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Swiss Confederation

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Notification authority for chemicals

Guidelines for notification, reporting and declaration of new substances in accordance with the Swiss Chemicals Ordinance (ChemO SR 813.11).

2.3.2021

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1 Introduction

The provisions governing the obligation to notify, report and declare new substances are contained in the Ordinance on Protection against Dangerous Substances and Preparations (Chemicals Ordinance; ChemO, SR 813.11). Please note that the translation of the Chemical Ordinance is for your convenience only. Legal standard is the German, French or Italian version.
The ChemO https://www.admin.ch/opc/en/classified-compilation/20141117/index.html refers repeatedly to the provisions of the EU chemicals legislation, specifically to the following regulations, their annexes, amendments and adaptations:

- (EC) Regulation No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH Regulation**)
- (EC) Regulation No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (**CLP Regulation**)

2 General information on the requirement to notify substances

The obligation to notify a new substance that is placed on the market in Switzerland (according to article 4, paragraph 1, letter i of the Chemicals Act, ChemA) in quantities of 1 tonne or more per year is stated in article 24 ChemO.

- The manufacturer (the definition includes the importer) must **notify a new substance before it is placed on the market for the first time in Switzerland**.
- The notifier (manufacturer, importer or only representative) must have his habitual residence, registered office or subsidiary in Switzerland.

A new substance must be notified not only as such or as a component of a preparation, but also if it forms part of an object[1] from which it can be released when used under normal or reasonably foreseeable conditions of use. Furthermore, the notification authority can require the notification of a substance contained in an object if it assumes that the substance can be released during the use of the object (article 24, paragraph 3, ChemO).

According to article 4, paragraph 1, letter a of ChemA, **new substances** are defined as those which are not existing substances. An existing substance is a substance registered under Article 5 REACH, with the exception of substances that:

[1] Object defined according to article 2, paragraph 2, letter a ChemO:
an article, consisting of one or more substances or preparations, which during production is given a special shape, surface or design which determines its end use function to a greater degree than does its chemical composition

1. are placed on the market in higher quantities than those registered in the European Economic Area (EEA)[2]; or
2. are registered exclusively as intermediates, insofar as they are not monomers[3]; (art. 2 par. 2 let. f ChemO).

As of 1 June 2008, substances that are imported or manufactured in the EU or EEA in quantities of 1 tonne or more per year per manufacturer or importer, must be registered with the European Chemicals Agency (ECHA, http://www.echa.europa.eu). Questions on REACH can be referred to the REACH Helpdesk:

REACH-Helpdesk
http://www.reach.admin.ch
Tel. +41 (0)58 465 12 53
reachhelpdesk@bag.admin.ch

- new substances are subject to notification regardless of classification (exemptions: art. 26 ChemO)
- new substances that are exempt from the obligation to notify must be reported when they are classified as dangerous or PBT or vPvB, nanomaterials purposefully containing fibres or tubes with a length of more than 5 µm.
- If a substance becomes subject to notification because it is no longer registered under Article 5 of the EU REACH Regulation, the manufacturer may continue to place it on the market without notification until the end of the calendar year which follows The Notification Authority may extend the period by a maximum of two years upon reasoned request.
- when a preparation has been reported to the chemical products register, new substances must be notified or reported nonetheless (or declared, as regards substances placed on the market for product and process-orientated research and development only)

Further guidance documents and help for interpretation are available here on New substances in a nutshell (admin.ch):

- Existing substances and new substances
- General map of obligations for substances
- Guidelines Reporting and Notifying new substances in RPC

The notification must be carried out by a natural person or legal entity resident or with an established place of business or subsidiary in Switzerland who intends to manufacture, obtain or import a new substance.

Article 2 paragraph 2 letter d ChemO states that a substance manufactured by **one** company head-quartered outside Switzerland may also be notified by an only representative with habitual residence, registered office or subsidiary in Switzerland. In addition to the usual technical dossier documents, the only representative must also submit an authorization from the foreign manufacturer and a list of all the importers whom it represents. The quantity of the new substance which is likely to be imported annually by each of the importers represented on the list must be stated.

[2] a substance may be placed on the market without notification up to a maximum of the upper limit of the registered quantity category. For example, if a substance is registered in the EU in the quantity category 10 -100 tons per year, it may be placed on the market in Switzerland up to a maximum of 100 tons per year without notification.

[3] a substance that is registered exclusively as an intermediate under strictly controlled conditions as defined in Art. 18 para. 4 of the EU REACH Regulation, i.e. without data on the physical, toxicological and ecotoxicological endpoints, may not be used for any other purpose in Switzerland without notification.

- The quantity that a manufacturer places on the market in Switzerland determines the scope of the technical dossier for a notification (see Annex I of these guidelines).
- The same quantity thresholds applicable to registration in the EEA also apply to the notification in Switzerland (1, 10, 100, 1000 t/year).
- The obligation to notify is generally applicable for quantities in Switzerland of more than 1 tonne per manufacturer or importer (exemptions from the obligation to notify in accordance with Article 26 Paragraph 1 Letter c).

The simple fact of exporting a new substance from Switzerland is not considered to be placing on the market as defined in Article 4, Paragraph 1, Letter i of the ChemA. Accordingly, if a new substance is manufactured in Switzerland and exclusively exported, the provisions for notification (Article 24 ff ChemO) do not apply, since these refer to placing on the market.

