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Title:

Analysis of REACH environmental legislation and related costs affecting companies: the case of eco-toxicological standards in the textile, clothing, leather, and footwear sectors

Supervisor:

Prof. Anna D'ambrosio

Candidate:

Alberto Pilo Pais

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1 General Introduction

Before the entry into force of the REACH Regulation, the rules governing the production, marketing, and use of dangerous substances and preparations were based at the EU level on Directive 67/548/EEC, on dangerous substances and Directive 1999/45/EC on dangerous preparations.

In June 1999, the European Commission was appointed by the Council of Environment Ministers to reform the whole body of legislation on chemicals. The work was concentrated on the preparation of the White Paper "Strategy for a Future Chemicals Policy", presented by the European Commission in February 2001. From the outset, the White Paper's content turned out to be more than just a radical regulatory framework reform.

Based on the contents of the White Paper, the Commission presented the first draft of the new Community Regulation, known by the acronym REACH, in May 2003 and, after a long, arduous, and hard-fought period of discussions, Comparisons, interventions between the Member States and stakeholders, was approved in December 2006.

The REACH Regulation is the mediation between distant positions (environmental organizations and industrial associations) that, over the years, have been compared until a compromise has been reached, representing a very important step forward for a better knowledge of chemicals in all their aspects.

A remarkable novelty of the approach followed by the Commission in drawing up this complex and delicate legislation is the importance given to the openness towards all the sectors concerned, which has been achieved with the involvement of all the interested parties and Civil society, too, who have thus been able to freely express their point of view in a process that has sought to achieve maximum results with the maximum consensus of all parties involved (stakeholder). The involvement is also expected on numerous occasions that can be presented in the normal course of the ECHA (European Chemical Agency) activity created for implementing and managing the Regulation.

Another feature, which is not normal in other situations, is the transparency and the maximum dissemination of news and information (with the exclusion only of sensitive and confidential) with their timely and regular publication on the ECHA website. Concerning the functioning of the Agency, much attention has been paid to ensuring its maximum independence in delivering opinions and judgments, a concept that is closely linked to transparency, the most important task of which is precisely to demonstrate the correctness of this behavior and with efficiency, setting modalities and times for the answers and organizing a Quality System for the control of the modalities of the carried-out activity.

The REACH Regulation has not only had repercussions in Europe but also worldwide for exports to the EU but also in terms of knowledge of the intrinsic properties of substances and their dangers. Awareness of the safety of chemical use has increased in the US, and many other nations are moving in the direction of REACH. It is expected that this will also have a positive impact at the European level, as cultural upgrading will take place in the many Member States and, with appropriate dissemination of the Regulation and the initiatives taken and the positive results that will be achieved, the image of chemistry will be significantly improved.

The second part is an overview of Porter’s hypothesis and Greenwashing, with more relevant examples of the companies Coca-Cola, Eni, H&M, and Ikea. After that, the focus will be on the network of the global textile market, clothing, leather, footwear, and the rules of safety, and environmental protection, which threaten consumers and penalize businesses operating in the legal sector, risking further weakening the system of "Made in Italy". In this already problematic context, the offer of voluntary certification models is growing internationally, creating confusion both among professionals and, even more so, among exporting companies. At the same time, driven by environmental movements, the market’s focus on safe and sustainable products is spreading.

The US market, an important and growing market for Italian exports in the textile and clothing sectors, is no exception, it is highly structured in terms of rules and regulations governing technical standards and is

characterized by a dual regulatory level, State and Federal, which are often uneven. As a result of the low average level of tax protection, there are numerous obstacles to imports of a mainly technical and regulatory nature. In most cases, they are inconsistent with regulatory measures, standards, and technical requirements for safety, health, and environmental compliance.

Finally, the third chapter contains the information and data found and evaluated for the comparative analysis of the eco-toxicological standards that characterize Europe on the one hand and the United States on the other, in the textile, clothing, leather, and footwear sectors.

This analysis aims to move towards trade relations with the United States governed by an agreement that aims both to remove non-tariff barriers to trade and to protect consumers, both aspects of particular interest for Made in Italy companies. It is crucial that competition is based on common rules, that the quality and safety package is environmentally friendly, and that the added value of national excellence is protected.

A summary of existing laws and regulations in the US and guidance on private voluntary standards are provided. In addition, the identification of the critical issues for the system of Italian companies emerged from the comparison of laws, regulations, and voluntary standards in the USA and Europe, and that highlight the different needs of the two markets. It further analyses the impact of these critical issues on the various sectors covered by the survey, the competitiveness of Italian SMEs, and their ability to respond to the needs of the US market.

2 Reach Regulation Form

REACH[1] stands for the Regulation on the **Registration, Evaluation, Authorisation, and Restriction** of Chemicals. The Regulation entered into force on 1 June 2007 and aims to streamline and improve the previous European Union (EU) chemicals legislative framework.

The purpose of REACH is to improve the protection of human health and the environment by maintaining competitiveness and strengthening the spirit of innovation in the European chemical industry. The idea is that the industry itself is best placed to ensure that the chemicals it produces and places on the Community market are not harmful to human health or the environment. This requires that the industry first has some knowledge of the properties of its substances and manages the potential risks. In turn, the authorities concentrate their resources to ensure that the industry complies with the requirements and takes action on SVHC (Substances of Very High Concern) or intervene when there is a need for Community action.

2.1 Agency of ECHA and its main committees

The European Chemicals Agency (ECHA)[2] is an EU agency based in Helsinki. The primary goal is to promote safe chemical use by constructing a knowledge center to sustainably manage these hazardous substances.

ECHA has a hierarchical structure with a management board headed by committees that deal with specific issues and can support both the activities of the Commission and the Board of Appeal.

The Committee mainly deals with REACH issues related to the evaluation and authorization of substances. The main task of the Committee is to resolve the differences of opinion between the Member States to achieve a unanimous agreement. In particular, the Committee deals with proposals for the identification of SVHC substances and provides opinions on the draft ECHA recommendation regarding the substance evaluation procedure.

The main committees are:

One person from each member state will make up the **Committee of Member States (MSC)**, which will have a three-year renewable term.

The **Committee on Risk Assessment (RAC)** prepares opinions on the risks to human health and the environment from using chemicals. The issues addressed by the RAC are related to the REACH and CLP (another Regulation on the classification, labeling, and packaging of substances and mixtures) procedures. This board evaluates proposals for harmonized classification, restrictions, and authorizations. Member States nominate candidates, but the RAC members are appointed by the ECHA Management Board. Also, in this case, the mandate is triennial and renewable.

The **Committee for Socio-economic Analysis (SEAC)** is responsible for preparing opinions on the socioeconomic impact that would result from the application of regulatory measures concerning chemicals. As in the case of the RAC, the members of the SEAC are appointed by the Management Board of ECHA from among the candidates chosen by the Member States. Three years are allotted for the tenure, which is renewable.

The committees meet about four times a year, meeting dates and agendas are available on the ECHA website.

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[1] ECHA, Understanding REACH. Available at: http://bit.ly/3WQde49

[2] ECHA, EU institutions, and bodies. Available at: http://bit.ly/3Enok9r

2.2 Principles of REACH

The REACH Regulation is based on several principles which can be summarised as follows:

- **precautionary principle:** decision and health risk management tool adopted by the European Union (EU): if the scientific assessment of risk is incomplete or not definitive and, therefore, does not allow to exclude potentially dangerous effects, the production and use of such substances shall be excluded. In the interim, and pending final scientific conclusions, protective measures must be taken, the stringency of which must be proportionate to the degree of protection required, also considering the socio-economic benefits that the use of this substance represents
- **duty of care:** the commitment of companies to ensure that every step of the activity is carried out in full compliance with the principles of protection defined in REACH
- **No data no market principle:** without the communication of the required data and the consequent Registration it is not allowed to carry out the manufacture, import, and placing on the market of the chemicals covered by the Regulation
- **Dissemination and sharing of data:** must be as extensive as possible, consistent with the principle of confidentiality, to all actors in the supply chain; this principle is greatly considered as regards data sharing to avoid unnecessary testing and costs and to exclude new tests on vertebrate animals
- **Access to information:** must be guaranteed to all stakeholders, mainly through the creation of a public database; this principle is considered in the highest consideration and is not limited to a type of information top-down, but stakeholders are called upon to give their qualified opinion which ECHA undertakes to take into account.
- **The reversal of the burden of proof principle:** with the advent of REACH is no longer the responsibility of the authorities to control the risk assessment system, but the industry is obliged to:
    - Demonstrate whether the substance (as such or in preparation or an article) has hazardous characteristics or not
    - Carry out a comprehensive risk assessment for each specific use
    - Demonstrate that the risks are adequately controlled
    - The socio-economic benefits offset or outweigh the possible risks

The REACH standard controls all processes in which chemicals are used. In particular, **the main sectors under observation** are manufacturing, clothing, Technological, and detergent companies. But the rule is applied not only in industry but also to control the materials that come into contact with people every day. For example, cleaning products used daily or paints on the walls surrounding us.

2.3 REACH's objectives

The main objectives of REACH[1] are the following:

- Improving the protection of human health and the environment against the possible risks posed by chemicals
- Promoting alternative methods of substance hazard assessment
- Increasing the competitiveness of the EU chemical industry, a key sector for its economy
- Ensuring the free movement of substances in the internal market of the European Union

More and more comprehensive information on:

- Dangerous properties of the products handled
- Risks associated with exposure
- Security measures to be applied

The REACH replaces around 40 regulations with streamlined and improved Regulations. Other chemicals (e.g., cosmetics, detergents) or related regulations (e.g., health and safety of workers handling chemicals, product safety, products for the construction industry) not replaced by REACH, will continue to apply. REACH was developed to avoid overlapping or conflicting with other chemical legislation. This norm ensures that the industry takes more responsibility for the risk management of chemicals and provides users with correct safety information.

At the same time, it envisages the possibility of the European Union taking additional measures on highly dangerous substances, for which additional action is needed at the EU level. The Commission has foreseen the creation of ECHA with the role of central coordination and implementation of the whole process.

All chemical manufacturers and importers must identify and manage the risks associated with the substances they manufacture and market. For substances produced or imported in quantities **equal to or greater than 1 tonne per year** for each individual holding, companies and retailers must demonstrate that they have complied with the Regula usings of a registration dossier to be submitted to the Agency.

Once the registration dossier has been received, the Agency may check compliance with the Regulation and evaluate testing proposals to ensure that the evaluation of chemicals does not lead to unnecessary testing, especially on vertebrate animals. The authorities may also select substances defined as "extremely worrying" for further evaluation where appropriate.

REACH also provides for an authorization system to ensure that SVHC is adequately controlled and gradually replaced by safer substances or technologies, which will bring general benefit to the society using them. These substances will be investigated as a matter of priority and, over time, included in the list. After such inclusion, the industry will have to apply for the Agency's authorization to continue using them.

Finally, EU authorities may impose restrictions on the manufacture, use, and placing on the market of substances that pose an unacceptable risk to human health or the environment. Manufacturers and importers must provide their downstream users with the necessary information on the intrinsic risks so that they can safely use the substances concerned. For this purpose, the classification and labeling system and safety data sheets (SDS) shall be used, where appropriate. Certain substances may be exempted from all or some of the obligations under REACH.

Over the years many tools have been developed by ECHA to inform, direct, guide, and clarify both for the industry and the authorities (website, IT programs, Technical Guides, Technical Manuals, FAQ...) to facilitate

[1] European Commission website. Available at: http://bit.ly/3Tv6c1G

proper compliance with the complex regulation. The guidance documents were drawn up and discussed in the framework of projects led by the European Commission, with the participation of all stakeholders: industry, Member States, non-governmental organizations, and the European Commission itself.

National Technical Assistance Services (Help Desk) have been established in each Member State to provide the industry with information on their obligations under the REACH regulation, in particular about the registration of substances. To remedy a lack of information found at the European level by the DUs (Down-stream Users), especially Small and Medium Enterprises (SMEs), a more widespread information network of national Help Desks was established at the beginning of 2013 using the Enterprise Europe Network (EEN). It is present in all the Member States of the Union and is particularly targeted at SMEs.

2.4 Territory

REACH is now in effect in all 28 EU Member States (Austria, Belgium, Bulgaria, Celia, Cyprus, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, United Kingdom, Romania, Slovakia, Slovenia, Spain, Sweden, Hungary) and also those of the European Economic Area (EEA) area (Norway, Iceland, Liechtenstein).

Therefore, the movement of chemicals in these countries is free as a domestic market, while the borders for imports continue to exist for non-EU countries (Switzerland, Turkey, China, India, USA, Brazil, South Korea, Thailand, and Japan). They can continue their export activity in the EU or register directly through their company with a registered office in the EU or by appointing an Exclusive Representative (Only Representative) also with a registered office in the EU.

2.5 Included chemicals and required entities

The obligated subjects[1] are the manufacturers and importers of chemicals of the European Union regardless of whether they are classified and labeled dangerous or not dangerous, in quantities equal to or greater, over a calendar year, to one ton. In the case of the manufacture and importation of a particular substance, obligations shall be imposed on all manufacturers and importers of that substance without distinction. The scope of the application does not require all chemicals to be subject to compliance. Some types, such as radioactive substances, waste, and non-insulated intermediates, have been excluded. Other types of substances have instead been exempted, which means that they do not fall within the scope of the particular end-use to which they are directed.

Substances under regulatory control[2] are:

- Pharmacologically active substances and excipients that are intended for medicinal products for human and veterinary use
- Food additives intended for use in foodstuffs for human consumption
- Flavoring substances intended for use in foodstuffs and source materials for their preparation
- Feed and additives intended for use in animal feed

[1] Thomas Petry and Richard Meads, “An analysis of the proposed REACH regulation”, March 2006

[2] Olivier Fuchs (December 2009), “REACH: A New Paradigm for the Management of Chemical Risks”. Available at: http://bit.ly/3WV5rC3

- Plant protection products and active substances intended in these products
- Biocidal products and active substances intended in these products

In the case of polymers, it will be necessary to control the monomeric substances present: in fact, monomeric substances will have to be subjected to simplified registration procedures only if the following three requirements are satisfied:

- Have not already been registered
- Are present in the polymer by weight 2%
- In quantities of at least 1 ton/year of monomer

Substances imported into the European Community for research and development activities are not subject to registration for five years.

Mixtures are a set of several substances, and their registration is not foreseen but that of each component of the mixture itself provided that the total amount of each component is present in quantities equal to or greater than one tonne/year.

2.6 Stages of Regulation

The system foresees these phases[1]: Preregistration, Registration, Evaluation, Registry of Intentions (RoI), Authorization, Restriction, Harmonization

2.6.1 Preregistration

Before the registration phase, the new legislation introduced a pre-registration phase for all stakeholders (manufacturers and importers). It should be added that the new regulation gives the possibility to manufacturers/suppliers outside the Community to appoint, to fulfill the pre-registration and, subsequently, the registration an "Only-Representative".

The "Only-Representative" can be a natural or legal person, established within the European Union, with sufficient knowledge about the treatment and handling of chemicals and information about them. Preregistration is not binding on Registration, but it is an essential phase as it allows the benefit of the transitional period that permits continuing to place substances on the market until the registration obligation is triggered.

The planned data to be communicated to the Helsinki Agency (ECHA) are very simple:

- The name of the substance
- The EINECS number (European Inventory of Existing Commercial Chemical Substances) and the CAS number (Chemical Abstracts Service is a numerical identifier that uniquely identifies a chemical substance)
- Their name and address and the name of the person to be contacted
- The deadline for registration according to the tonnage band

[1] European Commission Environment Directorate General (October 2007) “REACH in brief”. Available at: http://bit.ly/3tmvrIW

At the end of the pre-registration period, the Substance Information Exchange Forum (SIEF) is established substance by substance to exchange the pre-recorded available data to limit the execution of new tests and to jointly prepare a data package to be submitted together (Joint Submission), thus limiting costs and time. After the above date, it will be possible to enjoy the advantages of pre-registration for manufacturers/importers who, for the first time, manufacture/import a substance. The pre-registration must be made within six months of the first manufacture/import and 12 months before the expected registration deadline according to the tonnage range.

