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Strategy for Chemical Safety

for the interdepartmental implementation of the chemicals legislation



Imprint

Strategy for Chemical Safety

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Preamble

Bearing in mind the results of the evaluation of the interdepartmental implementation of the chemicals legislation carried out in 2013 the Federal Council mandated the federal authorities to prepare a common strategy.

The present strategy expresses the common understanding of the federal authorities involved in the implementation of the chemicals legislation at the federal level in regard to chemical safety, and is intended to strengthen cooperation. It builds up trust externally as the objectives pursued are clearly demonstrated to stakeholders, other federal authorities and politicians.

The strategy has been prepared by the five federal authorities (FOPH, FSVO, FOEN, FOAG and SECO) involved in the federal implementation of the chemicals legislation and will be put in place jointly.

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Introduction

1.1. Importance and risks of chemicals

Chemicals are part of our everyday life. They are contained *inter alia* in paints, medicinal products, cleaning agents, fertilisers, pesticides, but also in furniture, smartphones, heat pumps and many other objects in daily use. Chemical products and technologies enable innovations in all areas of life, for example fuel-efficient cars, energy-efficient houses or self-cleaning surfaces. Today, ca. 100 000 chemical substances are produced. The importance of chemicals is also confirmed by the worldwide annual production of chemicals which has multiplied in the last hundred years from 1 million tonnes in 1930 to more than 400 million tonnes at present. The OECD¹ continues to anticipate strong growth.² The benefits of chemicals are manifold, but they also involve risks for the environment and human health.

- *Tox Info Suisse* reports more than 10 000 domestic accidents per year involving chemical products. Moreover, chemicals are associated with allergies, cancer diseases, congenital defects, diabetes, obesity and disorders in reproductive capacity and fertility. The OECD estimates that each year chemicals cause 350 000 unintended premature deaths worldwide. In 2014 the SUVA recognised more than 17 000 cases of occupational illnesses attributed to chemicals (not including asbestos) and their harmful effects on human health.³ The related costs amount to more than 28 million CHF.
- In the environment, damage due to chemicals also leads to considerable costs. In the Kölliken landfill site the remediation costs amounted to around 660 million CHF.⁴

Consequently, risks for the environment and health need to be minimised when chemicals are used. Chemicals management⁵ is of primary importance for this.

1.2. Legal framework

Protection objectives

The Federal Constitution empowers the Confederation to protect the health and the environment against damage from hazardous chemicals and in this regard to enact regulations relating to chemicals.⁶ The following protection objectives arise from the Constitution:

- The protection of human health,
- Safety of professional users of chemicals,
- The protection of the environment,
- The protection of agricultural crops.

The protection objectives are the subject of various federal acts that contain provisions relating to chemicals. In particular, these federal acts include the Chemicals Act (ChemA), the Environmental Protection Act (EPA), the Water Protection Act (WPA), the Foodstuffs Act (FoodA) and the Agriculture Act (AgricA).

Chemicals legislation

The Swiss chemicals legislation includes at the ordinance level eight Federal Council ordinances that regulate the use of chemicals, and are primarily based on the abovementioned Acts.

¹ All abbreviations used in the Strategy are described in more detail in the List of Abbreviations.

² See OECD Environmental Outlook to 2050; <http://www.oecd.org/env/indicators-modelling-outlooks/oecd-environmental-outlook-1999155x.htm>

³ <https://www.unfallstatistik.ch/d/publik/unfststat/pdf/Ts16.pdf>

⁴ http://www.smdk.ch/index.cfm?setcatlist=66&publication_id=93&publication_action=dsp_publicationdetail&content=0801&par-agraph=3

⁵ See Glossary.

⁶ Art. 74, Art. 104 para. 3 let. d, Art. 110 para. 1 let. a, Art. 118 para. 2 let. a. Cst. (<https://www.admin.ch/opc/de/classified-compilation/19995395/index.html>)

Figure 1: Federal Council Ordinances in the Chemicals Legislation

Chemicals Ordinance	Ordinance on Chemical Risk Reduction	Ordinance on Biocidal Products	Plant Protection Products Ordinance
Chemical Fees Ordinance	Ordinance on Good Laboratory Practice	PIC Ordinance	PRTR Ordinance

Chemicals in the scope of the chemicals legislation refer to chemical substances and their mixtures (preparations), including biocidal products (BP) for use against harmful organisms, and plant protection products (PPP) for use against diseases and pests as well as weeds in crops.⁷ Micro- or macro-organisms that are incorporated in PPP and BP fall within the scope of the chemicals legislation and are therefore also implicitly subject to the present strategy.

The provisions of the chemicals legislation are directed towards manufacturers, importers and traders, to professional and private users (agriculture, traders, non-professional users, etc.) of chemicals as well as to manufacturers of articles.⁸

Chemicals that are considered to be foodstuffs, cosmetics, therapeutic products, feedstuffs, weapons and ammunition or waste are largely or completely exempt from the chemicals legislation. These chemicals are regulated by specific legislations. There are other areas with provisions on chemicals which are likewise not subject to the chemicals legislation, but play an important role in the scope of the integral chemicals risk management. These include *inter alia* the regulatory areas soil pollution, water protection, air pollution control, transport of hazardous goods, accident prevention, construction products and residues in foodstuffs.

Implementing organisation

The implementation tasks for the application and enforcement of the rules of the chemicals legislations are split between the Confederation and cantons.⁹

- In particular, the Confederation is responsible for the verification of the manufacturers' declared classification of substances and preparations, the risk assessment of selected substances, the examination of notifications and applications for authorisation for substances, BPs and PPPs as well as for their confirmation or authorisation, the notification procedure for hazardous substances and preparations as well as for the international cooperation.
- The cantons are responsible for the market surveillance. In regard to random sample checks the cantons monitor substances, preparations and articles as well as PPPs and BPs, which are present on the market, to ascertain their conformity with the chemicals legislation and compliance with the handling requirements.