- The notification authority for chemicals must be informed of substances which do not have to be notified (art. 26 par. 1 let. d ChemO) and which are intended solely for process-orientated research and development (article 34 ChemO, see Chapter 10 of these guidelines).
- Substances which do not have to be notified but which are

a. classified as dangerous substances
b. PBT[4] or vPvB[5] (article 4 ChemO, see definition below);
c. in annex 3 ChemO (candidate list, substances of very high concern)
d. nanomaterials purposefully containing fibres or tubes with a length of more than 5 µm.
must be reported with the notification authority for chemicals (article 48 ChemO) unless they are listed as an exception under article 54 ChemO.

3 Use of Data from Previous Notifiers / Duty to establish prior notification / Use of existing test results

Use of Data from Previous Notifiers
If the Notification Authority notices that a new substance has already been notified in Switzerland, it communicates the names and addresses of previous notifiers to the notifier.
Pursuant to art. 29 ChemO, the Notification Authority may refer to data from a previous notifier instead of data produced by the notifier if:

- the new notifier proves with a letter of access from a previous notifier that the latter agrees to the Notification Authority consulting its data; or
- the data protection period (5 years after submission of additional information, 12 years after notification in Switzerland) has expired

The notifier must not refer to data from previous notifiers regarding:

- the identity and purity of the substance and the nature of any impurities;
- action to render the substance harmless.

Fee: 500 CHF

For a notification pursuant to art. 29 ChemV (notification by a further notifier) in principle a IUCLID substance export file must be submitted, completed as described in annex III of the present guidance, with the chapters 1-3. If no SDS is provided, chapter 11. Guidance on Safe Use (action to render the substance harmless) has to be completed additionally.

Publication
With reference to Article 73 paragraph 6 of the Chemicals Ordinance (ChemO), the notification authority for chemicals publishes data on notified substances,

[4] Substances are considered persistent, bioaccumulative and toxic (PBT) if they fulfil the criteria defined in Sections 1.1.1–1.1.3 of Annex XIII to the REACH Regulation.
[5] Substances are considered very persistent and very bioaccumulative (vPvB) if they fulfil the criteria defined in Sections 1.2.1 and 1.2.2 of Annex XIII to the REACH Regulation.

- which are in no case confidential according to Article 73 paragraph 5 ChemO[6]
- whose data protection period of 12 years has expired in accordance with Article 30 ChemO.

In the case of the latter, the notification authority for chemicals may use data from previous tests on vertebrate animals for the notification of a second notifier in accordance with Article 29 ChemO without compensation.

The manufacturer must use IUCLID 6 to create a PDF printout of her substance dataset ("create PDF" under "substance dataset") and send it to the notification authority for chemicals as follows:

1. confidential information is flagged as such by the notifier in its IUCLID 6 substance dataset (CBI flag, as when submitting a registration under REACH).
2. before creating the PDF printout, the settings shown in the screenshot below** are made:
- under "Flags for confidentiality" remove "CBI".
- leave "Data for which a confidentiality flag may be set, but it is not".
- under "Detail level of document fields" leave "fields marked "confidential"" empty
3. after creation, the manufacturers must carefully review the PDF excerpt again before sending it to the notification authority for chemicals.
4. the public excerpt will be published on the website of the notification authority for chemicals.

[6] The following are not deemed confidential under any circumstances:
a) the trade name;
b) the name and address of the person subject to notification, declaration or reporting requirements;
c) the physicochemical properties;
d) procedures for proper disposal, for possible recycling or reuse, and for other ways of rendering materials harmless;
e) the summary of results of toxicological and ecotoxicological tests;
f) the degree of purity of a substance and the identity of the impurities and additives that are relevant for classification;
g) recommendations regarding precautions during use and emergency measures in the event of an accident;
h) information that appears in the safety data sheet, with the exception of the identity of intermediates;
i) suitable analytical methods for determining the exposure of human beings and presence in the environment.

PDF/RTF Settings

Working Context: Complete table of contents

Include cover page

Included Annotations

Include annotations

Include legal entity

Include legal entity

Detail level of document fields

Detailed fields (e.g. needed for robust study summaries)

Fields marked "confidential"

Include fields with no value

Flags for confidentiality

Select information to be included*

Data for which a confidentiality flag may be set, but it is not.

press Esc to close

Flags for regulatory programme

Select information to be included*

- No regulatory purposes
- AU: AICIS
- CA: CEPA
- CA: PCPA
- EU: BPR
- EU: CLP
- EU: PPP
- EU: REACH
- JP: CSCL
- NZ: HSNO
- OECD: CoCAP
- US: EPA HPVC
- US: FIFRA
- US: TSCA
- other:

Reduced category content

Reduced category content

Select documents to be included

Create PDF

Create RTF

Mandatory advance enquiries
Article 31 ChemO requires all further notifiers to establish whether the substance has already been notified before any studies involving vertebrates are carried out. In this procedure, the potential further notifier must demonstrate its justified interest to the notification authority for chemicals and enquire whether it is necessary to carry out animal studies, which must not be repeated.
A justified interest can be claimed, for example, if the requestor seriously intends to notify the substance.

If the notification authority for chemicals already has sufficient information on the substance and if none of the conditions pursuant to art. 29 par. 1^{bis} is met, it

a. tells previous notifiers about the data use intended by the new notifier, as well as its name and address
b. informs the new notifier about the names and adresses of the previous notifiers

For such a request, the substance quantity placed on the market must be submitted (art. 31 par. 2 ChemO), as well as substance identity information (described in annex 4 ChemO, which corresponds to section 2 of annex VI REACH).

Use of existing test results (art. 32 and 33 ChemO)
The first and the further notifier shall make every effort to reach an agreement on data sharing and compensation. They may obtain an arbitration opinion. Previous notifiers are entitled to adquate financial compensation from the second notifier for having had its data used.