2.6.2 Registration

The next step is the Registration for which the submission of a much larger dossier is required, it must contain a series of information including:

- Identity of substances
- Information on the manufacture and use of substances
- Classification and labeling
- Guidelines for using the material

Moreover, the size of the dossier varies according to the tonnage bands taken into account and the number of information also increases according to the tonnage range in which the registrant is located. The tonnage/year bands identified in the legislation are as follows:

- ≥ 1-tonne
- ≥ 10-tonne
- ≥ 100-tonne
- ≥ 1000-tonne

To verify the tonnage range in which, in the case of import, each importer must add up all the quantities imported, in one year, for a given substance, also from different suppliers, in the three years preceding pre-registration: their average is the data to be taken into account.

Registration Dossier

As mentioned above, the number of items of information is proportional to the total range reported.

a. The dossier for the "≥ 1-tonne" band should contain in particular this information:
    - Physicochemical properties: Information on melting point, density, boiling point, vapor pressure, flammability, oxidation, and explosion characteristics are required.
    - Acute toxicity information: acute oral toxicity, Ames test (a screening method for chemical agents for possible carcinogenicity).
    - Eco-toxicological information: biodegradability.
b. The dossier for the "≥ 10-tonne" range should contain, in addition to the information already required for the previous range, the following additional information:
    - Information and data on Physico-chemical properties: hydrolysis, analysis of the absorption coefficient to soil

- Acute toxicity data and information: mammalian acute toxicity, eye, and skin irritation, mutagenicity
- Ecotoxicological information and data: acute toxicity in fish, inhibition of respiration by activated sludge
- Information and data on toxicity: short-term toxicity (28 days): kinetic toxic behavior, reproductive toxicity analysis

In addition, starting from this tonnage range, a CSR (Chemical Safety Report) is also required. This report shall include a chemical safety assessment of the substance. The assessment of safety risks to human health and risks to the environment is required.

c. The dossier for the "≥ 100-tonne" range includes, in addition to the information already requested for the previous ones, these additional data and information:

- Information and data on physicochemical properties: information and data on stability in organic solvents, the identity of significant products resulting from the decomposition process, dissociation constant, and viscosity
- Eco-toxicological information and data: on Daphnia reproduction, decomposition on surface water, soil, sediment, information and data on fish bioaccumulation, an additional soil absorption coefficient, and effects on terrestrial organisms such as micro-organisms, invertebrates, and plants
- CSR

d. Finally, the dossier of the "≥ 1000-tonne" band will be the sum of all the information that is already required for the three preceding bands plus possible studies that may emerge from the tests done previously. These additional studies may cover:

- Toxicity, carcinogenicity, and mutagenicity
- Breeding on birds
- Testing of long-term effects on invertebrates, plants, and sediment organisms
- CSR.

To facilitate the complex work of preparing dossiers, it is possible to set up groupings of registrants (consortia or similar) to facilitate the exchange of available data and the joint commissioning of tests for missing data. These initiatives are appreciated by REACH because they simplify the work of preparing dossiers and reduce their costs but are left exclusively to private initiatives as regards modalities, management, participation, cost-sharing criterion, and any other organizational modalities.

Stages of Verification

ECHA assigns a submission number to each dossier received. This number is used as a reference in all correspondence relating to the registration until the registration number is assigned.

Administrative audit: all files are subject to an administrative audit called 'Business Rule', aimed at verifying that the files comply with the prerequisites for management by ECHA.

Passing the Business Rule only serves as a confirmation of acceptance of the dossier for processing and does not imply the completion of the registration. If a Business Rule is not passed, the registrant must correct the file and resubmit it.

Technical verification: once the dossier has been accepted for processing, the next step is the "Technical Completeness Check" (TCC) phase in which the dossier is checked to ensure that it includes all the required

data; In the event of deficiencies, the declarant will be required to re-submit a complete dossier. In parallel with the TCC check, the declarant will receive an invoice, which must be paid within a certain expiry date.

Decision: If the technical integrity check is successful and the invoice is paid, the dossier is considered complete and the Agency's REACH-IT system automatically assigns a registration number.

Registration Number

The Agency shall immediately notify the registration number and the date the registrant is concerned. From now on the registrant will use the registration number for all subsequent correspondence related to the registration procedures. In addition, the registration number must be incorporated into the SDS for any supply made after receiving this registration number.

The registration number consists of 18 digits of which the last 4 refer to the registering company; for distributors, the omission on the SDS of the last four digits is allowed, but they are required to provide this data within seven days at the request of the inspector.

2.6.3 Evaluation

This phase involves the examination and evaluation of the various registration dossiers by ECHA and the competent authorities of the Member States.

The evaluation process shall confirm the compliance of the reported data with the obligation to provide adequate information on registered substances to ensure their safe use. The evaluation is also an important tool for identifying substances of concern to replace them with safer alternatives. The evaluation process also allows ECHA to request further information or testing if essential data are missing from the registration dossiers received.

The Agency publishes an evaluation report by the end of February each year, consisting of three stages:

1) Evaluation of information
2) Evaluation of test proposals
    - Adequacy and relevance of the tests proposed in the registration dossier to ascertain whether they are really necessary to meet the information specified in the REACH Regulation
    - Examination of the need for tests on vertebrate animals taking into account the scientifically valid information provided by third parties during the consultations
3) Examination and evaluation by Member States (MS)
    - Substance evaluation

Purpose: To examine and determine whether there are grounds for believing that the test substance presents a risk to human health or the environment. Only registered substances may be evaluated. In May 2011, ECHA and MS agreed on the criteria for prioritization of substances to be included in the evaluation process for the preparation of the so-called "Community Rolling Action Plan" (CoRAP) to take into account:

- The risk characteristics of substances
- Exposition
- Total tonnage

As a result of this activity, operators may be required to provide additional information. Furthermore, data and information contained in various dossiers indicate that the chemical may present a risk to health and the environment and present problematic properties such as persistence or bioaccumulation. The Authorities ask the operator for both new information and new tests even if not provided in the technical annexes of the Regulation.

The evaluation process may also conclude that the substance should be subject to the authorization or restriction procedure.

2.6.4 Registry of Intention - RoI

The competent authorities of the Member States (MSCA) and/or ECHA may, at the request of the Commission, prepare the following proposals:

- Identification of extremely problematic substances (SVHC)
- Classification and labeling
- Restrictions

The purpose of the public register of intentions is to enable interested parties to be aware of the substances for which the authorities intend to submit the above control proposals. Consequently, facilitate the preparation of stakeholder observations. This also avoids duplication of work and promotes cooperation between MS and Member States' competent authorities (MSCA) and/or ECHA to verify whether other authorities have worked in the past or are preparing for this type of proposal.

There are three distinct parts to the Registry of Intentions:

- List of current intentions of the MS and/or the Commission
- Proposals still in one of the three stages of the decision-making process
- List of intentions withdrawn after evaluation by an MS or ECHA

The register is available on the ECHA website and is regularly updated. The following data are presented: name of the substance, EC and/or CAS number, applicant country, date of submission of the dossier, date by which comments should be submitted, and technical justification for the request.

2.6.5 Authorization

The authorization shall be granted temporarily and shall be subject to a fee both for the authorization itself and for its revision or renewal. The process is quite complex and requires a lot of resources. The description of the "Substitution Plan" is fundamental in the authorization request.

Authorization may be requested by a single company or group of companies. Only those operators, both manufacturers, and importers, who place on the market the following categories of substances are obliged to fulfill the relevant obligations:

a. Chemicals that meet the standards for being classified as carcinogenic
b. Substances meeting the criteria for classification as mutagens
c. Chemicals that meet the criteria for being categorized as hazardous for reproduction
d. Substances that are very persistent or bioaccumulative
e. Substances with endocrine-disrupting properties

These high-risk substances will gradually be included in the Annex of the REACH Regulation. Once included, they cannot be placed on the market or used from a certain date ("sunset date") unless the company has been granted a permit.

Stages of the procedure

The authorization procedure consists of four phases; the obligations of the industry are covered in the third stage; all stakeholders have the opportunity to contribute to stages 1 and 2.

1) Phase 1: Identification of substances of very high concern (SVHC)

The identification of these substances is the responsibility of the competent authorities of the Member States or the Agency (on behalf of the European Commission). Interested parties (stakeholders) can comment on substances during the preparation of the dossier. The result is a list of identified substances (Candidate List) to be examined and proposed for the authorization process.

2) Phase 2: Priority examination procedure

The REACH Regulation provides that ECHA shall recommend to the European Commission the substances to be passed as a priority, considering the opinion of the MS Committee. The purpose of this phase is to determine which substances on the Candidate List should be subject to authorization as a priority based on their hazardous characteristics; Stakeholders are also invited to submit their comments. At the end of the prioritization procedure, the following decisions are taken:

- The substance will be subject to authorization or not
- Which uses of the listed substances will not need authorization
- The "expiry date" by which a substance can no longer be used without authorization

ECHA is required to submit this list at least every two years.

3) Phase 3: Authorization request

Applications for authorization must be submitted within the deadlines set for each use and not exempted from authorization. They shall include:

- A chemical safety reports
- A review of potential substitute materials or technologies
- If necessary, socioeconomic analysis

Where the analysis of alternatives indicates that a suitable alternative exists, the applicant shall submit a replacement plan.

4) Phase 4: Granting of authorizations

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) shall verify whether the application includes all relevant information and, if necessary, jointly request additional information from the applicant, and on that basis, formulate their draft opinions.

Authorizations are granted by the European Commission if the applicant can demonstrate that the use of the substance in question is "properly controlled". Where the risk is not adequately controlled, an authorization may be granted provided that it is demonstrated that the socioeconomic benefits outweigh the risks and that there are no alternative substances or technologies. Downstream users may only use these substances for authorized uses. For this purpose, they shall:

a. Obtain the substance from an undertaking that has been granted authorization for that use, and comply with the conditions of that authorization
b. Inform the Agency that they are using an authorized substance
c. Submit their request for authorization for their uses

5) Revision

All authorizations will be reviewed, on a case-by-case basis, after a specified period. They may be subject to review at any time. If, concerning the time when the Authorisation was issued:

a. There have been changes affecting the risk to health and the environment
b. There is new information about alternative products

2.6.6 Restrictions

Restrictions restrict or prohibit the production, placing on the market, or use of certain substances which constitute an unacceptable risk to human health and the environment. A Member State or ECHA may, at the request of the European Commission, propose restrictions. This intention must be communicated to the ECHA which includes it in the Registry of Intentions (RoI) where the list of substances divided into categories is publicly available:

(a) Proposals for restriction; (b) Under consideration for restriction; (c) Proposals removed.

Any person may comment on the proposed restriction of a substance. The most likely stakeholders are companies, organizations representing industry or civil society, individuals, and public authorities.

The comments received in time are taken into account by the ECHA Committee on Risk Assessment (RAC) and the Committee on Socio-economic Analysis (SEAC).

After publishing the draft opinion of the two technical committees, ECHA organizes another public consultation where stakeholders can comment only on the draft SEAC opinion.

- Opinion of Committees

RAC shall assess whether the suggested restriction is the appropriate measure to reduce the risk to human health and the environment. The SEAC weighs the advantages and disadvantages of the restriction for the company based on the information expressed in the proposals and the comments received. The draft opinion of the SEAC shall be subject to public consultation. ECHA forwards the two opinions of the Scientific Committees to the European Commission which draws up an amendment to the list of restrictions if the Council of Ministers or the European Parliament does not oppose the restriction.

- List of restrictions

To facilitate access to information and to supplement the available information on the substance of interest, ECHA has developed and networked a table organized as follows: substance or group of substances, EC number, CAS number, consolidated text, Appendix (if available), new adjustments, Q&A and FAQ.

2.6.7 Harmonization

It is certainly very appropriate that the classification and labeling of certain dangerous chemical substances should be harmonized to ensure that risk is properly managed throughout the European Community.

The MS, manufacturers, importers, and downstream users may make a proposal for harmonized classification and labeling for a substance and the MS may propose the revision of existing harmonizations. This intention must be communicated to ECHA, which shall include it in the Registry of Intentions (RoI) where the list of harmonization proposals is publicly available in the categories: (a) proposals for harmonization; (b) under consideration for harmonization (c) Proposals for harmonization eliminated.

The prepared dossier is submitted to the public consultation and the opinion of the RAC.

At the end of the process, suppliers must ensure harmonized classification and labeling of the substances supplied and adequately inform downstream users about their hazardous effects and the most appropriate way to ensure safe use.

2.7 Enforcement

"Enforcement" of REACH generally means a series of actions taken by the Member States to start verifying the effective application of the Regulations by the companies involved. For example, the registration or pre-registration of substances or the correctness of the compilation of SDS.

Enforcement is the responsibility of Member States and therefore they must ensure that they have established an official control system and drawn up a legislative plan of sanctions for non-conformities. ECHA has no responsibility in this regard but in its structure, there is the Committee called FORUM (Forum for Exchange of Information on Enforcement) which is composed of representatives of the national competent authorities and has as its purpose the coordination of the application of REACH in the Member States and of the supervisory measures established in each acceding country. These checks are carried out based on the elaboration of the "REACH-EN-FORCE project" which is updated annually.

The recurrent statements are:

1) Every five years, the MS shall submit to the Commission a report on the operation of the REACH Regulation in their respective territories, including information on the outcome of official inspections, the monitoring carried out, the sanctions envisaged, and other measures taken. The first report was submitted on 1 May 2010.
2) Every five years, the Agency shall submit to the Commission a report on the operation of the REACH Regulation, including in the report information on the joint transmission of data and an overview of the explanations for the separate transmission of information. The first report was submitted on 1 May 2011.
3) Every three years; to promote non-animal testing methods, the Agency shall submit to the Commission a report on the state of application and use of those testing methods and the strategies used to generate information. The first report was submitted on 1 May 2011.
4) The Commission must issue a general report every five years on:
    a. experience with the operation of this Regulation; the report shall also include the information referred to in paragraphs 1, 2, and 3 above
    b. the size and distribution of the resources allocated by the Commission for the development and evaluation of alternative testing methods

2.8 Supervision

One of the most important elements to ensure the correct application of REACH is that of inspections, as indicated by the Regulations themselves, which require the Member States to implement concrete supervisory and control measures.

Therefore, competent authorities should establish a system of official controls ensuring that appropriate supervisory and control activities are undertaken to verify the full implementation of the requirements by all actors in the distribution of substances, from production/import, use, placing on the market of substances, as such or contained in mixtures or articles.

European supervisory bodies:

CLEEN - Chemical Legislation European Enforcement Network: for the exchange of information

ECLIPS - European Classification and Labelling Inspections of Preparation including SDS (CLEEN body): harmonized SDS inspections of substances and mixtures.

The supervisory activity may concern, where applicable, the verification of:

1) the submission of registration, notification, test proposal, or application for authorization
2) compliance with the established restrictions
3) the existence and effectiveness of a management and control system by all actors in the chain, covering the following aspects:

    - The requirements for the registration
    - The presence of the chemical safety report (CSR), where applicable
    - Verification of the data contained in the chemical safety assessment by the conditions of production, import, use, and placing on the market of the substance, preparation, or articles
    - The verification of the application of the risk management measures envisaged and their effectiveness
    - Information sharing throughout the supply chain
    - Verification of the completeness of the data reported in the safety data sheets
    - Verification of the completeness of the data in the labels applied on the packages

Member States are expected to send the Agency a report on the control measures organized and the results achieved.

