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Abteilung Luftreinhaltung und Chemikalien
Bundesamt für Umwelt BAFU

Regulation of chemicals

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FOEN

EPFL, Concepts and tools for sustainable chemicals manufacture
April 10, 2025



Contents

- Introduction
- Basics of chemicals legislation
- Enforcement of chemicals legislation
- Regulations & case studies



Chemicals - why regulate them?



Economic significance of chemicals

Increase in global production:

1930: 1 million tons / year

today: 400 million tons / year

Approx. number of
chemical substances: 100,000

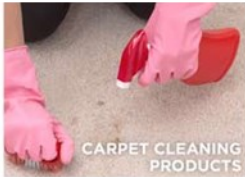
seemingly unlimited possibilities
of use ...





Chemicals: their benefits and their risks

Chemicals are
useful in
everyday life



Chemicals are a risk
to health and the
environment





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Basics of chemicals legislation

- In Switzerland
- In the EU



Legal basis in Switzerland

Basis: Protection goals of the Federal Constitution:

- Protection of human health
- Safety of professional users of chemicals
- Protection of the environment
- Protection of agricultural crops



Implementation: Federal laws and Federal Council ordinances



A bit of history



- 17th century: the state recognized that the sale of chemicals (poisons) "without control" could lead to dangerous situations for the population.
- 1772, Bern: strict regulation of the sale and handling of poisons

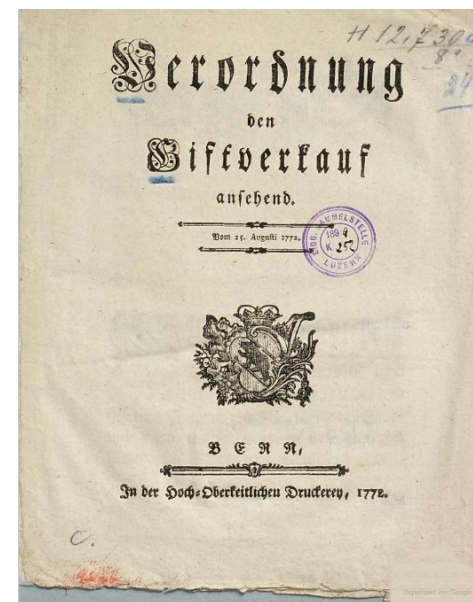
«[...] So haben daraufhin Wir aus landesväterlicher Vorsorg uns entschlossen, den Giftverkauf zur Sicherheit des Publici in mehrerm einzuzielen; und verordnen demnach [...]»

- Sales restrictions:

«Niemanden erlaubt seyn soll, Gift zu verkaufen, als in Unsrer Hauptstadt denen Apothekern...»

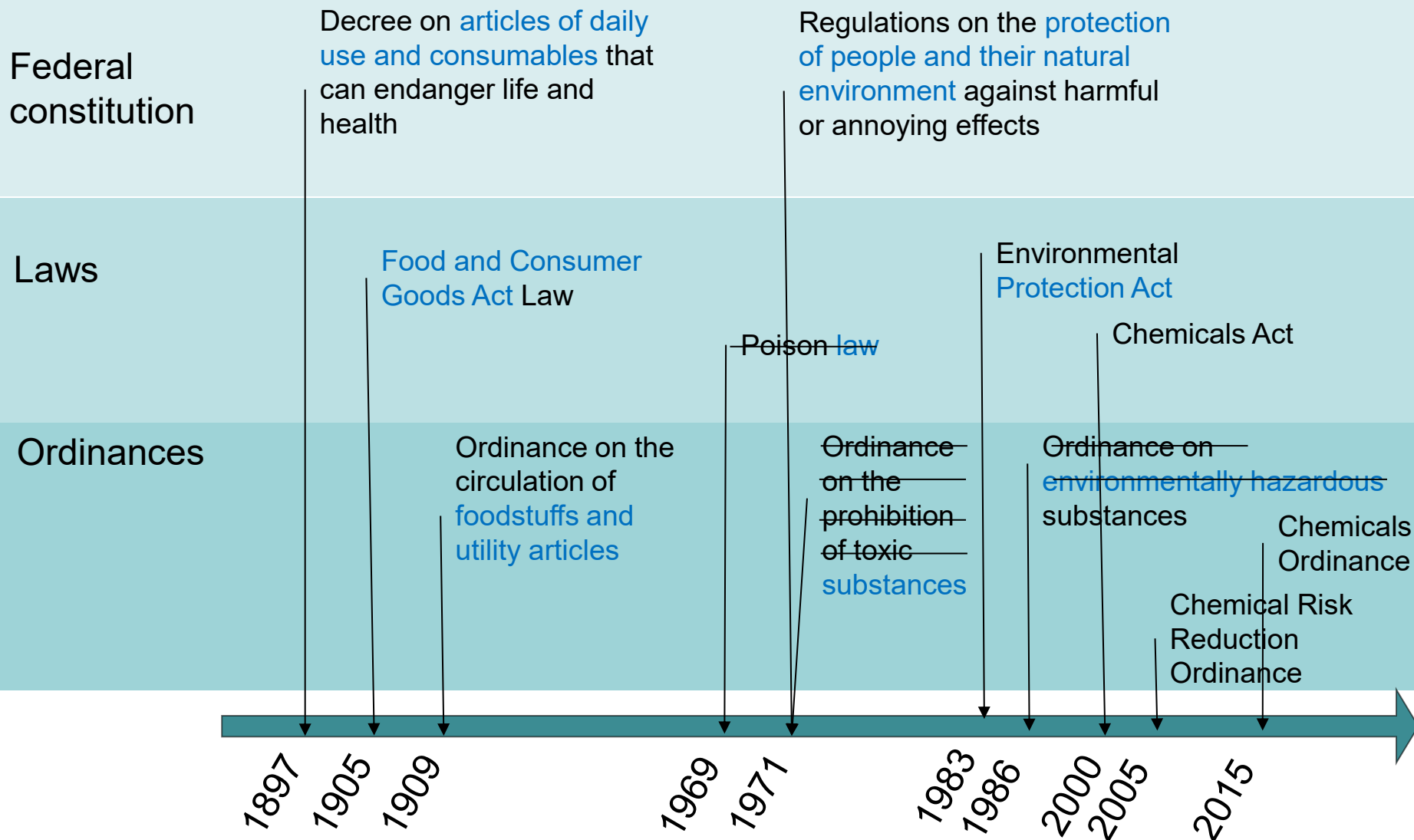
- Handling instructions:

«Dass die zum Giftverkauf bestellte Personen damit, mit aller erforderlichen Vorsicht umgehen, und das Gift wohlverwahrt unter dem Schlüssel halten...»



