METHODOLOGY FOR THE SCREENING OF SUBSTANCES TO BE USED IN MANUFACTURING AND ACCOMPANYING POLICIES

APRIL 2018

Version 2.0

Index

1. INTRODUCTION 3

2. INCLUSION OF SUBSTANCES IN THE RSL AND MRSL. 2016 PROPOSAL 4

2.1 Screening methodology of substances for their inclusion in the RSL 4

2.2 Screening methodology of substances for their inclusion in the MRSL 5

2.2.1 First Stage. Pre-selection of substances for their inclusion in the MRSL. Creation of the "Inventory". Revision of general chemical substance regulations and lists of hazardous or potentially hazardous substances. Revision of substances used in the textile and footwear manufacturing industries 6

2.2.2 Second stage. Evaluation of the substances included in the "inventory" with regards to their hazardous properties and use (or potential use) in the textile and footwear manufacturing industry 9

2.2.3 Third stage. Compilation of the final Manufacturing Restricted Substances Lists 15

3. POLICIES TO BE IMPLEMENTED AS A CONSEQUENCE OF THE INCLUSION OF A SUBSTANCE IN ONE OF THE LISTS. 2016 PROPOSAL 18

4. UPDATING THE RSL/MRSL. 2016 PROPOSAL 21

5. UPDATES TO THE METHODOLOGY FOR THE SCREENING OF SUBSTANCES TO BE USED IN MANUFACTURING. PROPOSAL 2018 21

5.1. *THE INVENTORY OF CHEMICAL SUBSTANCES USED IN TEXTILE AND FOOTWEAR MANUFACTURING* 21

5.2. UPDATES AND IMPROVEMENTS TO THE METHODOLOGY FOR THE EXPERIMENTAL AND COMPUTATIONAL PROTOCOLS FOR THE DETERMINATION OR ESTIMATION OF TOXICITIES OF SUBSTANCES 33

1. INTRODUCTION

Inditex firmly believes that the RSL (Restricted Substances List in the articles) and the MRSL (Restricted Substances List in the Manufacturing processes) are powerful instruments to bring about a positive change in the textile and footwear manufacturing chain. In this sense, these lists are a common and shared tool for Inditex and the different units of its supply chain to work together to improve sustainability in manufacturing. Taking into account the different types of processes and materials (substances, mixtures of substances or articles) used in different types of processing units (wet and dry) and with the aim of improving the usefulness of the lists for each type of manufacturing unit, Inditex has prepared focused lists for different types of industrial units and installations.

It must be clarified that Inditex is aware that the toxicity of a substance depends only on its chemical structure and not on its origin or the type of formulation or material in which it is contained or present. Consequently, there is only one List of Substances the use of which is Restricted in the Manufacturing of articles for Inditex. The focused lists described below are a way to help the manufacturing units to better focus their efforts to prevent and eliminate the use of the listed substances in their installations. In any case, all units must comply with the bans/restrictions included in all of the lists.

- ***RSL***: There is one list only that applies to all apparel, footwear and accessories manufactured in any of the installations of Inditex' supply chain.

- ***MRSL***: There are three lists to be used, separately or in combination, by:
  - Units that work with substances and mixtures of substances (as defined by REACH). These are commonly known as *wet processing units*, and are comprised by dyeing mills, printing mills, tanneries, laundries, among others.
  - Units that process articles (as defined by REACH[1]). These are units that process solid objects (parts), such as fabrics, threads, buttons, zippers, among others but

[1] Regulation (EC) Number 1907/2006 of the European Parliament and Council (REACH)

which do not carry out chemical processes (such as dyeing, printing, laundering, finishing, coating, among others.).

The MRSL itself is divided into three sections (see below for a detailed explanation):

- Banned Substances: *MRSL for Wet Processing Units and MRSL for Parts Suppliers*
- Innovation Substances.
- Transitional Exceptions Substances.

2. INCLUSION OF SUBSTANCES IN THE RSL AND MRSL. 2016 PROPOSAL

2.1 Screening methodology of substances for their inclusion in the RSL

Substances included in the RSL for finished articles are selected according to the following methodology:

I. Continuous revision of regulations of the countries and supranational entities where Inditex has commercial presence.

II. Selection of those "substances the use of which is legally limited" in any of the countries or supranational entities where Inditex has commercial presence, and which, if present in the product above certain levels, could be hazardous for human health. In the CTW 2016 (Clear to Wear contains Inditex RSL for textile and footwear articles), these substances are: formaldehyde, prohibited azo dyes and legally regulated arylamines, certain phenols, Cadmium, Lead, Mercury, Chromium, Chromium(VI), Nickel, other metals, certain phthalates, flame retardants, pesticides, short chain chlorinated paraffins, perfluoroorganics compounds (PFCs), dimethyl fumarate, certain organotin compounds, allergenic dyes, N-nitrosamines, asbestos, polycyclic aromatic hydrocarbons (PAHs) and organochlorinated compounds.

III. Selection of the strictest among the limits for each of the selected substances of the RSL set by the applicable regulations.

IV. Inclusion of other substances which are not legally regulated but which have been detected in articles and may present a risk for human health such as, for instance, certain isocyanates.

V. Revision of the RSL (Clear to Wear standard) will take place at least once yearly (made public at Inditex website).

The full criteria for the selection of chemicals will be made public with each update of the RSL, including the specific regulations, legislations or scientific evidence supporting the inclusion of each particular substance.

2.2 Screening methodology of substances for their inclusion in the MRSL

Inditex will make use of a three-stage process to compile the Manufacturing Restricted Substances Lists referred to in the Introduction of this document:

- *First Stage*. Creation of an "inventory" of pre-candidates for inclusion in the MRSL.
- *Second Stage*. Assignment of the level of hazard posed by each individual substance included in the "inventory" and its actual or potential use in the textile and footwear manufacturing industry. The product of this stage of evaluation will be a list of "candidate substances" (a list of substances which are candidates for inclusion in the MRSL).
- *Third stage*. Evaluation of the alternatives for the phasing out of the candidate substances from the textile and footwear manufacturing industry. According to the hazard level of each substance and the existence, or lack thereof, of alternative substances or processes for their substitution, the candidate substances may be:
    - *Included in the MRSL as "Banned Substances".* The use of these substances for the manufacturing of articles for Inditex will be subjected immediately to the bans/restrictions established in the MRSL.
    - Included in the "Innovation List", section of the MRSL. Hazardous substances for which there are no safer alternatives currently, Inditex will push for the development of alternatives for their use in order to obtain them within a short as possible period, in any case no longer than 28 months since their inclusion in this section of the MRSL (see below for details). The use of any substance placed in the "Innovation List" affected by any national or

supranational environmental or product health regulation can only be performed in accordance to the most stringent regulation applicable worldwide.