ECHA has organized and implemented training courses for inspectors and has also drawn up, to harmonize the implementation procedures in the various Member States, a handbook "Minimum criteria for REACH inspections". To facilitate the control process, ECHA also organized an Information System: "REACH Information Portal for Enforcement" (RIPE) This allows inspectors from all REACH member states to easily and securely access information sent by companies to ECHA. The new portal, developed in the field of REACH-IT, allows REACH inspectors to find basic information such as the actual sending of files, from whom, since when, the tonnage range, the manufacturing plant, intended uses, classification and labeling, instructions for safe use and other important information such as Physico-chemical, toxicological and eco-toxicological properties.

Every five years, the MS shall submit to the Commission a report on the operation of the REACH Regulation in their respective territories, including information on the outcome of official inspections, the monitoring carried out, the sanctions envisaged, and other measures are taken.

2.9 Fines

To ensure the transparency, impartiality, and consistency of the implementing measures of the Member States, the Member States should establish, by the Regulation, an appropriate framework of sanctions allowing the application of effective sanctions, proportionate and dissuasive in the event of non-compliance, as it may result in damage to human health and the environment[1].

The sanctions established by the Member States must be notified to the European Commission, which must also be informed immediately of any changes.

It is also laid down that, the planned five-year report on the operation of the REACH Regulation in their respective national territories, shall also include information on the outcome of official inspections, monitoring carried out, the penalties provided for, and other measures taken during the period covered by the report.

[1] Fabrizzio Ciatti, Daniel Vencovsky, Jana Vencovska, Meg Postle, (June 2021), "Development of REACH – Review of evidence on the benefits & costs of REACH". Available at: http://bit.ly/3g28nfA

3 Impact of environmental regulations on companies

3.1 The concept of Porter's hypothesis

In 1991, the economist Michael Porter established the conventional knowledge about the impact of environmental regulation on the company's business, stating that a specially designed regulation could increase its competitiveness.

According to Porter "strict environmental regulations do not inevitably hinder competitive advantage over competition". The vision of environmental regulation challenged by virtually all economists until then saw companies with the need to reduce their externalities, such as pollution, forced to reduce their profits. But in the last twenty years, much has been written about what is now known as the "Porter Hypothesis" (PH)[1].

This paradigm whereby environmental regulations forced companies to place some of their inputs in pollution reduction, causing non-productivity from the business perspective, was reworked by Porter and van der Linde in 1995. The two authors suggest that pollution is often a waste of resources and that reducing pollution can lead to improved productivity where these resources are used.

Porter and van der Linde also introduce five reasons why specially created regulations can lead to these results:

- Regulations tell companies which resources are more prone to inefficiency, and which are the potential technological improvements
- Information-gathering regulations can achieve greater benefits by raising corporate awareness
- Regulations reduce uncertainty about which investments to make for environmental sustainability
- Regulations create pressure that stimulates innovation and progress
- The regulations standardize the field of transition of innovations

However, it is recognized by both sides that innovation does not always offset costs, especially in the short term. The PH is often called upon to persuade the business community to accept environmental regulations, with the possibility of benefiting from additional investors.

In short, ad-hoc environmental regulations can lead to a situation of "win-win", that is not only protecting the environment but also increasing profits and competitiveness through improving products or their production processes or enhancing their quality.

[1] Stefan Ambec, Mark A. Cohen, Stewart Elgie, and Paul Lanoie, "The Porter Hypothesis at 20 Can Environmental Regulation Enhance Innovation and Competitiveness?". Available at: http://bit.ly/3UMjxUs

3.2 The concept of greenwashing

Since the mid-sixties, several companies have realized the potential advantages of linking their brand to the themes of environmentalism, to the point that the well-known American advertiser Jerry Mander[1] (1972) coined the term "ecopornography" to describe the constant attempt to exploit environmental issues for exclusively commercial purposes.

Unsurprisingly, CSR initiatives (Corporate Social Responsibility) were originally presented as compensation mechanisms for the problems caused by companies to society and the environment. From the point of view of communication, the initiatives of social responsibility were immediately described as initiatives of the Communication Functions aimed at manipulating the image of companies to achieve positive effects with the association to sustainability.

Since the early 1980s, in parallel with the rise of environmental issues (e.g., ozone hole) to the attention of the public, there has been a rapid spread of "green" advertising campaigns and it is precisely in these years that the term greenwashing is coined by the New York environmentalist Jay Westervelt.

In a 1986 essay, Westervelt criticizes hotel companies for the widespread practice of placing a "green card" in every room to promote the reuse of towels under the slogan "Save the Planet". However, the same businesses did not demonstrate any more dedication to environmental protection (e.g., programs to reduce energy consumption).

Greenwashing and environmentally unethical practices have been progressively analyzed in terms of risk to society and future generations. Currently, there seems to be a sharing among scholars that social and environmental responsibility goes beyond compliance with regulations, but fully includes the dimension of ethics as a decisive element for sustainability.

Most definitions of greenwashing place emphasis on environmental issues[2]. Therefore, greenwashing is interpreted as behavior resulting from the intersection between poor environmental performance and positive communication on this performance, concerning both the corporate and the product levels. In a broader sense, greenwashing refers to the set of practices of corporate identity (identity-washing), which tend to "make up" or hide the most controversial aspects from the point of view of sustainability.

In this perspective, greenwashing is defined as the set of practices by which companies manage communication with their stakeholders in one or more constituent dimensions of sustainability. Therefore, greenwashing practices aim to create reputational capital and strengthen the organization's legitimacy in the institutional context. This is essentially done through two symbolic communication techniques:

- Decoupling is the appearance of meeting the requests of the parties concerned, without actual changes in organizational practices
- Attention deflection is the implementation of a series of practices (self-certification) that tend to highlight the indicators that show the positive impact of its activity to avoid "unveiling" the complex of their performances that are not very significant from the point of view of sustainability or even unethical

However, a practice that can be seen as greenwashing does not automatically imply the "bad faith" of the enterprise[3]. In some cases, it happens that there are superficialities or errors in the management of communication. The risks of greenwashing typically emerge when you move from the philosophy of

[1] Rémi Bazillier, Julien Vauday, "The Greenwashing Machine: is CSR more than Communication". Available at: http://bit.ly/3X9hHPF

[2] UN Environment, "Benefits of Chemicals Control". Available at: http://bit.ly/3tqotTk

[3] Priyanka Aggarwal, Aarti Kadyan, (October 2011), "Greenwashing: The Darker Side Of CSR"

government to operational, from the plan of the principles of sustainability to the implementation of socially responsible practices.

Although the subject has been known for some time, there are not particularly many studies that have dealt with the issue of greenwashing systematically, trying to circumscribe it and explain its effects. A smaller number then tried to give guidance on how to address or discourage such practices from the point of view of communication management.

To reduce this gap, it is useful to analyze the activities and decisions of communication for sustainability, checking how possible errors in management (strategic and operational) can affect the accusations of greenwashing. If you consider sustainability as the backbone of your business approach, the analysis of the determinants of greenwashing cannot be reduced to a simple list of tactical errors to avoid, however, it is necessary to assess all the activities and decisions relating to communication management. In other words, it is essential to clarify the role of communication in the management of the sustainability-oriented enterprise, which cannot be limited to the operational management of communication campaigns, but increasingly is characterized by distinctive managerial skills, they are essential to align government decisions with the values, cultural profiles and needs of different stakeholders.

3.2.1 Four examples of Greenwashing and eco-friendly fake

Coca-Cola[1]

In June 2021, the multinational Coca-Cola, already from the early 2000s at the center of disputes related to sustainability issues, was sued by the Earth Island Institute, a non-profit environmental organization, on charges of misleading marketing. In the complaint, the Earth Island Institute claimed that the company was deceiving consumers by marketing itself as sustainable and environmentally friendly, while "polluting more than any other beverage company and workings actively to prevent effective recycling measures in the United States". The initiatives referred to by the organization were, for example, the "Every Bottle Back" and "World Without Waste" campaigns, or the company's claim that its plastic bottles and caps were designed to be 100% recyclable. Contrary to the company's claim, according to the complaint, Coca-Cola is the world's largest producer of plastic waste, generating 2.9 million tonnes of plastic waste per year. It also uses around 200,000 plastic bottles per minute, accounting for one-fifth of the world's production of polyethylene terephthalate (PET) bottles. This production of plastic is also based on fossil fuels, with significant consequences also on CO2 emissions.

The excessive production of plastic waste is mainly linked to the deficiencies in the recycling system: only 30% of bottles can be effectively recycled, something that has long been known among the protagonists of the plastics industry. Yet, according to the complaint, Coca-Cola not only did not implement an effective recycling strategy but actively opposed the "bottle Bills" The European Commission has proposed that the European Parliament should give its assent to the Council's common position.

[1] Sharon Donovan, "Earth Island Institute Files Lawsuit Against Coca-Cola for False Advertising". Available at: http://bit.ly/3tpSHG4

Eni[1]

In January 2021, the Italian Competition Authority ("Autorità Garante Della Concorrenza e del Mercato", AGCM) issued a measure against the Italian energy giant Eni for greenwashing. The Authority thus examined some claims issued between 2016 and 2019 by Eni relating to "ENIdiesel+", presented as organic, green, and renewable diesel, with the possibility of reducing CO2 emissions by up to 40%. The AGCM considered that advertising as "misleading, within the meaning of the Consumer Code", since it emerged from a European Commission study that plant additive present in the product do not reduce either the environmental impact or consumption.

Consequently, the Regional Administrative Court of Lazio[2] (TAR) ruled that Eni was forbidden to continue to use those advertising messages, as "it is not allowed in advertising to consider green diesel for transport. That is a fuel that by its nature is a highly polluting product. Nor declare that through its use you can take care of the environment". The Regional Administrative Court has ordered therefore a fine of 5 million euros (that is the maximum).

H&M[3]

In 2019, the Swedish fast fashion giant H&M was also accused of greenwashing. The Norwegian Consumer Authority, an independent government body, has investigated possible violations of the company's misleading advertising legislation. In particular, the collection of H&M's "Conscious" was examined, which, although identified as green, would not give "precise information" on the real sustainability of products.

Thus, the Authority accused H&M of the fact that the public domain information was too vague, referring to the "minimum 50% of recycled, organic or Tencel materials".

"Our opinion is that H&M is not clear or specific enough in explaining how the clothes in the Conscious collection are more sustainable than the other products of the sale brand", the Deputy Director General of the Consumer Authority, Bente Ģverli, said.

The Consumer Authority has not issued a measure against H&M but has taken the opportunity to push the Swedish company to find better communication on its production chain.

Ikea[4]

Ikea, which focuses heavily on the image of a sustainable group and has said it wants to become carbon positive by 2030, was also called into question in 2020 on the theme of greenwashing. The company has been accused by the British environmental group Earthsight of sourcing illegally felled timber from Russia and Ukraine.

In the report "Flatpacked Forests: Ikea's Illegal Timber Problem and the Flawed Green Label Behind It", Earthlight documented how much of Ukraine's state-owned forest enterprises had failed to comply with timber sourcing regulations, in particular by felling trees without the necessary environmental impact assessments and deforestation beyond authorized borders.

In the survey, the environmental group also estimated that Ikea was responsible for consuming one tree per second to meet the global demand for its products. The Swedish group is considered a fast-fashion model in

[1] La Nuova Ecologia, "Eni Diesel+, il Tar del Lazio conferma la condanna per greenwashing". Available at: http://bit.ly/3WXbKox

[2] Transport & Environment's (T&E), "Storica sentenza per greenwashing al TAR del Lazio". Available at: http://bit.ly/3EqqVPR

[3] Dezeen (August 2019), "H&M called out for "greenwashing" in its Conscious fashion collection". Available at: http://bit.ly/3fXwPyC

[4] EarthSights, "IKEA's illegal timber problem and the flawed green label behind it". Available at: http://bit.ly/3O3Q8De

the furniture industry, thus encouraging the use of wood and deforestation. An accusation to which the group has answered by starting the program of repurchasing and sale of used furniture.

3.2.2 What are the risks of greenwashing and how to avoid it

There are various risks associated with greenwashing practices[1]. One of the main is the loss of confidence. And once consumers discover that they have been deceived, it is very difficult to rebuild the image and reputation of the company. The damage can be even greater than the benefit that the company hoped to obtain.

Another danger is the lack of concrete action to achieve sustainability objectives. If a company sees its greenwashing slogans rewarded, it could be satisfied with that result without committing itself and making the necessary investments to improve its production model.

As far as the financial sector is concerned, it is particularly important to identify the companies that have incorporated sustainability into their organization, especially for ESG investors. Otherwise, the risk is to finance projects and businesses that do not benefit the environment and people.

3.2.3 How can you avoid greenwashing Traps?

Europe is coming to the aid of creating stringent legislation on what can be called green. The main regulatory instrument is the EU Taxonomy, adopted by Parliament in 2020, to uniquely define, within the financial markets, "the economic activity sustainable from the environmental point of view". An increasing number of companies will then be required to give their report on the sustainable activities and the real results achieved through the non-financial declaration of companies as reiterated by the EU NFDR (Non-Finance Reporting Directive) Mutual funds should specify the degree of alignment of their assets with the taxonomy, as established by the SFDR (Sustainable Finance Disclosure Regulation).

But that is not enough, standardization systems must be as clear and as mandatory as possible. And before buying a product or an investment tool just for the green features, you must inquire carefully.

3.3 Variables that affect ecological consumption choices

A company interested in making its offer as close as possible to the expectations of the demand is confronted with the need to identify the factors that influence the choice of an ecological product and to evaluate its "weight" in the reasons for purchase, to develop a marketing strategy[2] that considers the most significant and consistently identify the content of environmental communication. The paragraph aims to analyze these factors and their contribution to the process of maturing consumer purchasing decisions, with particular reference to the most significant variables involved in the dynamics of ecological consumption[3]:

1. The price of the product

[1] Viorel Nita, Valentina Castellani, Serenella Sala (2017), “Consumer's behavior in assessing the environmental impact of consumption”. Available at: http://bit.ly/3fUTiMV

[2] Sant'Anna School of Advanced Studies – Management Institute (June 2020), “Green Consumer Behaviour: Insights from survey and experiments”. Available at: http://bit.ly/3fWeK4b

[3] International Journal of Environmental Research and Public Health, “Factors Affecting Green Purchase Intention: A Perspective of Ethical Decision Making”

2. The Quality or Performance of the product
3. The "visibility" of the environmental characteristics of the product and the commitment of the company
4. The corporate image
5. Environmental information
6. Guarantees (and certifications)
7. The "proximity" (to the consumer) of the environmental effects of the product

3.3.1 The price of the product

Price is traditionally a priority factor in guiding consumers' purchasing choices and it is therefore immediate for the company to ask how this can affect ecological consumption. In the past, an interpretation of the purchasing dynamics of ecological products has been consolidated which signaled the tendency of consumers to perceive such products as "inferior" compared to competitors, from the point of view of performance and quality (For example, the use of recycled raw materials or the replacement of some substances with others with less environmental impact, derived from plants rather than synthesis, are often considered reductive interventions of product effectiveness).

This interpretation has often been accompanied by the observation that the development and production of ecological products implies a commitment on the part of companies in terms of technological investments, selection of raw materials, and process innovations, inevitably reflected in higher production costs (and therefore prices). This meant that consumers were unwilling to bear the burden of a greater economic effort to purchase an environmentally friendly product, contributing analytically to explaining the poor market success of these products.

In more recent times, the report "more environmentally friendly product = higher production costs = higher price" has undergone a process of substantial revision, stimulated by increasingly frequent cases, where manufacturers have managed to achieve significant economic benefits.