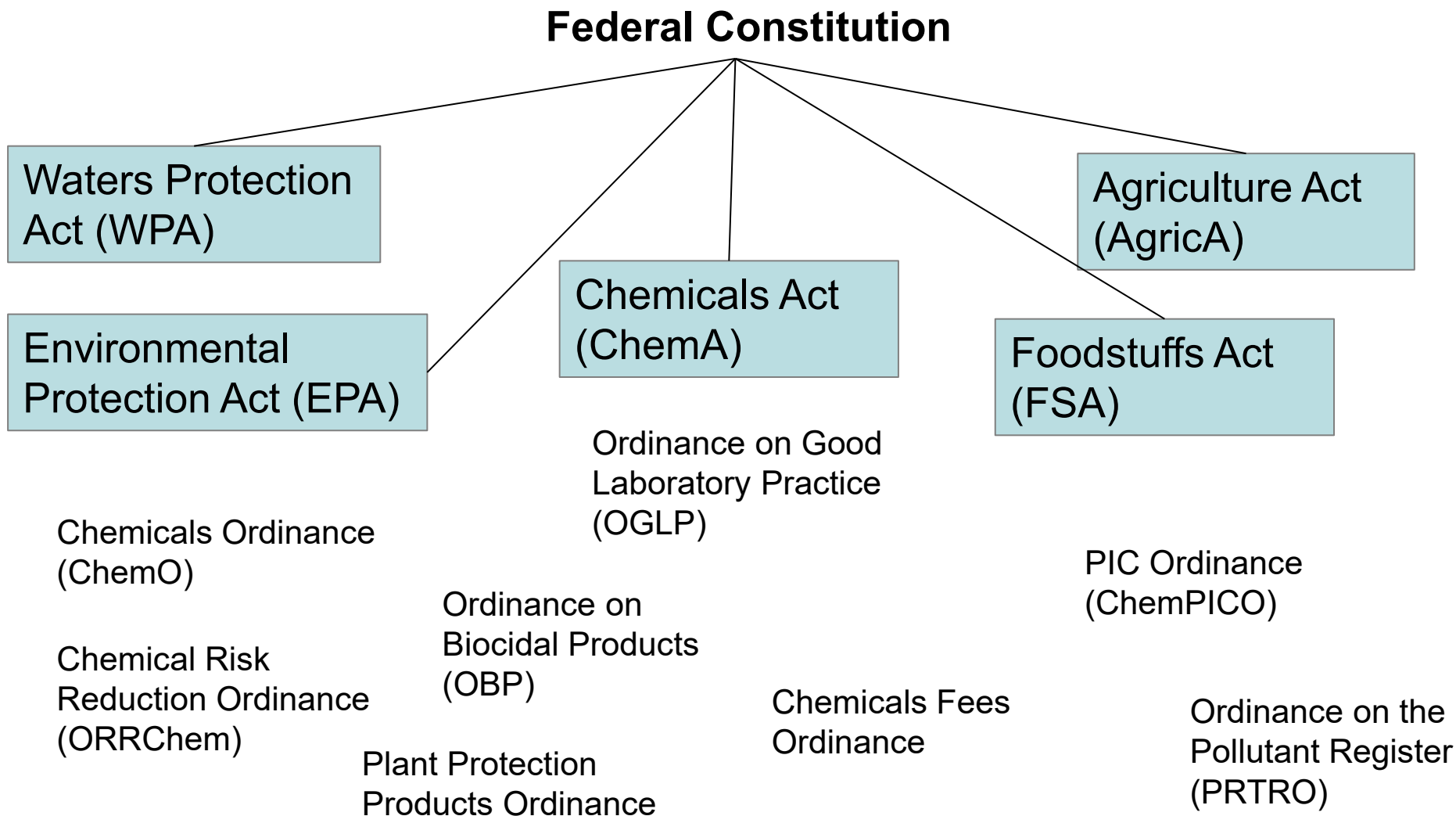


A bit of history





Overview of chemicals legislation





Overview of chemicals legislation



Subject of regulation:

- Chemicals = chemical substances and mixtures (preparations) made from them, including biocidal products and plant protection products

Affected parties:

- *Manufacturers* of chemicals and articles containing chemicals
- Importers and distributors (*placing on the market*) of chemicals and articles containing chemicals
- Professional and private *users* of chemicals



Overview of chemicals legislation



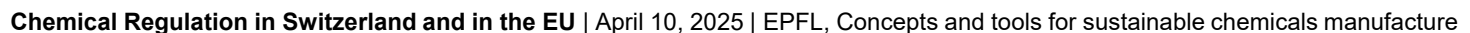
Instruments:

- Prohibitions and restrictions (with exceptions)
- Authorization requirements / approval requirements
- Labeling requirements
- Reporting obligations
- Documentation obligations
- Duties of care



Vision:

- Chemicals have no harmful effects on the environment or human health during their entire life cycle.
- If an effect in the environment is intended, the chemicals are used in such a way that (as far as possible) no harmful side effects occur.





Federal Chemical Safety Strategy

Goals:

- No data - no market
- Risk assessment and risk reduction
- Substitution
- Sustainable chemistry
- State of knowledge
- International standards
- Duty of care
- Proper and efficient enforcement
- Minimization requirement



30 Measures



REACH



- REACH = Regulation concerning the **R**egistration, **E**valuation, **A**uthorization and **R**estriction of **C**hemicals)
- European Regulation (EC) 1907/2006
- One of the most modern chemical regulations in the world



REACH



Is REACH applicable in Switzerland?

