EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Green Labs

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TASK FORCE-GREEN LABS
Chemical Strategy for Sustainability

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Chemical Strategy for Sustainability

Chemicals are essential components of our daily lives, for the well-being, high living standards and comfort of modern society.

They are used in many sectors, including health. However, some chemicals have hazardous properties which can harm the environment and human health.

There is an increase in health problems that can be partially explained by the use of chemicals. Some man-made chemicals are found in the most remote places in the environment, but also in our bodies. Chemicals are everywhere.

Clinical labs must choose safer, more sustainable alternatives to hazardous chemicals.

Comprehensive chemical legislations should be implemented in the clinical laboratories all around Europe.

Hazardous chemicals

- They are associated with cancer, neurodevelopment disorders, reproductive, metabolic, cardiovascular and respiratory diseases.
- In general, the most vulnerable population subgroups will more likely develop **pollution-related diseases** (e.g. **children of low socioeconomic status**).
- Exposure to chemicals, even at low doses, can promote **long-term health outcomes**, such as, decreased fertility, lower birth weights and neuropsychiatric conditions in children–10-15% of all births present neurobehavioral development disorders, attention deficit hyperactivity disorder (ADHD) and autism spectrum disorder.
- There is an increasing number of different hazardous chemicals in human tissues and blood, which can induce **toxic combination effects** that are greater than the effects of each individual chemical separately.
- **Combined exposure to hazardous chemicals** has been associated with lower birth rates and reduced fetal growth.
- There is a major economical impact due to exposure to **endocrine disrupting chemicals**, with €157 billion spent each year for female reproductive diseases alone.

Hazardous chemicals

Certain chemicals cause cancers, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems, weaken human resilience and capacity to respond to vaccines and increase vulnerability to diseases. Exposure to these harmful chemicals is therefore a threat to human health.

In addition, **chemical pollution** is one of the key drivers putting the Earth at risk, impacting and amplifying planetary crises such as **climate change, degradation of ecosystems and loss of biodiversity**.

New chemicals and materials must be inherently safe and sustainable, from production to end of life, while new production processes and technologies must be deployed to allow the **chemical industry's transition to climate neutrality.**

Hazardous chemicals

- They can cause stratospheric ozone depletion and affect ecosystems, flora and fauna, decrease water and air quality, contaminate land and affect insect pollinators, especially if used and/or discarded with disregard for current legal, scientific and technical guidelines.
- Chemical pollution contributes to the climate change and loss of biodiversity.
- In the healthcare sector, disposal of untreated waste can promote the contamination of drinking water, groundwater, and surface water if landfills are not adequately built; inappropriate waste incineration can result in air pollution and ash residue, generation of carcinogenic dioxins and furans from chlorine-containing substances and spread of toxic metals from lead, mercury and cadmium-containing materials.
- Recent data points to over 2.5 million possibly contaminated sites in Europe, with 14% known to be contaminated and in need of damage control measures. Therefore, **new production processes and technologies, as well as new chemicals, must be sustainable throughout the product life cycle**.

Hazardous chemicals

The economic toll concerning the contamination of the environment is significant, since there are very high costs of remediation related to the loss of drinking water, land and fish stocks.

The **cost of healthcare waste disposal** corresponds to **25% of the global healthcare sector** spending in the United Sates (US).

In addition, decontamination of natural resources as well as buildings and infrastructure is extremely expensive - **polychlorinated biphenyls (PBCs)** contamination represented an expenditure of **€15 billion** between 1971 and 2018 in the EU.

Determining the hazardous potential of chemicals

- Physicochemical properties
- Quantity produced/imported and used in each product application
- Duration and frequency of exposure
- Transformation and degradation products
- Major impurities and additives
- Likely pathways to the environment, environmental distribution and degradation or transformation
- Duration and frequency of emissions to different environmental compartments and its respective dilution
- Likely routes of exposure and absorption in humans
- Geographical scale of exposure
- Matrix dependent release of the chemical
- Accurate exposure data availability
- implemented or recommended risk management

Chemicals strategy

The EU's chemicals strategy for sustainability towards a toxic-free environment

Chemicals are essential for the well-being, high living standards and comfort of modern society. They are used in many sectors, including health, energy, mobility and housing.