Today there are many experiences of companies that, from the development of environmentally friendly processes and products, have drawn significant savings in resources and materials thanks to, For example, more rational use of technology and a reduction in waste and energy consumption. This has reversed the traditional logic of "transfer" of costs on the final price of the product, allowing, in some cases, a lower selling price.

The appearance on several markets of environmentally friendly products sold at prices lower than those of "traditional" competitors has contributed to changing consumer attitudes towards supply. If in the past the higher price of ecological products could be considered a necessity, today the experiences of many companies convince the market to consider the price a variable not strictly dependent on the environmental quality choices of the manufacturer and, Thus, even more, "crucial" in determining purchasing decisions. This would lead to price being considered a relevant factor, in line with traditional competitive dynamics, especially when it exceeds that of competitors. If this happens the product is penalized by the choices of consumers (even those environmentally "more aware", less and less willing to "justify" the surcharge related to production costs).

However, it must be borne in mind that the price, in addition to reflecting the cost of production, also represents a signal to the consumer regarding the quality and performance of the product. In this logic, even a price lower than that of competing "non-ecological" products could constitute a competitive disadvantage. As has been said the ecological product can be linked to a perception of "poor quality" or of lower suitability for use than traditional substitutes. If its price was too low, it would give the consumer a "negative" signal, confirming this

perception. The price differential of the ecological product compared to the traditional is ultimately a relevant factor even in cases where it could benefit the final consumer.

The experiences of companies, therefore, suggest that the price of ecological products should not be significantly different from that of substitutes (neither higher nor lower).

If it were superior the consumer would not be willing to purchase, as it would not be able to justify the increased expense for a product that, as a rule, considers low performance. On the other hand, the excessively low price would only validate this belief in the eyes of the consumer, triggering a vicious circle from which it would be difficult to get out.

This calls into question the second factor that affects ecological purchasing choices: the perceived quality of the product.

3.3.2 The Quality or Performance of the product

The quality of the product, therefore, remains an essential factor of the purchase choices: in most cases, the consumer is not, in fact, willing to give up the quality of the product in exchange for better environmental performance.

This is also apparent from recent surveys. For example, a survey carried out in April 2018 by the Eurobarometer Observatory, aimed at highlighting the views of European citizens on the issue of sustainable production and consumption, polled, inter alia, the relative weight in the choices of purchase of citizens of four factors, price, quality, the environmental impact of products and brand products, noting the undisputed primacy of quality.

According to the survey, the environmental impact of products is considered more important than their quality only by 7% of respondents. 46% said they considered it "equally important", while 44% of respondents considered it "less important" than quality. Compared with the variable price, the environmental impact of products is instead considered "more important" by 19% of respondents, "equally important" by 45%, and "less important" by 33%. The surveys, therefore, seem to confirm the interpretation that consumers are only willing to consume environmentally friendly products if, in terms of quality and effectiveness, they are equivalent to traditional products.

This approach is underpinned by the belief that the environmental performance of the product in the eyes of the consumer is "distinct from" and "comparable with" its performance in terms of use effectiveness or quality. That is, it is supposed that the consumer compares the ecological qualities of the product with its "non-environmental" performance and, although motivated to purchase products with less environmental impact, does not renounce the effectiveness of the product. This approach has characterized the marketing strategies of many companies that have undertaken in the past initiatives to enhance ecological product lines. Based on the observation of these dynamics, it was believed that the green consumer was willing to reward a product as much as it was able to differentiate itself from the competition, emphasizing its environmental qualities even at the expense of those "traditional".

It may be useful, from this point of view to "approximate" traditional and ecological qualities by distinguishing between "subjective" and "collective" benefits associated with the consumption of a product:

The subjective benefit is the advantage that the consumer perceives in the purchase and use of that specific product, compared with other competitors, more or less ecologically subjective benefit can be represented by the relationship between perceived quality and price, that is the concept of the value of the product, understood in its classical sense. This parameter also distinguishes products that are "friendly" towards the user himself (organic food, herbal products, fabrics without dyes, etc.) attributable to a concept of "ecology of the person" and which have no lower environmental impact than competitors

The collective benefit of the product can instead be understood as the level of the environmental impact of the product throughout its life cycle, as perceived by the consumer.

If you show on a map these two types of benefit (increasing respectively on the axis of ordinates and abscissae) you get four quadrants, representing the different possible locations of a product, this is because of how this is perceived by the consumer. By assigning to each axis two levels (high and low), it is possible to make some considerations regarding the four quadrants that come to be determined within the map (*Figure 2.1*):

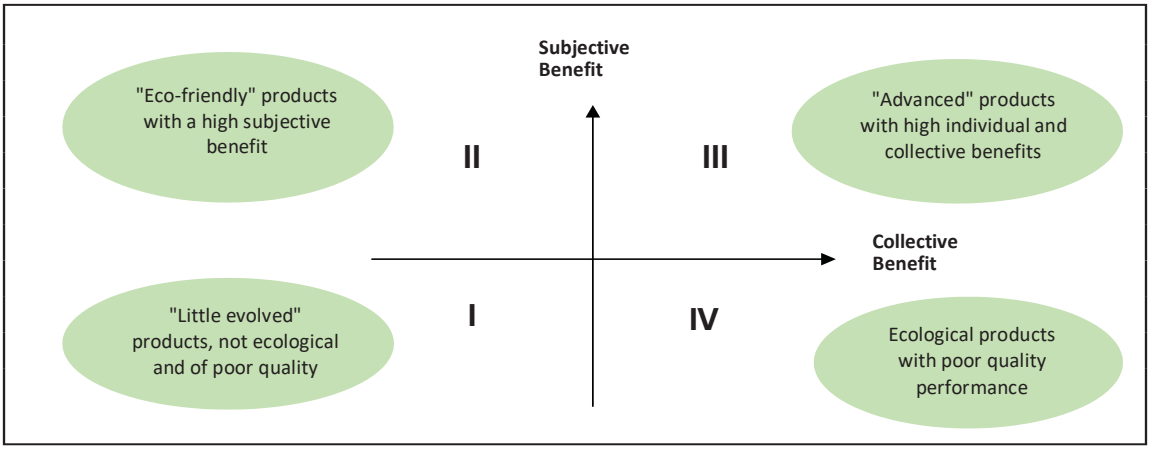

Figure 2.1: Subjective and collective environmental benefits

- In the dial are placed the products "little evolved", which combine poor ecology and little value
- In the second quadrant there are products with a high subjective benefit, perceived as less ecological
- In the III quadrant are placed those products that can adequately satisfy both their subjective and collective performance
- Finally, in the fourth quadrant are positioned ecological products characterized by lower performance of use than competitors.

In the perception traditionally more diffused between the consumers, the ecological products are placed in the fourth quadrant, characterized by elevated environmental performances but from a little effectiveness, while the traditional products are positioned in the left part of the diagram (whatever their effectiveness).

In the past, companies that have launched eco-friendly products have essentially aimed to differentiate their products, placing them on the right side of the graph, however, they were inevitably confined by consumer perception within the fourth quadrant, because they were not able to associate (in fact or communication strategies) the performance qualities with the ecological ones.

However, the concept of reduced environmental impact as a distinct quality, comparable, and in many cases alternative to the performance qualities of the product must be changed in consumer opinion and, to an even greater extent, in the strategies of companies. Today, companies are increasingly confronted with consumers' need to consider environmental performance as an integral part of overall product quality. The results of the surveys mentioned do not, therefore, indicate the lack of willingness of consumers to give up certain services (those of use) in favor of others (those ecological), but the need to consider these as essential components of the quality and effectiveness of the product.

For companies that offer low environmental impact products to the market, the challenge is to place themselves in the third quadrant, where the environmental characteristics integrate with the performance qualities and do not come, Therefore, perceived by the consumer as a limit to the effectiveness of the product.

The trends emerging from the most innovative companies are indicative of a significant change in the strategies for the enhancement of ecological products currently in place. If in the past attempts to enhance ecological products based on exaggerated differentiation and the creation of niche markets have prevailed, today it is understood that a product is successful only if it guarantees competitive performance across the board. Among these benefits, the environmental impact takes on increasing importance and is conceived as a "qualitative surplus" that, in some cases, becomes decisive for the reasons of purchase.

3.3.3 The "visibility" of the environmental characteristics of the product and the commitment of the company

For the consumer to seize the ecological surplus associated with a product, and thus recognize that it is positioned in the third quadrant, it is essential that it concretely perceives the environmental benefits related to its consumption. In other words, consumers who are willing to reward an environmentally friendly product must be convinced that, through the act of buying, they can contribute to environmental improvement.

As anticipated, ecological consumption is often configured as an alternative behavior available to the individual who intends to commit to the environment. To be an effective option, in many cases, the purchase of a product must offer the consumer the certainty of being able to somehow "compensate" the lack of other conscious behaviors (for example, participation in recycling or separate waste collection programs).

In other words, the consumer who chooses the act of purchase as a form of manifestation of his ecological sensitivity is led to choose those products that offer greater opportunities to contribute to environmental improvement. In this sense, the challenge for manufacturers is therefore to make more concrete and "visible" the improvement associated with the consumption of their products.

In this logic, there are types of products for which the best environmental performance is "self-evident" and tangible since the simple visual contact that the consumer has on the shelf. This, for example, is the case for unpackaged toothpaste, a toothbrush with interchangeable heads, and detergents equipped with a refill. The design, composition, materials, and packaging of these products are sufficient to unequivocally demonstrate to the prudent consumer the lower environmental impact related to their consumption (see for example the products in *Figure 2.2*).

Figure 2.2: On the left side there is an organic and ecological Bamboo toothbrush, and, on the right, it is a sustainable toothpaste packaging design

In other cases, however, the consumer cannot verify the product's eco-compatibility through its "visible" characteristics but must use the same. This is an example of concentrated detergents, which allow the use of

small quantities for the same washing capacity or reusable packaging for other functions. In these cases, the producer cannot rely on the "visibility" factor of the environmental benefits at the time of purchase and the advertising campaigns of these products are generally characterized by an explicit description of the ecological benefits associated with their purchase and consumption.

Figure 2.3 shows an example of an advertising campaign for ALL's detergent, the concentrated formula of which allows a lower use of resources and a lower production of waste. The advertising message relies on the combination of individual benefits and environmental benefits.

Figure 2.3 An advertisement of the ALL brad, for Ultra-Concentrated detergent Liquid

Finally, there are products in respect of which the consumer is not able to determine directly the highest eco-compatibility (for example, for household appliances it is not possible to perceive environmental effects related to the product that go beyond energy or water consumption). This can discourage the act of purchase, in the absence of certainty that this represents a concrete contribution to environmental improvement. In these cases, however, the consumer must be able to recognize the ecological nature of the product. Since this is not immediately visible or "experiential" during use, other factors can influence the consumer's perception of the lower environmental impact of the product (and on which companies can intervene to promote this perception). Among them, the main ones are:

- Image of the company (or the perception of its commitment on the environmental front)
- Information on the environmental performance of the product
- Presence of guarantees that the product (if not even "visibly") is more environmentally friendly than others

3.3.4 The corporate image

In the process of maturing their purchasing decisions, the consumer pays increasing attention to the corporate image. In many cases, in fact, for a consumer particularly sensitive to environmental issues it is difficult to consider a product, even if this shows "visibly" a reduced environmental impact, dissociating it from the perceived image and credibility of the manufacturing company. A company whose environmental commitment is not known or perceived, or which in the past has had negative experiences in the field of environmental protection, can hardly be credible in the eyes of the consumer when proposing a line of ecological products.

For the consumer, it is therefore important to know the behavior of the producer, also through the consolidation of a "positive" environmental image. This can influence the act of purchase through mechanisms of trust (built

over time) and "brand loyalty", in cases where the company has taken a position strongly oriented to the enhancement of its environmental commitment in its sector.

The decision to purchase a product is increasingly based on knowledge and information relating to the entire processing and marketing process. The purchase is, as well as a tool to meet their needs, an approval expressed by the consumer towards the management policy of the company and, therefore, also its social and ecological behavior. It should also be borne in mind that the perception of the corporate image may depend significantly on the sector to which the company belongs.

The analysis of the consumer's willingness to change brands is equally interesting compared to their established consumption habits. Consumers today also report a certain "willingness to change", attributing to the brand of the product a weight lower than one might expect (and especially lower, in the survey carried out than the "low environmental impact").

Finally, one aspect that should not be overlooked is the confidence that consumers place, especially for certain categories of products, in distributors, to whom they recognize a particular commitment to the issues of ecology. Distributors, in fact, through their brands or simply their policies aimed at selecting certain types of products, play a fundamental role in ensuring the consumer on the actual environmental quality of the products that he intends to buy.

3.3.5 Environmental information

Information is the main tool to make the consumer aware of both the ecological value of the product and the environmental commitment of the producer. The objective of environmental information is, in the first case, to highlight the environmental benefits related to the consumption of the product, for example by highlighting the problems it addresses; in the second, to underline the company's commitment to the environment, so that this positively affects the environmental image of the product. Environmental information must make the consumer aware of the environmental importance of his purchasing act and the contribution that his behavior makes to improving the environmental situation.

Given the particular content of environmental information, the forms of communication must go beyond the traditional promotional channels which, in this case, may have little impact on the consumer. The latter needs to have unambiguous information on the actual performance of the products. For this reason, particular attention is paid to reading the information on the labels of the packaging.

However, often the messages on the packaging are conflicting, and unclear and do not allow the consumer to distinguish between a generic reference to ecological values and the actual performance or quality of the product in the environmental field. In this respect, certain areas of information are currently regulated at the European and national level, typically those closely linked to the protection of the health and safety of consumers. Consider, for example, the food sector and the nutrition and consumer health claims provided on food labels, through so-called "nutritional claims" or "health claims". In terms of the correctness of the information, consumer protection rules currently prohibit any information:

- Inaccurate, incomprehensible, or misleading
- Raising doubts about the safety or nutritional adequacy of other products
- Encouraging or tolerating excessive consumption of a given product
- Which incites to consume a product by stating or suggesting directly or indirectly that a balanced diet does not provide all the necessary nutrients
- Trying to "scare" the consumer by referring to alterations in body functions

To this must be added the proliferation of forms of communication concerning the environmental characteristics of products, which are not always credible and poorly controlled. In this sense, information must be accompanied by an adequate guarantee of the veracity and reliability of the content transmitted to the consumer.

3.3.6 Guarantees (and certifications)

Another element that can "replace" the lack of ecological visibility of the product, or the impossibility of "experimenting" it through use, is represented by the forms of guarantees related to the previously analyzed factors (environmental commitment of the company and information). In other words, when the consumer, to guide his purchasing choices, relies on the environmental image of the company or product information, he needs certainty about the veracity of the signals he receives. In these terms, the company's commitment to improving the environmental situation acquires greater credibility if "validated" by visible and accredited forms of certification.

Consumers feel a need for clarity and transparency about both information concerning businesses and their environmental commitment in general and information concerning the ecological characteristics of products. In both cases, the presence of forms of certification and guarantee issued by third parties may represent, for consumers, a strong element of credibility and guarantee the veracity of what the company communicates.

In particular, concerning products, the messages that reach consumers are often too generic or transmitted in technical and unclear language. Also in this case, therefore, the forms of certification of the declarations of product, conferring credibility to the contents of the information and guarantee of truthfulness, can represent a useful tool to support the purchase decisions of the consumers. The latter "reassured" that the ecological qualities of products are not only self-declared by companies, but correspond to actual environmental benefits, through the act of purchase would contribute to these benefits.

In any case, the visibility of the ecological characteristics of the product (or the related information and guarantees) is closely linked to the perception that the consumer has of the environmental problems related to the product. In other words, the "dimension" of the environmental issue, that is, the proximity of the specific problem to the personal sphere of the consumer, is also relevant in guiding the choices of ecological consumption of individuals.

