Federal Act on Protection against Dangerous Substances and Preparations

(Chemicals Act, ChemA)

of 15 December 2000 (Status as of 1 January 2017)

The Federal Assembly of the Swiss Confederation,

based on Articles 95 paragraph 1, 110 paragraph 1 letter a and 118 paragraph 2 letter a of the Federal Constitution[1],
and having considered the Dispatch of the Federal Council dated 24 November 1999[2],

ordains:

Chapter 1 General Provisions and Principles

Section 1 General Provisions

Art. 1 Purpose

This Act is intended to protect the lives and health of human beings against harmful effects arising from substances and preparations.

Art. 2 Scope

[1] This Act applies to the handling of substances and preparations.

[2] The handling of microorganisms is deemed equivalent to the handling of substances and preparations in so far as they are used in biocidal products or plant protection products.

[3] The Federal Assembly may by means of an ordinance extend the scope of this Act or of individual provisions to include:

a. organisms that have, or may have, dangerous properties within the meaning of this Act;

b. the protection of the lives and health of farm and household animals.

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1 SR **101**
2 BBl **2000** 687

4 The Federal Council shall provide for exemptions from the scope or from individual provisions of this Act in cases where:

a. lives and health are adequately protected by other federal legislation against harmful effects arising from substances and preparations;

b. substances and preparations are intended solely for through transit or export;

c. general defence or the tasks of the police and customs authorities necessitate such exemptions.

Art. 3 Dangerous substances and preparations

1 Substances and preparations are deemed dangerous if they are capable of presenting a hazard to life or health as a result of physico-chemical or toxic effects.

2 The Federal Council shall specify the properties deemed dangerous and define categories of danger.

Art. 4 Definitions

1 In this Act:

a. *substances* means chemical elements and their compounds in the natural state or obtained by any production process. A distinction is drawn between existing and new substances:
   1. substances shall be deemed to be existing substances if they are designated as such by the Federal Council,
   2. all other substances shall be deemed new;

b. *active substances* means substances and microorganisms including viruses which on account of their action are designed to be used as biocidal products or plant protection products;

c. *preparations* means mixtures or solutions composed of two or more substances;

d. *biocidal products* means active substances and preparations that are not plant protection products and which are designed to:
   1. deter, render harmless, destroy or otherwise control harmful organisms, or
   2. prevent damage from being caused by harmful organisms;

e. *plant protection products* means active substances and preparations that are designed to:
   1. protect plants and plant products against harmful organisms or prevent the action of such organisms,
   2. influence the life processes of plants other than as a nutrient,
   3. preserve plant products,
   4. destroy unwanted plants or parts of plants, or
   5. control the undesired growth of plants;

f. *manufacturer* means any natural or legal person who, by way of profession or trade, produces or extracts substances or preparations, or imports them for professional or commercial purposes;

g. *notifier* means any natural or legal person who notifies new substances to the notification authority, submits documentation on existing substances under review, or requests authorisation for active substances or preparations;

h. *notification authority* means the federal authority that receives in particular notifications of new substances, documentation on existing substances under review, or requests for authorisation for active substances and preparations, as well as other submissions, coordinates the procedures and issues the necessary rulings;

i. *placing on the market* means providing for or supplying to third parties and importing for professional or commercial purposes;

j. *handling* means any activity in connection with substances or preparations, in particular, production, import, export, placing on the market, storage, keeping, transport, use or disposal.

2 The Federal Council may define more precisely the terms specified in paragraph 1, as well as other terms used in this Act, draw further distinctions, and, in the light of new scientific and technological knowledge and in line with international developments, make adjustments and grant exemptions.

Section 2
Principles for the Handling of Substances and Preparations

Art. 5 Self-regulation

1 Any manufacturer who places substances or preparations on the market shall be responsible for ensuring that they do not endanger life or health. In particular, the manufacturer shall:

a. assess and classify substances and preparations according to their properties;

b. package and label them in accordance with the type of hazard concerned.