No, EU regulation is generally not applicable in Switzerland

Is REACH relevant in Switzerland?

Yes:

- For Swiss companies that
 - manufacture chemical substances in the EU
 - Export chemical substances to the EU
- *Autonomous implementation* of specific regulations in Annex 1.17 of the Chemical Risk Reduction Ordinance
 - same level of protection as in the EU
 - Avoidance of trade barriers



REACH



Goals:

- Ensuring a high level of protection for human health and the environment
- Less animal testing; promotion of alternative test methods (without or fewer laboratory animals)
- Ensuring the free movement of chemicals in the internal market
- Improving competitiveness and innovation (internal and external)



Basic principles

- Responsibility for safe production & use of chemicals
-> Industry
- Closing the regulatory gap with regard to data on old substances (placed on the market before 2008)
- Provision of data on hazards, minimizing costs and experimental animals; obligation to share data.
- Task of the authorities: regulatory risk management of substances, especially for uses where the industry cannot control the risks



"Registration"

- Anyone who **imports or manufactures** substances ≥ 1 t/a must register them
 - with a binding data set
 - in harmonized electronic format (IUCLID)
 - Chemical safety report (CSA) ≥ 10 t/a
- Safety data sheet adapted to registration data
- Update registration dossier regularly



REACH



"Evaluation", "Authorization" (according to Annex XIV REACH Regulation)

substances of very high concern:

- carcinogenic,
- mutagenic,
- toxic to reproduction,
- PBT/vPvB (very persistent and very bioaccumulative) or
- similarly worrying properties (e.g. endocrine disruptor).

Number of entries (substances and substance groups, Nov. 2023):

- List of candidates: 235
- Annex XIV: Number of entries: 59



"Evaluation", "Authorization" (according to Annex XIV REACH Regulation)

- From sunset-date: total ban, with the possibility of temporary exceptions
- Manufacturers or users applying for authorization must
 - Demonstrate adequate control of risks (if a limit has been set)
 - Demonstrate that the socio-economic benefits outweigh the risks (if no threshold has been set)



Risk assessment and risk management

Risk = Hazard potential X Exposure

(substance property) (contact with the substance)

1. hazard assessment

substance properties;
dose/effect; test data; ...

⇒ Predicted No-effect
Concentration, PNEC

2. exposure analysis

Expected concentration in a
specific compartment?

⇒ Predicted Environmental
Concentration, PEC

3. risk analysis (risk assessment):

Ratio PEC / PNEC

- < 1: not unacceptable risk
- > 1: unacceptable risk

4. risk management:

- Hazard communication (safety data sheet (SDS), label)
- Measures in the company (technical / organizational)
- Regulatory (bans, restrictions, specialist authorization for high-risk activities, risk reduction measures)



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Enforcement of chemicals legislation



Responsibilities: Confederation and cantons

1. Confederation

- Checking the manufacturer's obligations before placing on the market
- Notification and authorization procedures for substances, biocidal products and plant protection products
- Authorizations for the import, export, placing on the market and use of certain goods and substances
- international cooperation



FOPH · FOAG ·
FSVO · FOEN ·
SECO



Responsibilities: Confederation and cantons

2. cantons

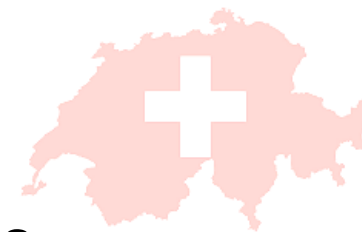
- Market control: checking substances, preparations and articles as well as biocidal products and plant protection products for their conformity with chemicals legislation and compliance with handling regulations





Review of self-regulation – Procedure

- Duty of self-regulation for manufacturers and importers of chemicals (Art. 5 ChemA and Art. 5-23 ChemO):
 - Classification, packaging and labeling
 - Exposure scenario
 - Safety data sheet
- Review of self-regulation by the FOPH, FOEN and SECO in their respective areas of responsibility (Art. 81 ChemO)
- Coordination by / contact via the Notification Authority for Chemicals





Review of self-regulation – example 1

Fabric softener:

- Problem:
 - possible health hazards due to allergenic fragrances / other hazardous substances
 - Possible threat to the environment (less biodegradable surfactants)
- Procedure: Check with manufacturers whether fabric softeners are correctly classified and labeled and whether the bans have been complied with.

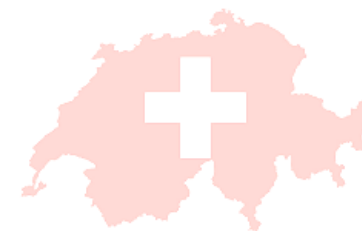




Review of self-regulation – example 2

Chainsaw oils:

- Problem: direct emissions in the forest
- Procedure: Check with manufacturers whether the chainsaw oils have been correctly assessed and classified and whether users are made aware of the restrictions on use in the forest.

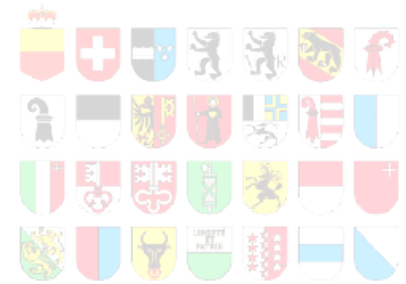




Market control campaigns: example 1

Market control batteries (2022/2023):

- Problem:
Batteries can contain mercury (Hg), cadmium (Cd) and lead (Pb). These substances are regulated.
- Procedure: 80 commercially available portable batteries were sampled by the cantons throughout Switzerland and analyzed for Hg, Cd and Pb. All were compliant.

