Classification of organisms
Module 5 (2022)

Criteria to evaluate the potential for improper use of organisms and their inclusion in the federal government list

1 Introduction and purpose

The FOPH maintains a publicly accessible, non-conclusive list of organisms with a high potential for improper use (Art. 26 para. 2 ContainO)[1] with the consent of the FOEN and after consulting the State Secretariat for Economic Affairs SECO, the Federal Food Safety and Veterinary Office FSVO, the Federal Office for Agriculture FOAG, the Federal Office for Civil Protection, the Swiss National Accident Insurance Fund SUVA and the Swiss Expert Committee for Biosafety SECB. Improper use means the handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biodiversity and their sustainable use (Art. 3 let. j ContainO). To determine the risk of improper use of organisms, corresponding criteria are also provided.

This list, as set out under Art. 26 para. 2 ContainO and the criteria are intended to make it easier for enterprises and enforcement authorities to assess the risk of improper use. They serve as a guideline to specify which organisms present the greatest threat in this regard and the nature of the threat.

The question of whether an activity involving one of these organisms really poses a threat to humans and the environment and requires additional measures in this regard ultimately also depends on the risk assessment as set out under Annex 2.2 number 1 ContainO. This means that the actual threat posed by organisms with potential for improper use depends on the way in which it is handled. The list of evaluation criteria on the potential for improper use of organisms and the list are intended to help put in place appropriate safety measures to counteract improper use (Art. 12 para. 2 ContainO). These include in particular:

i. Employment of at least one person to prevent the improper use of organisms (Annex 4 number 1 let. c ContainO).
ii. Appropriate measures to minimise any previously identified risk of improper use of the organisms, such as restricting access to premises and recording the identity of persons with access to the organisms used (Annex 4 number 1 let. k ContainO).
iii. Putting in place certain safety measures that take account of the improper use of organisms (Annex 4 number 2.1 let. b^{bis} ContainO).

2 List of organisms with a high potential for improper use

The list of organisms with high potential for improper use (Annex 1) supplements the lists of official classifications of bacteria, viruses, parasites and fungi in Switzerland. [2] When drawing up the list in Annex 1, consideration was taken of the Swiss list of organisms, the lists in Annex 2 numbers 1C351 and 1C354 of the Goods Control Ordinance[3] and the Australia Group[4] list. The list takes account of criteria to evaluate organisms in terms of their potential for improper use.

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[1] SR 814.912, Ordinance of 9 May 2012 (status as of 1 January 2020) on Handling Organisms in Contained Systems (Containment Ordinance, ContainO) https://www.fedlex.admin.ch/eli/cc/2012/329/en

[2] https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/publications-studies/publications/classification-of-organisms.html

[3] SR 946.202.1 Ordinance on the Export, Import and Transit of Dual Use Goods, Specific Military Goods and Strategic Goods of 3 June 2016 (status as of 1 January 2022), https://www.fedlex.admin.ch/eli/cc/2016/352/en

[4] https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/index.html

3 Criteria to evaluate the properties of organisms with regard to their improper use

3.1 Criteria to evaluate the properties of organisms

In general, all criteria from Annex 2.1 number 1 ContainO can be used to evaluate the potential of an organism for improper use on the basis of its properties. To evaluate the potential for improper use, the potential threat situation that improper use can result in should also be incorporated.

3.1.1 Evaluation criteria for pathogenic microorganisms

The questions on the properties of pathogenic microorganisms that should be asked with regard to potential for improper use, are listed in Table 1.

Table 1 Questions on the criteria of pathogenic microorganisms with regard to their potential for improper use to clarify Annex 2.1 number 1 letter r, ContainO (see also[5][6]).
The questions are based on criteria a-q of Annex 2.1 number 1 para 2 ContainO and can be used to determine the potential of an organism for improper use. If one or more questions can be answered with 'yes', this indicates potential for improper use.

	CRITERION	QUESTION
a.	Pathogenicity and lethality	Is the microorganism a high-risk pathogen, i.e. does it cause significant disease and mortality in humans or in agricultural crops and livestock, or is it systemically relevant to the environment and biodiversity?
b.	Virulence or attenuation	Is it highly virulent or has the attenuated pathogen reverted to virulence?
c.	Mode of infection, effective infection dose and the infection routes	Is it highly transmissible, particularly by means of aerosols, between humans or between other species, or from other species to humans? For vector-borne pathogens: is the vector endemic/viable in Switzerland?
d.	Production of non-cellular components such as toxins and allergens	Is it highly toxic or does it show increased absorption/effectiveness; is it stable with regard to improper use?
e.	Reproductive cycles and survival structures	Does it have potential for rapid reproduction in the host, in the environment, or as dormant forms for long-term dormancy in the environment; does it have increased stability outside of the host?
f.	Host range	Has the original host range or cytotropism expanded so that e.g. humans or livestock/crops could now be harmed?
g.	Degree of acquired or natural immunity of the host	Is immunity/resistance of host organisms unlikely due to lack of exposure, altered host range of the organism, or because of harmful effect of organism on the immune system of host organisms?
h.	Pattern of resistance or sensitivity to antibiotics and other specific agents	Is resistance or sensitivity to antibiotics and other specific agents increased in relation to humans or livestock/crops?
i.	Availability of appropriate prophylaxis and therapy	Are appropriate prophylaxis and therapy not or no longer available in relation to humans or livestock/crops, meaning they could be harmed?
j.	Presence of oncogenic nucleic acid sequences	Is it highly tumorigenic in association with infection caused by these microorganisms?
k.	Mutagenicity	Is it highly mutagenic in association with infection by microorganisms containing mutagenic sequences?
l.	Virus production and viral shedding in cell lines	Is there viral shedding with potential for improper use as per evaluation of the above criteria?
m.	Parasitic properties	Does the microorganism mutate in such a way that it can cause greater harm to humans or livestock/crops?