3.3.7 The "proximity" (to the consumer) of the environmental effects of the product

The consumer has traditionally interpreted the ecological product as synonymous with a "natural" product, free of substances harmful to human health or made with virgin materials and not synthetic. Individuals tend to establish a close link between their health and the environment, considering environmentally compatible what does not harm the person, the health of the individual, or his closest "environment" (urban, local, or national).

Surveys also generally confirm the tendency for consumers to view environmental problems primarily as health hazards. In other words, individuals, even if they are particularly concerned about the deterioration of the environment, tend to limit their sensitivity to those aspects of the environmental problem that most concern them. More generally, the data confirm the long-established assumption in the analysis of the psychological profile of the consumer that interest in environmental issues reflects (at least in part) concern that the damage caused to the environment may in some way affect one's health.

In these terms, in directing its purchasing choices, the consumer pays particular attention to the proximity of the specific environmental problem to which the product remedies. The possibility of saving the Amazon

forests or of preventing global warming, for example, is certainly less significant for the consumer than the lack of carcinogenic substances or the possibility of not producing waste.

It is important, therefore, to identify different levels or "dimensions" of the environmental problem, which corresponds to a different degree of attention and interest on the part of the consumer (and therefore a different mode of participation in the solution of the problem):

- A global dimension (e.g.: deforestation, climate change, depletion of the ozone layer, acidification, etc.), concerning which the consumer may decide to adopt behaviors independent of consumption (e.g.: joining an environmental association, participating in protests, etc.)
- A local dimension (eg noise, urban traffic, water pollution, etc.), for which citizens may consider changing some of the behavior, how to make greater use of public transport or participate in separate collection programs
- An individual dimension (e.g.: presence of carcinogenic substances in products, genetically modified foods, etc.), for which the act of purchase represents the mode of participation "par excellence" in the solution of the environmental problem.

In these terms, it is possible to identify the ability of the product to ensure individual health as one of the main determinants of ecological consumption. These are, in synthesis, the dynamics that guide the process of maturation of the choices of purchase of the consumers and, for the interested company to "influence" such process, it is opportune to set a marketing strategy according to modalities times to value the dimension "individual" of the environmental aspect to which the company turns its efforts and its commitment to improvement. It will be a matter of communicating to the consumer the relevance of his purchasing act for the solution of macro-environmental problems while highlighting the significance of these problems also for his health and his future well-being.

4 Practical case

Comparative analysis between Europe and the United States of eco-toxicological standards in the textile, clothing, leather, and footwear sectors.

4.1 Laws, norms, and main private standards

The primary objective of this chapter is to achieve a scientific comparison between the eco-toxicological standards governing the textile, clothing, leather, and footwear sectors in the US and European markets[1], to highlight their differences and common points.

In addition to the laws and regulations in force, there are voluntary brands such as Ecolabel (European Community trademark) and numerous brands and private specifications of large commercial groups, brands, and certification bodies that, just to remedy the lack of uniform regulation, you are equipped with internal regulations and standards. For the areas of interest of the study, the main feature of the documents described is the RSL, or the Restricted Substances Lists which list a series of (families of) Dangerous substances, which could be used in the processing cycle and then found on final articles: these substances should be regulated to avoid problems to the environment and consumer health.

In the following paragraphs, the main product safety regulations, and the regulation of chemicals in the two reference markets, Europe and the USA, are examined: these are often generic standards covering many sectors, including textiles, clothing, leather, and footwear.

The main US laws[2] and regulations in force include:

- Customs and Border Protection (CBP)
- Consumer Product Safety Improvement Act (CPSIA)
- Toxic Substances Control Act (TSCA)
- California Proposition 65
- Federal Hazardous Substances Act
- Flammable Fabrics Act
- Washington Children's Safe Product Act

4.1.1 Customs and Border Protection (CBP)

The US Customs Administration U.S. Customs and Border Protection (CBP), approved by the Italian Customs Agency, deals, among other things, with:

- Verification of plant health requirements for products from abroad
- Protection of US borders against the entry of toxic substances

[1] Official Journal, "Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance)"

[2] Lisa M. Benson, Karen Reczek, "A Guide to United States Apparel and Household Textiles Compliance Requirements". Available at: http://bit.ly/3trLNQK

- Protection of domestic industry against unfair foreign competition

The customs legislation derives from the application of the Trade Act 2002 and the Custom Modernisation Act, which entered into force on 8 December 1993 and is known as the "Mod Act". The provisions contained in it have transferred to the importer the legal responsibility to declare the value, classification, origin, and duty rate applicable to the goods released, according to the cardinal principle of "Informed compliance"This involves the sharing of responsibilities arising from customs operations between CBP (U.S. Customs and Border Protection) and importers.

All products imported into the United States must be properly labeled. Textile products are subject to numerous labeling rules issued by the Federal Trade Commission (FTC) pertaining t the composition of the fabric, washing instructions, and the declaration of the presence of specific materials. The US customs requires special and additional certifications and/or authorizations from competent federal agencies for certain products, including textiles, wool, and fur, as they are considered trade sensitive.

They are therefore subject to more checks than other semi-finished products. With specific reference to the footwear sector, like the textile sector, in addition to the normal documentation attesting to the characteristics of the imported products, the entry of each product must be accompanied by additional documents relating to the origin, customs tariffs, and wool products.

4.1.2 Consumer Product Safety Improvement Act (CPSIA)

The 2008 Consumer Product Safety Improvement Act (CPSIA) is an American law that limits the levels of hazardous substances in products imported or manufactured in the United States. The law amends and improves many provisions of the CPSC (Consumer Product Safety Commission), including the CPSA Consumer Product Safety Act. It increases the CPSC budget, imposes new tests, requires requirements, and sets new limits for some common substances in most consumer goods (including clothing, shoes, and accessories), especially those intended for children from 0 to 12 years (“children’s product”).

At the end of 2011, the CPSC strengthened the CPSIA requirements for toys and products intended for children, defining them as "any consumer product created and intended primarily for children 12 years or younger".

They must have the following characteristics:

- Comply with all applicable safety requirements
- Be tested for compliance at a third-party laboratory, accredited and accepted by the CPSC
- Be accompanied by a specific certificate of conformity (Children’s Product Certificate)
- Have the traceability information imprinted on the product and packaging, if possible

Failure to comply with these requirements could mean the delay or even the seizure of products at the entrance of the United States, as well as the application of fines or sanctions, defined by the CPSC.

CPSIA focuses mainly on two types of substances, lead, and phthalates, according to the following indications:

- Lead in surface coatings and paints is reduced from the previous limit of 600 ppm to 90 ppm (from August 2009). The total content of Pb in baby product substrates is reduced to 300 ppm (from August 2009) and 100 ppm (from August 2011)

- Phthalates[1] have been banned since February 2009 in all children's and toys (import, production, or distribution) in concentrations greater than 0,1% since being present in children's items and toys that can be put in the mouth

4.1.3 Toxic Substances Control Act (TSCA)

The Toxic Substances Control Act, passed by the United States Congress in 1976, is administered by the US Environmental Protection Agency (EPA).

This law aimed to protect the population from "unreasonable risk of injury to health or the environment", through regulation of chemicals produced and put on the market.

In the context of TSCA, the term "chemical substance" means any organic or inorganic substance, with a specific molecular identity, including any combination of these substances that occurs in whole or in part, as a result of chemical or natural reactions, and any element or radical.

The law divides the substances into two main categories: the "existing chemicals", that is the substances already on the market when the law was approved, and the "new chemicals" which are all the substances placed on the market after the act of 1976.

- "Existing chemicals" regulation

The substances already on the market, about 62,000, were simply approved, considering them free of "unreasonable risks" and included in the TSCA Inventory list. There are very few tests and research carried out on these substances: in the context of the law, the EPA has little authority to obtain sufficient information about the risk from manufacturers. In practice, EPA has to comply with several formalities before making requests, including primarily demonstrating that there is an unreasonable risk to human health and the environment for the test substance.

- "New chemicals" regulation

Companies must notify the EPA of their intention to market a substance not in the TSCA Inventory using the so-called PreManufacturing Notice (PMN).

No toxicity tests are required in the PMN, from which EPA is to determine, using computer models, whether the substance may present "unreasonable risks to human health and the environment".

Since receiving the PMN, EPA has only 90 days to act before the product is put on the market: if you can't prove that there are real risks, there is no way to stop production.

Upon completion of the review of the PMN, the company that submitted it must produce a Notice of Commencement of Manufacture or Import (NOC) and send it to the EPA within 30 days.

A substance becomes part of the TSCA Inventory and becomes an "existing chemical" as soon as a complete NOC arrives at the EPA.

EPA has developed this model to allow companies to voluntarily test the health and environmental risk related to their new products. Overall, however, there is insufficient data to fully assess the risk of new substances.

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[1] Phthalates are a family of petroleum-derived organic chemicals used as plasticizers but also as solvents and optimizers of consistency and yield of different products. These are the most common plasticizers in the world and have been used for decades in processing polyvinyl chloride (PVC), which help make it more flexible and softer. There are various types, all are in liquid form (they resemble oil) and are practically odorless, but do not always have a plasticizing function.

The list (Inventory) currently has approximately 84.000 substances, but only 200 approximately have been correctly tested.

TSCA does not separate substances into "toxic" and "non-toxic", but rather prohibits their production or importation if such substances are not included in the TSCA Inventory. If a manufacturer or importer wants to market a substance whose status they do not know about against Inventory, they can obtain a written determination from the EPA if it demonstrates a "genuine intent" or provides a good use of the substance.

Over the years there have been many criticisms of this law, given the lack of real toxicity data and therefore guarantee of safety. This has also curbed investment in "green chemistry" and technological development. To overcome the critical nature of the TSCA, many States have also adopted internal laws, creating a complex situation that should be standardized.

CSIA - proposal of reform change

Since 1976 the TSCA has hardly undergone any significant reforms. The only major reform attempt was launched in 2013, under the name of CSIA "Chemical Safety Improvement Act".

This reform would lead to improvements in almost all sections of the law. It would allow the EPA to have more power to request toxicity data from manufacturers/importers and, as a federal law, it would annul the various nationally born laws. CSIA would give more safety guarantees because it requires that all the substances and the "existing chemicals" are evaluated.

EPA should establish which are the priority chemicals, which are potentially the most dangerous, and proceed to a safety assessment, using the best scientific tools available. Based on the results obtained, EPA should establish restrictions for the substance to reach a safety standard, otherwise, it may decide to ban the substance itself. CSIA would therefore make it easier for EPA to request tests and information from substance manufacturers. The reform would also ensure better control over imported products. There is also a provision for more consumer information while protecting intellectual property.

4.1.4 Proposition 65 (Safe Drinking Water and Toxic Enforcement Act)

Proposition 65 was introduced in California as a popular initiative in 1986. This law required the State to publish a list of chemicals known to be carcinogenic or toxic to reproduction.

The list is updated at least once a year and currently includes more than 800 substances, including lead, cadmium, mercury, phthalates, acrylamide, DEHP, bisphenol A, etc.

The enforcement agency is the Office of Environmental Health Hazard Assessment (OEHHA) which is part of the California Environmental Protection Agency (Cal/EPA).

OEHHA is tasked with maintaining an up-to-date list of chemicals subject to law enforcement: periodically new substances are added to the list and occasionally some are removed.

The law does not prohibit the use of harmful substances but imposes on the companies that use them the obligation to inform the public about the exposure to such substances and the possible risks. In short, the consumer must be informed and able to decide for himself whether to limit his exposure. Prop 65 does not apply to undertakings with fewer than 10 employees.

When a new substance is added to the list, companies have a year to adjust, changing their products or giving notice to consumers. For many of the substances on the list, safety levels have been established which are divided into NSRLs (No Significant Risk Levels) for carcinogens and MADLs (Maximum Allowable Dose Levels) for substances causing reproductive problems and expressed in μg/day. The maximum acceptable

limits are independent of the levels set in Europe or the USA (by Federal law) and are often considerably lower, so compliance with European and US standards does not guarantee compliance with Prop 65.

For substances, without safety limits, it is mandatory to provide a warning to users every time a minimum amount is found. The standard warning language is as follows:

WARNING: "This product contains chemicals known to the State of California to cause cancer, congenital malformations, and other reproductive damage"

This is a rather alarming communication but one to which California consumers are becoming accustomed, given the frequency of such warnings.

Mechanisms to increase the list of substances:

There are four main ways to add a substance to the Prop 65 List.

1) Decision by two Committees of Experts which are part of the OEHHA, and which are based on the best scientific knowledge available. The two Committees are the CIC (Carcinogen Identification Committee) and the DART (Developmental and Reproductive Toxicant Identification Committee)

2) A substance is formally identified as carcinogenic or toxic to reproduction by an authority considered authoritarian for Prop 65 (US Environmental Protection Agency, Food and Drug Administration, National Institute for Occupational Safety and Health, National Toxicology Programme, Agency for Research and Cancer)

3) A state or federal agency formally requires a substance to be identified as carcinogenic or toxic to reproduction

4) A substance meets certain scientific requirements and is identified as carcinogenic or toxic to reproduction in the California Labor Code. This was the method adopted to define the first list of substances and continues to be used as a working basis.

Inquiries for companies doing business in California

Companies wishing to do business with California must produce a "clear and reasonable" notice before intentionally exposing anyone to a substance listed.

The ways of warning can be different: product labels, job notices, publication of notes in magazines, etc... From the moment a substance enters the list, there are 12 months to prepare the warnings.

Prop 65 also prohibits companies from discharging substances from the list into drinking water. Discharges have 20 months to adjust to changes. By law, the warning must be provided unless the exposure is below the safety levels, defined by the "Safe harbor levels".

Safe harbor levels

To help companies assess whether the warning is necessary or not, the OEHHA has developed Safe harbor levels. If the exposure to substances is lower than these levels, the warning is not necessary and the discharge into drinking water is not prohibited.

These levels consist of No Significant Risk Levels (NSRLs) for carcinogens and Maximum Allowable Dose Levels (MADLs) for substances causing birth defects or reproductive damage.

- NSRL is defined as the level of exposure that causes no more than one cancer case in 100,000 individuals exposed to the substance for 70 years.

- MADL is derived from the concept of "no observable effect level", which is the level of exposure that has shown no danger to humans and laboratory animals. Prop 65 requires that this level be divided by 1000 to define the MADL, and to have ample safety margins.

OEHHA has established safety levels of around 300 substances to date and is continuing to work on other substances, according to a priority list. Priority depends on the availability of scientific data, exposure potential, the interest shown by stakeholders, and input from private individuals or the Attorney General's office.

In the case of substances on the list for which the safety limits have not yet been defined, the warning should be provided, unless the company can demonstrate that exposure levels do not pose significant risks to cancer or the reproductive system.

OEHHA has developed regulations to guide the calculation of such levels. Given the complexity of these calculations, however, the party is often discouraged and relies on professionals if they believe there are requirements to avoid the warning.

Legal problems

Prop 65 has the merit of increasing public attention to hazardous substances and encouraging manufacturers to exclude substances from their products. This law, however, involves companies that want to trade in California very high costs to test products, develop alternative substances to those on the list, reduce discharges, prepare warnings, etc...

It is also important to note that, in the case of end products destined for the Californian market, producers of raw materials and semi-finished products are also required to comply with Prop 65 and provide the notice required by law. For the reasons expressed, OEHHA is working to make the demands of the law clear and follow scientific rigor.

4.1.5 Federal Hazardous Substances Act

The Federal Hazardous Substances Act (FHSA) obliges the labeling of articles considered dangerous for the health of the consumer, also giving information on how to proceed in the immediate event of problems. The FHSA allows the Consumer Product Safety Commission to prohibit the circulation of articles deemed dangerous for which the labeling itself is not considered sufficient to prevent the risk.