If no agreement is reached, the new notifier can ask the notification authority for a decision about the level of the financial compensation. This request can be made 4 months after reception of the information pursuant to art. 31 par. 3 ChemO at the earliest. The new notifiers informs previous notifiers about the request. The notification authority issues the decision about the level of the financial compensation 60 days after reception of the request.

If an arbitration opinion is presented to them, it is binding for the notification authority, unless the parties raise objections pursuant to art. 189 par. 3 of the Swiss Civil Procedure Code. If there is no arbitration opinion, the notification authority particularly considers

a. the proven efforts made by the previous notifiers for obtaining the test results
b. the remaining data protection period for the data concerned

The notification authority uses data from previous tests on vertebrates for the notification pursuant to art. 24 ChemO, subject to other agreements between the notifiers, as soon as

a. the new notifier and the previous notifier have reached an agreement about data sharing and compensation or the notification authority has issued a decision
b. the new notifier has paid the compensation or has obligated himself to it by a signed promissory letter

4 Submission and processing of the technical dossier

The notifier must write the signed accompanying letter in an official language (German, French or Italian) and submit it on paper or electronically with certified signature (certified signature act, RS 943.03). The official language used by the notifier determines the language in which correspondence between it and the authority will be written. The other documents in the dossier may be written in English instead of an official language. Preferably, submit the notification using the E-application for chemicals (RPC): https://www.rpc.admin.ch/rpc/private/

Submit the technical dossier as an **IUCLID6 export file**. Preferably, upload it using the E-application for chemicals (RPC): https://www.rpc.admin.ch/rpc/private/

The data and documents that the technical dossier must contain are listed in Article 27 ChemO. They are the following:

a. the substance quantity placed on the market;

b. a technical dossier with the following details, listed in detail in annex 4:
   1. identity of the notifier,
   2. identity of the substance,
   3. information on manufacture and use,
   4. classification and labelling,
   5. guidelines on safe use,
   6. if applicable, an exposure assessment,
   7. robust study summaries relating to the physical and chemical properties,
   8. robust study summaries relating to harmful effects on people,
   9. robust study summaries relating to harmful effects on the environment;
c. if the quantity placed on the market per year is 10 tonnes or more: a chemical safety report according article 28;
d. a proposed safety data sheet in the case of dangerous substances or PBT or vPvB substances.
e. all available documentation and information on properties, exposure and harmful effects of the substance on people and the environment, unless these are already apparent from the technical dossier according to letter b.

For substances developed using genetic resources or with traditional knowledge related to them, the manufacturer must

- inform on his own initiative the notification authority
- indicate the registration number pursuant to art. 4 of the Nagoya Ordinance (NagO, RS 451.61 https://www.admin.ch/opc/en/classified-compilation/20150120/index.html), as a proof of the NagO notification submitted to FOEN https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/nagoya-protocol.htmlhttp://www.bafu.admin.ch/biotechnologie/13477/16459/index.html?lang=en

Letter a: The substance quantity that must be stated corresponds to the estimated quantity that is manufactured, imported or placed on the market in the calendar year of notification. If the notification is only submitted towards the end of the year (e.g. in November), the quantity for the next complete calendar year must be stated.

Letter b, section 6: *If the substance quantity placed on the market is less than 10 tonnes per year, a*

simplified exposure assessment is sufficient. If this quantity is exceeded, a comprehensive exposure assessment must be carried out as part of the chemical safety assessment (see letter c).

Letter b, sections 7-9: *A "robust study summary" according to article 2, paragraph 2, letter n, ChemO, is a detailed summary of the aims, methods, results and conclusions of a comprehensive test report, with information sufficient for an independent assessment of the test, such that, if possible, the comprehensive test report need not be consulted. Robust study summaries replace the full study reports and facilitate the assessment, provided they are of good quality. If this is not the case, full studies should be submitted and the authorities can ask the notifier to submit a full study report.*

Letter c: *A chemical safety report is required*

- *for new substances subject to notification and whose substance quantity placed on the market is 10 tonnes per year or more or if*
- *the chemical safety report is available in the EEA, provided that it can be obtained by the manufacturer with reasonable effort;*

The chemical safety report contains the chemical safety assessment according to the provisions of Annex I REACH. The chemical safety assessment comprises the following steps (article 28, ChemO):

a. human health hazard assessment;
b. physicochemical hazard assessment;
c. environmental hazard assessment;
d. PBT and vPvB assessment;
e. if the substance fulfils the criteria specified in Article 14 paragraph 4 REACH:
1. an exposure assessment covering all identified uses,
2. a description of the risks associated with all identified uses.

A chemical safety report is not required for new substances placed on the market in the form of preparations provided the concentration of the substance is below the following levels:
a. the cut-off values referred to in art. 11 (3) CLP
b. 0.1 percent by weight for PBT or vPvB substances.

***Letter d:** If the new substance is imported as such, a corresponding safety data sheet in accordance with the requirements of article 20, ChemO, must be submitted with the notification dossier if the substance is dangerous, PBT or vPvB. If the substance is imported in a preparation or in an object, the submission by the notifier of the manufacturer's safety data sheet is recommended.*

The notification must contain **all available documentation and information** on

- properties
- exposure and
- harmful effects

of the substance on people and the environment, unless these are already apparent from the technical dossier. If certain data cannot be submitted, **at least a dossier corresponding to the quantity placed onto the market in Switzerland must be submitted, together with all information the manufacturer disposes of.**

The notification authority can request the full study reports and, if available and procurable by the notifier with reasonable effort: robust study summaries or test reports exceeding the scope of the technical dossier and which are relevant to the assessment and to classification (article 27, paragraph 5, ChemO).

