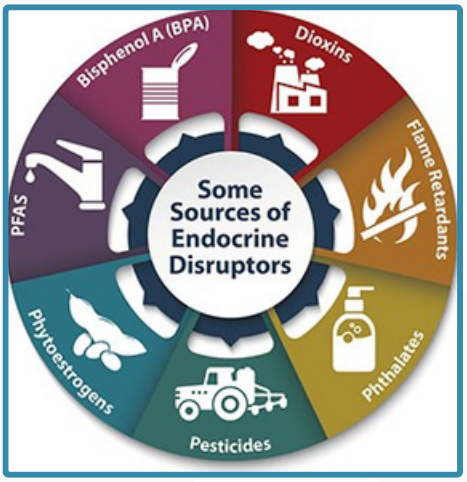
ENDOCRINE DISRUPTORS AND RESEARCH ACTIVITY

SAFE SUSTAINABLE SOLUTIONS

Analytical approach to determine the presence of endocrine disruptors

All those substances capable of interfering with the hormonal system, producing negative effects, are defined as "endocrine disruptors". In all organisms, hormones relate the nervous system and bodily functions, such as growth and development, immunity, metabolism, reproduction, and behavior. Substances that interact with the hormonal system but do not cause harmful effects are called "substances with hormonal action" or "substances with endocrine action". However, the line between endocrine action and endocrine interference is not always clear as, in some cases, the effect may only be evident much later after exposure.
According to the European REACH regulation, endocrine disruptors can be identified as substances of very high concern along with chemicals known to cause tumors, mutations and reproductive toxicity. The goal is to reduce their use and permanently replace them with safer alternatives.
ECHA's updated list of endocrine disruptors can be consulted at the following link: https://echa.europa.eu/it/ed-assessment



Endocrine Disruptors and Your Health
National Institutes of Health
U.S. Department of Health and Human Services

Some European countries are particularly proactive to the issue of Endocrine Disruptors; France has in fact produced dedicated legislation; Furthermore, lists of substances have been released on the market by FDE (Food and Drink Europe) which, in addition to the lists released in France, refer to the lists published by the Danish EPA.

What regulations are currently in force?

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Endocrine disruptors are subject to EC Regulation 1907/2006 (known as the REACH Regulation - from the acronym "Registration, Evaluation, Authorization of Chemicals") which concerns the registration, evaluation, authorization and restriction of chemical substances produced or imported into the EU in quantities greater than one ton per year.

In France, in October 2023, a legislation relating to endocrine disruptors was published, which establishes that producers or importers of products marketed on French territory must inform consumers of the presence of substances with proven, presumed suspicious endocrine disrupting properties if these substances are present in concentrations higher than 0.1% by weight. This same concentration limit is the same as that provided for many of the SVHC (Substances of Very High Concern) dangerous substances of the REACH regulation.
Link to the Candidate List ⟶ https://echa.europa.eu/it/candidate-list-table.

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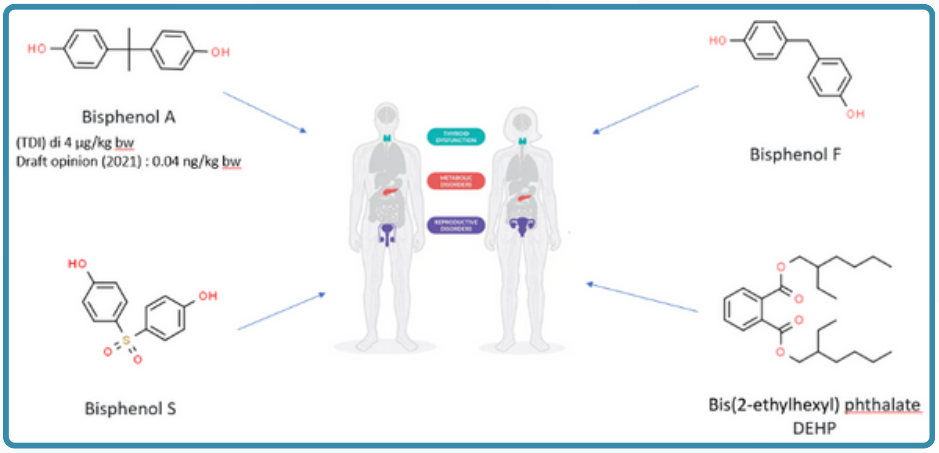
What chemicals can disrupt the endocrine system?

According to the Endocrine Society, there are nearly 85,000 man-made chemicals in the world, and 1,000 or more of these could be endocrine disruptors, based on their unique properties. Examples of substances active on the endocrine system, sometimes present in food and feed, are pesticides, constituents of materials in contact with food such as bisphenol A (BPA) or PFAS, as well as environmental pollutants, such as dioxins and PCBs.

Food Contact Center manages, through the coordination of study and research activities of some PhD students and in collaboration with the Institute of Clinical Physiology of the CNR (Pisa), the analytical evaluation that correlates the presence of these chemicals in packaging with exposure human, searching for substances and their metabolites in human samples (urine, blood, breast milk, etc.).



OUR SOLUTIONS

Food Contact Center is able to verify the presence of the various substances listed through target-untarget screening tests with multiple techniques. Given the different chemical nature of these substances, various analytical techniques are necessary, such as ICP MS, HS-GCMS, GC-MS and LC-QTOF (combined with a specific database produced by the laboratory in collaboration with italian National Council of Research and the SCIEX® group) in order to identify inorganic compounds, volatile, semi-volatile, and non-volatile, polar and non-polar organic compounds, in line with internationally recognized analytical and scientific risk assessment principles. Each technique is complementary to the other, and allows a detection of all possible contaminants, as per the JRC guideline for food contact.
The target-untarget screening approach designed is very advantageous for multiple reasons:

- **the proposed approach lends itself to semi-quantitative checks of substances with limited specific migration in an UNTARGET-TARGET manner, simultaneously allowing both a risk assessment and economic savings;;**
- **it allows the expert technician to distinguish within the results obtained which of these substances it is then necessary to subject to the execution of the TARGET (targeted) analysis, making the screening analyzes reliable and with good analytical confidence;;**
- **The laboratory also provides a screening of inorganic elements, in line with the risk assessment logic.**

These analysis are then interpreted by referring to the specific databases created by the Food Contact Center for endocrine disruptors.

The Laboratory Management

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