- *Included in a "Transitional Exception List" section of the MRSL*. Hazardous substances for which there are no safer alternatives currently and the development of alternatives for their use in specific, narrowly defined applications, in a reasonable timespan is not deemed feasible. Inditex will push for additional research and development of alternatives for their use in order to obtain them within a short as possible period since their inclusion in this section of the MRSL (see below for details).
- *Not included in the MRSL,* for substances of low toxicity (see below for details)

Substances included in the manufacturing MRSL are selected according to the following protocol:

2.2.1 First Stage. Pre-selection of substances for their inclusion in the MRSL. Creation of the "Inventory". Revision of general chemical substance regulations and lists of hazardous or potentially hazardous substances. Revision of substances used in the textile and footwear manufacturing industries

The selection of the substances for their inclusion in the Inditex "Inventory" is critical to the success of the "cleansing" of the processing units (both wet and dry). The selection is performed by a process of accumulation, which takes place through searches for potential substance candidates in:

A. Substances for which hazard information is available:

- general EU and other official listings of industrial chemicals which possess any of the following undesired properties:
  - they are persistent, bioaccumulative and/or toxic,
  - carcinogenic, mutagenic and/or reprotoxic, or
  - endocrine disruptors of equivalent concern.

The general chemical substance regulations to be consulted are, among others:

- **Regulation (EC) Number 1907/2006 of the European Parliament and Council (REACH)**

  Substances of Very High Concern (SVHC), defined as those substances that are carcinogenic, mutagenic or toxic for human reproduction (CMR 1A and CMR 1B) or those persistent, bioaccumulating and toxic substances (PBT) or those very persistent and very bioaccumulative substances (vPvB), and any other substance that gives rise to an equivalent level of concern, including but not limited to Endocrine Disrupting Chemicals (EDC), are selected for inclusion in the "Inventory". The SVHC candidate list, which is available on the ECHA website, will also be considered for this purpose.
- **Regulation 1272/2008 on Classification, Labelling and Packaging (CLP)**

  Substances that are Carcinogenic, Mutagenic, and Toxic to Reproduction (CMR) 1A and 1B are selected for inclusion in the "Inventory".
- **EU Water Framework Directive list of priority hazardous substances 2008/105/EC**

  Priority substances under the Water Framework Directive are selected for inclusion in the "Inventory".
- **Chemical Risk Reduction Ordinance (ORRChem)**

  Substances prohibited by the Ordinance (Annexes 1 and 2) are selected for inclusion in the "Inventory"..
- **Hazardous Substances Data Bank (Toxnet, National Institutes of Health, USA)**
- **KEMI hazardous chemicals in textiles list**
- **OSPAR list of substances for priority action**
- **Stockholm Convention on POPS**
- **Rotterdam Convention**
- **Carcinogens listed by IARC**

  Substances classified as 1, 2A and possible 2B.
- **The EU Ecolabel Directive for textiles (2014-350)**

- Databases and lists of hazardous chemicals from reputed private third party and non-governmental organizations with clear, sound and published methodologies for the screening of industrially used substances, such as, among others:
  - Greenpeace
  - International Chemical Secretariat (Chemsec) (SIN list)
  - Bluesign
  - Any other reputable stakeholder

All substances included in the aforementioned lists are automatically placed in the "Inventory" list.

B. Substances for which hazard information is not available:

Substances used in the textile and footwear manufacturing industries, regardless whether there exist information on their hazards or not. The list of these substances will be derived from the work of Inditex' own "Observatory on industrial chemicals". The observatory functions in the following way:

- Its members are experts in the fields of textile and footwear manufacturing, wet textile and leather operations, dyestuff, pigment and auxiliaries manufacturing from Industry, Professional Organizations and Academia.
- They collate information from all available sources, such as academic literature, industry technical publications, information obtained from chemical manufacturers upon request, personal information from industry's "old hands", academic publications among other to compile a "Dictionary of chemical substances used in textile manufacturing". This Dictionary, when completed, should contain information of all the chemical substances used in every possible operation performed in the textile and footwear manufacturing chains, including their formulations, chemical structures, range of applications (uses in textile and footwear manufacturing) and technical information on their uses and applications.

- The main sources of information used for compiling the Dictionary are:
  - Chemical manufacturers participating in The List, by Inditex program,
  - Industrial associations of chemical manufacturers of dyestuff, pigment and auxiliary chemicals,
  - Chemical manufacturers located in Inditex manufacturing clusters which are direct providers of Inditex supply chain
  - Professional associations of practitioners of textile and footwear manufacturing in Inditex manufacturing clusters.
  - Technical reports from reliable sources such as: KEMI (Swedish Chemical Agency), The Danish Environmental Protection Agency, RIVM (Netherland National Institute for Public Health and Environment) and Greenpeace.
- All substances included in the Dictionary are automatically placed in the "Inventory" list. This inclusion will take place when the substance is included in the "Dictionary", regardless whether the "Dictionary" is completed or not.
- Once the "Dictionary" is completed, revisions to update it will take place at least once yearly.

2.2.2 Second stage. Evaluation of the substances included in the "inventory" with regards to their hazardous properties and use (or potential use) in the textile and footwear manufacturing industry

The methodology for evaluating if a substance is to be included in the "candidate substances" will consider if:

A. Filter I: Substances used (or potentially used) in the textile and footwear manufacturing industry

Only substances known to be used, have been used or may be potentially used in the textile and footwear manufacturing industries or may reasonably appear as contaminant in substances, mixtures of substances or parts (or articles) supplied to the textile and footwear

manufacturing units will be evaluated for inclusion in the list of "candidate substances" to be considered for inclusion in the MRSL.[2]

B. Filter II. Hazardous (or potentially hazardous) substances

For their inclusion in the MRSL, the following general principles should be applied:

Principle 1.-Responsible inclusion. Level of Hazard

Inditex will make use of the principle of responsible inclusion of substances in the MRSL. This means that all substances which are classified as hazardous at this stage (see below) will be included in the MRSL.
In order to classify a substance as hazardous one of the following 2 criteria should apply:

Criterium 1.- Hazardous based on publicly available data, the level of hazardousness of a substance will be determined by taking into account a specific definition of hazard after a comprehensive revision of the literature by a dedicated and independent staff. In the case that there is not any available and clear information, go to Criterium 2.

Criterium 2.- Hazardous based on Inditex available data, substances for which there is no available reliable toxicity information (Criteria 1), Inditex will carry out an *ad hoc* experimental determination of their toxicity by using the best available techniques.[3] Inditex will update the toxicity screen based on the current state of the art in order to implement the

[2] The scope of the textile and footwear manufacturing industries is considered to be those processing units described in the introduction of this document

[3] The 2016 implemented toxicity scheme is based on:
First, a study of the "molecular structural relationship" will be evaluated by a panel of independent experts from Industry, Academia and specialized Research Institutions by making use of computational toxicology tools. For authoritative reviews see, for instance: (a) Raies, A. B., Bajic, V. B. In silico toxicology: computational methods for the prediction of chemical toxicity. WIREs Comput. Mol. Sci. 2016, 6, 147-172. (b) Valerio Jr, L. G. In silico toxicology for the pharmaceutical sciences, Tox. Appl. Pharmacol. 2009, 241, 356-370 and
Second, an experimental determination of toxicity by using Inditex Toxicity Screen will be carried out. If the LC50 value measured is more than 1% of the average toxicity of structurally analogous substances, the substance under evaluation will be studied to be included the MRSL. All substance excluded in the study should be included as Watched Substance

most suitable and comprehensive hazard screening protocols for all hazard endpoint: CMR, PBT, vPvB and EDC.