[5] Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens 2017 https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf

[6] Dual-Use Quickscan of the Dutch Biosecurity Office https://dualusequickscan.com/en/

	CRITERION	QUESTION
n.	Potential contamination with pathogenic microorganisms	Is there potential for contamination with pathogenic microorganisms according to evaluation of the above criteria?
o.	Environmental aspects	When it degrades (e.g. in combination with the criteria under let. e), does it cause potential harm to the environment?
p.	Experience with the spread of closely-related types of organism in Switzerland or in other countries	Relevant to section 3.1.2 only
q.	Availability of suitable techniques to record, detect, identify, monitor and combat these organisms	If the microorganisms concerned have potential for improper use according to evaluation of the criteria above, are suitable technologies to record, detect, identify , monitor and combat these organisms lacking?

High potential for improper use cannot be ruled out for microorganisms in groups 3 and 4 (see also Canada's 'Human Pathogens and Toxins Regulations' (SOR/2015-44)[7], but may also apply to microorganisms in group 2.

The following animal and plant pathogens have high potential for improper use:

a. highly infectious and eradicable epizootic diseases in accordance with Arts 2 and 3 of the Epizootic Diseases Ordinance;[8]

b. genetically modified epizootic diseases to be tackled and observed in accordance with Arts 4 and 5 of the Epizootic Diseases Ordinance, if this results in greater potential for harm;

c. quarantine organisms in accordance with Art. 4 of the Plant Health Ordinance.[9] The list of plant pathogens compiled by the Australia Group can also be used as a reference;[10]

d. genetically modified potential quarantine organisms and regulated non-quarantine organisms in accordance with Arts 5 and 5a of the Plant Health Ordinance, if this results in greater potential for harm.

3.1.2 Alien organisms

The criteria to evaluate the potential for improper use of alien small invertebrates or invasive organisms are listed in Table 2.

Table 2 Questions on the criteria with regard to potential for improper use of alien small invertebrates or invasive alien organisms.
The criteria are those set out under Annex 2.1 no. 3 ContainO. For a detailed discussion of the impact of alien small invertebrates or invasive alien organisms, see also IUCN The Environmental Impact Classification for Alien Taxa, Categories and Criteria.[11]

	CRITERION	QUESTION
a.	Life cycle and reproduction, in particular with regard to asexual reproduction	Does the organism have low generation time and/or a high number of offspring?
b.	Presence of host organisms in the environment	Is there a high number of sensitive species and individual host organisms? Is it possible that one or more native species permanently go extinct at a local level?

[7] https://lois-laws.justice.gc.ca/eng/regulations/SOR-2015-44/page-2.html#h-823271

[8] SR 916.401 Epizootic Diseases Ordinance (EzDO) of 27 June 1995 (Status as of 1 May 2021) https://www.fedlex.admin.ch/eli/cc/1995/3716_3716_3716/de

[9] SR 916.20 Ordinance on the Protection of Plants from Particularly Harmful Organisms (Plant Health Ordinance, PHO) of 31 October 2018 (Status as of 1 August 2020), https://www.fedlex.admin.ch/eli/cc/2018/682/de

[10] https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/plants.html

[11] IUCN (2020). IUCN EICAT Categories and Criteria. The Environmental Impact Classification for Alien Taxa First edition. Gland, Switzerland and Cambridge, UK: IUCN. X + Xpp. https://doi.org/10.2305/IUCN.CH.2020.05.en

	CRITERION	QUESTION
c.	Environmental aspects and viability, in particular with regard to cold tolerance and diapause	Does it have good viability (ability to survive) with regard to physical conditions?
d.	Potential contamination with microorganisms that may be pathogenic for humans, animals and plants	Are the spread and transmission of new pathogens through small invertebrates likely? Would parasitisation lead to irreversible suppression and local eradication of one or more native species?
e.	Invasiveness and ability to suppress native species	Are irreversible effects on biodiversity possible (e.g. suppression or local eradication of one or more native or protected species)?
f.	Threat to human, animal and plant health by the organism due to its allergicity, pathogenicity, toxicity, or property as a vector	If transmission takes place, would disease lead to irreversible suppression or local eradication of one or more native species?
g.	Harm to other organisms, in particular through competition and hybridisation	Could competition or hybridisation result in irreversible suppression and local eradication of one or more native species?
h.	Harm to resource cycles	Is there a high likelihood of irreversible harm to chemical or physical ecosystems?
i.	Effects on the functioning of the ecosystem	Is the ecosystem likely to be harmed leading to local eradication of one or more native species?
j.	Resistance or sensitivity to pesticides, herbicides and other agents	Is it likely that microorganisms can no longer be controlled, leading to irreversible damage to the ecosystem?
k.	Availability of suitable techniques to detect the organism in the environment and to combat it	If the microorganisms concerned have potential for improper use according to evaluation of the criteria above, are suitable technologies to record, detect, identify , monitor and combat these organisms lacking?