Submit the technical dossier as a **IUCLID 6 export file**. Consult Annexes I and III to these guidelines to find out which Chapters you need to complete.

The IUCLID software (International Uniform Chemical Information Database) can be obtained free of charge either as a standalone version or networked version (see chapter 6 of these guidelines). The electronic IUCLID export file (*.i6z) can simply be submitted electronically. Preferably, upload it using the E-application for chemicals (RPC): https://www.rpc.admin.ch/rpc/private/. A printout should not be sent in addition!

All data required should be entered in the mandatory notification form, i.e. in the relevant fields of IUCLID. The technical dossier must be submitted to the notification authority for chemicals. **Preferably, submit the notification using the E-application for chemicals (RPC):**
https://www.rpc.admin.ch/rpc/private/

The notification authority for chemicals will examine the dossier for formal completeness. This includes, for example, checking whether the test reports for non-clinical tests assessing properties dangerous for health or the environment that have been submitted have been produced in compliance with the principles of Good Laboratory Practice (GLP) as specified in the Good Laboratory Practice Ordinance (GLPO; SR 813.112.1).

The notification authority will only forward the dossier to the evaluation units (State Secretariat for Economic Affairs (SECO), the Federal Office of Public Health (FOPH) and the Federal Office of the Environment (FOEN)) if it is complete. It is therefore recommended that the notifier should first use the IUCLID **"working context" "validate" function** (setting of the quantity range according to the substance quantity placed on the market). See Chapter 6 of these guidelines.

The evaluation units will examine the aspects of the dossier for which they are responsible to see whether the data are complete and plausible in scientific terms and whether the test reports are based on tests as required by art. 43 ChemO.

If a test is neither recognised by the European Commission nor specified in the OECD testing guidelines, or the notifier can plausibly explain why a specified method is not suitable for determining a physical or chemical property of the substance, other test methods may be used. In this case, howev-

er, the notifier must be able to demonstrate that the tests produce valid results and that animal welfare has been taken adequately into consideration if animal studies are carried out (article 43, paragraph 3, ChemO).

Targeted risk assessment
Art. 16 ChemA stipulates that new substances subject to notification must undergo a targeted risk assessment, without indicating when this has to happen. Art. 37 par. 2 ChemO states more precisely that in specific cases a targeted risk assessment can be conducted during evaluation of notification data.

A targeted risk assessment often requires additional information and a delay of several months. Evaluation unit's experience has shown that there are particular situations where it is possible to assess a specific risk and to fix risk reduction measures during evaluation of notification data already. If for instance the dossier data indicate a positive mutagenicity and the foreseen use of the substance is not limited to a professional activity, then the authorities may prohibit the distribution to private users, at least as long as this property has not been better evaluated. If the authorities do have access to information that is not contained in the notification data, they may use them for risk assessment.

For the authorities as well as for the notifier, it is more efficient is the result of this targeted risk assessment is communicated in one single step, i.e. with the notification's acceptation (see art. 39 par. 2 ChemO). As stipulated in art. 16 ChemA, the notifier is informed about the proposed risked management measures and consulted, before a decision is taken. No further tests are requested (art. 16 par. 1 ChemA) at this stade of risk assessment so that the notification process be met, unless the notification dossier must be completed pursuant to art. 38 par. 2 ChemO.

Acceptation of the notification
If the dossier is incomplete or flawed, the notification authority for chemicals will request the notifier to remedy this situation (article 38 ChemO). If examination of the dossier shows that it is complete and adequate for assessing the dangers and risks associated with the substance, the notification authority for chemicals will decide to accept it in agreement with the evaluation units (article 39 ChemO).

If a targeted risk assessment was performed in parallel with evaluation of the notification dossier and if risk management measures have to be taken, they are indicated in the decision accepting the notification.

A **targeted risk assessment** can be performed in parallel with the evaluation of a notification. Risk management measures to be taken by the notifier are announced in the decision.

The authorities have a period of 60 days in which to examine a notification (article 40 ChemO). The period[7] begins on the day after the complete technical dossier is received by the notification authority for chemicals. It ends at the end of the last day of the period.

If the notification authority for chemicals does not decide to accept the notification or does not comment materially on the notification within the period of time mentioned before, the substance may be placed on the market once this period expires (article 40 letter b ChemO). If the authorities request supplementary data or documents, the period starts again.

[7] Article 22a of the Administrative Procedures Law (VwVG, SR 172.021)
Suspension of deadlines
Statutory and official deadlines which are determined in days are suspended:
a from the seventh day before Easter until and including the seventh day after Easter;
b from 15 July to 15 August inclusive;
c from 18 December to 1 January inclusive.

Once the procedure has been completed, the notifier will receive an invoice for the processing fee. The fee is determined by the amount of work performed by the authorities and is based on the Chemical Fee Ordinance (ChemGebV, SR 813.153.1). See annex II of the present guidance document.

During the first six years after the reporting, declaration or notification of a new substance, an alternative chemical name request is not necessary. After that, the chemical name pursuant to art. 18 (2) CLP must be used, or a request for using an alternative chemical name must be submitted (art. 14 and 15 ChemO).