It then defines the rules and requirements, updating them over time, to determine whether labeling is necessary for a particular article or whether a trade is prohibited. Mandatory labeling is required for articles deemed to be a toxic, corrosive, flammable, irritant, sensitizing, or otherwise potentially liable to cause harm to humans during a reasonably foreseeable use, including possible accidental ingestion by children.

FHSA considers items that have to do with the people or places where people live. Using labeling, specific information is provided on the behavior to be taken towards certain products to ensure their protection and that of children. Each possible risk has its precise definition in the FHSA and, where possible, analytical methodologies are specified to assess the potential hazard of articles. It also recommends that you examine the finished item that will reach the consumer and not its components separately. For example, a product is:

Toxic, if it can cause immediate or long-term harm to the person if inhaled, swallowed, or brought into contact with the skin

- Corrosive, if it destroys tissue, for example, skin or eyes
- Irritating, if, if not corrosive, causes substantial damage to the skin or body area with which it comes into contact, either immediately or after prolonged and repeated use
- Sensitizer is capable of producing a sensitization reaction by coming into contact with a person. This reaction becomes apparent during the second contact (trigger phase)

The FHSA has defined a list of prohibited articles, for which labeling was not enough to inform the consumer: among these, for now, there are no products belonging to the categories examined in this study. Toys and childcare articles containing substances prohibited by the FHSA have been banned, as a child can easily come into contact with them.

4.1.6 Flammable Fabrics Act

The Flammable Fabrics Act FFA regulates the production of highly flammable articles, textiles, and non-ferrous, through the definition of standards for clothing, carpets, and pajamas for children and other families of non-textiles. The aim is to eliminate flammable and as such dangerous textile articles from the market. The standards also define the test methods to be carried out on textile products that are classified into 3 different bands depending on the rate of grafting and propagation of the flame.

The minimum standards laid down for Class 3 provide for the non-use in the clothing sector of textiles belonging to it, due to the rapid and intense combustion. Textiles classified in Classes 2 and 3 are those produced from silk and cotton fibers. The standards apply to all textiles used in clothing, both for adults and children, while many children's nightwear have to meet even more stringent requirements.

The tests to be carried out are quite severe, they must be carried out on several samples, before and after their drying and water washing. Years of testing have shown that typically products made from nylon, polyester, acrylic, and wool fibers, and mixed them, meet the requirements of the law.

In any case, companies are required to perform representative tests of their production, keeping the results for possible future disputes. In addition, legislation requires that tests be followed by authorized laboratories (third-party testing), located in the USA, or abroad and fully meet the requirements for the acceptance of laboratories by the CPSC Consumer Products Safety Commission and then accredited by it.

From the point of view of non-tariff barriers, the provisions of the CPSIA (Consumer Product Safety Improvement Act) which, since 2008, require exports of silk fabrics and clothing to be subject to the FFA (Flammable Fabrics Act) should therefore be noted. Therefore, requiring a special certification of conformity (General Certificate of Conformity and Testing) attesting to the conformity of the product with the established safety standards on flammability.

4.1.7 Washington Children's Safe Product Act (CSPA)

The law[1] starts from the principle that the prevention of exposure to toxic products is the most guarantor and economic way to protect the health of people and the protection of the environment. In this context, it defines the requirements that children's items must have to be sold in the State.

Among the different requirements, the SCPA also limits the presence of lead, cadmium, phthalates, and formaldehyde in these articles and defines a series of tests to be carried out to ensure that they comply with

[1] Michael O`Grady, "Summary of Washington State Children's Safe Products Act". Available at: http://bit.ly/3tpKUIc

the law. CSPA publishes the results of the tests carried out: it emerges that many articles comply with the law, but there are also several differences due mainly to the presence of phthalates, cadmium, and lead. In addition, several articles have found the presence of formaldehyde and other volatile organic substances, which raises questions about textile and footwear articles that are to be exported to the State.

4.2 The standard for private entities

The situation, in addition to the regulatory framework, is characterized by the spread of forms of "sustainability specifications", requiring suppliers not to use certain substances and/or chemicals deemed unsustainable for environmental and health impacts or to use others within threshold limits, sometimes lower than those that can be detected analytically.

These initiatives are often inspired by marketing logic that pays little attention to the actual feasibility of requests or is sometimes "suggested" by environmental organizations with an ideological and anti-industrial approach.

The main feature of the "sustainability specifications" are the RSL, the Restricted Substances Lists that list several dangerous substances, which can be used in the processing cycle and therefore present on articles and which should be regulated to avoid problems for the environment and consumer health.

The "sustainability specifications" may originate from large distribution chains or individual Italian or American brands, but also from recognized bodies of third countries, whose certification is required by American importers/distributors. These certifications sometimes go beyond the "simple" request for conformity of the article to an RSL and also take into account the use of chemicals. In some cases, they even require the use of chemicals purchased exclusively from recognized suppliers.

This is the case for the following two examples:

Zero Discharge Programme ZDHC - It is a program promoted by an association including several brands, among others Nike, Levi Strauss, M&S, Inditex, H&M, and Puma, to reduce the risk to the consumer and the release into the environment of dangerous substances from textiles and footwear (throughout their life cycle), through the use of "safe" chemicals. The program has involved over time chemical companies and other stakeholders to reach 2020 the zero level of release from all items, eliminating hazardous substances from production.

Bluesign System - This is a certification system promoted by a Swiss body that wants to ensure the sustainability of textile articles, reducing the impact of production on people and the environment. More than a product certification, it is a process certification, issued after a series of controls in the company, aimed at excluding the use of hazardous substances. Defines the requirements for each step of production, based on the definition of BAT (Best Available Technology), and imposes limits on the presence of many hazardous substances in the final article, through a restricted substances list that also takes into account the REACH Regulation. It also takes into account principles of ethical sustainability and social responsibility.

4.3 Problem for the Enterprise System

4.3.1 Identification of problems for Italian companies and supply chains

In terms of global trade, Italy has historically played an important role. Below is the weight that has been covered in terms of global exports of the main nations in 2020, in the textile sector[1]. In 2020, as shown in *Figure 3.1,* Italy ranks eighth in terms of exports: it generates 2.9% of world exports, compared to 3.3% in 2009. In recent years, we note the advance of developing countries and the increasingly important role of China.

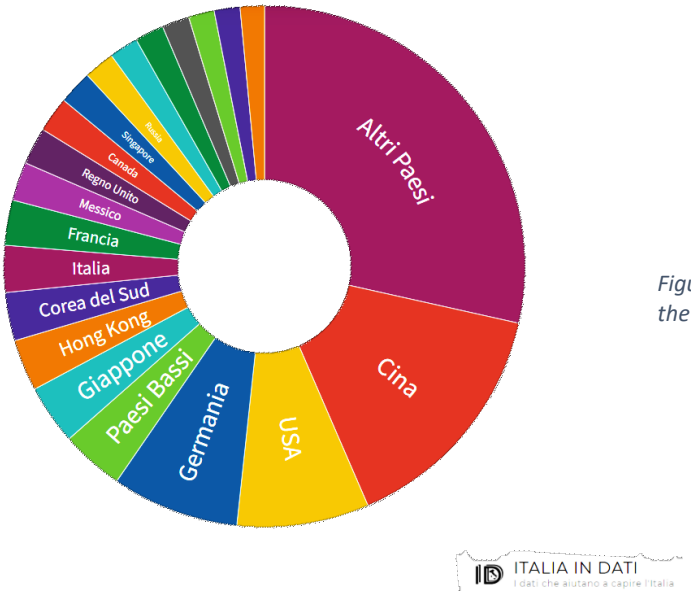

Figure 3.1: Data from "ID ITALIA IN DATI" show the weight that the major countries will have in terms of world exports in 2020

This market, and in particular that of the United States, is however very complex in terms of rules and rules governing technical standards and characterized by a dual regulatory level, the state and the federal, often uneven. This complexity takes the form of non-tariff barriers designed to reduce imports, as they consist of rules applied in such a way as to render difficult or particularly costly their transposition and/or compliance by foreign producers. They can be quality standards on certain products or health regulations; generally, these are constraints that are justified for health or safety reasons or requirements that concern health standards are imposed.

Within these standards, be they regulations, private brands, or specifications related to chemicals, there is no specific distinction for the 4 sectors specified: usually differs only between "textile" and "leather", defining their analytical limits and methods.

Consequently, the analysis was conducted on these two macro-categories, highlighting the problems for Made in Italy companies arising from the current situation. In the following paragraphs, the findings of the precise assessment of the requirements required by these rules and rules for the articles of the sectors of interest are reported.

[1] Iolanda D'amato, "La filiera del vero: Contraffazione e autenticità dei prodotti Made in Italy"

4.3.2 Chemical requirements such as technical barriers

The hazardous substances potentially present in the articles are all considered at any initiative aiming at a convergence of requirements between the US and the EU. For these substances, the "non-existence" in the articles or the presence within certain defined limits is required.

Often such data must be certified and supported by analyses carried out in accredited laboratories. Trying to narrow the field a lot and give an indication of the most frequent and/ or important criticalities you can list the following chemicals:

- Phthalates
- Lead
- Cadmium
- Formaldehyde
- Alkylphenols and nonylphenols

Phthalates:

Compounds are mainly used to make soft PVC articles. They can be found in textiles, such as rubbery inserts applied to children's pajamas and women's clothing, or footwear.

Lead:

Metal can be present in traces in chemical mixtures used in the production processes both in textiles and footwear.

Cadmium:

Metal can be present in traces in chemical mixtures and dyes used in the production processes both in textiles and footwear.

Formaldehyde:

Readily available substance: may be present in chemical mixtures, polymers, or as a reaction residue. Consequently, it can be detected in articles.

Alkylphenols and nonylphenols:

They are present in detergents used, mainly in the Far East, in many processes and therefore found in articles both textile and footwear.

There is also a specific problem for those who produce and market articles in polyamide (nylon). California's Office of Environmental Health Hazard Assessment OEHHA intends to reduce the emission value (VOC) in the caprolactam environment[1] and this would in practice amount to excluding the use of nylon, especially in the carpet market, Also, throughout the textile industry.

[1] Cyclic organic compound, which may be obtained from benzene, toluene, or phenol, is used in the manufacture of polyamide fibers

European manufacturers have been working on this topic for some time now and have commissioned a study to demonstrate that the limits of VOC/caprolactam dangerous for health are much higher than those that the OEHHA intends to introduce.

Finally, again concerning the production and consequently trade in articles made of nylon fibers, It should be noted that some environmental associations and private brands are promoting requirements relating to the prohibition of the use of benzene and cyclohexanone in the production stages, which, taken literally, would make it virtually impossible to produce nylon of any kind.

4.3.3 Application of REACH: consequences for companies

The European REACH Regulation correctly sets the regulatory and safety perspective. However, there is a third, little considered, which is the prospect of industrial sustainability starting from the system of companies producing articles.

To date, the provisions on articles do not ensure a level playing field and consumer health protection between European article manufacturers and importers of finished articles[1]. On the contrary, the application of the Regulation leads to a further imbalance between European producers (with constraints and costs) and producers outside Europe (naturally exempt), without defining precise requirements for importers of articles, such as large retailers and/or US brands, based on which you can control the imported items. Moreover, its application to the textile, leather and footwear sectors entails a series of problems that can be summarized in the need for companies to change the production processes and the articles themselves, with the risk of not being able to carry out certain processes. It is therefore easy to imagine that, in the future, the work that can no longer be carried out in Europe (because of the use of dangerous substances) will be carried out by countries outside the EU, and given the current legislation, the relative articles will be imported without problems with serious damage for the competitiveness of the Italian and European manufacturing enterprises and poor protection for the health of the consumer.

Finally, industrial sustainability is very important for Italy where the implementation of the Regulation takes place in very diverse industrial realities and especially of small or very small dimensions. For example, in the case of dyes, in Italy, there are several companies, small in size and with few employees, that handle many hundreds of dyes. All dyes are imported, mainly from Asia. For these companies, it becomes impossible to deal individually, for each dye, with the preparation of the documentation required by the REACH Regulation. The prospect is to cease the activity or to enormously reduce the number of colorants with, in both cases, negative consequences on the manufacturing chains that would have to be supplied by other companies and at higher costs. It is worth noting that, in the event of the closure of these companies, the conditions for the citizen and the environment would not be improved, since Italy (and Europe) imports from the same countries that sell dyes, even textile products, which are colorful on-site. It would therefore remain the same problem, due to the possible exposure of the consumer to dangerous substances present in dyes and therefore in imported clothing.

Finally, it should be noted that US companies also buy dyes in Asia but do not have to register. So, they have neither constraints nor costs, while many productions of articles the Large Distribution Organization and American Brands are carried out in this area of the world and therefore theoretically can involve the same issues as above.

[1] Authors Antonia Reihlen, Heike Lüskow (February 2007), “Analysis of studies discussing Benefits of REACH”. Available at: http://bit.ly/3hGcEFK

4.3.4 Comparison between TSCA and REACH

The Toxic Substances Control Act, described in the previous paragraph 4.1.3, aims to protect the population from "unreasonable risk of injury to health or the environment", through the regulation of chemicals and produced Masses on the Market.

Both TSCA and REACH should equally ensure the safety of the chemicals used. However, the approach is substantially different. With the TSCA, the request for toxicological testing is at the discretion of the EPA or voluntarily. However, with REACH, it is manufacturers who have to provide the toxicity data and the amount of information required depends on the volume of consumption of the product and the size of the risk. Under REACH, therefore, it is the duty of manufacturers, importers, or users, to find and transmit to the competent authorities the scientific evidence: it is not the task of the authority itself, as in the case of EPA. In the TSCA, moreover, most information is confidential, unless a health problem has been demonstrated. REACH provides more information to the public and shares the results with government authorities and European organizations. The acquisition of this information, however, ends up enormously increasing the costs of chemical companies that in turning them on manufacturing. The consequence is that the production, marketing, and use of chemicals in the United States are far less constrained than in Europe by the REACH Regulation.

This also has an important impact on the cost structure of both the companies that market the chemicals, and the textile and footwear companies that use them, this will inevitably have an impact on the selling costs of the various items and thus on the possibility of being marketed. The perverse spiral that is generated potentially risks making Made in Italy companies much less competitive than those in the US that also enjoy new policies in favor of manufacturing and significantly lower energy costs.

4.3.5 Application of CPSIA: critical issues and related issues

The Consumer Product Safety Improvement Act[1] (CPSIA) of 2008, described in the previous paragraph 4.1.2, is a US law that limits the levels of hazardous substances in products imported or manufactured in the US.

The CPSIA focuses mainly on two types of substances, lead, and phthalates, imposing certain tests and new limits. It also takes into account some common substances, present in most consumer goods (including clothing, shoes, and accessories), especially those intended for children from 0 to 12 years, "children's product", defining their limits.

Products intended for children under 12 years must have the following characteristics:

- Comply with all applicable safety requirements
- Be tested for compliance in a third laboratory accredited and accepted by the CPSC
- Be accompanied by a certificate of conformity (Children's Product Certificate)
- Have traceability information printed on the products themselves and, where possible, on the packaging

The law requires that manufacturers of consumer goods subject to the rules of the Consumer Product Safety provide a General Certificate of Conformity (GCC) that ensures that the product complies with the applicable safety rules. The certificate must accompany the product throughout the distribution chain to the seller and

[1] United States – Consumer product safety Commission, "The Consumer Product Safety Improvement Act (CPSIA)". Available at: http://bit.ly/3WTFFhB

must be available for inspection by the CPSC. This procedure, which requires tests to be carried out by accredited third-party laboratories, entails significant costs for businesses and is not reflected at the EU level for imported products.