However, most chemicals have hazardous properties which can harm the environment and human health.

The EU already has sophisticated chemicals laws in place, but global chemicals production is expected to double by 2030. The already widespread use of chemicals will also increase, including in consumer products.

The European Commission published a chemicals strategy for sustainability on 14 October 2020. It is part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal.

https://ec.europa.eu/environment/strategy/chemicals-strategy_en

European Commission

Chemicals Strategy for Sustainability
Towards a toxic-free environment

- The Chemicals Strategy will:

  - **Ensure better protection** of human health and the environment from hazardous chemicals
  - **Boost innovation** for safe and sustainable chemicals
  - Enable the transition to chemicals that are **safe and sustainable by design**

It is a first step towards the **Zero pollution ambition** for a toxic-free environment announced in the **European Green Deal**.

doi:10. 2779/221541
ISBN 978-92-76-22959-9
https://ec.europa.eu/environment/chemicals/index_en.htm

Key actions in the Chemicals Strategy

- **Banning the most harmful chemicals** in consumer products - allowing their use only where essential
- **Account for the cocktail effect of chemicals** when assessing risks from chemicals
- **Phase out per - and polyfluoroalkyl substances (PFAS)** in the EU, unless their use is essential
- **Boost the investment and innovative capacity** for production and use of chemicals that are **safe and sustainable by design** throughout their life cycle
- **Promote EU's resilience of supply** and sustainability **of critical chemicals**
- Establish a simpler "**one substance one assessment**" **process** for the risk and hazard assessment of chemicals
- **Play a leading role globally** by championing and promoting high standards and not exporting chemicals banned in the EU

https://ec.europa.eu/environment/chemicals/index_en.htm

Indicators

The Commission is developing a framework of indicators on chemicals to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemicals legislation.

This framework is being developed with the European Chemicals Agency (ECHA) and the European Environment Agency (EEA).

It will also establish key Performance Indicators, in close cooperation with stakeholders, to measure the industrial transition towards the production of safe and sustainable chemicals

LEGISLATIONS

Chemicals-related legislations have more than 100 directives and regulations. This section pertains only to the most important documents.
United Nations (UN) Sustainability Development Goals
World Summit on Sustainable Development (WSSD): achieve the environmentally sound management of chemicals and all wastes throughout their life cycle.
European Green Deal (EGD)
European List of Wastes (LoW)
EU Waste Framework Directive
Basel convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.
Globally Harmonized System of Classification and Labelling of Chemicals (GHS), formally adopted in July 2003 by the United Nations Economic and Social Committee.
EU Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH)
•Regulation on the Classification, Labelling and Packaging of hazardous substances (CLP)
UN Environment Program on Mercury
International Organization for Standardization (ISO):
-ISO 14000
-ISO 14001:2015
-ISO 9000
-ISO 15189
-ISO 19011
Environmental, health and safety guidelines (EHS) from the International Finance Corporation (IFC) on occupational health and safety.
Other EU documents

EU LEGISLATIONS

The existing EU legal framework on chemicals, in particular the REACH and Classification, Labelling and Packaging (CLP) Regulations, are the strictest legislation in the world, regulating chemical substances, affecting industries throughout the world.

The Chemicals Strategy suggests that they should be reinforced with targeted revisions of both Regulations to ensure that there is sufficient information on chemicals manufactured or imported into the EU.

EU LEGISLATIONS

Implementation and enforcement of European chemicals legislation is needed to ensure compliance for the whole life cycle of chemicals: **production, placing on the market, release, and disposal.**

Currently almost 30% of the alerts on dangerous products on the market involve risks due to chemicals.

Only one third of the registration dossiers of the chemical substances registered by industry under REACH are fully compliant with the information requirements.

EU LEGISLATIONS

The Commission will carry out audits on the enforcement systems of the Member States and make proposals to further strengthen the principles of **'no data, no market'** and the **‘polluter-pays'**.