Essentially, six federal authorities are involved with the federal enforcement of the chemicals legislation:

The Federal Office of Public Health (FOPH), the Federal Office for Agriculture (FOAG), the Federal Food Safety and Veterinary Office (FSVO), the Federal Office for the Environment (FOEN), the State Secretariat for Economic Affairs (SECO) and the Notification Authority for Chemicals (NA-Chem). Annex II provides further details on the organisation for the federal enforcement of the chemicals legislation.

⁷ In other contexts the term "Chemicals" sometimes refers only to chemical substances and mixtures.

⁸ Articles include e.g. floor coverings and textiles.

⁹ See ChemA chapter 5: Implementation, Art. 31 ff. <https://www.admin.ch/opc/de/classified-compilation/19995887/index.html>

1.3. International Context

Switzerland has ratified *inter alia* the following UN conventions in the field of chemical safety and transposed them into its legal system:

- *Stockholm Convention* on Persistent Organic Pollutants (POP Convention),
- *Rotterdam Convention* on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade (PIC Convention),
- *Vienna Convention* and *Montreal Protocol* on the protection of the ozone layer,
- *Minamata Convention* on the protection of mankind and the environment from the negative effects of mercury (Mercury Convention),
- *Aarhus Convention* of the United Nations Economic Commission for Europe (UN ECE) on the Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters and the *PRTR Protocol* on Pollutant Release and Transfer Registers.

Moreover, Switzerland supports various UN resolutions that demand the worldwide introduction of the Globally Harmonized System (GHS) for the classification and labelling of chemicals, as well as careful management of chemicals (*inter alia Strategic Approach to International Chemicals Management* (SAICM)¹⁰ and Agenda 2030¹⁰). As Switzerland is a member of the OECD the Council decisions of the OECD are also binding for Switzerland.

In view of the close economic ties between Switzerland and the EU the Swiss chemicals legislation has been harmonised in certain areas with the corresponding EU legislation (“autonomous adaptation”). This is intended to avoid technical barriers to trade. In addition, harmonisation contributes to the further development of the level of protection for health and the environment in Switzerland.

In the context of the bilateral agreement on the mutual recognition of conformity assessments (MRA)¹⁰ Switzerland committed to adopt equivalent provisions to EU legislation for the authorisation of BPs and for the coordination of good laboratory practice (GLP)¹⁰. The parties in these legal fields thereby receive a simplified mutual market access. At the same time Switzerland is involved in the preparation of Community regulatory decisions.

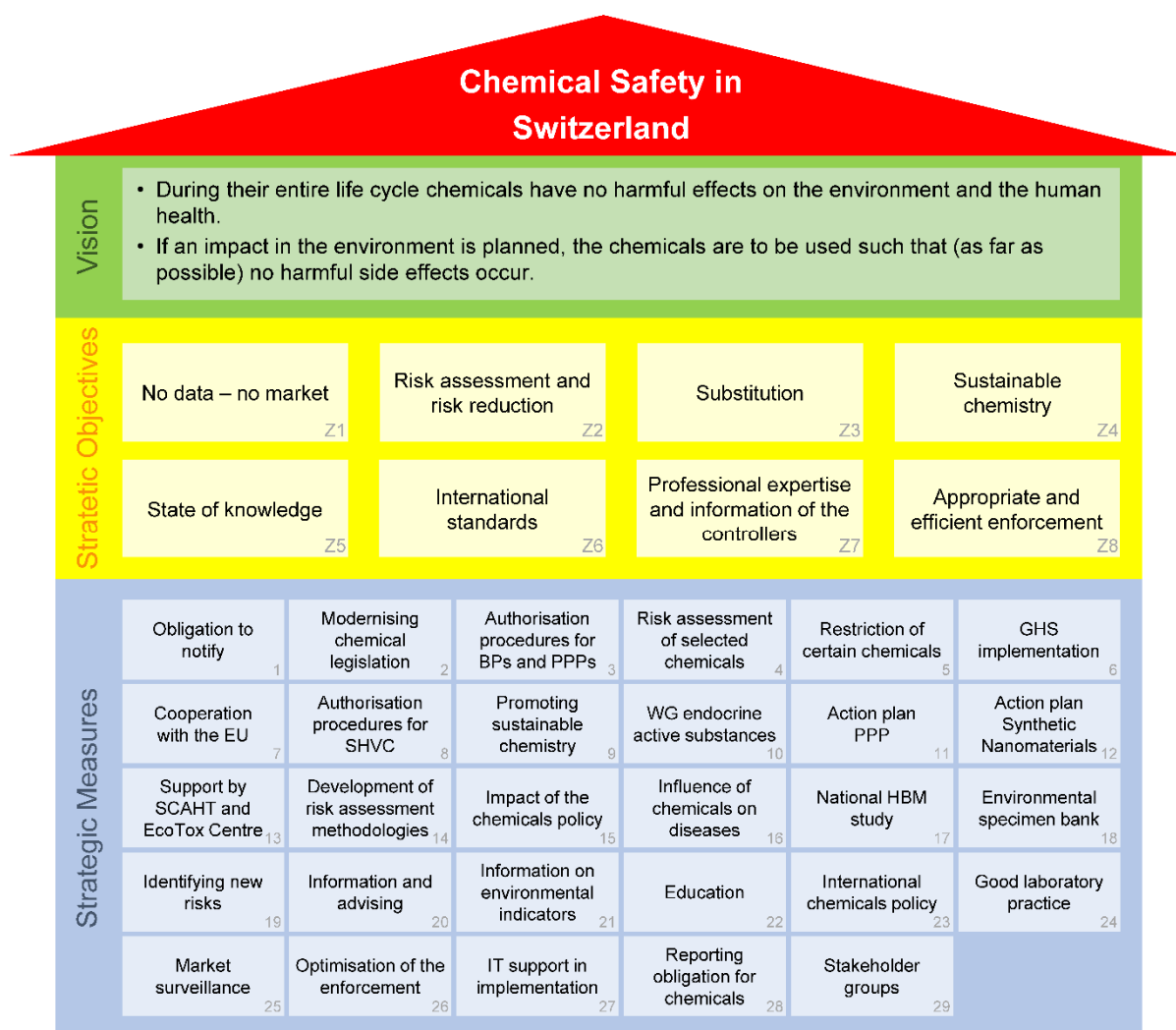
¹⁰ See Glossary.