The law has caused initial protests from producers because of the too-short deadlines, the lack of evaluation of the production process, and the magnitude of the impact. It has also created confusion among products that require GCC or not. Finally, there were problems with testing in the case of companies with a wide variety of products.

Following this, the CPSC added the Rule, known as the "Component Part Testing Rule", which allows US importers to rely on the suppliers of the various components to meet the requirements of the final article.

4.3.6 Proposition 65: sanctions and possible legal consequences

Proposition 65, described in the previous paragraph 4.1.4, is a law introduced in California on the popular initiative in 1986. This law required the state to publish a list of chemicals known to be carcinogenic, teratogenic, or toxic to reproduction. The list is updated at least once a year and currently includes about 850 substances.

Prop 65 provides for companies that want to trade in California very high costs to test products, develop alternative substances to those on the list, reduce discharges, prepare warnings, etc...

In case of non-compliance with the obligation to issue the notice, the penalties are very high and can reach $ 2,500 per day for each violation, as well as other possible sanctions based on severity, exposure extension, volunteering, and more. On average, a company involved in these actions costs around $50-$70,000.

Another controversial aspect is that, in addition to the Office of the General Prosecutor, any subject, public or private, can play the role of the public prosecutor in the interest of the community and exercise action against alleged violations of the law, with the reimbursement of attorney's fees to be paid by the defendant. Therefore, many Consumer Associations and law firms actively search the market for products to be analyzed and, if they do not comply, sue the manufacturers for violation of Proposition 65. The type of products that have already been challenged in these legal acts includes many Italian products, including shoes, belts, leather products, and clothing accessories. It is also important to note that, in the case of end products destined for the Californian market, producers of raw materials and semi-finished products are also required to comply with Prop 65 and provide the notice required by law. Italian companies are systematically required to subscribe to the absence of articles on all 850 substances listed.

This statement is however impossible to prove both because absence means "zero" and zero in chemistry is non-existent data, but above all because it cannot be excluded a priori that in the chemical mixtures used in the production processes there may be infinitesimal parts of substances present in the list. If we consider that only 850 substances for 250 have been defined as an acceptable limit, it is impossible to provide concrete guarantees. Nor do all the specific analytical methodologies exist and, if they exist, the costs of global analysis would be too high.

4.3.7 Flammability standards: differences between EU and US

In the EU there are no special harmonized regulations relating to the flammability of textiles and companies have a general obligation to place on the market only safe products, using, if necessary, the fire resistance test standard and the flammability test standard for children's nightwear.

However, there are no mandatory tests or certification requirements for textiles produced in Europe.

The US legislation, on the other hand, requires textile products to be tested and tests to be carried out by authorized laboratories (third-party testing), located in the USA or abroad, but fully meet the requirements for the acceptance of laboratories by the Consumer Products Safety Commission (CPSC) and then accredited by this.

In terms of non-tariff barriers, mention should be made of the CPSIA (Consumer Product Safety Improvement Act) provision which, since 2008, has made exports of silk fabrics and clothing subject to the Flammable Fabrics Act (FFA)Therefore, requiring a special certification of conformity (General Certificate of Conformity and Testing), certifying that the product meets the established safety standards for flammability.

This procedure constitutes an unjustified barrier to market access since silk (protein fiber as well as wool, the products of which are exempted from the certification requirement) is improperly treated as cotton and artificial cellulosic fibers, however, they are flammable products and therefore subject to conformity tests.

The removal of these standards would be the optimal solution: alternatively, the exclusion of silk from the list of flammable tissues would be desirable. In the case of products intended for children under 12 years of age, a further test must be carried out by accredited third-party laboratories, a procedure which entails significant costs for businesses and which, as in the previous case, is not reflected at the EU level for imported products. Harmonization would be desirable, leading to a common classification of flammability levels and acceptance of test results, without the intervention of accredited laboratories. Alternatively, the number of EU laboratories recognized by the USA should be increased.

4.3.8 Private standards: costs and risks for the competitiveness of SMEs

As already described, in addition to the regulatory framework, the situation is characterized by the spread of "sustainability specifications" which require suppliers not to use certain substances and/or chemicals, considered unsustainable for the impact on the environment and health and to use others within certain limits.

The main feature of the specifications is the RSL, the Restricted Substances Lists, which list several dangerous substances, which can be used in the processing cycle and therefore present on articles and which should be regulated to avoid problems to the environment and consumer health.

The problem for Made in Italy companies becomes therefore to be able to respond promptly and scientifically to all the requests of RSL, without having to submit to laboratory tests much of the production, with very high analytical costs and unsustainable for the company.

This criticality is further aggravated when, in addition to compliance with the RSL, the "certification" is required by a third-party entity about:

- How chemicals are used (see Bluesign)

- To the use of chemicals purchased exclusively from suppliers approved by ZDHC (see paragraph ZDHC Zero Discharge)

ZDHC: consequences for chemical and manufacturing companies

The "ZDHC Zero Discharge" certification[1] is sometimes required for Italian companies, to sell to US companies. As seen in the previous paragraph "The standard for private entities", this certification aims to reduce the risk to the consumer and the release into the environment of dangerous substances, from textile and footwear articles, throughout their life cycle.

It should first be noted that the approach, specifications, and requirements of ZDHC Zero Discharge have the following consequences:

- Put out immediately the suppliers of Italian chemicals because they force textile companies to buy exclusively from some specific chemical suppliers
- Increase costs for manufacturing companies as these chemicals have higher costs
- Oblige textile companies to strict separations of chemicals and processed materials, greatly complicating management and consequently increasing production costs

The justification for this approach is that impurities (restricted hazardous substances) may be present in chemical mixtures is therefore necessary to take action to ensure the minimum possible quantities of the chemicals produced. As a result, chemical mixtures containing these restricted substances (such as impurities), beyond the limits provided by ZDHC's RSL, cannot be used.

ZDHC has consequently asked chemical companies to define lists of mixtures marketed that meet the criteria of their RSL, to have them tested by ZDHC, and to make these mixtures available to textile companies: some chemical companies have accepted. In reality, it seems to be a cartel of companies that in doing so try to grab and divide the market, resulting in a real distortion of the market itself. Textile companies that produce for their customers, associated with ZDHC, must use only chemical mixtures on the ZDHC list.

Bluesign: complexity and cost

As seen in the previous paragraph "The standard for private entities"[2], it is a certification system promoted by a Swiss body that wants to ensure the sustainability of textile articles, reducing the impact of production on people and the environment. More than a product certification, it is a process certification that is issued after a series of controls in the company aimed at excluding the use of hazardous substances.

Companies are screened for: both mixtures and chemicals purchased and used operating conditions in the production departments, and the environmental impact of discharges into water and air.

The screening, therefore, assesses the textile fibers, the chemical products, the dyes, the water, and the energy used; the data on the health of workers; the safety of the workplace; the policies for improving safety, etc. It also checks that the operating conditions comply with the existing legislation in the country.

[1] ZDHC MRSL Update, "Principles and Procedures - The Roadmap to Zero Programme". Available at: http://bit.ly/3Tv7ycT

[2] Bluesign System, "A sustainable commitment". Available at: http://bit.ly/3fXyJ2e

Following the screening, information is given on any chemicals to be replaced, the equipment to be purchased to reduce emissions, and the parameters to be changed to improve operating conditions, and the safety of employees.

The operation has very high costs that an Italian SME, especially if of reduced dimensions, absolutely cannot afford. However, it should be considered that, in principle, if the whole operation can make sense for a production site in Bangladesh, for example, it has very little for a production site in Italy. Italian companies must submit to strict legislation regarding emissions into air and water, as well as the protection of the health of the exposure during the production cycle, with constant checks by the competent authorities (ASL, ARPA, etc.). In addition, they buy mixtures and chemicals that comply with the REACH Regulation and certainly adopt policies of social responsibility, also in this case having substantial reference legislation and well-defined contracts.

4.3.9 Risks for consumers and consequent critical issues for businesses

Related to the use and presence of dangerous chemicals is the health risk following the use of the articles that contain them, which penalizes both the consumer and the companies of Made in Italy.

On this subject, the two main sources of information, related to textile/ footwear products circulating on the European market, able to offer an overall vision, are:

The report of the European RAPEX alert system

During 2019, Member States submitted a total of 2364 notifications of dangerous products. Notifications are therefore constantly increasing compared to past years with a + 3.8% compared to 2018. Of these, 1981 concerned products presenting a serious risk to consumers.

The Rapex 2019 report showed that the most subject to corrective action was clothing, textiles, and fashion (25%). Among the most frequently notified risks related to the above-mentioned categories are chemical risk, strangulation risk, and injury risk. As regards the origin of products at risk, China remains firmly at the top of the list of countries of origin of dangerous products with 1459 notifications (64%).

The Report of the Textile and Health Association "Chemicals in textile products and allergic reactions"

The report was expressly requested to the Association by the European Commission DG Enterprise as Textiles and Health was the only entity in Europe able to provide data at the national level.

The data shows the following situation:

- About 7/8% of skin diseases are related to textiles and footwear
- The origin of diseases is often linked to the presence of substances no longer on sale in Europe
- In cases where it was possible to define a precise cause-effect relationship, the offending animals were always imported
- Allergic contact dermatitis is constantly growing

The report also denounces that, in this already critical situation, the application of the REACH Regulation to the textile/footwear sectors, if not properly managed, may create further problems with the risk of moving other processes abroad and further penalize European and Italian manufacturing. It should also be noted that,

paradoxically, given the current state of European legislation, articles excluded from the internal market by countries such as China, Vietnam, and Saudi Arabia because they do not comply with the eco-toxicological requirements laid down by their laws, are imported and sold in Europe.

Finally, large retailers and US brands also produce in Asia and consequently also from them can cause a possible risk for the consumer and a problem for Italian companies, because the imported dangerous articles are competitive with the Italian fees, not only thanks to the lower cost of labor but also thanks to the use of untested chemicals and therefore cheaper and also used in conditions that do not protect the environment at all. It is, therefore, necessary to operate to:

a. prevent textile articles containing chemical substances, the use of which in Europe is prohibited or restricted, from being placed on the European market
b. develop an effective Import Control System

4.3.10 Impact of critical issues on Italian companies

The issue of the impact of critical issues on Italian companies must be placed in the context of the ongoing re-manufacture in the USA. Reliable forecasts indicate that by 2025 the difference between the total costs for the production of medium and low-labor-intensive manufactured goods will be reduced by up to 10%, so the "re-manufacture" of the USA is not a long-term goal: The repatriation of American investments from areas once considered to have a high comparative advantage is already underway and will soon reach percentages ranging from 20 to 35%.

These circumstances are not the only ones that make the USA a fearsome producer and exporter of quality products. Access to an extraordinary energy resource such as shale gas will produce a significant reduction in the cost of supply of the American industry.

To this already critical context should be added non-tariff barriers, even if in the case of the USA it seems improper to refer to barriers related to market access as NTBs (Non-Tariff Barriers) rather than deliberately protecting certain sectors, it is a question of differing regulations. Such divergences, however, create important managerial problems for Italian enterprises, and above all, they are very expensive.

Considering the above, responding to the needs of the US market weighs on SMEs and the Made in Italy supply chains, both as an ability to respond independently, given the average company size and the consequent skills present in them, and as additional costs. This has a serious impact on the competitiveness of the system.

The AAFA American Apparel & Footwear Association states that different and contradictory regulatory requirements are listed among the largest costs by their associated enterprises. While, according to estimates, non-tariff barriers, regulations, and technical requirements would constitute on average 41 percent of additional costs for European companies. The difficulties in meeting the requests often do not concern the final customer and not even his direct supplier, but the actors upstream of the chain, without the awareness of the technical and economic problems that such requests involve.

To the "blacklist" of substances are added in fact requests for guarantees and technical requests, without scientific support and extended to the entire supply chain. Such requests oblige the upstream actors (the Companies producing the Made in Italy) to face difficult management that generates:

- Administrative burdens, also linked to the demand for guarantees on behalf of upstream suppliers of the supply chain

- Additional management costs, such as the use of external advice, given the complexity of the requests
- High laboratory costs for product testing
- Additional production costs due to the difficulty of replacing certain substances in an economically or technically acceptable way
- Trade problems
- The indication of using specific producers and/or chemical suppliers is often not Italian

4.4 Operational Proposal

4.4.1 Needs and consequences for the business system

The analysis focused in particular on the need to identify a common ground for scientific and regulatory comparison between American standards and regulatory agencies and their European counterparts. It has taken into account the existing laws and regulations on product safety, the regulatory inconsistency between the different US states, and that due to the dual state and federal regulatory level. The demands and costs of the laboratory tests on the products and the numerous other variables that heavily affect the competitiveness of Italian exports in the USA were also analyzed.

The aim of the study is therefore to provide an instrument to facilitate the progress of negotiations by defining a framework for discussion and technical dialogue between the authorities and the bodies responsible for regulating technical legislation in the fields concerned, to achieve concrete results in terms of proposals for harmonization, mutual recognition or technical equivalence.

About the system of companies, in particular exporting SMEs, the study intends to provide a detailed map of the regulations and systems in force in the US market, promoting as much as possible the understanding, the search for similar or comparable devices already known and, where possible, the most cost-effective technology solution to meet their requirements. Task this not secondary, having the companies and the supply chains of Made in Italy have a series of needs summarized as follows:

- Identify possible critical issues in advance and find solutions
- Respond to any requests made to them in the area of product safety
- Enhancing the safety requirements of articles
- Differentiate from competitors at low prices
- Defend, protect and promote entire supply chains that operate by ensuring the health and also sustainability
- Avoid having to take certain processes out of the EU
- Check the imported articles placed on the market

These needs begin to be the heritage of the Italian fashion brands that are changing the way they are facing the market, also under the pressure of environmental movements that, in recent years, have put fashion under

accusation, both for environmental damage and working conditions, facts also supported by some serious incidents that have affected public opinion.

Moreover, a report by one of the world's leading business banks, Goldman Sachs, claims that brands must push to enhance Made In and the production chain, as customers are increasingly demanding and looking for quality but also, or above all, the legitimacy of the product. In essence, the great players of fashion must implement a policy aimed at:

- Map their supply chain
- Identify the risks present in it
- Ensure responsible supply chain management
- Thereby preventing risks with appropriate management and monitoring systems

In practice, they must adopt a policy that ensures traceability of the supply chain and transparency of information.

The need for Brands to ensure due diligence in the supply chain will be increasingly felt, already in the short term. In the search for answers to the needs of the various actors of the Italian supply chains and to propose actions to solve the critical issues, the industrial system of Made in Italy is in a favorable position, thanks to a system approach, with which he began to map and make transparent its supply chain.

The supply chains are starting to be transparent: we know the different stages of processing, the mixtures, and the chemicals used, as well as how they are used. To protect the competitiveness of the manufacturing system, a particularly robust national initiative would therefore be needed, based on the "transparency of the supply chains" of Made in Italy and using what has already been done and is still ongoing in our country, to pursue the actions listed below.

The general assessment of turnover growth and cost reduction for Italian SMEs, which could be determined by the pursuit of these actions, indicates very high data even if there is a difficult estimate. The AAFA (American Apparel & Footwear Association) states that different and contradictory regulatory requirements are listed among the largest costs by associated companies while, according to estimates, non-tariff barriers, regulations, and technical requirements, would account for an average of 41% of the additional costs for European businesses.

The EU, for its part, states that the solution to maximize the benefits for both sides lies in the most advanced liberalization scenario, which involves:

- 100% tariff liberalization
- 25% reduction of NTBs (Non - Tariff Barriers)
- 25% reduction of barriers in services
- 50% liberalization of public procurement

The forecasts for this scenario (period 2022-2027) are, within the EU, those of an average annual growth of GDP of 0.48%, equal to about 86.4 billion euros, and, in the US, those of an average annual growth of GDP of 0.39%, or about 65 billion euros. European exports to the USA should increase by 28.03% (about 187 billion euros), while the US exports to the EU by 36.57% (159 billion euros).