Substances having chronic effect on health and the environment are identified as of very high concern under REACH as well as those listed in Classification, Labelling and Packaging (CLP) Regulations.

In order to prevent negative long-term effects, the exposure of humans and the environment to these substances of concern should be **minimised** and/or **substituted**.

The most harmful ones should be especially banned from consumer products and allowed only for proven essential societal use and where no acceptable alternative exist.

EU CHEMICAL STRATEGY

The Commission will strengthen the principles of **'no data, no market'** and the ***'polluter-pays'*** under REACH, in particular by requiring **compliance of all registration dossiers** and revoking the registration numbers in case of non-compliance.

The EU is still lacking a comprehensive information base on all substances placed on the market and on their overall environmental footprint, including their impact on climate, and this hinders the proper management of chemicals and products and does not allow for a full sustainability assessment.

In particular polymers, which are the fundamental building blocks of plastics, are not subject to registration under REACH.

Furthermore, information required for substances in the low and medium tonnages under REACH does not fully allow to identify substances with critical hazard properties.

Strengthening information requirements on the carcinogenicity of substances and on other critical hazards at all production levels plays a fundamental role in the successful fight against illnesses such as cancer.

In addition, the efficiency and effectiveness of the REACH evaluation procedures need to be improved.

SUSTAINABLE CHEMICALS FOR THE GREEN AND DIGITAL TRANSITION

The EU has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally.

in order to develop and deploy the sustainable chemicals that enable the green and digital transitions and to protect environment and human health, in particular that of vulnerable groups, innovation for the green transition of the chemical industry and its value chains must be stepped up and the existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals.

This includes ensuring that all chemicals are used more safely and sustainably, promoting that chemicals having a chronic effect for human health and the environment - substances of concern – are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products.

Classification list of hazardous substances and chemicals

The classification list of hazardous substances and chemicals can be found in the **"Regulation on the Classification, Labelling and Packaging of hazardous substances (CLP)"** EU document and the EU Regulation on the **registration, evaluation, authorization and restriction of chemicals (REACH).**

The **European Waste Catalogue** classifies waste from human or animal healthcare and/or related research and further divides it into sections applicable to chemicals in clinical laboratories:

- 18 01 Wastes from natal care, diagnosis, treatment or prevention of disease in humans
- 18 01 06 Chemicals consisting of or containing hazardous substances
- 18 01 07 Chemicals other than those mentioned

According to the ECHA/CLP inventory, there are over **120 000 registered chemicals** and **2 327 hazardous substances out of 4 231** that have a harmonized classification of "**harmful to the aquatic environment**". In Europe, the most common soil contaminants include heavy metals, mineral oils and polyaromatic hydrocarbons (PAH).

REACH Implementation

- **Registration** Without registration, substances cannot be manufactured or imported into the EU ("No data no market").
- **Evaluation** The European Chemicals Agency (ECHA) is a European Union (EU) regulatory agency responsible for implementing and administering chemicals legislation.

  a) Substance evaluation

  b) Dossier evaluation
- **Authorisation** Substances of very high concern cannot be placed on the market or used unless the company is granted an authorisation.
- **Restrictions** REACH includes a restriction process for certain substances of very high concern if they pose an unacceptable risk to health or the environment. Such substances may be limited or even banned, if necessary.

REACH & CLP revisions under the Chemicals Strategy

REACH revision is led jointly by DG Environment and DG GROW and will include a thorough assessment of possible impacts of potential changes on

- the protection of human health and the environment
- the use of animal testing
- the functioning of the internal market
- and the competitiveness and innovation of European industry and businesses

CLP revision led jointly by DG Environment and DG GROW and will include a thorough assessment of possible impacts of potential changes to CLP on the protection of human health and the environment and the functioning of the internal market.

Essential uses

The Commission is defining criteria for essential uses.

This will ensure that the most harmful chemicals are only allowed if their use is necessary for health or safety reasons, or if their use is critical for the functioning of society and if there are no acceptable alternatives from the environmental and health viewpoints.

These criteria will guide the application of the concept of essential uses in all relevant EU legislation for both generic and specific risk assessments.