2. Strategy for Chemical Safety

2.1. Overview

The present strategy focusses on those aspects of chemical safety in Switzerland which fall under the regulatory area of the chemicals legislation. It is conceived as an interdepartmental strategy for the federal authorities FOEN, FOPH, FSVO, FOAG and SECO involved in the federal implementation of the chemicals legislation and thereby also creates a basis for any sectorial strategies of these federal authorities in the field of chemical safety.

Figure 2: Strategy for Chemical Safety



2.2. Vision

Vision of Chemical Safety

- During their entire life cycle¹¹ chemicals have no harmful effects on the environment and the human health.
- If an impact in the environment is planned,¹² the chemicals are to be used such that (as far as possible) no harmful side effects occur.

2.3. Strategic Objectives

The strategic objectives substantiate the vision and demonstrate what the involved federal agencies want to achieve in regard to chemical safety in the period up to 2020. They represent a yardstick for measuring the success of the federal agencies' activities.

Table 1: Strategic Objectives

No.	Title	Objective
Z1	No data – no market	Manufacturers dispose of the required data for all chemicals that are intended to be placed on the market in order to assess the risks to the environment and to human health, and in order to be able to provide information required for safe use.
Z2	Risk assessment and risk reduction	Chemicals may be marketed only if the assessment demonstrates that no unacceptable ¹³ risks to human health and the environment result from the intended use. If necessary, the competent authorities shall take measures to reduce the risks arising from a chemical.
Z3	Substitution	Chemicals with risks to health or the environment shall be replaced by lower-risk alternatives.
Z4	Sustainable chemistry	The fundamental principles of sustainable chemistry ¹³ are respected in the manufacture, use and waste management of products as well as in the development of new processes and products.
Z5	State of knowledge	Tests for the properties of chemicals and the assessment of their risks to health and to the environment are based on scientifically sound methods and strategies, which also refer to the 3R Principles ¹³ . Switzerland plays an active role internationally in order to further develop the relevant state of knowledge and continually adapts its chemicals legislation to it.
Z6	International standards	The international standards for the careful handling of chemicals are developed by participating in <i>inter alia</i> the United Nations Environmental Programme (NEP), in the WHO, the FAO, the ILO and the OECD. This enables Switzerland's needs as a business location to be taken into account. Switzerland is committed to these standards and is an advocate for their worldwide implementation, also in regard to the sustainability objectives 2030 defined by the United Nations ¹³ .
Z7	Professional expertise and information of the controllers	Anyone who manages chemicals, <ul style="list-style-type: none"> • has the knowledge that ensures safe handling, • is aware of the responsibility for safe handling and • receives the information required for this.
Z8	Appropriate and efficient enforcement	The competent authorities guarantee a proper and efficient enforcement of the chemicals legislation and encourage manufacturers, importers, traders and users to fulfil their obligations when handling chemicals.

¹¹ Entire life cycle means that the effects of chemicals are to be taken into account from the raw material extraction, production, further processing, storage and transport up to the use and disposal in Switzerland and abroad.

¹² The claim "no harmful side effects" relates to chemicals that are intended to achieve a change in the environment, e.g. pesticides. The intended environmental impact is that the pests are eliminated. An impact on health is always a side effect; chemicals never target health.

¹³ See Glossary

2.4. Strategic Measures

The strategic measures are those activities with which the involved federal authorities want to achieve the set strategic objectives in the medium term. Strategic measures are those that are of crucial importance to achieve the objectives.¹⁴

The strategic measures for the timeline 2017–2020 are listed below in the Table (some measures have already been taken).

Table 2: Strategic Measures

	Title	Strategic Measures	Objectives	Involved federal authorities
M1	Obligation to notify	Placing certain chemical substances on the market requires a notification. ¹⁵ The federal authorities evaluate the documentation submitted by the manufacturers and make non-confidential data available to the public.	Z1 No data – no market Z2 Risk assessment and risk reduction Z8 Appropriate and efficient enforcement	FOEN, FOPH, SECO, NACChem
M2	Modernising chemicals legislation	Placing on the market of substances that have not been registered in the EU, and synthetic nanomaterials, is subject to the notification requirement. Intermediates placed on the market and the use of synthetic nanomaterials are subject to a reporting obligation.	Z1 No data – no market Z2 Risk assessment and risk reduction Z8 Appropriate and efficient enforcement	FOEN, FOPH, SECO, NACChem
M3	Authorisation procedures for PPPs and BPs	Placing BPs and PPPs on the market requires an authorisation. Application documentation is scientifically examined, <i>inter alia</i> in regard to health and environmental risks, and in regard to proof of efficacy. Authorisation decisions are temporary. Where necessary, restrictions on use are stipulated. For BPs and PPPs which contain an active substance to be replaced (substitution candidates) the procedures for the comparative evaluation ¹⁶ are used.	Z2 Risk assessment and risk reduction Z1 No data – no market Z3 Substitution	FOEN, FOPH, SECO, FOAG, FSVO, NACChem
M4	Risk assessment of selected chemicals	The in-depth risk assessment of selected chemical substances with a high risk potential is realised by taking into account of or by cooperating in international programmes of WHO, UNEP, OECD, EU etc.	Z2 Risk assessment and risk reduction Z6 International standards	FOPH, FOEN, FSVO
M5	Restriction of certain substances	As a consequence of Swiss risk assessments the Confederation, in a mode of autonomous implementation of EU Regulations and by the implementation of international conventions, examines restrictions for certain chemicals and imposes them.	Z2 Risk assessment and risk reduction Z6 International standards	FOPH, FOEN, SECO, FOAG, FSVO

¹⁴ These measures generally tie up significant resources and last for several years.