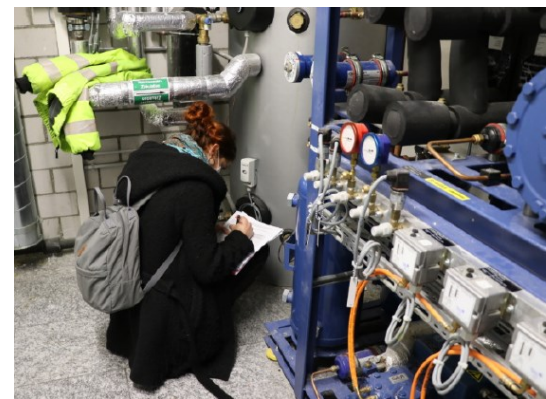




Market control campaigns: example 2

Market control of refrigerants (2019-2022):

- Problem:
 - Emissions of ozone depleting or climate active gases
 - Installations which are placed on the market contrary to the prohibitions of the ORRChem
 - Installations which are operated without respecting the obligations (leakage check, notification, maintenance booklet ...)
- Procedure:
 - On-site inspection of 800+ systems
 - Inspection of 600+ systems based on their documentation



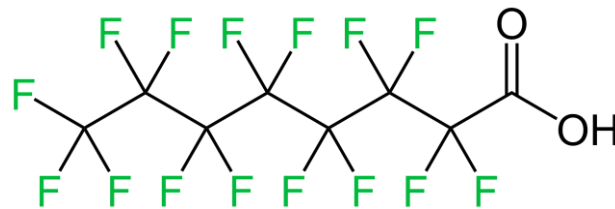


Regulations & case studies: Industrial Chemicals

- Substances of very high concern substances
- PFAS
- Substances that deplete the ozone layer or stable in the atmosphere
- Endocrine disruptors
- Microplastics
- Heavy metals, mercury
- Plant protection products
- Biocides
- International trade
- Pollutant register



PFAS as an (extreme) example of persistent substances

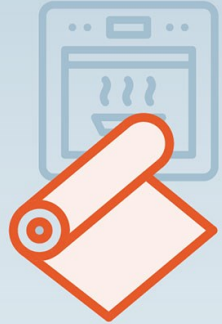


- Widespread in the environment
- Extremely persistent in the environment ("eternal chemicals")
- a risk to the environment and human health
- Can accumulate in the food chain

Restrictions in Annex 1.16 ORRChem for the most problematic PFAS; updating of the regulation



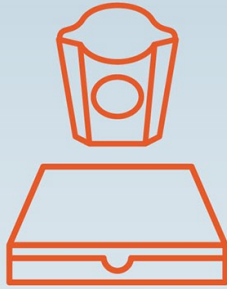
PFAS - versatile use



Backpapier



Beschichtete
Pfannen



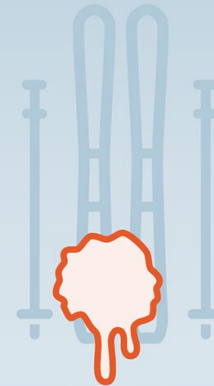
Fast-Food-
Verpackungen



Imprägnier-Spray

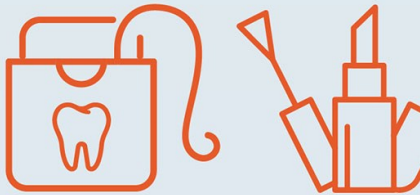


Outdoor-Kleidung



Ski-Wachs

© BAFU/shutterstock



Zahnseide

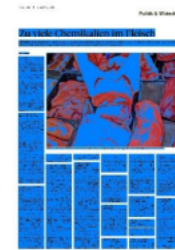
Kosmetika

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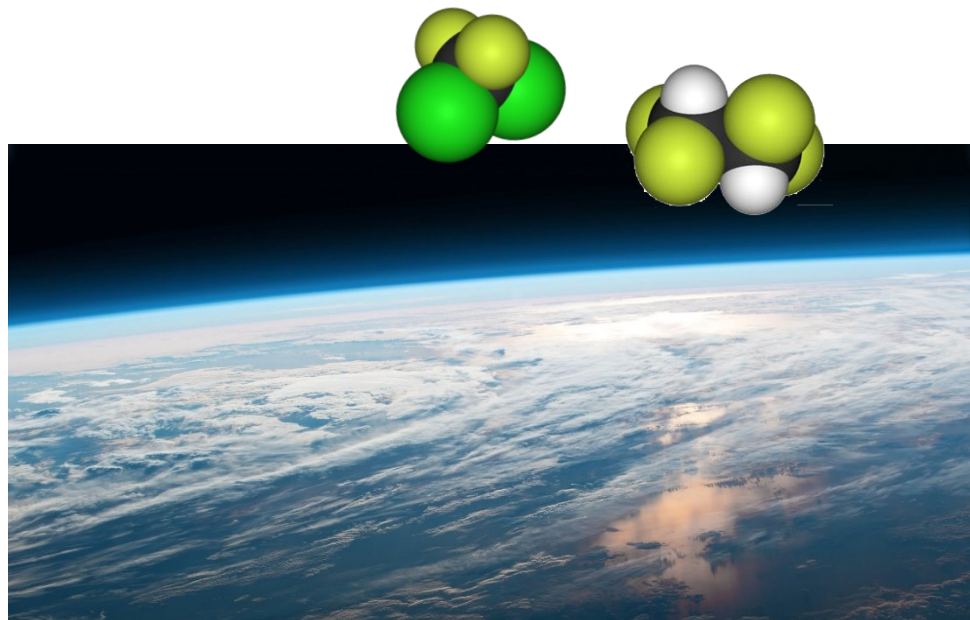
Zu viele Chemikalien im Fleisch

PFAS-Alarm in der Ostschweiz Der Kanton St. Gallen hat überhöhte Fluorchemikalien-Belastungen in Fleisch, Milch und Böden entdeckt. Jetzt ergreift die Regierung Massnahmen. Und fordert einen nationalen Aktionsplan.