All relevant stakeholders will be consulted on the development of the concept and the policy options in Spring 2022.

The Commission plans to present the criteria on essential uses of chemicals by the end of 2022 and introduce the concept in the proposal for the **REACH revision.**

combination effects of chemicals

combination effects of chemicals have gained relevance, which consist of exposure at low concentrations of different hazardous chemicals, even if all substances are below the **Predicted No-Effect Concentration (PNEC)**.

One substance, one assessment

The ‘**one substance, one assessment**’ process aims to improve **effectiveness, efficiency** and **coherence** of the safety assessment of chemicals across chemicals legislation.

Zero-tolerance approach to non-compliance

Enforcement and compliance of EU chemicals legislation to ensure the highest level of protection of health and the environment from hazardous chemicals

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

EFLM TASK-FORCE GREEN LABS

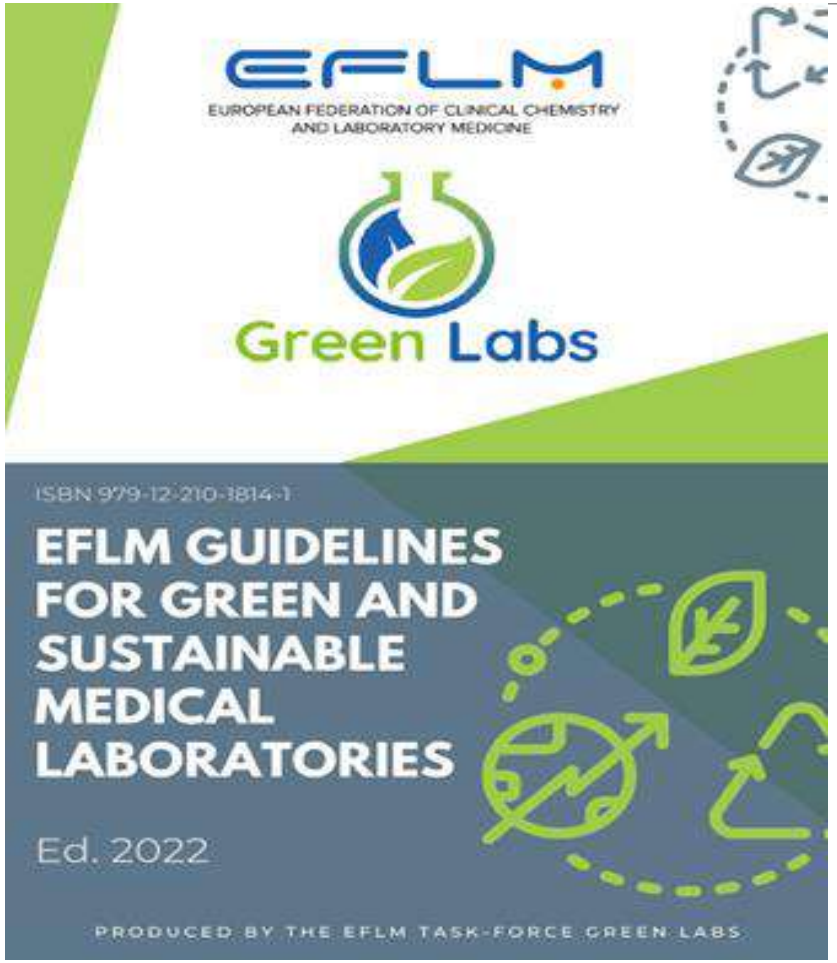
Chair: Tomris Ozben

aimed
to implement
sustainable
practices
in medical
laboratories

EFLM and its Member Societies will lead the laboratory medicine community for the shift to carbon neutrality in line with the European Green Deal (EGD) Investment Plan, which is aimed at making Europe the world's first climate-neutral continent

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

EFLM GUIDELINES FOR GREEN AND SUSTAINABLE MEDICAL LABORATORIES



To help EFLM National Societies in the transition to Green Lab!

EFLM Task-Force Green Labs first goal!

SUSTAINABLE/GREEN CHEMISTRY

Design of chemical products and processes that minimize or eliminate the use or generation of substances hazardous to humans, animals, plants, and the environment.