Details for *Criterium 1.- Hazardous based on publicly available data*:

Inditex Hazardous Definition: A substance is classified as hazardous if it is classified as:

- persistent, bioaccumulative and toxic,[4] and/or
- very persistent and very accumulative,[3] and/or
- carcinogenic, mutagenic and reprotoxic,[5] and/or
- endocrine disruptors of equivalent concern.

Inditex Hazard Assignment from Publicly Available Data and Information: The preferred sources for assigning these classifications will be REACH, CLP, GreenScreen (full assessment), TOXNET (Toxicology Data Network, National Institutes of Health, USA). In the case of GreenScreen, Inditex dedicated staff will study and analyze the toxicology information included in the database to recognize some of the hazardous properties described in *Inditex Hazardous Definition.* The major of the substances classified as Benchmark 1 and some of the Benchmark 2 excluding the ones whose hazard endpoint do not match with *Inditex Hazardous Definition* such as Respiratory Sensitization, Skin Irritation, Eye Irritation, Flammability and Reactivity mainly.

Details for *Criterium 2.- Hazardous based on Inditex available data*:

Inditex Hazardous Screening Protocol: Inditex is aware that the toxicity of a substance depends on its chemical structure and not on its origin or the type of formulation or material in which it is contained or present. Consequently, Inditex has implemented a toxicity screening based on this principle. In this respect, substances for which the hazard classification mentioned in the previous paragraph is not available, their level of hazardousness will be determined by comparison of their toxicities with the

[4] To identify PBT and vPvB chemical substances the PBT/vPvB assessments under the previous EU chemicals legislation was initially employed as source for the hazard assessment

[5] To identify CMR chemical substances the CLP (EC 1272/2008) was directly used as a source for the hazard assessment

toxicities of structurally related substances which have been classified as hazardous according to Criterium 1. For this purpose, the existence or lack thereof of a close structural relationship between the substance under evaluation and a substance

- which is already included in the MRSL, or
- which is classified as (i) persistent, bioaccumulative and toxic, (ii) very persistent and very accumulative, (iii) carcinogenic, mutagenic and reprotoxic, or (iv) endocrine disruptors of equivalent concern (see above)

will be established.[6] If it is established that a close structural relationship exists, the substance under evaluation and the substances found structurally close to it will be subjected to the determination of their level of toxicity by using Inditex Toxicity Screening. Comparison of the toxicity level of the substance under consideration with those of the hazardous substances structurally close to it will be used to determine the relative level of hazard posed by the substance under consideration (see below).[5,7]

Principle 2.-Responsible exclusion- Exclusive rather than inclusive

It should be clearly stated that if a substance is not listed in the MRSL this does not mean that it is a non–hazardous substance. This non listing only means that all reliable information currently available point to the conclusion that there is no scientific reason to classify it as a hazardous substance at the present moment. There are several reasons why a substance may not have been listed in the MRSL: (i) all publically available data point to the conclusion that it is a non-hazardous substance and (ii) all Inditex currently available data concludes there are no reasons to classify it as a hazardous substance.

Inditex will make use of the principle of responsible exclusion of substances from the MRSL. This means that all substances for which no evidence has been found that they can be

[6] The "close structural relationship" mentioned will be evaluated by a panel of independent experts from Industry, Academia and specialized Research Institutions by making use of computational toxicology tools. For authoritative reviews see, for instance: (a) Raies, A. B., Bajic, V. B. In silico toxicology: computational methods for the prediction of chemical toxicity. WIREs Comput. Mol. Sci. 2016, 6, 147-172. (b) Valerio Jr, L. G. In silico toxicology for the pharmaceutical sciences, Tox. Appl. Pharmacol. 2009, 241, 356-370.

[7] An experimental determination of toxicity by using Inditex Toxicity Screen will be carried out. If the LC_{50} value measured is more than 1% of the average toxicity of structurally analogous substances, the substance under evaluation will be studied to be included the MRSL.

classified as hazardous (as a consequence of the application of the previously described protocol) will be placed in a Watched Substances List but not included in the MRSL. This means that Inditex will periodically evaluate (at least once a year) any new information or data on the toxicity of the substances listed in the Watched Substances List in order to include them in the MRSL should the new information or data point to the conclusion that they should be classified as hazardous (see above).

Alternatively, the following substances will be classified as hazardous and placed in the list of "candidate substances":

1. Substances which are classified in any of the hazardous categories listed of the previous list

2. Substances for which there is no available reliable toxicity information on them, but an experimental determination of toxicity by using Inditex Toxicity Screen gives an LC_{50} value which is higher than 1% of the average toxicity of a set of hazardous substances structurally analogous to the substance under consideration,[8] and its inclusion is recommended by the panel (see details below)

The following protocol will be used to select the set of structurally analogous hazardous substances to be used as a benchmark for the determination of the relative toxicity level of any substance under consideration:

- The tools of computational toxicology[5] will be used to determine the close structural relationship of the substance under consideration to substances contained in a reference set of hazardous substances. The substances found to be closely structurally related to the substance under consideration will be placed in a "subset of structurally related hazardous substances" to be submitted to Inditex Toxicity Screening

[8] When an official hazard classification for a substance does not exist, its toxicity will be individually evaluated by revision of published scientific literature (peer-review articles and reviews) and risk assessments and EU or other national studies (such as TOXNET, for instance) of the substance.

- The reference set of hazardous substances used for the screening process will be composed of:
    a. All the substances in the "Inventory" classified as:
        - persistent, bioaccumulative and toxic,[3]
        - very persistent and very accumulative,[3]
        - carcinogenic, mutagenic and reprotoxic,[4]
        - endocrine disruptors of equivalent concern.
    b. All the substances listed in the MRSL
- The toxicities of the selected "subset of structurally related hazardous substances" will be measured by using Inditex Toxicity Screen, and their LC_{50}, determined. Analogously, the toxicity of the substance under consideration will be measured, and the ratio of its LC_{50} and the average of the LC_{50} values of the "subset of structurally related hazardous substances" will be determined.