¹⁵ Pursuant to Art. 9 in connection with Art. 4 ChemA, <https://www.admin.ch/opc/de/classified-compilation/19995887/index.html>

¹⁶ See Glossary

	Title	Strategic Measures	Objectives	Involved federal authorities
M6	GHS implementation	GHS is implemented in Switzerland, taking into account the CLP Regulation of the EU and any future amendments.	Z2 Risk assessment and risk reduction Z6 International standards	FOPH, FOEN, SECO, FOAG, FSVO, NAChem
M7	Cooperation with the EU	The federal authorities perform the functions resulting from the existing MRA in the fields BP and GLP. They deepen the technical cooperation (participation in expert bodies etc.) with the EU Commission, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). The formal cooperation is extended, e.g. by a cooperation agreement with ECHA or through an agreement on the mutual recognition of authorisations for PPPs.	Z2 Risk assessment and risk reduction Z5 State of knowledge Z8 Appropriate and efficient enforcement	FOEN, FOPH, FOAG, FSVO, SECO, NAChem
M8	Authorisation procedures for SHVC	Chemical substances of very high concern (SHVC) are, as in the EU, subject to an authorisation procedure in order to promote the development of lower risk alternatives.	Z3 Substitution Z2 Risk assessment and risk reduction Z4 Sustainable chemistry	FOEN, FOPH, SECO, NAChem
M9	Promoting sustainable chemistry	Projects and initiatives are promoted especially by: <ul style="list-style-type: none"> • Networking the research institutes active in this field and the federal authorities. • Financial and content-related support of the <i>Global Chemical Leasing Programme</i> of UNIDO. • Promotion of a <i>Best Practice</i> for assessing chemical substitutes and alternatives. • Creation of an incentive system for the <i>Safe-by-Design</i> approach in the innovation phase.¹⁷ • Substitution of SVHC (see M8). • Supporting training and consultancy for a sustainable use. 	Z4 Sustainable chemistry Z3 Substitution Z2 Risk assessment and risk reduction	FOPH, FOEN
M10	WG endocrine active substances	A Working Group (WG) "Endocrine active substances" steps up the cooperation in this field and ensures that the relevant activities by the federal agencies are coordinated.	Z2 Risk assessment and risk reduction Z5 State of knowledge Z6 International standards Z7 Professional expertise and information of the controllers Z3 Substitution	FOEN, FOPH, FSVO, SECO, FOAG, Swissmedic
M11	Action plan PPP	The action plan of the Federal Council on Risk Reduction and Sustainable Use of PPPs contains ca. 50 specific measures in the following areas for action:	All objectives	FOAG, FSVO, FOEN, SECO, FOPH

¹⁷ In the framework of the Research and Innovation promotion by the Confederation, e.g. in the field of nanomaterials.

Title	Strategic Measures	Objectives	Involved federal authorities
	<ul style="list-style-type: none"> • Existing risks are specifically reduced. • Independently of the risk, the potential for reducing the use of PPPs and their emission levels is used. • New possibilities are developed in order to reduce the uses of PPPs and their emission levels. • An improved understanding of the effects and sustainable use of PPPs. 		
M12 Action Plan Synthetic Nanomaterials	The action plan Synthetic Nanomaterials of the Federal Council contains a catalogue of measures in order to fill in methodological and legal gaps in the field of nanomaterials.	All objectives	FOEN, FOPH, FOAG, SECO, FSVO, NACHEM
M13 Support for SCAHT and Ecotox Centre	The strategic monitoring group of the Confederation for the Swiss Centre for Applied Human Toxicology (SCAHT) and the advisory group for the Ecotox Centre shall encourage these two Centres to support the involved federal authorities in the implementation of the Chemicals strategy.	Z5 State of knowledge Z6 International standards Z2 Risk assessment and risk reduction	FOEN, FOPH, SECO, FSVO, FOAG, Swiss-medico
M14 Development of risk evaluation methodologies	Harmonised alternative test methods as well as new assessment approaches shall be developed for the risk evaluation of chemicals. Development shall be realised by cooperating in particular with SCAHT, Ecotox Centre, Agroscope and the planned 3R Competence Centre as well as with the OECD, with the <i>European Union Reference Laboratory for alternatives to animal testing</i> (EURL-ECVAM), with ECHA and EFSA.	Z5 State of knowledge Z6 International standards Z2 Risk assessment and risk reduction	FOPH, FOEN, FOAG, SECO, FSVO
M15 Impact of chemicals policy	The involved federal authorities shall identify and describe indicators enabling to estimate the impact of the Swiss Chemicals Policy on the environment and health. Ongoing activities and initiatives of WHO, UNEP, OECD and the EU shall be supported, when possible, by Swiss projects and activities (see M16–18).	Z5 State of knowledge Z2 Risk assessment and risk reduction Z6 International standards	FOEN, FOPH, SECO, FOAG, FSVO
M16 Influence of chemicals on diseases	Knowledge about relationships between certain diseases and exposure to chemicals shall be deepened. Ongoing work and initiatives of WHO shall be supported (see M15, M17).	Z5 State of knowledge Z2 Risk assessment and risk reduction	FOPH, SECO
M17 National HBM study	The setup of a national Human biomonitoring Study (HBM Study) that <i>inter alia</i> contains a collection of health data and human biological samples. This should enable relationships between exposure to chemicals, nutrient deficiencies and behaviours and the occurrence of illnesses to be investigated. The project is integrated into the HBM Research project of the EU (HBM4EU).	Z5 State of knowledge Z2 Risk assessment and risk reduction	FOPH, FSVO, SECO