5 IUCLID

In the EU, the IUCLID software is required for registering substances (Article 111 REACH). This program and all associated documents and supplementary databases can be downloaded free of charge from the following address:

http://https://iuclid6.echa.europa.euhttps://iuclid6.echa.europa.eu

Submit IUCLID export files (but not the write-protected dossier files, see Annex III of these guidelines) to the notification authority for chemicals preferably **using the E-application for chemicals (RPC):** https://www.rpc.admin.ch/rpc/private/

In **IUCLID use the "validate" function under "working context"** (setting of the quantity range according to the relevant substance quantity specified in Article 25 ChemO). Check the dossier for completeness prior to submission. As a result:
- the number of queries from the notification authority is minimized
- forwarding to the evaluation unitsis accelerated (the notification period begins on the day after receipt of the **complete** notification dossier at the notification authority for chemicals)
- the risk of a dossier being rejected due to missing data is reduced

Submit additional or supplementary test report summaries as an export file (allows the relevant endpoints to be imported).

In the event of problems with IUCLID, support is available from the REACH helpdesk

6 Good Laboratory Practice (GLP)

The ordinance on good laboratory practice (OGLP, RS 813.112.1) rules how tests comply with the requirements of Good Laboratory Practice. Pursuant to art. 13 OGLP, the following may be used to demonstrate compliance:

- A document showing that the tests were carried out by a testing body which at the time of testing was listed in the Swiss directory of testing bodies which comply with the principles of GLP;
- A signed test report (draft not acceptable) in which the study director confirms in an official language or in English that the test was carried out in compliance with the principles of GLP.

For notification dossiers with robust study summary but without study reports, copies of the Swiss or foreign GLP attestations must be **either attached in IUCLID or sent in separately**

If the test has been carried out in another country, the test report must be accompanied by a directory or certificate from the competent authority showing that the testing body was participating in the official monitoring programme at the time of testing. The notification authority for chemicals may request different documentation from countries which are not members of the Organization for Economic Cooperation and Development (OECD) if this documentation is necessary to evaluate compliance with the principles of GLP.

7 Supplementary information

In addition to the data provided when the notification is submitted, additional data and test reports may be necessary if certain volumes are exceeded.

Article 46 paragraph 1 letter b ChemO requires the notifier to inform the notification authority for chemicals immediately and unbidden in writing if the substance quantity placed on the market is expected to reach one of the quantity thresholds according to article 47, paragraph 1, ChemO (10 tons, 100 tons, 1000 tons or more per year, respectively). In this case the notifier must specify which tests it intends to carry out in order to produce the supplementary information (see table below). This corresponds to the provisions of the REACH Regulation and, particularly for tests on vertebrates, animal protection requirements. After receiving this information, the notification authority for chemicals shall inform the notifier about the relevant data already in its possession (article 32 and article 47, paragraph 2, ChemO). Once the tests have been specified, the authorities will draw up a timetable for the implementation of the additional tests after consulting the notifier and taking account of test programmes that are already under way in the EEA.

Article in the ChemO	**quantity placed on the market**	**Additional data and test reports**
Article 47, paragraph 1, letter a	for quantities of 10 tonnes or more per year	Information according to Annex 4, section 9, letter b and section 10, letter b, and a chemical safety report according to article 28
Article 47, paragraph 1, letter b	for quantities of 100 tonnes or more per year	Information according to Annex 4, section 8, letter b, section 9, letter c, section 10, letter c, and a chemical safety report according to article 28
Article 47, paragraph 1, letter c	for quantities of 1000 tonnes or more per year	Information according to Annex 4, section 9, letter d, section 10, letter d, and a chemical safety report according to article 28

Additionally to information submitted during notification or which are described in the technical dossier depending on the quantities placed on the market, all new information available must be submitted. Furthermore, unsolicited submission of documents concerning exposition and properties of the substance is mandatory (e.g. new robust study summaries, chemical safety report).

If the risks associated with a substance cannot be adequately evaluated, the notification authority will, if so requested by an evaluation unit, require the notifier to submit additional information or tests relating to the substance or its transformation products (article 47, paragraph 3 ChemO).

Supplementary to the above data and test reports, the notification authority for chemicals may request the notifier to provide individual or all test reports which exceed the scope of the technical dossier and which have been prepared or commissioned by the notifier or can be obtained with a reasonable effort.

Furthermore, article 46 paragraph 1 letters a and c to g ChemO stipulates that the notifier must inform the notification authority for chemicals immediately in writing if:

a. the following details, listed in detail in annex 4, ChemO, change:
    1. identity of the notifier,
    2. identity of the substance,

3. information on manufacture and use,
4. classification and labelling,
5. guidelines on safe use,
6. any implemented exposure assessment,

c. the substance quantity placed on the market has more than doubled or more than halved compared to the last notified quantity;
d. the notifier has new information about the effect of the substance on humans or the environment;
e. the notifier places the substance on the market for a new use, or is aware that the substance is being used for purposes that it has not disclosed to the notification authority;
f. the notifier produces, or commissions, test reports for the substance that exceed the scope of the technical dossier specified in article 27, paragraph 2, letter b;
g. it can obtain further test reports that exceed the scope of the technical dossier specified in article 27, paragraph 2, letter b.

In this context, only representatives and importers are required to fulfil the following obligations:

- The only representative must ensure that it has up-to-date information, particularly concerning the volumes of a substance which are imported annually by the importers whom it represents.
- Importers who use an only representative to notify a new substance must inform the latter on an annual basis of the volume of a substance which has been imported.

8 Reporting of new substances that are exempt from the obligation to notify

For dangerous or PBT, vPvB substances subject to a mandatory notification or declaration procedure, an additional reporting is not required. However, manufacturers of new substances that are exempt from notification according to article 26, ChemO (see Chapter 3 of these guidelines), must report these within 3 months after first placing them on the market and independently of the obligation to establish a SDS (art. 48, art. 19 ChemO):

a. dangerous substances
b. substances assessed as PBT or vPvB;
c. substances in annex 3 ChemO (candidate list)
d. nanomaterials purposefully containing fibres or tubes with a length of more than 5 µm. Materials with a water solubility of less than 100 mg per liter or with a half-life of 40 days or more in the lungs are considered being biopersistent.