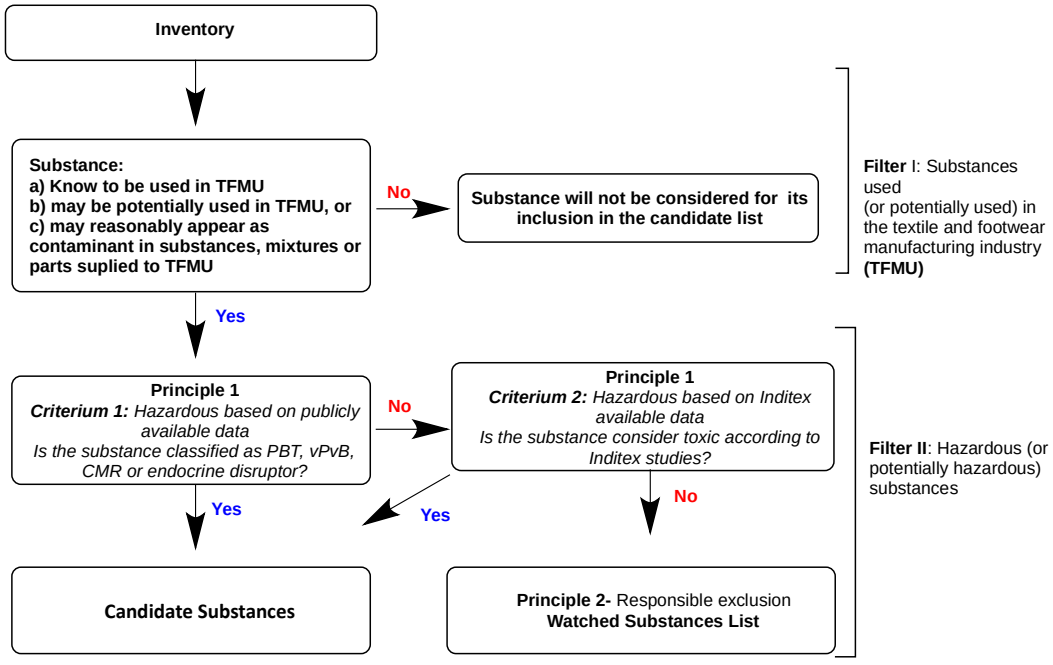
Additionally and always after the scientific literature review, the potential hazard posed by substances included in the "Inventory", but which do not fulfill any of the conditions listed above, may be evaluated by a panel of independent experts from Industry, Academia and specialized Research Institutions, taking into account all publically available toxicity and exposure data. The panel will then make a recommendation on the inclusion or not of the substance in the list of "candidate substances". This additional evaluation will be performed always for substances for which an experimental determination of toxicity by using Inditex Toxicity Screen gives an LC_{50} value higher than 1% of the average toxicity of structurally analogous hazardous[9] substances.

The substances with a negative recommendation by the Panel to be included in the MRSL List after *Criteria 2.- Hazardous based on Inditex available data* should be classified as "Watched Substances" being suggested a systematic and annual application of the *Criteria 1.- Hazardous based on publicly available data.*

[9] In this context, hazardous substances are defined as substances:
- which are already included in the MRSL, or
- which are classified as (i) persistent, bioaccumulative and toxic, (ii) very persistent and very accumulative, (iii) carcinogenic, mutagenic and reprotoxic, or (iv) endocrine disruptors of equivalent concern

The substances with a positive recommendation by the Panel to be included in the MRSL List *Criteria 2.- Hazardous based on Inditex available data* should be classified hazardous substances.

The substances with a negative recommendation to be included in the MRSL after *Criteria 1.- Hazardous based on publicly available data* should be classified as "hazardous substances"



2.2.3 Third stage. Compilation of the final Manufacturing Restricted Substances Lists

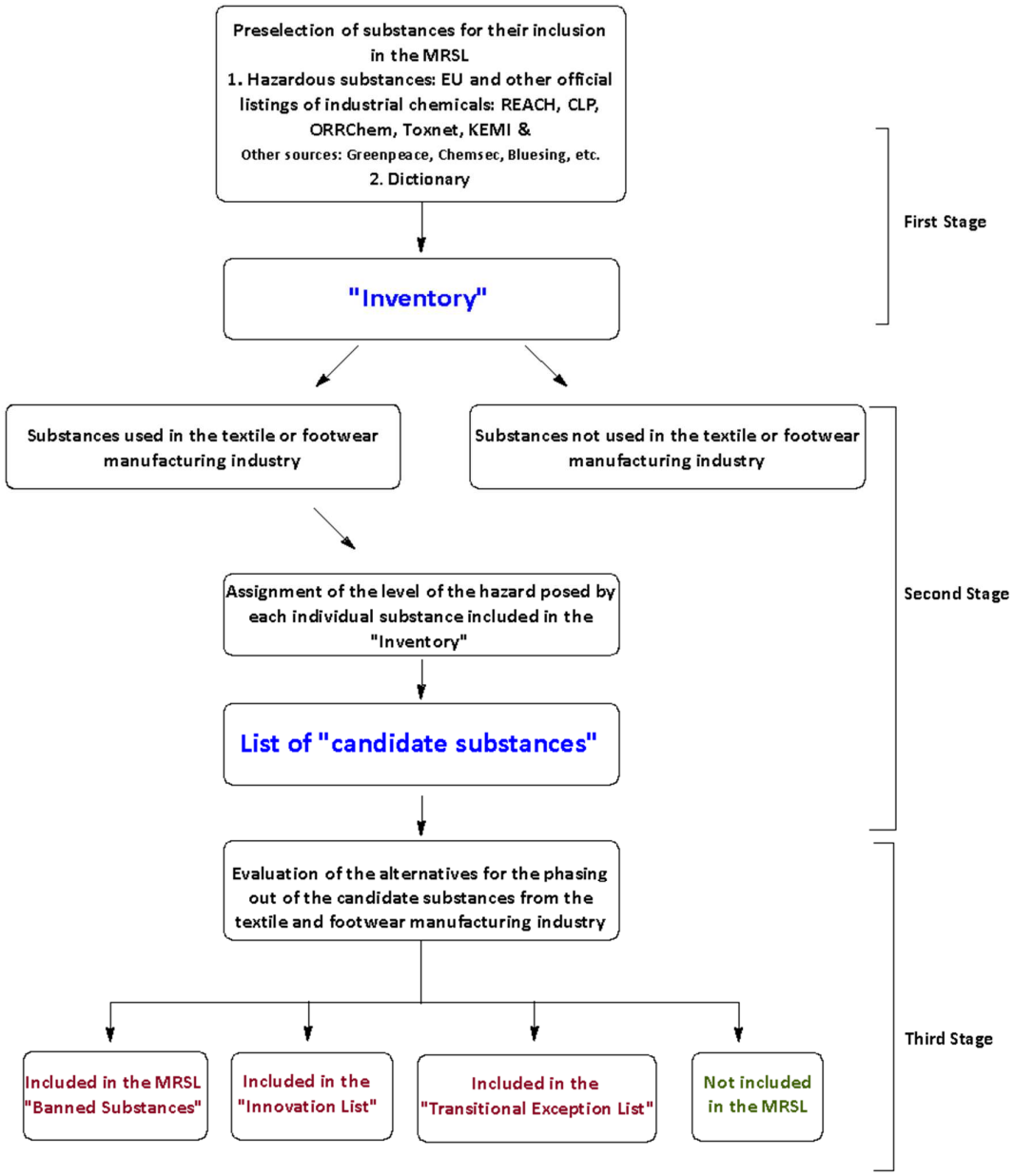
Taking into consideration the criteria mentioned above, the substance under evaluation may be:

- Included in the MRSL in the section "Banned substances", if the substance is hazardous and alternatives for its use in the textile and footwear manufacturing industry exist.
- included MRSL, in the section "Innovation List", if it fulfills the criteria for inclusion in the MRSL and there are no known alternatives for its use, but the development of alternatives for their use are likely to be successful within a short as possible period, in any case no longer than 28 months since their inclusion in this section of the MRSL.

This situation is most likely to occur when alternatives to the use of the substance in question exist for other branches of the manufacturing industry, which are perceived as readily adaptable for textile and footwear manufacturing.