Title	Strategic Measures	Objectives	Involved federal authorities
M18 Environmental Specimen Bank	The federal authorities shall carry out a feasibility study for the creation of an Environmental specimen bank, while taking into account existing monitoring programmes.	Z5 State of knowledge Z2 Risk assessment and risk reduction	FOEN, FOAG
M19 Identifying new risks	The federal authorities draw up suitable procedures in order to swiftly identify chemical-related risks to the environment and health (e.g. using expert hearings, systematic screening of scientific literature, indications from other countries, findings from their own observations).	Z5 State of knowledge Z2 Risk assessment and risk reduction Z6 International standards	FOPH, FOEN, SECO, FOAG, FSVO
M20 Information and advising	The federal authorities inform, support and advise in particular manufacturers, downstream users, the general public and the enforcement authorities.	Z7 Professional expertise and information of the controllers Z8 Appropriate and efficient enforcement Z2 Risk assessment and risk reduction	NACem, FOPH, FOEN, SECO, FOAG, FSVO
M21 Information on environmental figures	The federal authorities inform the public of the emissions of pollutants in air, water and land as well as of waste transfers.	Z6 International Standards Z8 Appropriate and efficient enforcement	FOEN
M22 Education	<p>Aspects of chemical safety and sustainable use are promoted in schools (compulsory primary and secondary schools), in vocational education, higher professional education and in professional further education, in particular by:</p> <ul style="list-style-type: none"> • Supporting the teachers with teaching materials/modules on chemical safety which are oriented towards the Swiss curriculums <i>Lehrplan 21</i> (discipline NPS Nature, People, Society; competence area NPS 3) and <i>Plan d'Études Romand</i>. • Recommendations for the revision or new development of educational ordinances and educational curricula for vocational basic education and of examination regulations and guidelines in the higher vocational training. • Defining the requirements for obtaining special licences for the use and of expertise for the delivery of certain chemicals. 	Z7 Professional expertise and information of the controllers Z2 Risk assessment and risk reduction Z4 Sustainable chemistry	FOEN, FOPH, SECO, FOAG, FSVO

	Title	Strategic Measures	Objectives	Involved federal authorities
M23	International chemicals policy	The federal authorities collaborate on international programmes and regulations (e.g. with SAICM, UNEP, UNECE, WHO, OECD).	Z6 International standards	FOPH, FOEN, FSVO, SECO
M24	Good laboratory practice	The federal authorities coordinate and harmonise GLP-relevant aspects in national and international fields and ensure the monitoring of certain GLP test facilities. The principle of mutual acceptance of data (MAD) ¹⁸ in the context of the OECD is supported.	Z6 International standards Z8 Appropriate and efficient enforcement	FOPH, FOEN, Swissmedic, NACChem
M25	Market surveillance	Controls are carried out in order to monitor the actions of the parties, and to ensure the legality of the actions. In particular, the compliance with self-regulation, notification obligations, registration obligations and authorisation requirements are controlled.	Z8 Appropriate and efficient enforcement Z1 No data – no market Z2 Risk assessment and risk reduction Z7 Professional expertise and information of the controllers	FOEN, FOPH, FOAG, SECO, NACChem
M26	Improving the enforcement	Enforcement of the chemicals legislation is evaluated and if needed, adapted, also in regard to the utilisation of synergies from international collaboration.	Z8 Appropriate and efficient enforcement Z2 Risk assessment and risk reduction Z4 Sustainable chemistry	FOPH, FOEN, SECO, FOAG, FSVO, NACChem
M27	IT support in implementation	IT instruments will be developed and employed which are compatible with the development of international (e.g. IUCLID, R4BP) and national Standards (e.g. Chemicals Product Register). An e-administration will be developed for the processing and should contribute to an increased efficiency.	Z8 Appropriate and efficient enforcement Z2 Risk assessment and risk reduction	NACChem, FOPH, FOEN, SECO, FOAG, FSVO
M28	Reporting obligation for chemicals	Manufacturers are obliged to report the most important information on their chemical substances and preparations to the National Product Register. This register serves in particular in an advisory capacity for the information centre for poisoning emergencies (<i>Tox Info Suisse</i>).	Z8 Appropriate and efficient enforcement Z2 Risk assessment and risk reduction	NACChem, FOPH, FOEN, SECO, FOAG
M29	Stakeholder groups	A regular exchange takes place with the most important stakeholder groups (<i>inter alia</i> cantonal enforcement authorities, unions, industrial and trade associations as well as consumer protection and environmental associations).	Z7 Professional expertise and information of the controllers Z8 Appropriate and efficient enforcement Z2 Risk assessment and risk reduction Z3 Substitution Z4 Sustainable chemistry	FOEN, FOPH, FOAG, FSVO, SECO, NACChem

¹⁸ See Glossary

3. Implementation

A regular report on the implementation of the chemicals legislation must be submitted to the Federal Council.¹⁹ These reports shall also take into account the status of achievement of the objectives. The chemicals and PPP steering committee²⁰ is responsible for the implementation of the Chemical Safety Strategy. When implementing the measures other federal strategies have to be taken into account. Any conflict of objectives has to be solved by balancing of interests.

3.1. Targets and indicators

With regard to the implementation of the strategy the strategic objectives are made operational with target values, and indicators are assigned to each target value. This enables the achievement of the intended medium-term objectives to be measurable and verifiable.

Table 3: Target values for the period 2017–2020

No	Strategic target	Target(s) 2017–2020	Indicators
Z1	No data – no market	The intrinsic properties for all chemicals (as such and in articles) used in Switzerland are known. The chemicals (as such) are correspondingly classified and labelled, and the manufacturers divulge the relevant safety information in the safety data sheets to the professional or commercial users.	Results of controls
		A notification requirement is introduced for substances that are placed on the market in amounts of ≥ 1 tonne/year and not registered in the EU.	Qualitative (met, partially met, not met)
		The notification requirement for substances that are placed on the market in amounts of ≥ 1 tonne/year is extended to synthetic nanomaterials.	Qualitative (met, partially met, not met)
		All substances, which require notification, as well as PPPs and BPs have been legally placed on the Swiss market (also applies to Z2).	Results of controls
Z2	Risk assessment and risk reduction	Only those chemicals that have been assessed with regard to their risks to the human health and the environment are placed on the Swiss market. Necessary risk reduction measures have been put in place. Manufacturers fulfil the self-regulation obligations.	Results of controls
		The placing on the market and the use of substances with unacceptable risks for the environment and health are adequately restricted.	Qualitative (met, partially met, not met) Compare the Swiss regulations with EU law (<i>inter alia</i> REACH ²¹ Annex XVII) and international agreements
		Switzerland participates in international programmes and initiatives for the risk assessment of certain chemical substances.	Qualitative (met, partially met, not met)
		In the Swiss chemicals legislation the criteria for identifying endocrine disruptors are defined. They	Qualitative (met, partially met, not met)

¹⁹ Reporting for 2013-2016 is currently under preparation; the next reporting period will cover 2017-2020.