2 The Federal Council shall issue regulations on the nature, extent and review of self-regulation. In particular, it shall specify:

a. test methods, the principles of Good Laboratory Practice (GLP) and the criteria for assessment and classification;

b. packaging and labelling requirements.

Art. 6 Placing on the market

Having completed the appropriate self-regulation procedures, the manufacturer shall be entitled to place substances and preparations on the market without the prior consent of the authorities. The following exceptions apply:

a. notification is required for placing new substances on the market as such or as a constituent of a preparation (Art. 9);

b. authorisation is required for placing biocidal products or plant protection products on the market (Art. 10 and 11).

Art. 7 Obligation to inform purchasers

[1] Any person who places substances or preparations on the market must inform purchasers about properties and hazards relevant to health, and about the appropriate precautions and protective measures.

[2] The Federal Council shall issue regulations concerning the nature, content and scope of such information, in particular the distribution and content of a safety data sheet.

Art. 8 Duty of care

Any person involved in the handling of substances or preparations must pay due regard to their dangerous properties and take any measures necessary to protect life and health. In particular, due consideration must be given to the relevant information provided by the manufacturer.

Chapter 2
Notification of and Authorisation for Specific Substances and Preparations

Art. 9 Notification of new substances

[1] The notification authority shall review and assess the documents submitted in conjunction with the federal authorities responsible for the technical matters in question (assessment authorities) and shall inform the notifier of the outcome within a period specified by the Federal Council.

[2] A substance for which notification has been submitted may be placed on the market if the notification authority has accepted the notification or if it has not requested any further documents or information concerning the notification within the above-mentioned period.

[3] The Federal Council shall issue regulations on the requirements and the procedure for the notification of new substances. It shall specify any exemptions from mandatory notification, taking into account in particular the intended use, the type of substance or preparation and the quantities that are to be produced or placed on the market.

Art. 10 Authorisation for biocidal products

[1] The notification authority shall review and assess the documents submitted in conjunction with the assessment authorities and shall issue its decision – taking the

risk assessment into consideration (Art. 16) – within a period specified by the Federal Council.

2 Authorisation shall be granted for a biocidal product in particular if, when used as intended:

a. it is sufficiently effective;

b. it does not have any unacceptable adverse effects on the health of humans or of farm or household animals.

3 Authorisation may be withheld or revoked if the health risks give rise to concern and if another active substance is available for which authorisation has been granted for biocidal products of the same type, which is associated with a considerably lower health risk and which does not entail any significant economic or practical disadvantages for users.

4 The Federal Council shall specify the types of authorisation and the authorisation procedures, as well as any exemptions from mandatory authorisation for biocidal products. Authorisation shall be granted for limited periods.

Art. 11 Authorisation for plant protection products

1 Authorisation shall be granted for a plant protection product in particular if, when used as intended, it does not have any unacceptable adverse effects on the health of humans or of farm or household animals.

2 In other respects, the types of authorisation and the authorisation procedures, as well as any exemptions from mandatory authorisation for plant protection products, shall be determined by the relevant agricultural legislation. When issuing the appropriate implementing regulations, the Federal Council shall give due consideration to the protection of health within the meaning of this Act.

Art. 12 Obligation to request information in advance

Before notifiers conduct the animal experiments required for notification or authorisation, they must enquire at the notification authority as to whether the substance or preparation concerned has already been notified or authorisation has already been granted.

Art. 13 Second notification and second authorisation

1 Notification or authorisation in accordance with Articles 9–11 shall also be required in cases where substances or preparations subject to mandatory notification or authorisation have already been notified by another notifier or authorisation has already been granted to another notifier.

2 The Federal Council shall establish a special procedure for second notification or authorisation and, giving due consideration to the interests of the original notifier, shall specify the conditions under which:

a. the second notifier may refer to notification documents already submitted;