- included in the MRSL, in the section "Transitional Exception List", if it fulfills the criteria for inclusion in the MRSL and there are no known alternatives for its use, but the development of alternatives for their use for specific, narrowly defined applications, in a reasonable timespan requires additional research and development incentives including setting a phase-out timeline aiming for no longer than 18 months adapted case by case dependent on annual alternatives and functional need assessments. This situation is most likely to occur when alternatives to the use of the substance in question for other branches of the manufacturing industry do not exist, or which are perceived as not readily adaptable to textile and footwear manufacturing. The inclusion of a substance in a "Transitional Exception List" must be restricted to its use in certain specific, narrowly defined applications,
- not included in the MRSL if the substance is not hazardous

The workflow of the screening methodology is shown in the following figure.


Preselection of substances for their inclusion in the MRSL
1. Hazardous substances: EU and other official listings of industrial chemicals: REACH, CLP, ORRChem, Toxnet, KEMI &
Other sources: Greenpeace, Chemsec, Bluesing, etc.
2. Dictionary
"Inventory"
First Stage
Substances used in the textile or footwear manufacturing industry
Substances not used in the textile or footwear manufacturing industry
Assignment of the level of the hazard posed by each individual substance included in the "Inventory"
List of "candidate substances"
Second Stage
Evaluation of the alternatives for the phasing out of the candidate substances from the textile and footwear manufacturing industry
Included in the MRSL "Banned Substances"
Included in the "Innovation List"
Included in the "Transitional Exception List"
Not included in the MRSL
Third Stage

3. POLICIES TO BE IMPLEMENTED AS A CONSEQUENCE OF THE INCLUSION OF A SUBSTANCE IN ONE OF THE LISTS. 2016 PROPOSAL

- *If a substance is included in the MRSL*

  A ban on the use:

  - of the substance (as such or as part of a mixture of substances), and
  - of articles (parts) in which the substance is present above ALATCA[10] levels,

  in any unit or installation of Inditex supply chain will come into effect immediately upon inclusion of a substance in the MRSL. Action plans will be drawn:

  - to promptly communicate the ban to all suppliers and their manufacturing units, and
  - if necessary, to help suppliers and manufacturing units with the implementation of the appropriate substitution measures.

- *If a substance is included in the "Innovation List"*
  - Adequate partners will be sought to push for research and development of safer and more sustainable alternatives if none currently exist
  - A deadline for the phase out of the substance will be set and published.
    - A deadline for substituting each specific substance will be set after the adequate partners are identified and contacted and the initial research plans are drawn (this process shall not take longer than 4 months). According to the complexity of each specific situation, the deadline for substitution may vary from 4 months to a maximum of 28 months from the introduction of the substance in the "Innovation List".
    - The commencement of the implementation of the substitution of each substance shall take place within the deadline specified for it.
    - Inditex is fully committed to implement the substitution solutions as soon as possible
    - a) if the substitutes are proven to be technically viable or

[10] As Low As Technically and Chemically Achievable (ALATCA) means those levels of traces that can be achieved through best practices approaches to control of raw materials and the manufacturing process. ALATCA is an evolution of the ALARA (As Low as Reasonably Achievable) concept: See: http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/iccr5_contaminants_en.pdf

- b) if the function ensured by the substance is proven to be no longer necessary based on a functional need assessments,

Inditex will push for alternatives to be found and implemented in the shortest amount of time possible.

- Inditex will update and publish in its web page:
  - an annual progress report on all the actions (contacting partners, research and innovation studies carried out, progress of the implementation of substitutions, functional need assessments etc.) developed to substitute or eliminate need for each substance in the "Innovation List"
  - a final report of each completed substitution process. This report will be issued within a month of the complete implementation of the substitution process in the entire supply chain.

- *If a substance is included in the "Transitional Exception List"*
  - The ban on the general use of the substance in the units and installations of Inditex supply chain will take place immediately. The use of the substance, as part of a mixture of substances, or of articles (parts) in which the substance is present above ALATCA[12] levels will be permitted, but only for certain specific, narrowly defined applications, setting a phase-out timeline aiming for no longer than 18 months adapted case by case dependent on annual alternatives and functional need assessment.[11] and always with the option to expand it. The use of the substance outside those specific applications will be prohibited. The use of any substance placed in the "Transitional Exception List" affected by any national or supranational environmental or product health regulation can only be performed in accordance to the most stringent regulation applicable worldwide.
  - Specific action plans will be drawn and implemented by Inditex to ensure the correct stewardship on the use of the substance. The following actions will be taken:

[11] The selection of those "specific, narrowly defined applications" for which the use of the substance is permitted will be supervised by a panel of independent experts from Industry, Academia and specialized Research Institutions.

- creating a database of the processing units of Inditex supply chain which use the substance in any way (as part of mixtures or articles, and always only within the limitations to its application set in the "Transitional Exception List" section of the MRSL)
- Auditing the processing units included in the database to check their preparedness to use the substance in a responsible way, especially with regards to workers exposure and treatment of effluents.
- closely monitoring the amounts and levels of the substance in the materials (chemicals and parts) used by the processing units included in the database
- closely monitoring the levels of the substance in the effluents of the processing units included in the database
- Annually reducing as much as possible the allowed applications of the substance

- Closely work with the Chemical Industry to push for the development of alternatives for the use of the substance
- Inditex will review annually the situation of the alternatives of use for the substances included in the "Transitional Exception List" with the aim of updating their status. A review of any possible alternatives appeared in the previous year will be performed, as well as of any new toxicity or toxicology information made available on each substance. The result of this review may result in any of the following outcomes:
  - maintaining the substance in the "Transitional Exception List" for one additional 6 months- 1 year if no viable, safer alternatives have been found, and its use is still deemed necessary pending functional need assessments
  - placing the substance in the "Innovation List" if promising viable alternatives are under development, and launching the corresponding substitution studies, as described in the If a substance is included in the "Innovation List" section of this document,
  - placing the substance in the "Banned Substances" list if Inditex forfeits the functionality provided by the substance in the manufacturing of its

articles, and promptly communicating the ban to the entire supply chain,

- Further restricting or banning some of the allowed uses of the substance
- further control actions on the use of the substance in the processing units

- Inditex will make available the detailed reports of these review processes in its web page annually. The reports will include detailed information on all the functional need assessments, alternatives considered and the documentation/information used to reach the interim or final decisions.

4. UPDATING THE RSL/MRSL. 2016 PROPOSAL

The evaluation of substances for their inclusion in the RSL/MRSL is a continuous process. Inditex will update the lists at least once yearly (published in Inditex website).

The full criteria for the selection of chemicals will be made public with each update of the MRSL, the *"Innovation List"*, and the *"Transitional Exception List"*, including the specific regulations, legislations or scientific evidence supporting the inclusion of each particular substance.

As a resource for the textile and footwear manufacturing industries and other stakeholders, Inditex will make public the content of the ""Dictionary of chemical substances used in textile manufacturing" in its web page.