The main advantages, compared mainly in terms of GDP growth, therefore seem to be attributed to Europe. Moreover, the EU also considers that the greatest benefits of the agreement are expected from commitments to reduce technical barriers and, above all, from greater regulatory convergence. Consequently, it can be assumed that, if the removal of non-tariff barriers were wider than 25%, the benefits for Italian SMEs would be very important.

The proposals aimed at protecting the Made in Italy chains, contained in this report, go exactly in this direction. It is possible to imagine that the consequences generated by the possible implementation of the single voluntary standard, which would provide Italian SMEs with a unique reference tool, can be identified in a very significant reduction in operating costs, normally elevated due to:

- Administrative burdens
- External advice
- Costs of analysis
- Additional production costs
- Difficulties and commercial disputes

Such cost reductions and the simplification of procedures and compliance would also increase competitive capacity in the global market.

4.5 Proposals aimed at protecting the Made in Italy sectors

In general, it is believed that the common effort of all the Italian supply chains in the implementation of the European Regulation REACH should not bring the final customer (in our case the US) to require further restrictions on the use of substances and their presence in articles. However, this general objective is disproved by the market, as indicated above. In addition, the REACH Regulation should be made perfectly complete and operational, including through controls, as regards the presence of dangerous substances in articles.

Consequently, three possible courses of action can be envisaged[1].

4.5.1 Elements of regulatory compromise

The General Product Safety Directive could be the European framework in which to develop a regulatory convergence operation. The Commission's report to the European Parliament and the Council on the application of the Directive states that the effectiveness of the Community framework for product safety has been improved by this application but that certain aspects can be improved, to ensure full consumer protection. It also identifies some priority areas for action:

- The safety of consumer products, in particular about traceability, reinforcing the obligation of the manufacturer or distributor to identify the products themselves
- Market surveillance, on the one hand through better coordination of Member States, based on exchanges of information and good practices (including customs cooperation) and, on the other hand, through standardization, by simplifying the procedures relating to product categories, establishing a presumption of conformity of these standards with the general safety requirements
- The possibility of finalizing the emergency measures adopted within the framework of the early warning system, to carry out the withdrawal of dangerous products

As for the United States, the starting point could be the first and only attempt to improve the TSCA (Toxic Substances Control Act), the reform known as CSIA (Chemical Safety Improvement Act). This reform would

[1] CAN Federmoda, Confartigianato Imprese Moda, Casartigiani, "Politiche per lo sviluppo del settore moda – La composizione del settore e i suo valore aggiunto". Available at: http://bit.ly/3GbHZuu

lead to improvements in almost all sections of the law. It would give the regulator, EPA, more power to request toxicity data from manufacturers/importers, and, as a federal law, it would annul the various national laws.

Moreover, in the USA, there has been a lot of criticism of the TSCA Toxic Substances Control Act over the years, given the lack of real toxicity data and therefore of safety guarantees. This has also hindered investment in "green chemistry" and technological development, which has also led many States to adopt internal laws and has led to a complex situation that should be standardized. CSIA would give more safety guarantees because it requires that all the substances and the "existing chemicals" are evaluated, bringing the American legislation to the European Regulation REACH. However, the European REACH Regulation presents, to date, several problems, including that of not being uniformly applied and not taking into account textile/footwear articles produced in non-EU countries and marketed in Europe, on the presence of dangerous substances. An in-depth review of REACH itself would therefore be needed to ensure that articles containing substances banned or restricted in Europe cannot be imported into Europe.

In practice, efforts should be directed towards the adoption of new regulations to which mutual recognition between the United States and Europe can be applied in the following way:

1. Exchange information between government authorities
2. Have a shared priority list of hazardous chemicals found in articles
3. Promote the definition and alignment of analytical methodologies for the research and assay of such substances
4. Implement mandatory consultation before any new rules are issued

Consideration of Proposition 65 should also be involved in the work of regulatory convergence by analyzing among the 850 substances listed therein, only about 50 identified in the study that may potentially be present in textile/footwear articles. Such an analysis should not disregard the definition of limits of presence and analytical methodologies.

Finally, it should be considered, in the regulatory redefinition, how much the CPSIA (Consumer Product Safety Improvement Act) and the FFA (Flammable Fabrics Act) impose as requirements, laboratory tests, and certifications on articles that are to be placed on the US market. These procedures do not find, for now, any feedback at the EU level for imported products and, on the contrary, generate significant costs for Made in Italy companies.

As it is easy to imagine the complexity of the above, combined with the complexity of the articles in question (and their manufacturing methods) and the mandatory involvement of the competent authorities on both sides of the Atlantic means that the time frame for achieving this possible regulatory convergence is long. Instead, the definition and subsequent adoption of a single voluntary standard could have much shorter lead times, more practical and concrete ways of implementation, and greater benefits for the business system, as described in the next point.

4.5.2 Proposal for a single voluntary standard

Industry associations, civil society, and US and EU governments are aware that neither full harmonization nor mutual recognition seems feasible based on existing structured legislation. In addition, the parties have clarified that they do not intend to amend their legislation: REACH is not amenable and the draft of the TSCA reform does not provide for any mandatory registration of chemicals, as a condition for their placing on the market (which is crucial for REACH) and nothing comparable to an authorization. Therefore, the approach must focus on mutual recognition or the adoption of common standards. There are two convergent needs to defend the competitiveness of the Italian manufacturing sector:

- Guarantee the consumer quality products, characterized by an intrinsic high safety, through simple but effective application methods
- Involve companies and associations of companies to take an active part in the use of "safe" substances, to ensure a higher competitive profile, also in terms of safety, Made in Italy articles

Moreover, the EU itself argues that convergence and harmonization of requirements to ensure product safety and consumer protection should be based on a common list of chemicals whose presence is prohibited and/or restricted in articles.

There is therefore a need, as expressed not only by companies in the production chains, but also by the main industrial groups in the fashion industry, to define and adopt a common standard, or an unambiguous reference to prohibited and/or restricted hazardous substances. For this reason, it would be important to promote a multi-level lobbying action that interests companies, associations, national institutions, and European institutions, to protect an increasingly high quality of Made in Italy articles, both in terms of protecting human health and the environment.

The action should involve the Institutions, the Associations of the production chain (including who represents the producers of chemicals/ substances, who transforms them, and who makes the final product), and the Italian fashion brands, in the awareness of the common interest in competitiveness and would initially lead to the establishment of a detailed map of the requirements and guidelines for sustainability. Subsequently, the definition of a genuine voluntary Single Standard regulating critical parameters in the textile/leather/footwear sectors will follow. The Standard would be voluntary but authoritative, as shared among all interested parties and, if possible, endorsed by the competent authorities such as the Ministry of Economic Development, the Ministry of Health, and the Environment.

The objective would be an agreement for the elimination of non-tariff barriers to trade and for the protection of consumers, both aspects of particular interest for Made in Italy companies. It is crucial that competition is based on common rules, that the quality-safety-environmental package is guaranteed, and that the added value of national excellence is protected.

The realization of the voluntary single Standard would lead to the standardization of analytical methodologies, which is also desired by the AAFA (American Apparel & Footwear Association). To achieve the common goal of ensuring product safety and certainty for businesses, analytical methods must be common. This would also solve the problem of the costly duplication of tests (which are also characterized by poor repeatability of the results), which today are often carried out on both sides of the Atlantic, thanks to the adoption of a single test method and a single harmonized certificate, The EU and the United States of America.

In addition, once the Voluntary Single Standard has been established, the parties will be able to make a lasting effort to ensure its efficiency over time. In other words, the EU and the US should ensure a high level of ex-ante cooperation to verify whether and how new market indications can be incorporated into the Standard.

Finally, the Voluntary Single Standard could be disseminated at the European and international level to provide a starting point in the methodological approach to issues of standardization and regulatory convergence in the broad sense, potentially extendable to international regulations through the ISO, as well as to other important markets for Italian exports.

4.5.3 Market control

The majority of entrepreneurs are talking about an effective control system for the safety of articles in circulation, with particular reference to imported articles. The control carried out, in income, from the Customs and, on the market, from the responsible organs turns out still too much weak in confronts of the materials and the imported articles, also considering the enormous number of commodity types and chemical substances

used. It would be desirable more timely support for the N.A.S., specifically dedicated to textiles, clothing, and leather goods. In fact, at the national level, the only checks are carried out by the N.A.S. of all of Italy, in collaboration with the Ministry of Health and with the fundamental contribution of the Textile and Health Association: However, these interventions are marginal and also implemented only a posteriori, following reports.

From historical data of 2020 in possession of "Textile and Health", it emerges that the articles "incriminated" are produced in the following countries:

- 52% of China
- 9 % India
- 5% Bangladesh
- 2% Thailand
- 2% Italy
- 2% Spain
- 1% Morocco
- 1% Georgia
- 1% Portugal
- 1% Belgium
- 24 % Unknown country

24% of the cases, where the producer country is unknown, can however be traced back to the Far East, which makes it possible to say that 92% of the incriminated articles come from this geographical area.

In 4% of cases, articles produced in European countries are also investigated: this fact highlights how, for the protection of consumer health, the "Made In" is not in itself a guarantee. Given the fact that often large retailers and US brands produce in the offending areas, the controls, helping to remove non-compliant and/or counterfeit items from the market, help the competitiveness of Italian manufacturing companies.

Therefore, a particularly robust national initiative would be needed to provide economic resources to:

- Increase the number of controls
- Review the reference requirements, sharing them with the USA, to enable the Higher Institute of Health to make the necessary risk assessments and the competent Authorities in a position to seize the goods
- Establish a database of substances found in imported articles

5 Conclusion

The report analyzed the environmental legislation REACH, which with its regulations and directives of the European Community enters the lives of citizens of many different states. These rules, however, precisely because they deal with specialized and complex issues, are often composed of hundreds of pages and are written in English, becoming comprehensible only by professionals, with a serious loss in terms of simplification and transparency. The REACH Regulation, however, on the manufacture and use of chemicals, concerns more than a few specialists in the field.

First of all, the provisions of REACH affect companies that manufacture chemical products, in addition, to the entire chain of marketing and use of chemicals: importers, distributors, small businesses, and craftsmen.

The REACH Regulation has important consequences for the quality of life and the health of citizens, who are the end users of manufactured products and those most interested in living in a healthy environment and preserving it for future generations. For these reasons, both the individual citizen and the small chemical company must be put in a position to update, consult, and understand the prescriptions and the obligations provided by the European Community.

The theme of the environment and, more generally, sustainability is assuming an increasingly strategic role in the activities of companies, which continue to strive to identify new opportunities for growth and opportunities to further improve and increase their competitiveness.

Society is increasingly attentive to the environmental implications of industrial policies and choices, the required standards of quality of life are rising, and the demand for and availability of information on these aspects is increasing.

The objective is to offer operational support for the definition and implementation of an environmental marketing and communication strategy that can provide motivation and arguments, identify the main difficulties, identify opportunities and select the most effective content and tools.

Environmental communication is a strategic lever and a competitive opportunity of great interest for the most innovative companies. In this field, today companies are increasingly demonstrating the need to have references and tools that can be used to support the definition of effective marketing strategies and communications, often finding a lack of useful information from a methodological and, above all, operational point of view.

The recognition of the importance of environmental communication has translated, on a practical level, especially in the issuing, by national and international bodies and bodies, of guidelines and standards aimed at establishing a series of "general principles" to be the basis of correct environmental communication or, at best, aimed at operationally supporting companies only in a specific area of communication, that of environmental reporting and sustainability. Much less rich is, conversely, the "tools" available to companies on the issues of marketing and environmental advertising, and product communication.

On the one hand, marketing and environmental communication have greater strategic importance, due to the growing maturity, competence, and awareness of the recipients of corporate communication (and in particular of the consumer, not only intermediate but also final). This requires companies to a design effort and a vision not limiting in the short term but on the contrary, the ability to define an approach with long-term horizons, related to sustainability for future generations.

The message and content of the communication are crucial elements in defining a strategy. However, this should be interpreted more broadly than simply the "content" to be attributed to environmental communication. When the company defines the message to be transmitted and the "thing" to communicate, it cannot prescind from the different points of view from which it can be watched. To set the strategy correctly, it is not only what you want to communicate, but also what you can communicate, that is, the actions carried out and the

results achieved by the company that could be valued in the eyes of stakeholders or that, on the contrary, it is not appropriate to communicate. This is particularly relevant in a traditionally sensitive area such as the environmental implications of the activities of an organization that conducts activities that, for example, generate significant impacts on the territory. On the other hand, it is also important "what" stakeholders expect to know through environmental communication and how much they perceive what is transmitted to them.

In addition, the paper sought to clarify better the comparative report of the eco-toxicological standards that characterize Europe and the United States, in the textile, clothing, leather, and footwear sectors. This analysis aims to move towards trade relations with the United States governed by an agreement that aims both to remove non-tariff barriers to trade and to protect consumers, both aspects of particular interest for “Made in Italy” companies. It is crucial that competition is based on common rules, that the quality - safety - environmental package is guaranteed, and that the added value of national excellence is protected.

In the paper emerged the main critical issues for the system of Italian companies emerged from the comparison of laws, regulations, and voluntary standards in the USA and Europe, which highlight the different needs of the two markets. Finally, it analyses the impact of these problems on the various sectors covered by the survey, the competitiveness of Italian SMEs, and their ability to respond to the needs of the US market. Given the great complexity of the sectors considered and the fragmentation of the types and sizes of the company, the analysis is not intended to be exhaustive of all possible problems, the Committee on the Environment, Public Health, and Consumer Protection. On these problems, some possible operational proposals have been suggested to seek solutions to the problems that have emerged, to protect the competitiveness of “Made in Italy” companies and supply chains.

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7 Acronyms

AAFA = American Apparel & Footwear Association

BAT = Best Available Technology

CAS = Chemical Abstracts Service

CBP = Customs and Border protection

CBP = Customs and Border Protection

CIC =Carcinogen Identification Committee

CLEEN = Chemical Legislation European Enforcement Network

CoRAP = Community Rolling Action Plan

CPSC = Consumer Product Safety Commission

CPSIA = Consumer Product Safety Improvement Act

CSR = Chemical Safety Report

DART = Developmental and Reproductive Toxicant Identification Committee

DUs = Down-stream Users

ECHA = European Chemicals Agency

ECLIPS = European Classification and Labelling Inspections of Preparation including SDS

EEA = European Economic Area

EEN = Enterprise Europe Network

EINECS = European Inventory of Existing Commercial Chemical Substances

EPA = Environmental Protection Agency

EU = European Union

FFA = Flammable Fabrics Act

FHSA = Federal Hazardous Substances Act

FORUM = Forum for Exchange of Information on Enforcement

FTC = Federal Trade Commission

GCC = General Certificate of Conformity

GCC = General Conformity Certificate

MADLs = Maximum Allowable Dose Levels

MS = Member States

MSC = Committee of Member States

MSCA = Member States' competent authorities

NOC = Notice of Commencement of Manufacture or Import

NSRLs = No Significant Risk Levels

NTBs = Non - Tariff Barriers

OEHHA = Office of Environmental Health Hazard Assessment

PMN = PreManufacturing Notice

RAC = The Committee on Risk Assessment

RIPE = REACH Information Portal for Enforcement

RSL = Restricted Substances Lists

SDS = Safety data sheets

SEAC = The Committee for Socio-economic Analysis

SIEF = Substance Information Exchange Forum

SMEs = Small and Medium Enterprises

SVHC = Substances of Very High Concern

TCC = Technical Completeness Check

TSCA = Toxic Substances Control Act