Green chemistry is applied throughout its life cycle, including the design, production, use and final disposal of a chemical product.

Green chemistry is also known as sustainable chemistry. Green chemistry should be used to sustain quality life on earth.

Although the chemical industry has very positive contributions, they also cause pollution problems. Green Chemistry ensures that chemistry is made in a way that does not harm the environment or human health.

- Created by Paul Anastas and John Warner
- Started to develop in early 1990s, published in 1998
- These principles can be grouped into "Reducing Risk" and "Minimizing the Environmental Footprint"

Aim of EFLM Task Force Green Labs on Green Chemistry

- The aim of Green Chemistry is to reduce chemical-related impact on human health and virtually eliminate contamination of the environment through dedicated, sustainable prevention programs.
- Green chemistry searches for alternative, environmentally friendly reaction media and at the same time strives to increase reaction rates and lower reaction temperatures.
- The concept of Green Chemistry, along with the EU strategy for a non-toxic environment, can be viewed as part of the global sustainability goals.
- Safe and sustainable-by-design chemicals is a pre-market approach that strives to deliver substances that minimize their health and environmental impact.

OBJECTIVES of the EFLM CHEMICAL STRATEGY

The aim of the module on "Green Chemistry" is to educate and inform about the hazardous chemicals and effective ways to decrease the hazardous chemicals in laboratories.

•Standardization of green chemistry and sustainability processes in clinical laboratories.

•Encouragement of laboratory medicine professionals to implement green chemistry and hazardous chemicals-related sustainability measures.

•Promote the increase in hazardous chemicals data from clinical laboratories, including new insights and outcomes.

•Support changes in community attitudes and behaviours concerning chemicals, specifically among healthcare professionals.

•Promote educational programs in green chemistry.

•Reach a significant number of European countries and clinical laboratories regarding chemical-related sustainability actions.

•Prevent air, water and soil contamination with hazardous chemicals and respective environmental, health and economic impacts.

•Improve occupational health.

•Increase resource efficiency.

•Reduce hazardous chemical waste collection, treatment and disposal expenditures.

•Promote sustainable procurement systems.

• Increase demand and innovation for safe and sustainable chemicals

ACTIONS

- Preparing action plans and guidelines concerning hazardous chemicals and green chemistry, which include guidelines, surveys and checklists.
- Training of the 49 National Society Representatives to become Green Lab Delegates/Ambassadors on the subject of green chemistry and hazardous chemicals.
- Promote meetings with the National Societies regarding hazardous chemicals and sustainability measures.
- Organize Workshops, Courses, Videos on Green Chemistry for the whole EFLM Community.
- Launch a call to receive applications for the EFLM certification for Green Labs, including sustainable chemistry.

Policy

Institute an environmental policy, provide documentation and a staff training program on environmental issues and best practices.

Appoint an environmental manager and obtain support from senior management by advocating for corporate responsibility, financial benefits and increased laboratory reputation among customers and the community.

Implement control measures to avoid or minimize the release of hazardous substances into the work environment and the number of exposed employees.

Promote audits to evaluate progress before and after sustainable measures.

Set the example through senior members and provide employee feedback.

Train workers in the use of hazardous chemicals, safe work practices and appropriate use of Personal Protective Equipment (PPE).

Advocacy

The community in general supports environmental initiatives.

Engage groups associated with the clinical laboratory, such as patients, clinicians, industry, contractors, colleagues, health and government authorities.

HOW CAN LABS REDUCE HAZARDOUS CHEMICAL USE

There are many resources available to help clinical labs to choose safer, more sustainable alternatives to hazardous chemicals.

In addition to using less hazardous chemicals whenever possible, labs should eliminate the use of mercury in both thermometers and fluorescence microscope bulbs.

By being mindful of the environmental impact of everyday actions in a lab, and by taking these simple, easy steps to minimize energy, water, and hazardous chemical use, as well as waste generation a clinical lab can be transformed into a safe, sustainable space.