Ozone-depleting substances (ODS) and substances stable in the air (SSA)

- ODS: chlorinated and/or brominated hydrocarbons
- ILS: fluorinated hydrocarbons, SF_6 , NF_3
- Replacement of ODS by SSA: "regrettable substitution"
- Endangerment of:
 - Ozone layer
 - Climate
 - Waters
(via degradation products)





Ozone-depleting substances (ODS) and substances stable in the air (SSA)

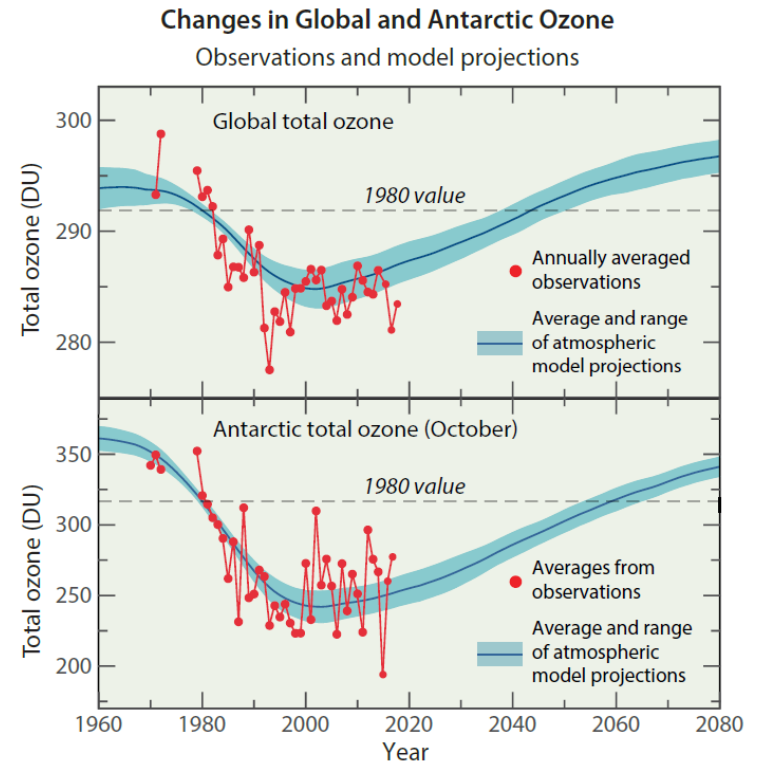
- regulated in Annexes 1.4 (ODS) and 1.5 (SSA) of the ORRChem
- anchored in the international measures of the Montreal Protocol
- Use prohibited, with exceptions for certain areas of application if there are no alternatives:
 - Refrigerants (Annex 2.10 ORRChem)
 - Extinguishing agents (Annex 2.11 ORRChem)
 - Aerosol dispensers (Annex 2.12 ORRChem)
 - Solvents (Annex 2.3 ORRChem)
 - ...



Ozone-depleting substances (ODS) and substances stable in the air (SSA)

Target for ODS:

- Measures achieve the restoration of the ozone layer and avoid future effects on health (skin cancer, eye cataracts)

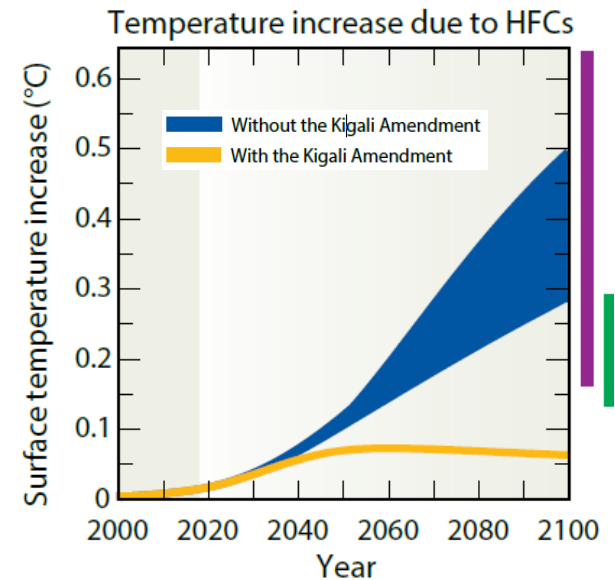
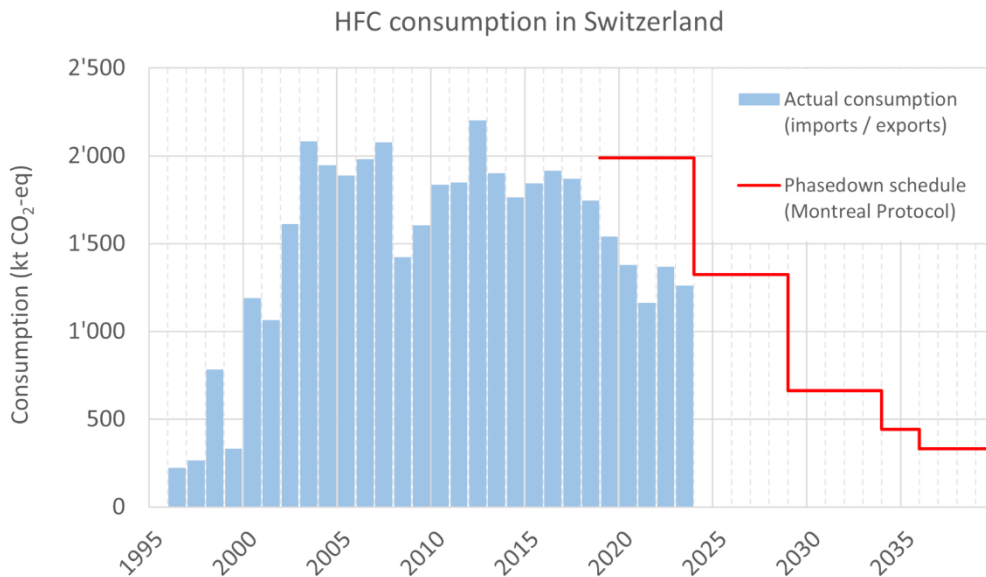




Ozone-depleting substances (ODS) and substances stable in the air (SSA)

Target for SSA:

- Measures make a significant contribution to reducing global warming





Microplastics

- Entry into the environment through
 - Tire abrasion,
 - Improper disposal of plastic waste
 - Use of cleaning and cosmetic products
- is only very slowly degraded, is widespread (detected in surface waters, groundwater used as drinking water, food and human organism).
- Additional hazards from chemicals contained in microplastics.



