and tools exist to support you in selecting which types of impact are the most relevant to assess and how to do it in practice.

Related tools/materials

- » [Guide on sustainable chemicals – German Environment Agency](#): A decision tool for substance manufacturers, formulators and end users of chemicals.
- » [Sustainability method selection tool](#): Developed by RIVM, this tool helps you find the best method for answering your sustainability questions.
- » [PROBAS database](#): Database includes values for energy and water consumption per type of substance/product.
- » [Material Input per Service Unit \(MIPS\) calculation](#): Database includes values for energy and water consumption per type of substance/product.
- » [Best available techniques Reference document \(BREFs\)](#): BREFs provide reference information for regulators to use when determining permit conditions.



2.4. Test, implement and improve

Following the selection of the most promising alternative, you will probably need to carry out an iterative series of steps that involves pilot testing, implementation of alternatives, and the continuous improvement of your process and product.

Test

Once you have selected your preferred alternative based on the assessments described in the previous section, run a pilot test. Small-case pilot testing can shed light on the full extent of the process, product and organisational changes needed in the full-scale adoption of the alternative. Carefully identify all other changes that could occur when implementing a substitution project at full capacity (e.g. impacts on supply chain).

Implement

Once a pilot test has been successfully launched and finalised, you can start to fully implement the alternative. Create a detailed implementation plan, outlining the series of actions required to implement the substitution.

Improve

Gather and collect feedback from all stakeholders directly affected by the adoption of the alternative and the changes brought about by it (e.g. your workers and customers). Make necessary continuous improvements based on the received feedback.

From a longer term perspective, make sure that you have a good chemical management system in place in your company to constantly assess the use of your chemicals and consider substitution where needed.

2.5. Inform your supply chain

Don't forget to tell your customers and suppliers what you are doing, as your alternative may have implications for them, too. Why not publicise your substitution? It could help you to gain an advantage over your competitors.

Keep in mind that your clients are also aware of the new substances or processes you are using. They can then make sure the necessary information is passed on to their clients.