5. UPDATES TO THE METHODOLOGY FOR THE SCREENING OF SUBSTANCES TO BE USED IN MANUFACTURING. PROPOSAL 2018

5.1. *THE INVENTORY OF CHEMICAL SUBSTANCES USED IN TEXTILE AND FOOTWEAR MANUFACTURING*

As a consequence of the work carried out to design and implement the methodologies and actions described in Inditex 2016 proposal for a **METHODOLOGY FOR THE SCREENING OF SUBSTANCES TO BE USED IN MANUFACTURING AND ACCOMPANYING POLICIES** several

improvements and modifications were introduced in key aspects and areas of the instruments and protocols which now comprise Inditex 2018 proposal of the abovementioned methodology. The specific improvements and modifications are described below.

The general workflow of the methodology proposed in the sections previously described in this document is still valid and applicable. The modifications described below are intended to substitute the specific protocols to which they refer to, while the rest of the protocols will be performed according to Inditex 2016 proposal.

The improved protocols refer to the following aspects of the methodology:

- Inventory
- Experimental determination of the toxicity of substances of interest
- Computational prediction of the toxicity of substances of interest

5.1.1. THE ROLE OF THE INVENTORY IN THE DEVELOPMENT OF THE MRSL

Over the past two years Inditex has developed an exhaustive process of study and classification of substances prior to their inclusion in the MRSL. The different stages of this screening methodology can be summarized in the following figure:

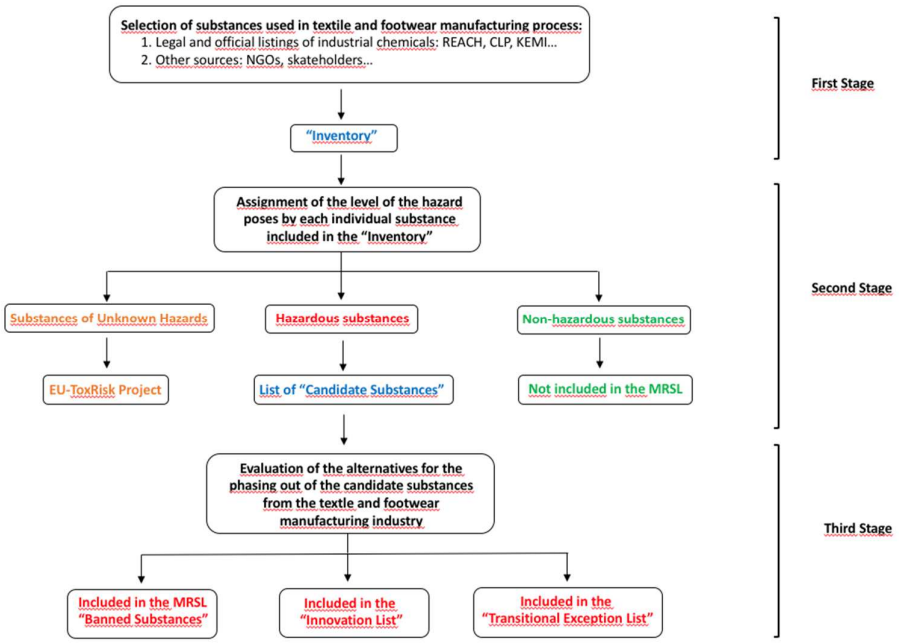


Figure 1. Screening methodology for inclusion in the MRSL

First Stage: creation of an Inventory of substances known to be used (have been used or may be potentially used) in the textile and footwear manufacturing industries.

In this first stage, the Inventory fulfills a double function: as a useful point of reference of which substances are involved in textile and footwear manufacturing processes, as well as a reservoir and source of information to enable the evaluation and classification of substances in the next stage of the process.

Second Stage: assignment of the level of hazard posed by each individual substance included in the Inventory. The product of this stage of evaluation will be a classification of three levels of "hazard" for the substances:

1.*Non-hazardous substances*: substances classified as non-hazardous and which, therefore, should not be included in the MRSL.

2.*Hazardous substances:* substances classified as hazardous which become part of the List of Candidate Substances for inclusion in the MRSL.

3.*Substances of unknown hazard:* substances of which the level of hazardous is unknown. These substances must be studied, case by case, for a specific assessment of their toxicity by in silico and / or in vitro methods (EU-ToxRisk project)

Third Stage: evaluation of the alternatives for the phasing out of the Candidate Substances from the textile and footwear manufacturing industry.

These substances can be included in one of the following lists according to the existence, or lack thereof, of alternative substances or processes for their substitution:

1.*Banned Substances List (MRSL)*: hazardous substances included in the MRSL for wet processing units and MRSL for parts suppliers. The use of these substances will be subjected immediately to the bans/restrictions established in the MRSL.

2.*Innovation List:* hazardous substances which fulfill the criteria for inclusion in the MRSL but there are no known alternatives for their use but alternatives exist for other sectors.

3.*Transitional Exceptions List:* hazardous substances which fulfill the criteria for inclusion in the MRSL but there are no known and safer alternatives currently for their use.

5.1.2. *THE INVENTORY. STRUCTURE AND CONTENT*

Structure and organization of the Inventory

The Inventory has been designed with the idea of creating a useful tool that covers all the relevant information (identification, technological uses, and toxicity) related to the chemical substances that are involved in the manufacturing process of textile and footwear articles.

To this end, the Inventory has been structured in 5 main sections summarized below:

1. **Substance Identification**: contains all the relevant information to make a uniquely identification of a substance.

   The information collected in this section allows to carry out the particular search of a substance included in the Inventory by searching for specific identifiers of the substance (Chemical name, CAS Number, EC Number, Chemical Structure and Molecular Formula).

2. **Substance Regulations**: contains all the information on restrictions / prohibitions on the manufacturing and use of substances as well as their toxicological classification present in the different legislations and official documents.

3. **Manufacturing Process**: contains information about the different stages in which the substance is used during the manufacturing process of footwear (e.g. cutting and leather treatment, upper construction, lasting and assembling, finishing...) and textile articles (e.g. yarn formation, fabric formation, finishing…), as well as the function that the substance performs in each of the mentioned stages (e.g. plasticizer, flame retardant, fixing agent…)

4. **Analysis Methods**: contains information about the test methods currently used for the analysis of substances in textile articles and footwear.

5. **Hazard Classification**: final summary of the toxicological classification of each of the substances according to all the information collected in the Inventory.

Working protocol to compile the Inventory

In order to develop a thorough compilation of all relevant data for the aforementioned sections, the following protocol has been designed:

1. Compilation of substances known to be used, have been used or may be potentially used in the textile and footwear manufacturing industries:

- For textile products: collection of substances used from the firsts yarn spinning process to fabric weaving, finishing and article fabrication.

- For leather products: collection of substances used from the treatment of fresh skins to the creation processes of the final leather articles.

The selection of the substances for their inclusion in the Inventory is performed by a process of accumulation. The information may result from bibliographic review of different sources (legal documents, databases, lists of interest, academic literature...) and information from manufacturers and stakeholders involved in the manufacturing processes.