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Brief Communication | [Open access](#) | Published: 03 February 2025

Bioaccumulation of microplastics in decedent human brains

[Alexander J. Nihart](#), [Marcus A. Garcia](#), [Eliane El Hayek](#), [Rui Liu](#), [Marian Olewine](#), [Josiah D. Kingston](#), [Eliseo F. Castillo](#), [Rama R. Gullapalli](#), [Tamara Howard](#), [Barry Bleske](#), [Justin Scott](#), [Jorge Gonzalez-Estrella](#), [Jessica M. Gross](#), [Michael Spilde](#), [Natalie L. Adolphi](#), [Daniel F. Gallego](#), [Heather S. Jarrell](#), [Gabrielle Dvorscak](#), [Maria E. Zuluaga-Ruiz](#), [Andrew B. West](#) & [Matthew J. Campen](#)



Microplastics

Current law in the EU and Switzerland

- Fall 2023: Regulations in the EU restricting the placing on the market of microplastics and preparations containing microplastics
([Regulation \(EU\) 2023/2055](#) amending Annex XVII to the REACH Regulation ([EC](#)) [No. 1907/200633](#))
- Autumn 2025: expected adoption of the REACH restriction on microplastics in products (including cosmetics, detergents and cleaning agents, plant protection products, fertilizers, infill granules for synthetic sports surfaces...).
(Amendment to Annex 2.9 ORRChem, under consultation)



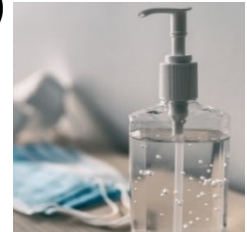
Biocidal products

Product types (PA)

Four main groups and 22 product types

(Annex 10 VBP <https://www.fedlex.admin.ch/eli/cc/2005/468/de>)

Hauptgruppen	Beispiele
Desinfektionsmittel (PA 1-5)	Hände-, Trink-, Badewasserdesinfektionsmittel, öffentliches Gesundheitswesen
Schutzmittel (PA 6-13)	Topf-Konservierungsmittel, Beschichtungsschutzmittel, Holzschutzmittel
Schädlingsbekämpfungsmittel (PA 14-20)	Rodentizide, Insektizide, Repellentien, Lockmittel
Sonstige Biozidprodukte (PA 21-22)	Antifouling-Produkte, Flüssigkeiten für Einbalsamierung und Taxidermie



Not authorized in Switzerland:

~~PA 15 Avizide (Bekämpfungsmittel gegen Vögel)~~

~~PA 17 Fischbekämpfungsmittel~~

~~PA 20 Produkte gegen sonstige Wirbeltiere~~

For biocides no macroorganisms
(only microorganisms)





Biocides: Mutual Recognition Agreement (MRA)

(Bilateral I):

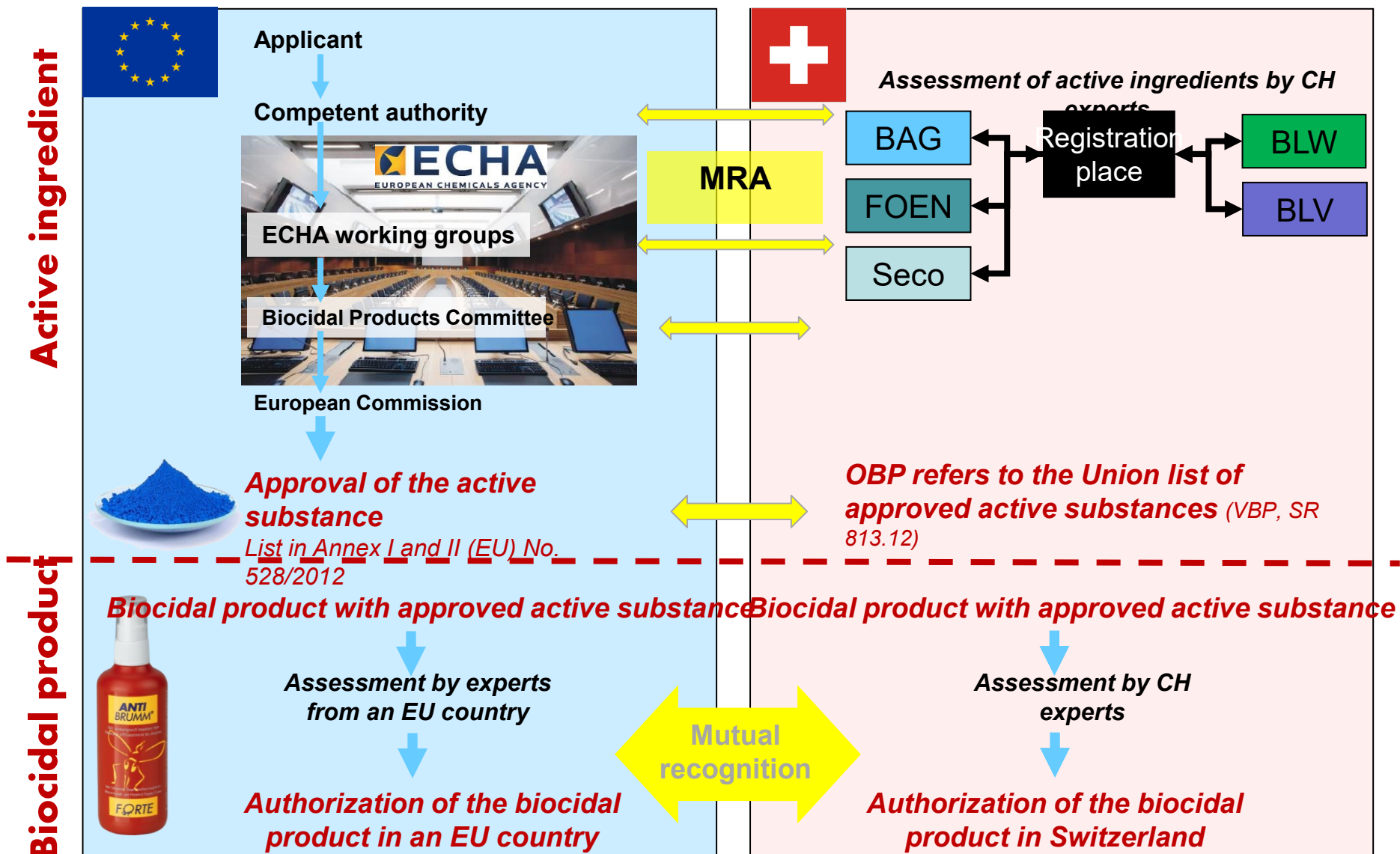
Mutual recognition of assessments for the authorization of biocidal products by Switzerland and the EU.