The reporting must contain the following data:
a. the manufacturer’s name and address;
b. name of the person responsible for placing on the market in the EEA in accordance with art. 17 par. 1 let. a CLP, if the manufacturer’s identity is not mentioned on the label;
c. the chemical name according to art. 18 par. 2 let a-d CLP
d. the CAS number,
e. the EC number,
f. the classification and labelling;
g. uses
h. for substances dangerous to the environment: the annual quantity placed on the market
i. for nanomaterials:
- composition, particle shape and average particle size as well as, if available, particle size distribution, specific surface to volume ratio, surface coating and surface functionalisation
- the estimated quantity to be placed on the market in one of the following categories: less than 1 kg 1–10 kg, 10–100 kg, 100–1000 kg, 1–10 t, 10–100 t, more than 100 t,

j. if applicable, the identification as a PBT or vPvB substance
k. the chemical safety report available in the EEA, provided the manufacturer can reasonably be expected to obtain it;

Reporting is to be submitted to the notification authority for chemicals using the E-application for chemicals (RPC): https://www.rpc.admin.ch/rpc/private/

Although the authorities do not issue any order, they can evaluate the submitted data. According to article 26, paragraph 2, ChemO, they can require certain test reports from the notifier, if there is reason to assume that a substance may represent a danger to humans or the environment.

Exemptions to the obligation to report are listed in Article 54 ChemO.

Intermediates subject to the obligation to report

- Intermediates in the form of monomers which are new substances
- Intermediates which are given to third parties, leaving the manufacturing site and placed on the market in quantities > 100 kg/a

Intermediates exempted from the obligation to report

Intermediates that

1. are not given to third parties,
2. do not leave the manufacturing site, or
3. are placed on the market in quantities less than 100kg per year

intermediate	given to third parties	leaves the manufacturing site	placed on the market in quantities > 100 kg/a	obligation to report
	yes	yes	yes	**yes**
	yes	yes	no	**no**
	yes	no	no	**no**
	yes	no	yes	**no**
	no	yes	yes	**no**
	no	yes	no	**no**
	no	no	yes	**no**
	no	no	no	**no**

9 Declaration of substances for product- and process-orientated research and development

Article 34 ChemO stipulates that the duty of declaration exists for notifiable new substances which are placed on the market solely for the purpose of product- and process-orientated research under the conditions stated in article 26 paragraph 1 letter d ChemO. The notifier in this case may be the manufacturer, importer or only representative (cf. general information on the requirement to notify substances, chapter 2 of these guidelines). A maximum period for exemption from full notification of five years from the date of application will generally be granted for product- and process-orientated research and development. This exemption from the duty of full notification can only be claimed if the substances placed on the market by the notifier meet the following conditions:

- exclusively for the purpose of product- and process-orientated research and development,
- in quantities no greater than those necessary for the stated purpose, and
- for a period not exceeding five years; in justified cases and after consultation with the evaluation units, the notification authority may extend this period by a further five or ten years;

ChemO defines product- and process-orientated research and development as the continuing development of a substance, during which tests are conducted in pilot or production plants in order to develop the production process or to test the applications of the substance (article 2 paragraph 2 letter m ChemO).

Applications for exemption must be made to the notification authority for chemicals in good time, i.e. at least 30 days before the notifier intends to place the substance on the market for the first time, so that the office has enough time to examine the dossier and the situation.

Article 2 paragraph 2 letter m and article 26 paragraph 1 letter d ChemO states that substances intended for research and development purposes may be distributed in the quantity required for the intended purpose for a maximum period of five years from the date on which they are first placed on the market. The quantity must be justified. After the five-year exemption period expires, these substances are subject to full notification if no prolongation demand is submitted. The notifier must write the accompanying letter in an official language (German, French or Italian) and submit it on paper or electronically with certified signature (certified signature act, RS 943.03). The official language used by the notifier determines the language in which correspondence between it and the authority will be written. The other documents in the dossier may be written in English instead of an official language.

- Submit the declaration documents as a IUCLID export file.

According to article 35, paragraph 2, ChemO, the declaration must include the following data and documents:
a. name and address of the manufacturer;
b. if the manufacturer has imported the substance: name and address of the foreign manufacturer;
c. the key information for identifying the substance;
d. the uses;
e. the expected quantity of the substance to be placed annually on the market in Switzerland;
f. the intended classification and labelling;
g. the research programme and a list of recipients of the substance;
h. for dangerous substances or PBT or vPvB substances: a proposed safety data sheet.

Enter the research programme into section 1.9 and the list of recipients of the substance into section 1.8 Recipients (under 1 General Information) of IUCLID.

If there is reason to assume that a certain substance which, according to article 26 paragraph 1 ChemO above, does not have to be notified could pose a risk to humans or the environment, the notification authority for chemicals will, at the request of an evaluation unit, require the manufacturer to submit certain test reports. The requirements that these test reports have to meet must not exceed the scope of the technical dossier as defined in annex 4, section 8, letter a, section 9, letter a and section 10, letter a, ChemO (article 26, paragraph 2, ChemO).