2. Compilation of legal/regulatory information of substances of concern:

A. Legislations reviewed to date and currently included in the Inventory

A complete revision of relevant EU Regulations on chemical substances, as well as other stringent international legislations and technical reports on the subject, has been carried out exhaustively:

a) <u>EU Regulations/Directives</u>:

- Regulation (EC) Nº 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**).
- Regulation (EC) Nº 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (**CLP**).
- Regulation (EC) Nº 850/2004 on Persistent Organic Pollutants (**POPs**)
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (**WFD**)

- Regulation (EU) Nº 528/2012 concerning the making available on the market and use of biocidal products (**BPR**) and Regulation (EC) Nº 1107/2009 concerning the placing of plant protection products on the market (**PPP Regulation**)

b) Country-specific regulations:

- Swedish Regulations:

  - SFS 1998: 944 The Chemical Products (Handling, Import and Export Prohibitions) Ordinance

- German Regulations:

  - German Commodity Ordinance (Bedarfsgegenständeverordnung -**BedGgstV**)

  - Regulation on Prohibitions and Restrictions on the marketing and placing on the market of certain substances, mixtures and products (Chemikalien Verbotsverordnung - **ChemVerbotsV**)

- Swiss regulations

  - SR 813.11 Chemicals Ordinance (**ChemO**)

  - SR 814.81 Chemical Risk Reduction Ordinance (**ORRChem**)

c) International Agreements:

- Stockholm Convention on Persistent Organic Pollutants

d) Relevant Databases:

- European Chemical Agency (ECHA) (C&L Inventory, Candidate List…)

e) Relevant Reports:

- MS Access database on Endocrine Disruptors (European Commission, DG Environment (DG ENV) commissioned DHI Water & Environment (DHI)-*"Study on enhancing the Endocrine Disrupter priority list with a focus on low production volume chemicals*"

- KEMI Reports 3/25 and 6/15 *"Chemicals in textiles– Risks to human health and the environment"*

A. Pending regulations and databases for revision

Additional databases of chemical substances of concern, compiled by reputable third party and international organizations, academic literature as well as additional industrial technical reports will be reviewed in order to complete the information on the toxicity of the substances under evaluation.

This supplementary review allows:

- to obtain complementary information about substances already covered by the legislation mentioned above, and/or
- to obtain information for those substances which, despite not being included in the current legislation, present some level of hazard that must be considered for the classification of the substance as hazardous/non-hazardous.

Examples of these regulations and databases are the review and incorporation of which is pending are:

- The EU Ecolabel Directive for Textiles
- Rotterdam Convention
- Hazardous Substances Data Bank (Toxnet, National Institutes of Health, USA)
- OSPAR List of Substances for Priority Action
- Carcinogens listed by IARC
- International Chemical Secretariat (Chemsec) (SIN List)
- Greenpeace
- Bluesign

1. <u>Determination of hazards endpoints and toxicological assessment</u>

The selected toxicological and ecotoxicological endpoints referred in the Inventory have been set according to the CLP and REACH criteria.

Hazard classes considered "of high concern" have been prioritized based, mainly, on the intrinsic properties established on "SVHC" criteria pursuant REACH Regulation. The "*Main Health and Environmental Hazards*" highlighted in the Inventory are the following:

- CMR (Carcinogenic, Mutagenic and Toxic for reproduction)
- Sensitization: skin and respiratory
- PBT (Persistent, Bioaccumulative and Toxic)

- vPvB (veryPersistent and veryBioaccumulative)
- Endocrine disruptors
- Aquatic toxicity: acute and chronic

Other hazard classes different from the above mentioned have also been considered in the Inventory:

Health Hazards	**Physical Hazards**	**Additional Hazards**
Acute Toxicity Skin Corrosion / irritation Eye damage / irritation Specific target organ toxicity-single exposure (STOT SE) Specific target organ toxicity-repeated exposure (STOT RE) Aspiration hazard	Explosive Flammable gas Aerosol Oxidising gas Gases under pressure Flammable liquid Flammable solid Self-reactive substance or mixture Phyrophoric liquid Phyrophoric solid Self-heating substance or mixture Substance or mixture which in contact with water emits flammable gas Oxidising liquid Oxidising solid Organic peroxide Substance or mixture corrosive to metals	Hazardous for the ozone layer

Table 1. Additional hazards reviewed for the Inventory

The regulations and reports described in section 2 of the present protocol have been essential sources in providing information for the selected endpoints. A detailed list of the main sources reviewed for each hazard is described in detail below:

Endpoints		**Regulations**
Main Health and Environmental Hazards	CMR	1.CLP Regulation 2.REACH Regulation and ECHA webpage: -SVHC -Self-classification (Registry and Notification) from manufacturers and importers
	Sensitizers (skin and respiratory)	
	PBT	1.REACH Regulation and ECHA webpage: -SVHC -Self-classification (Registry) from manufacturers and importers 2. POPs Regulation 3. Stockholm Convention on POPs 4.Water Framework Directive (WFD)
	vPvB	1.REACH Regulation and ECHA webpage: -SVHC -Self-classification (Registry) from manufacturers and importers
	Endocrine Disruptors	1.REACH Regulation and ECHA webpage: -SVHC 2.MS Database from European Commission 3. BPR and PPP Regulation

	Aquatic toxicity (acute and chronic)	1.CLP Regulation 2.REACH Regulation and ECHA webpage: -Self-classification (Registry and Notification) from manufacturers and importers
Other Hazards	Health Hazards	1.CLP Regulation 2.REACH Regulation and ECHA webpage: -Self-classification (Registry and Notification) from manufacturers and importers
	Physical Hazards	
	Additional Hazards	

Table 2. Main sources reviewed based on the selected endpoints

All the substances included in the Inventory will be evaluated according to the overall information reviewed, in order to assess their toxicity and assign the level of hazard for the selected endpoins. The result of this assessment is key to deciding which substances have a clear health and environmental hazard classification and must, therefore, be part of the MRSL.

5.1.3. *CURRENT STATE OF THE TOXICOLOGICAL ASSESMENT OF SUBSTANCES INCLUDED IN THE INVENTORY*

Following the work protocol described above and the screening methodology designed for the Inventory, the results of the hazard assessment of the substances included to date, is as follows:

Total of Substances included in the Inventory: 1545				
Hazard Classification for Main Hazards	**Main Hazards**			**Number of individual substances**
	Substances classified as hazardous: 666	**CMR**		234 (Harmonized and/or SVHC)
		Sensitiser	**Skin Sensitiser**	95 (Harmonized and/or SVHC)
			Respiratory Sensitiser	22 (Harmonized and/or SVHC)
		Aquatic Toxicity	**Aquatic Acute**	257 (Harmonized and/or SVHC)
			Aquatic Chronic	300 (Harmonized and/or SVHC)
		PBT		252 (POPs + WFD + Stock. Convention + SVHC)
		vPvB		23 (SVHC)
		Endocrine Disruptors		237 (European Commission Database for ED + Biocide Criteria + SVHC)
	Substances not classified as hazardous			1
	Substances for which there is no available information: 878	**No information on all the main hazards**		195
		No information for some of the main hazards		683

Table 3. Status of implementation (as of April 2018)

Currently, the Inventory consists of 1545 substances, organized in the following hazard levels:

- **Substances classified as hazardous:**

Substances classified as hazardous for, at least, one of the "*Main Health and Environmental Hazards*", according to the available public information (regulations, directives, official documents...):

There are 666 substances in the Inventory classified with this category, of which:

- 234 substances are classified as CMR (*Carcinogenic, Mutagenic and/or Toxic for reproduction*)
- 117 substances classified as Sensitisers (95 substances as skin sensitisers and 22 as respiratory sensitisers)
- 557 substances classified as hazardous to the aquatic environment (257 as aquatic acute and 300 as aquatic chronic)
- 252 substances classified as PBT (*Persistent, Bioaccumulative and Toxic*)
- 23 substances classified as vPvB (*veryPersistent and very Bioaccumulative*)
- 237 substances classified as Endocrine Disruptors

- **Substances not classified as hazardous:**

Substances not classified as hazardous to any of the "*Main Health and Environmental Hazards*", according to the available public information (regulations, directives, official documents...).