- Avoidance of duplication
- Avoidance of technical barriers to trade
- Facilitation of market access for CH and EU

Biocidal products that are authorized in the EEA can be recognized in Switzerland and vice versa.



Biocides: Mutual Recognition Agreement (MRA)





Biocidal products

Differentiation from plant protection products

Plant protection products

protects plants/harvest



Plant protection products in the cultivation zone to protect plants or plant products

Biocidal products

protects human health and products



Wood preservative (biocide) in the sawmill



Exposure models for PPPs and biocides

Plant protection products



- Mostly large-scale application in the environment
- Few application scenarios

Biocidal products

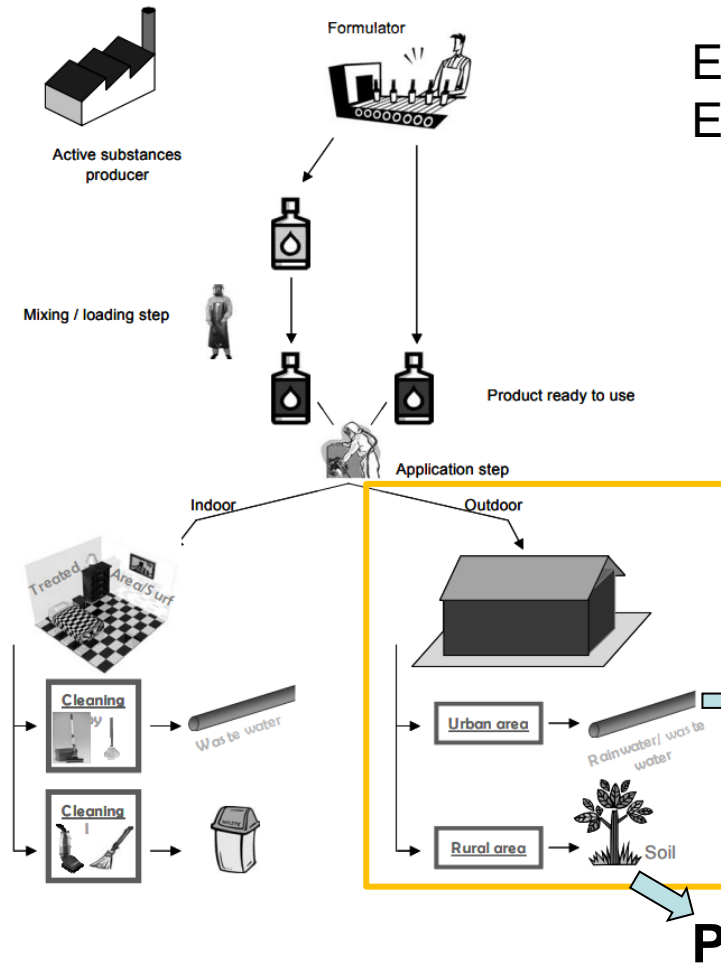


- Frequently selective, small-volume, indoor/outdoor
- Various application scenarios



Emission scenarios (ESDs) for biocides

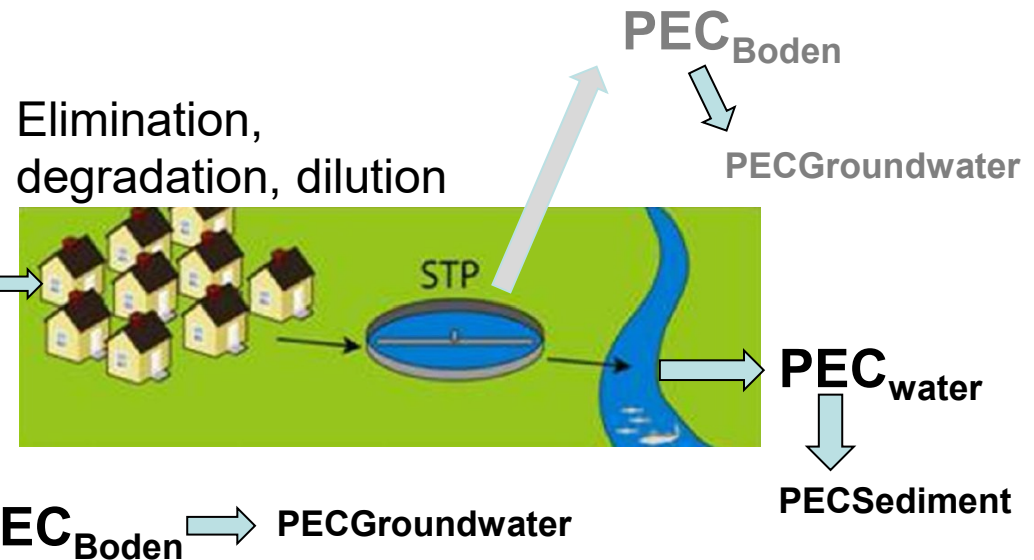
> 37 harmonized ESDs accepted by OECD member states



Estimate relevant input processes:

Example indoor/outdoor insecticide application (PT18)

Sewage sludge on fields
(not permitted in Switzerland):



<https://www.oecd.org/env/ehs/risk-assessment/emissionscenariodocuments.htm>



Further restrictions on the use of biocides

Prohibition or restriction of the use of particularly hazardous biocidal products:

- For biocidal products that are or contain pathogenic microorganisms, the restrictions according to Article 13 of the Release Ordinance (RO) apply.
- For wood preservatives, other preservatives, rodenticides, antifouling products and products against algae and moss, the restrictions and obligations in Annex 2.4 ORRChem also apply.
 - e.g. bans on the use of herbicides and biocides (against algae and mosses) on and along roads, paths, squares, terraces and roofs

Careful handling of biocides

The use of biocidal products should be limited to a necessary minimum and, where possible, alternative and preventive measures should be used.