Suggestions for Clinical Laboratories

Selection of solvents should be based on criteria of

(i) Worker Safety

(ii) Process Safety

(iii) Environmental and Regulatory Considerations

(iv) solvents should be classified in three categories as: **preferred, usable and undesirable.**

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Suggestions for Clinical Laboratories

SAFER CHEMICAL SUBSTITUTIONS SHOULD BE IMPLEMENTED. USING HAZARDOUS CHEMICALS SHOULD BE AVOIDED WHENEVER POSSIBLE.

CHEMICAL INVENTORY MUST BE MANDATORY FOR ALL LABS TO KNOW THE SUPPLIES NOT TO OVER ORDER.

CHEMICALS SHOULD BE DATED WHEN OPENED AND USED ON A FIRST-IN, FIRST OUT-BASIS TO KEEP SUPPLIES FRESH.

Greener Alternative Products

The **Merck Sigma Aldrich** company has 4 Categories of **Greener Alternative Products** fulfilling one of the four criteria below:

1. Re-engineered Products to improve their **environmental footprint**.

2. Products align with the **12 Principles** of Green Chemistry.

3. Enabling Products helps to make **greener alternatives** possible through enabling technologies.

4. **Design for Sustainability (DfS)** Developed Products demonstrate significant sustainability characteristics.

DOZN™ **Quantitative Green Chemistry Evaluator tool** of Merck Sigma Aldrich is a quantitative, industry-first tool that uses the 12 principles of green chemistry for **comparing the relative greenness of similar chemicals, synthetic routes, and chemical processes.**

(https://www.sigmaaldrich.com/TR/en/services/software-and-digital-platforms/dozn-tool).

https://www.sigmaaldrich.com/TR/en/technical-documents/technical-article/analytical-chemistry/green-chemistry-principles

Procurement

Healthcare represents approximately half of the EU government expenditure, with more than 15 000 hospitals.

Clinical laboratories should shift towards green alternatives by adopting a green purchasing policy, which includes selection and acquisition of products that minimize environmental impacts over their entire life-cycle:

- use recyclable
- recycled
- less toxic
- locally produced chemicals whenever possible.

Chemical inventory management and storage

- Do not store chemicals in the fume cupboard without a proper seal.
- Maintain and review the chemical inventory to avoid over-purchasing and guarantee that expired chemicals are disposed of adequately.
- Date and use chemicals and reagents as first in, first out.
- Purchase the minimum the amount of chemicals required.
- Share chemicals and reagents:

  -Increase collaboration between clinical laboratories.

  -Host chemical share/swap events.
- Chemical leasing or chemicals-as-a-service: a new business model in which the supplier contracts to provide only the amount of chemicals needed, which results in health, environmental and economic benefits for both sides.

Reduce and Recycle Solvents:

Reduce the use of organic solvents by recycling them, which reduces exposure and chemical waste – many solvents (acetone, acetonitrile, xylene, alcohol, formalin) can be efficiently distilled back to +99% purity through on-site recyclers and vendors:

- Xylene, alcohol and formalin may be recycled by the use of a CBG Biotech Supreme Solvent Recycler (Thermo-Fisher Scientific).

Small volumes need to be purchased intermittently to replace the dead volume lost during the recycling process, which is also economically favourable.

Chemical waste management

Chemical waste disposal must be as safe as possible. Label, store and dispose of hazardous chemicals according to procedures and considering specialized clinical laboratory waste; preferably, write **Standard Operating Procedures (SOPs)** for handling chemical waste/hazardous chemicals.

Rational number of tests

Laboratory testing costs approximately 3% of all clinical costs. Unnecessary tests should be avoided to reduce healthcare expenditure and laboratory budgets.

Auditing requests of laboratory tests to identify test redundancy can decrease the number of reagents and hazardous chemicals used.

World Health Organization **(WHO)** published an **Essential in Vitro Diagnostics (IVD) List,** which identified **35 test categories** of general IVDs that can be used for the diagnosis of several **common diseases** and **27 test categories** of IVDs for the management of **HIV infection, tuberculosis, malaria, hepatitis B and C, syphilis and HPV infection**.

Thank you for your attention