²⁰ See Annex II

²¹ See Glossary

No	Strategic target	Target(s) 2017–2020	Indicators
		are harmonised with the EU. The criteria serve as the basis for risk management decisions.	
		The sales restrictions for chemicals take into account the findings from current cases of poisoning.	Qualitative (met, partially met, not met)
		Measures have been adopted for risk reduction when chemicals are correctly used and against their unintended use.	Qualitative (met, partially met, not met)
Z3	Substitution	Substances of very high concern (SVHC) are substituted (also applies to Z4).	Qualitative (met, partially met, not met) Compare the Swiss regulations with REACH Annex XIV
		Procedures for comparative evaluation are used for BPs and PPPs, which contain an active substance to be replaced (substitution candidates).	Qualitative (met, partially met, not met)
Z4	Sustainable chemistry	The principles of sustainable chemistry are taken into account in research, development, production and application.	Qualitative (met, partially met, not met)
		The aspect of chemical safety is increasingly considered in funded innovation projects (e.g. from Innosuisse ²² in the field of nanotechnology or from UNIDO in the field of chemical leasing).	Quantitative: Proportion of the funded projects with modules for chemical safety Assistance in CHF for such projects
		Networking between stakeholders in commerce and industry, science and with the authorities serves the transfer of knowledge and enables a coordinated support of sustainable processes and applications.	Qualitative (met, partially met, not met)
Z5	State of knowledge	Research to clarify mechanisms of action of substances is supported (Adverse Outcome Pathways AOP).	Qualitative/Quantitative: Number of proposals introduced into the OECD working groups
		Switzerland participates in the Test Guideline Programme of the OECD in the development of testing guidelines that are based on alternative and animal-friendly methods.	Qualitative/Quantitative: WNT project (co-)chaired by Switzerland Participation of Switzerland in commenting on new/revised testing guidelines
		First proposals for indicators for the evaluation of the effects of chemicals management on health and the environment are put forward.	Qualitative (met, partially met, not met)
		The chemicals legislation is based on the current state of knowledge.	Qualitative (met, partially met, not met)
		Switzerland participates in scientific committees for the further development of knowledge in the field of safety and sustainable use of chemicals.	Qualitative: Projects at national and international level, in which Switzerland participates or which are (co-)financed by Switzerland

²² <https://www.kti.admin.ch/kti/de/home/ueber-uns/Innosuisse.html>

No	Strategic target	Target(s) 2017–2020	Indicators
.		A national cohort (see M17) has been launched regarding a national human biomonitoring programme.	Qualitative (met, partially met, not met)
Z6	International Standards	Switzerland contributes to international resolutions, conventions, guidelines etc. in the field of chemicals and also campaigns internationally for their implementation. All the UN conventions and resolutions ratified by Switzerland as well as OECD Council decisions which relate to chemicals legislation are adopted into Swiss law and implemented. The SAICM guidelines for the prudent risk management of chemicals are observed.	Qualitative (met, partially met, not met)
Z7	Professional expertise and information of the controllers	The manufacturers of chemicals meet their self-regulation obligations ²³ (see target Z1 and Z2).	Results of controls
		Non-confidential data from the notification dossier for chemical substances are accessible to the public.	Qualitative (met, partially met, not met)
		Professional and industrial users, who are active in the fields of bathing water disinfection, pest control, use of plant and wood protection products as well as in handling coolants, have the required special licences and training.	Results of controls
		All dealers who supply certain hazardous chemicals (see Annex 5 ChemO) have the required technical expertise. They inform the recipients on the correct handling.	Results of controls
		The basic elements for the safe handling of chemicals are included in the education ordinance and educational curricula. This also relates to the vocational basic education in professional categories, which need the handling of chemicals that are generally prohibited for adolescents.	Quantitative: number of educational curricula that meet the requirement Qualitative (met, partially met, not met)
Z8	Appropriate and efficient enforcement	The pre- and post-market implementation of the chemicals legislation is evaluated in regard to its efficiency. Possible measures for optimising the procedures and cooperation (within the Confederation and between the Confederation and the cantons) have been introduced.	Qualitative (met, partially met, not met)
		The chemicals legislative requirements for companies and their products are checked by the competent authorities by means of spot checks.	Results of the spot checks
		Switzerland participates in international priority projects to control companies and products.	Qualitative (met, partially met, not met)

²³ See Glossary

Annex

Annex I: Matrix of Objectives and Measures

In the following table, the measures applicable to each objective are shown. Dark coloured measures provide a major contribution, lightly coloured measures provide a complimentary contribution to the achievement of the objective.

Table 4: Matrix of Objectives and Measures

	Z1	Z2	Z3	Z4	Z5	Z6	Z7	Z8
	No data – no market	Risk assessment and risk reduction	Substitution	Sustainable chemistry	State of knowledge	International Standards	Professional expertise and information of the controllers	Appropriate and efficient enforcement
M1	Obligation to notify							
M2	Modernising chemicals legislation							
M3	Authorisation procedures for PPPs and BPs							
M4	Risk assessment of selected chemicals							
M5	Restriction of certain chemicals							
M6	GHS implementation							
M7	Cooperation with the EU							
M8	Authorisation procedures for SHVC							
M9	Promoting sustainable chemistry							
M10	WG endocrine active substances							
M11	Action plan PPP							
M12	Action Plan Synthetic Nanomaterials:							
M13	Support by SCAHT and EcoTox Centre							
M14	Development of risk assessment methodologies							
M15	Impact of the chemicals policy							
M16	Influence of chemicals on diseases							
M17	National HBM study							
M18	Environmental specimen bank							
M19	Identifying new risks							
M20	Information and advising							
M21	Information on environmental indicators							
M22	Education							
M23	International chemicals policy							
M24	Good laboratory practice							
M25	Market surveillance							
M26	Optimisation of the enforcement							
M27	IT support for the implementation							
M28	Reporting obligation for chemicals							
M29	Interest groups							