Clean endangered areas regularly and regularly **mop** forecourts with paving stones.



Use **jointing sand** on the forecourt in joints between paving stones or sow **flowers** that grow well between joints to prevent the growth of moss.



Algae and moss can be removed from forecourts using mechanical and physical methods.



SwissPRTR pollutant register

- The SwissPRTR is the publicly accessible pollutant register in Switzerland and contains:
 - Information on the release of pollutants and the transfer of waste and pollutants to wastewater.
 - Data from reportable establishments and diffuse sources.
 - Landing page: www.swissprtr.admin.ch
 - the annually updated public data for Switzerland ([download as xlsx document](#))
- Based on the PRTR Regulation and in fulfillment of international obligations under the Kiev Protocol (PRTR Protocol, UNECE)



SwissPRTR pollutant register

Abfallmengen

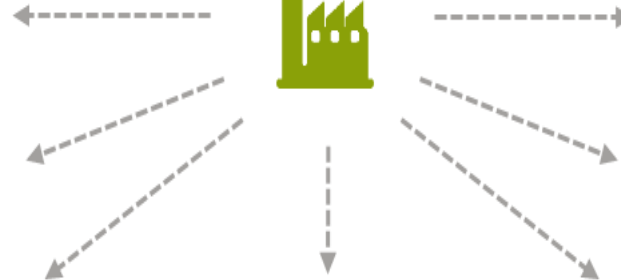
Verbringung ausserhalb des Standorts (Transfers)

Nicht gefährliche Abfälle (innerhalb des Landes oder grenzüberschreitend)

Gefährliche Abfälle (innerhalb des Landes)

Gefährliche Abfälle (grenzüberschreitend)

Betrieb (Standort)



Abwasserbehandlungsanlage ausserhalb des Standorts (Transfers von Schadstoffmengen im Abwasser)

Schadstoffmengen

Freisetzungen



Luft



Wasser



Boden

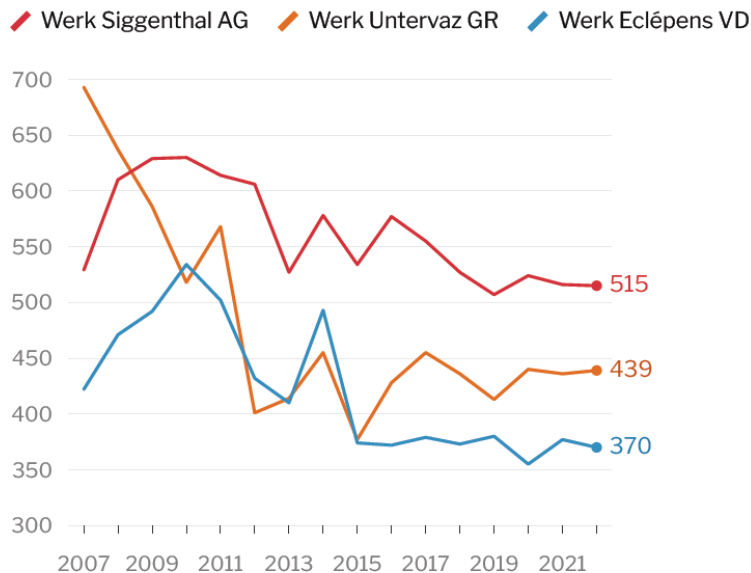


SwissPRTR pollutant register

Transparency as an operating principle

[Tagesanzeiger from January 30, 2025:](#)
[Article on CO₂ emissions from cement](#)
[production in Switzerland.](#)

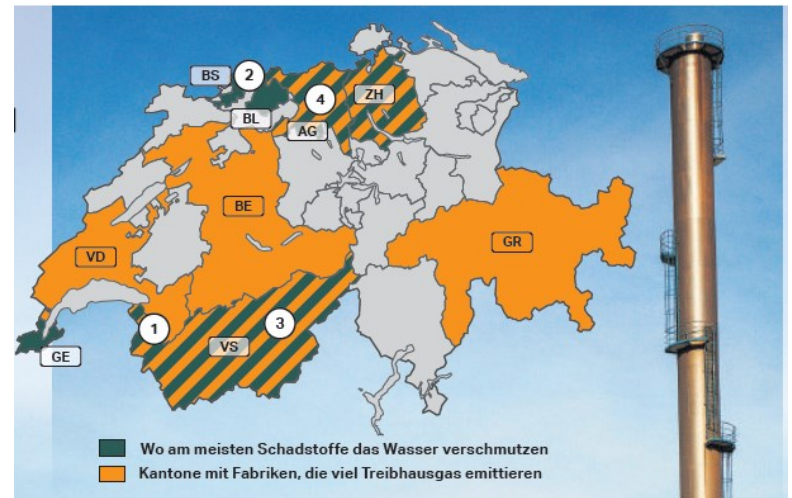
[SonntagsZeitung from July 5, 2015:](#)
[Where Switzerland is the dirtiest.](#)



Im dargestellten Zeitraum kamen unterschiedliche Berechnungsmethoden zum Einsatz.

Grafik: bit; Quelle: [Schadstoffregister SwissPTR](#)

Tons of carcinogenic substances in residential areas: an analysis of 10,120 reports on pollutant emissions from companies reveals problematic production processes





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Abteilung Luftreinhaltung und Chemikalien
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Summary / Outlook



The lecture in three sentences

- Chemicals are economically interesting and make our lives easier, but they also pose a risk to the environment and human health
- Swiss chemicals legislation ensures that the risk is minimized.
- Continuous adaptation of chemicals legislation to the state of the art and regular enforcement are essential for the protection of the environment and people