According to article 41, ChemO, the authorities have a period of 30 days in which to examine the application. The period[4] begins on the day after the application is received by the notification office. It ends at the end of the last day of the period.
If the notification authority for chemicals does not decide to accept the notification or does not comment materially on the declaration within 30 days, the substance may be placed on the market once this period expires (article 41 letter b ChemO). If the authorities request supplementary data or documents, the 30-day period starts again.

Once the procedure has been completed, the notifier will receive an invoice for the processing fee. The fee is determined by the amount of work performed by the authorities and is based on the ChemGebV (500 CHF).
A duty to provide updated information also applies to declarations (article 46, ChemO): accordingly, the notification authority must be informed immediately in writing in the event of any changes to the above-mentioned compulsory information for declarations (article 35, paragraph 2, ChemO).

Annex I.

1. Technical dossier: General provisions

- The information in the technical dossier must be submitted as a IUCLID export file).
- **Preferably, upload it using the E-application for chemicals (RPC):** https://www.rpc.admin.ch/rpc/private/.
- Information required by annex 4, sections 7-10 ChemO depend on the substance quantity placed on the market.

Generally, and independently of the quantities placed on the market in Switzerland, all available information must be provided (such as the chemical safety report and the robust study summaries).

2 General notifier information

2.1 The identity of the notifier is to be indicated, in particular:
a.Name, address, telephone number and e-mail address;b.Contact person;c.Location of the notifier's production site(s), as appropriate.

2.2 If the notifier is an only representative, the following information is to be additionally provided:
a.Name and address of the foreign manufacturer;
b.Location of the production site(s);
c.Authorisation from the foreign manufacturer stating that it has designated the notifier as its only representative;
d.Names and addresses of the importers represented;
e.the substance quantities that each importer expects to import annually.

3 Identification of the substance

The following information on the substance is to be provided:
a.data specified in Section 2 of Annex VI to the REACH Regulation;
b.for nanomaterials: data on composition and, where available, surface coating and surface functionalisation.

4 Information on manufacture and use

The following information is to be provided:
a.the estimated overall quantity to be placed on the market by the notifier in the calendar year of the notification;
b.the quantities for the notifier's own use;
c.the form or physical state in which the substance is made available;
d.a brief description of the identified use(s);
e.information on waste quantities and composition of waste resulting from manufacture of the substance, the use in objects and identified uses;
f.uses advised against (Section 1.2 of the safety data sheet).

5 Classification and Labelling

The following is to be indicated:
a.the classification of the substance in accordance with Article 6 for all hazard classes and categories in the CLP Regulation; if no classification has been given for a hazard class or differentiation of a hazard class, the reasons are to be provided;
b.the labelling of the substance in accordance with Article 10;
c.any specific concentration limits resulting from the application of Article 10 of the CLP Regulation.

6 Guidance on safe use

The following information is to be provided; it must be consistent with that in the safety data sheet, where such a safety data sheet is required in accordance with Article 19:
a.first-aid measures (safety data sheet, No. 4);
b.fire-fighting measures (safety data sheet, No. 5);
c.accidental release measures (safety data sheet, No. 6);
d.handling and storage (safety data sheet, No. 7);
e.transport information (safety data sheet, No. 14);
f.exposure controls/personal protection (safety data sheet, No. 8);
g.stability and reactivity (safety data sheet, No. 10);

h.disposal considerations: information on recycling and methods of disposal for industry and for the public (safety data sheet, No. 13).

7 Information on exposure (1-10 tonnes per year)
For substances where the quantity placed on the market is between 1 and 10 tonnes per year, the following information on exposure is to be provided:
a.Main use categories:
1.professional use,
2.industrial use,
3.private use;

b.Specification for industrial and professional use:
1.use in a closed system,
2.use resulting in inclusion into or onto matrix,
3.non-dispersive use by a restricted number of persons,
4dispersive use;

c.Significant routes of exposure:
1.human exposure: oral, dermal and inhalatory,
2.environmental exposure: water, air, solid waste and soil,
3.pattern of exposure: accidental/infrequent, occasional or continuous/ frequent.

8 Information on physicochemical properties
The following information is to be provided:
a.for quantities placed on the market of 1 tonne per year or more:
1.robust study summaries with regard to the information specified in Section 7 of Annex VII to the REACH Regulation,
2.for nanomaterials: the particle form and mean particle size and, where available, the number size distribution, specific surface area by volume and aggregation status;

b.for quantities placed on the market of 100 tonnes per year or more: in addition to the information specified in letter a, robust study summaries with regard to the information specified in Section 7 of Annex IX to the REACH Regulation.

9 Toxicological information
Robust study summaries are to be provided with regard to the following information:
a.for quantities placed on the market of 1 tonne per year or more: the information specified in Section 8 of Annex VII to the REACH Regulation;
b.for quantities placed on the market of 10 tonnes per year or more: in addition to the information specified in letter a, the information specified in Section 8 of Annex VIII to the REACH Regulation;
c.for quantities placed on the market of 100 tonnes per year or more: in addition to the information specified in letters a and b, the information specified in Section 8 of Annex IX to the REACH Regulation;
d.for quantities placed on the market of 1,000 tonnes per year or more: in addition to the information specified in letters a-c, the information specified in Section 8 of Annex X to the REACH Regulation.

10 Ecotoxicological information
Robust study summaries are to be provided with regard to the following information:
a.for quantities placed on the market of 1 tonne per year or more: the information specified in Section 9 of Annex VII to the REACH Regulation;
b.for quantities placed on the market of 10 tonnes per year or more: in addition to the information specified in letter a, the information specified in Section 9 of Annex VIII to the REACH Regulation;
c.for quantities placed on the market of 100 tonnes per year or more: in addition to the information specified in letters a and b, the information specified in Section 9 of Annex IX to the REACH Regulation;
d.for quantities placed on the market of 1,000 tonnes per year or more: in addition to the information specified in letters a-c, the information specified in Section 9 of Annex X to the REACH Regulation.