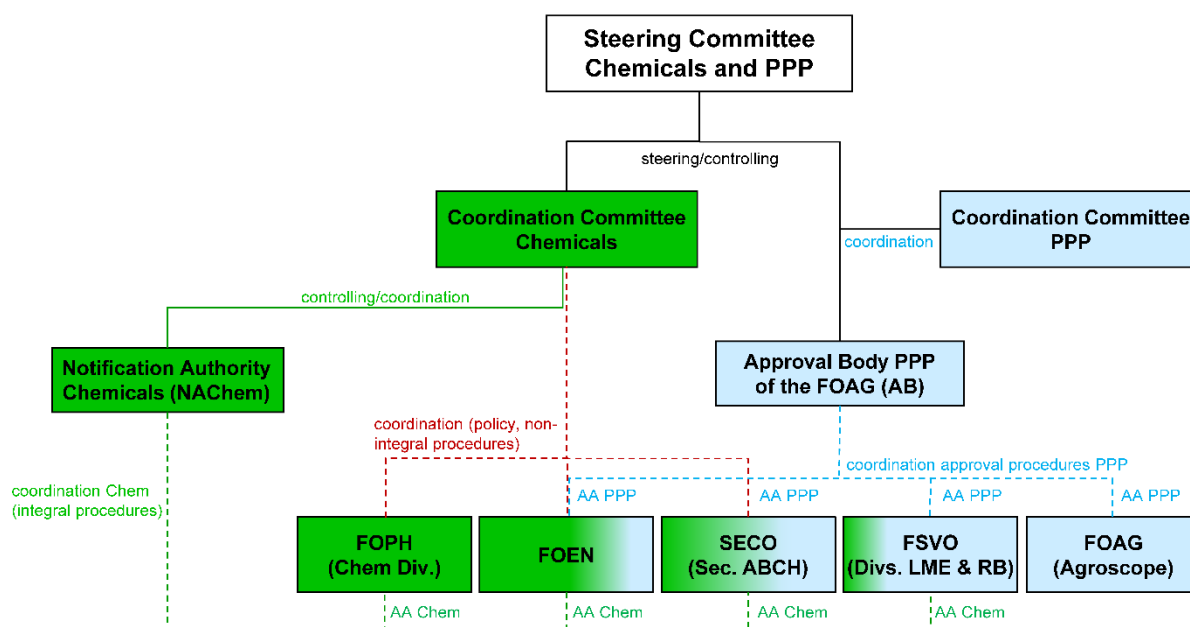
Annex II: Organisation of the Federal Implementation of the Chemicals Legislation

Essentially, six federal authorities are involved in the federal implementation of the chemicals legislation:

- Federal Office for the Environment (FOEN) for the interests of environmental protection and indirect health protection;
- Federal Office of Public Health (FOPH) for the interests of health protection;
- Federal Food Safety and Veterinary Office (FSVO) for the interests of food safety;
- Federal Office for Agriculture (FOAG) for specific interests in plant protection products;
- State Secretariat for Economic Affairs (SECO) for the interests of the protection of workers;
- Common Notification Authority for Chemicals (NAChem) of FOEN, FOPH and SECO, as the central authority for the notification and authorisation for industry.

The inter-agency implementation organisation can be described schematically as follows:

Figure 3: Federal Implementation of the Chemicals Legislation



The **Steering Committee Chemicals and Plant Protection Products** consists of the Directors of FOEN, FOPH, FSVO, FOAG and SECO. The activities of the steering committee in the framework of the chemicals implementation include:

- Defining and reviewing the strategy (see chapter 3),
- Managing the Notification Authority for Chemicals (NAChem) and the Authorisation Body for PPPs of the FOAG (AB),
- Managing the associated interdepartmental procedures.

The **Coordination Committee Chemicals** is composed of the Heads of the specialist departments, the specialist fields and the departments of the FOPH, the FOEN and SECO as well as of NAChem. The Heads of the specialist departments of the FOAG and FSVO have observer status. The activities of the Coordination Committee are:

- Supervision of the NAChem (controlling: achievement of objectives, budget, strategy), reporting to the Steering Committee, de-escalation of disputes between the involved federal authorities.
- Organisational coordination of the interdepartmental implementation procedures (notification, registration, authorisation) that are handled by the NAChem.

- Coordination of additional activities of the involved federal authorities in connection with the implementation of the chemicals legislation, in particular coordinating strategies in the chemicals implementation, technical and legal coordination of the chemicals legislation.

The **Common Notification Authority for Chemicals (NACChem)** of FOPH, FOEN and SECO, is the central authority for the notification and authorisation for industry. NACChem processes all notifications of existing hazardous substances and preparations as well as applications for registrations of new substances and for biocidal product authorisations.

The **Coordination Committee PPP** consists of the Heads and the Coordinators of the specialist departments of the FOAG, the FOEN, the FSVO and SECO as well as of the AB. The specialist department of the FOPH has observer status. The activities of the Coordination Committee PPP are limited to the coordination of specialised and strategic questions in connection with the implementation of the Plant Protection Products Ordinance (PlantPPO).

The **Approval Body PPP of the FOAG (AB)** is the central implementation organ for the approval of PPPs. It handles the applications from companies for the approval of PPPs.

In the involved federal authorities the specialist departments or specialist disciplines are responsible as the **Assessment Authorities (AA)** for handling the applications from the relevant specific specialist perspective.