- There is 1 substance in the Inventory classified in this category.

- **Substances for which there is no available information:**

Substances without available information or official classification on the "*Main Health and Environmental Hazards*".

There are 878 substances in the Inventory included in this category, such as:

- 195 substances due to lack of information on all the main hazards proposed.
- 683 substances due to lack of information for some of the main hazards proposed.

5.1.4. APPLICATION OF THE INVENTORY TO THE RESOLUTION OF TOXICITY ISSUES

Day-to-day work has shown that the utility of the inventory of chemical substances for the manufacture of textile articles and footwear goes beyond being a source of information on pre-selection of substances for the MRSL. The Inventory has also proved great relevance as a source of information for different purposes:

-Comparative of Regulations and legal documents in relation to prohibitions and/or restrictions on the use of substances in manufacturing processes.

-Comparison of toxicities for the selection of the most appropriate substances in the manufacture of textiles and footwear.

-Study of toxicities for the development of alternatives to the use of substances classified as hazard to health and the environment.

5.2. UPDATES AND IMPROVEMENTS TO THE METHODOLOGY FOR THE EXPERIMENTAL AND COMPUTATIONAL PROTOCOLS FOR THE DETERMINATION OR ESTIMATION OF TOXICITIES OF SUBSTANCES

To provide a science-based, sound procedure to create and update its RSL and MRSL, Inditex has set up a working group on the classification and determination and/or estimation of the toxicities associated with chemical substances used in the textile and footwear manufacturing industries. This working group is comprised by five scientific teams with complimentary expertises in several key areas:

At the University of Santiago de Compostela:

- A team in charge of analysing the information and regulations on the toxicities associated with chemical substances in use in the textile and footwear manufacturing sectors (at Center for Research in Chemical Biology and Molecular Materials). See previous chapter of this report for a summary of the work of this team and the methodology developed.
- Two teams in charge of the experimental determinations of toxicity endpoints of chemical substances, to fill the gaps of information detected in the regulations and the toxicity literature (at the Department of Genetics and at the Center for Research in Molecular Medicine)

- One team in charge of creating the database instruments (at the Department of Mathematics)

At University Pompeu Fabra (Barcelona):

- A Team in charge of computational prediction of toxicities of chemical substances (at Barcelona Research Park in Biomedicine).

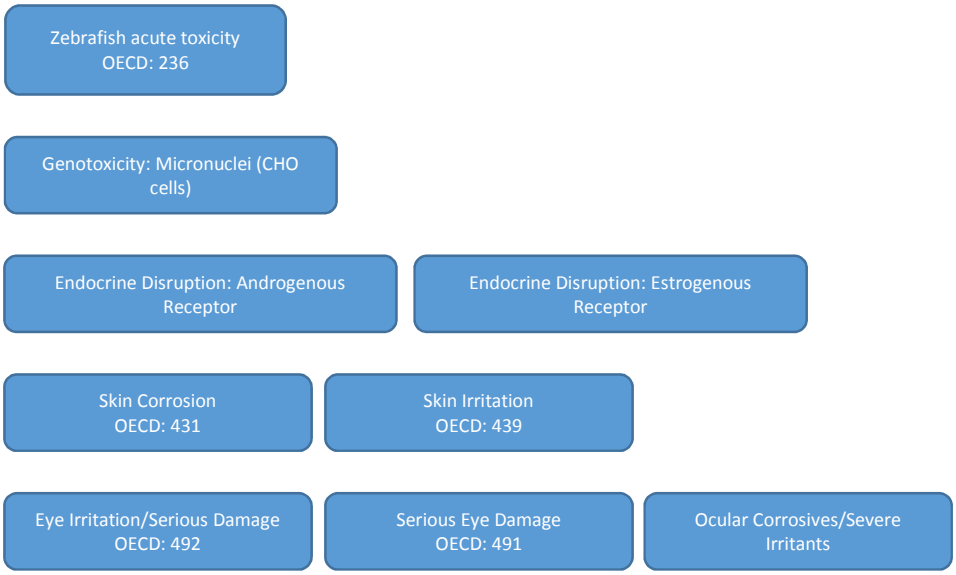
Experimental determination of the toxicity of the substances of interest

For the past five years we have been developing a comprehensive approach to estimate different toxicological endpoints by making use of several types of model experimental systems (non-animal testing). We have developed methods based on zebra-fish embryos to estimate aquatic toxicities, and cell and tissue methods to estimate human health related toxicities. The list of families of substances submitted to these toxicity evaluations are:

Perfluorocarbons, as well as their possible alternatives; diamines; chromium compounds; phthalates, and their alternatives; tanning compounds; silicone oils; chlorophenols; and organochlorinated compounds.

Additionally, we are currently developing combined zebra-fish embryo and cell evaluation studies in order to compare the results of both methods to feed the computational toxicity prediction models described in the next section. A brief description of this studies follows:

A series of *in vitro* evaluations (on cell lines) published by the OECD have been selected, listed in the following scheme:



The studies on cells are intended to delve into the processes over which the compounds evaluated are acting in a detrimental manner. These evaluations have been ranked, beginning with the evaluations of genotoxicity, which will continue with evaluations of endocrine disruption, irritation or corrosion of the skin and, finally, irritation, corrosion, severe damage or severe eye irritation.

A series of preliminary data has been obtained on a small number of compounds for genotoxicity studies. From the results obtained it can be affirmed that those genotoxic compounds in cells will also present a high toxicity in the test with zebrafish embryos. It is a fundamental first step for a good complementarity of results. From this analysis, the in vitro toxicological profile of each of the compounds will be completed and could be compared with the effects produced in the in vivo experiments. With the different endpoints evaluated, the toxicological footprint caused by each compound can be determined in great detail, as well as the development of toxicological profiles with different models.

Finally, after comparing the results of both models for a large number of compounds, the predictive capacity between both models will be evaluated in the different levels of toxicity studied.

Computational prediction of toxicities of substance of interest

The objective of this project is to provide a means to estimate the toxicities of a large number of substances for which experimental data may not be available as a first step before carrying out experimental determinations.

As a result of the methodology developed, 58226 unique substances with 355187 toxicological annotations were compiled. All this information is contained in two Excel files: one of them with information regarding the substances, their compounds and their structures; and another one with the annotations for each type of toxicity (CMR, PBT, vPvB, endocrine disruptors, sensitizers, and others). This information is currently being used to develop the toxicity calculation models.