11 Omission of certain tests
Certain tests specified in numbers 8-10 may be omitted if, according to the criteria specified in Annex XI to the REACH Regulation:

a.testing does not appear scientifically necessary;b.testing is technically not possible;c.the exposure assessment makes it possible for certain tests to be omitted.

Annex II.

Fees (CHF) for the notification of new substances (all fees shown in Swiss francs)

II. 1 Notification pursuant to Article 24 ChemO (before the substance is placed on the market for the first time in Switzerland)

Notification for a quantity (CH) of 1 ton or more up to 10 tons per year	Fee: **2000** Fee range (ChemGebV): 500 – 8000
Notification for a quantity (CH) of 10 ton or more up to 100 tons per year	Fee: **4000** Fee range (ChemGebV): 1000 – 13000 according to work required in the individual case
Notification for a quantity (CH) of 100 ton or more up to 1000 tons per year	Fee: **6000** Fee range (ChemGebV): 2000 – 25000 according to work required in the individual case
Notification for a quantity (CH) of 1000 tons or more per year	Fee: **8000** Fee range (ChemGebV): 2000 – 25000 according to work required in the individual case

II. 2 Additional data and test reports pursuant to Article 47 ChemO

substance quantity placed on the market of 10 tonnes or more per year: Information according to Annex 4, section 9, letter b and section 10, letter b, as well as a chemical safety report according to article 28	No legal deadlines: processing times according to the capacity of the authorities Fee: - change in CH quantity from 1 ton to 10 tons per year: **2000** Fee range (Chemical Fee Ordinance, ChemGebV, SR 813.153.1): 1000 – 12000 Determined by work required in the individual case
substance quantity placed on the market of 100 tonnes or more per year: Information according to Annex 4, section 8, letter b, section 9, letter c, section 10, letter c, as well as a chemical safety report according to article 28	No legal deadlines: processing times according to the capacity of the authorities Fee: - change in CH quantity from 1 ton to 10 tons per year: **2000** - change in CH quantity from 1 tonne to 100 tonnes per year: **4000** - change in CH quantity from 10 tonnes to 100 tonnes per year: **2000** Fee range (ChemGebV): 1000 - 23000 Determined by work required in the individual case
substance quantity placed on the market of 1000 tonnes or more per year: Information according to Annex 4, section 9, letter d, section 10, letter d, as well as a chemical safety report according to article 28	No legal deadlines: processing times according to the capacity of the authorities Fee: - change in CH quantity from 1 ton to 10 tons per year: **2000** - change in CH quantity from 1 tonne to 100 tonnes: **4000** - change in CH quantity from 1 tonne to 1000 tonnes per year: **6000** - change in CH quantity from 10 tonnes to 100 tonnes: **2000** - change in CH quantity from 10 tonnes to 1000 tonnes per year: **4000** - change in CH quantity from 100 tonnes to 1000 tonnes per year: **2000** Fee range: (ChemGebV) 1000 – 23000 Determined by work required in the individual case

Annex III

Checklist for completing **IUCLID** forms when notifying new substances.

The following points should be checked. The IUCLID export file (**Substance** dataset ==> Export to i6z; to be exported with one of the REACH templates; file type: *.i6z, not write-protected) should be updated if necessary.
In view of the publication: Please submit a public version (without confidential business information) of the PDF printout of the IUCLID 6 substance file (see chapter 3, section Publication).

- 1.1. Identification: current (!) address of the Swiss notifier (if an only representative: include authorization from the company) as **legal entity** (completed and up-to-date contact details under "Contact Information").
- 1.7. Supplier: address of the chemical manufacturer (current details!)
- 2 Classification and labelling (2.1 CLP): up-to-date?
- 2 Classification and labelling (2.2 DSD - DPD): up-to-date?
- 3.1 Technological process: if manufactured in CH
- 3.2 Estimated quantities: quantity placed on the market up-to-date?
- 3.3 Sites: if manufactured in CH (current details!)
- 3.5 Life Cycle description (incl. CH)3.7 Exposure estimates related to production: if manufactured in CH
- Results of all tests entered in IUCLID?
- Is any new information available since the IUCLID entry was last completed?
- Are the official GLP certificates available for all test laboratories that have performed non-clinical tests for assessing propertis dangerous for health or the environment?
- Is the substance placed on the market in Switzerland as such and must a SDS be established for the substance? If so: CH-SDS
- Is the substance produced in CH?
- if the quantity of a substance placed on the market per year is 10 tonnes or more: chemical safety report according to article 28;
- In principle, for a notification pursuant to art. 29 ChemO (notification by a further notifier), a IUCLID file with the sections 1-3 filled in as described above must be submitted. Furthermore, section 11 guidance on safe use (action to render the substance harmless) has to be completed if no SDS is provided.
- For substances developed using genetic resources or with traditional knowledge related to them, the manufacturer must inform on his own initiative the notification authority and indicate the registration number pursuant to art. 4 of the Nagoya Ordinance (NagO, RS 451.61 https://www.admin.ch/opc/en/classified-compilation/20150120/index.html), as a proof of the NagO notification submitted to FOEN https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/nagoya-protocol.htmlhttp://www.bafu.admin.ch/biotechnologie/13477/16459/index.html?lang=en

Software and information on IUCLID:
http://https://iuclid6.echa.europa.euhttps://iuclid6.echa.europa.eu