Glossary

3R Principles	The application of the principles of the 3Rs – <i>Replacement, Reduction and Refinement</i> – is intended to limit animal testing to the absolute minimum and to distress the animals as little as possible. Replace means replacing animal testing with alternative methods, Reduce means fewer animal tests, and Refinement means that the stress on the tested animal is reduced.
Agenda 2030	The Agenda 2030 for sustainable development contains 17 objectives (<i>Sustainable Development Goals</i> , SDGs) on various topics such as overcoming extreme poverty and hunger, education, health, water etc. Implications for chemical safety result from <i>inter alia</i> Objective 2 Sustainable Agriculture, and from Objective 3 Healthy life for all people.
Biocidal products	Chemicals for use against harmful organisms.
Chemicals Management	Processes, standards and framework conditions which allow social benefits to be realised from the use of chemicals, without any negative effects to the environment or to human health.
CLP Regulation	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. The EU introduced the GHS with the CLP Regulation.
Comparative Assessment	The concept of comparative assessment provides that active substances (in the case of PPP or BP), which although fulfilling all legal requirements, nevertheless have certain unfavourable properties for health and the environment, are to be declared as “candidates for substitution”. Plant protection products and biocidal products with such substitution candidates may only be authorised for use when no economic and feasible alternatives exist that are significantly safer for humans and the environment.
GHS	Global harmonised system for the classification and labelling of chemicals
GLP	Good Laboratory Practice regulates the implementation of safety checks for chemical products.
MAD	The OECD decision on the mutual acceptance of data (MAD) stipulates that data obtained from tests on chemicals in an OECD Member State according to the OECD testing guidelines and to the OECD basic principles of Good Laboratory Practice are accepted in other Member States for the purposes of the protection of human health and of the environment.
MRA	Agreement between the EU and Switzerland on the mutual recognition of conformity assessments.
Plant protection product	Chemicals used to combat diseases, pests and weeds in crops.
REACH	REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals and regulates the handling of chemicals in the EU.
SAICM	The global chemicals strategy SAICM (<i>Strategic Approach to International Chemicals Management</i>) is a framework agreement which aims to promote the sustainable management of chemicals.
Self-regulation	The responsibility and liability for correctly placing the majority of chemical products on the market lies entirely with the relevant manufacturers. The principle of self-regulation applies. In the context of self-regulation the manufacturer must ensure that its products do not harm human

health or the environment. In particular, the manufacturer must classify, package and label the products based on their properties, and compile exposure scenarios and a safety data sheet (see also Art. 5 ChemA, Art. 5 ChemO).

Sustainable chemistry

The endeavour when handling chemical substances in industry and laboratory, when manufacturing and using chemical substances and products, to protect the environment and its resources, in that fewer environmentally harmful chemical compounds are employed. At the same time the compounds used should be wholly returned again into the material cycle and processes with a low energy consumption should be applied.

Unacceptable risk

The decisive issue of risk management is whether the acceptance of the risk can be justified and the risk in this sense is "reasonable". In chemicals management this decision is mainly supported by the existence of scientifically founded effect thresholds, below which harm to health or damages to the environment are not expected. An unacceptable risk results from the use of a substance and if thereby an exposure occurs which exceeds the effect threshold. This simple concept of the "qualitative evidence" of risk differs from the "quantitative risk assessment" or "risk-benefit analysis" which are used in other technical fields and also in chemicals management when threshold values cannot be derived (e.g. frequently for CMR substances).

Abbreviations

AA	Assessment Authorities
AB	Authorisation Body for PPPs
AgricA	Federal Act on Agriculture (Agriculture Act)
AOP	Adverse Outcome Pathways
BP	Biocidal products
ChemA	Federal Act on Protection against Dangerous Substances and Preparations (Chemicals Act)
ChemFO	Ordinance on Fees for the Federal Enforcement of the Chemicals Legislation (Chemicals Fees Ordinance)
ChemO	Ordinance on Protection against Dangerous Substances and Preparations (Chemicals Ordinance)
ChemPICO	Ordinance on the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Chemicals in International Trade (PIC Ordinance)
CHF	Swiss Francs
CLP	Classification, labelling and packaging ²⁴
DETEC	Federal Department of the Environment, Transport, Energy and Communications ECHA European Chemicals Agency
ECVAM	European Centre for the Validation of Alternative Methods
FDHA	Federal Department of Home Affairs
EFSA	European Food Safety Authority
EPA	Federal Act on the Protection of the Environment (Environmental Protection Act)
EU	European Union
EURL-ECVAM	European Union Reference Laboratory for alternatives to animal testing
FOEN	Federal Office for the Environment
FoodA	Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act)
FOPH	Federal Office of Public Health
FOAG	Federal Office for Agriculture
FSVO	Federal Food Safety and Veterinary Office
GHS	Globally Harmonized System of Classification and Labelling of Chemicals ²⁴
GLP	Good Laboratory Practice ²⁴
ILO	International Labour Organization
IUCLID	International Uniform Chemical Information Database
MRA	Mutual Recognition Agreement ²⁴
NAChem	Notification Authority for Chemicals
OBP	Ordinance on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products)
OECD	Organisation for Economic Cooperation and Development
OGLP	Ordinance on Good Laboratory Practice
ORRChem	Ordinance on Risk Reduction related to the Use of certain particularly dangerous Substances, Preparations and Articles (Ordinance on Chemical Risk Reduction)
PIC	Rotterdam Convention on the Prior Informed Consent
PlantPPO	Ordinance on the Placing on the Market of Plant Protection Products (Plant Protection Products Ordinance)
POP	Persistent organic pollutants
PPP	Plant protection product
PRTR	Pollutant Release and Transfer Register

²⁴ See also Glossary

PRTR	Ordinance on the Register relating to Pollutant Release and the Transfer of Waste and of Pollutants in Waste Water (PRTR Ordinance)
R4BP	Register for Biocidal Products
REACH	Registration, Evaluation, Authorisation and Restrictions of Chemicals ²⁴
SAICM	Strategic Approach to International Chemicals Management ²⁴
SCAHT	Swiss Centre for Applied Human Toxicology
SECO	State Secretariat for Economic Affairs
SVHC	Substances of Very High Concern
TBA	Federal Act on Technical Barriers to Trade
UN	United Nations
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
WG	Working group
WHO	World Health Organization
WNT	Working Group of National Coordinators of the OECD Test Guidelines Programme
WPA	Federal Act on the Protection of Water against Pollution (Water Protection Act)