3.2 Organisms with low potential for improper use

If an organism does not meet the criteria set out under section 3.1, the potential for improper use is low. If the questions on criteria cannot be answered due to a lack of knowledge, the assessment should be repeated or continually added to throughout the activity.

Microorganisms in Group 3 in accordance with Annex 1.4 of the Major Accidents Ordinance have low potential for improper use as, due to their properties, they cannot spread uncontrollably among the public and in the environment.[12]

Microorganisms and their toxins from Groups 3 and 4 also have low potential for improper use if they have been attenuated, i.e:[13]

i. their genetic attenuation is documented;

ii. their genetic mutations or alterations are known to attenuate virulence in humans or relevant plant or animal models;

iii. the mutations have a low frequency of reversion to wild-type virulence;

iv. scientific papers support the attenuation;

v. quantitative measures demonstrating a change in virulence in an appropriate animal or plant model;

vi. have market approval.

[12] SR 814.012, Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO) of 27 February 1991 (Status as of 1 August 2019) https://www.fedlex.admin.ch/eli/cc/1991/748_748_748/en

[13] US Select Agents and Toxins List, CDC/USDA Federal Select Agent Program https://www.selectagents.gov/sat/list.htm and exclusions for attenuated strains https://www.selectagents.gov/sat/exclusions/index.htm and related guidance https://www.selectagents.gov/compliance/guidance/exclusions/docs/Exclusion_Guidance.pdf

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Annex 1

List of organisms that are pathogenic for humans and animals and have a high potential for improper use

The list contains viruses, bacteria and fungi that are pathogenic to humans and animals from groups 3 and 4 of the relevant FOEN enforcement guides (Classification of Organisms)[14], which are also listed in Annex 2 numbers 1C351 and 1C354 of the Good Control Ordinance[15] and the list of the Australia Group: Human and animal pathogens and toxins list for export control. [16] Strains of Clostridium from group 2 were also included if they produce botulinum toxins.

Note on other organisms that are pathogenic to animals and plants

Due to their heightened threat potential, the microorganisms that are pathogenic to animals and plants that are listed in the following ordinances and lists but not in Table 1, may also have high potential for improper use:

a. Highly-infectious and eradicable epizootic diseases in accordance with Art. 2 and 3 of the Epizootic Diseases Ordinance[17] respectively the list of highly-infectious and eradicable epizootic diseases.

b. Quarantine organisms in accordance with Art. 4 of the Plant Health Ordinance,[18] or respectively the list in Annex 1 to the Ordinance of the EAER and DETEC on the Plant Health Ordinance;[19]

c. A1 List of pests recommended for regulation as quarantine pests.[20]

[14] https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/publications-studies/publications/classification-of-organisms.html

[15] SR 946.202.1 Ordinance on the Export, Import and Transit of Dual Use Goods, Specific Military Goods and Strategic Goods of 3 June 2016 (Status as of 1 January 2022), https://www.fedlex.admin.ch/eli/cc/2016/352/en

[16] https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/human_animal_pathogens.html

[17] SR 916.401 Epizootic Diseases Ordinance (EzDO) of 27 June 1995 (Status as of 1 May 2021) https://www.fedlex.admin.ch/eli/cc/1995/3716_3716_3716/de

[18] SR 916.20 Ordinance on the Protection of Plants from Particularly Harmful Organisms (Plant Health Ordinance, PHO) of 31 October 2018 (Status as of 1 August 2020), https://www.fedlex.admin.ch/eli/cc/2018/682/de

[19] SR 916.201 Ordinance of the EAER and DETEC on the Plant Health Ordinance, https://www.fedlex.admin.ch/eli/cc/2019/787/de

[20] https://www.eppo.int/ACTIVITIES/plant_quarantine/A2_list

List of organisms with a high potential for improper use

A = pathogenic for animals, H = pathogenic for humans

	Viruses	Risk group
A	African horse sickness virus	3
A	African swine fever virus	4
H,A	Highly pathogenic avian influenza virus (HPAI)[21]	3
H	Chikungunya virus	3
A	Classical swine fever virus (Hog cholera virus)	3
H	Crimean-Congo hemorrhagic fever virus	4
H	Dobrava-Belgrade virus	3
H,A	Eastern equine encephalitis virus	3
H	Ebolavirus: all members of the Ebolavirus genus	4
A	Foot-and-mouth disease virus	4
A	Goatpox virus	3
H	Guanarito virus	4
H	Hantaan virus	3
H,A	Hendra virus (Equine morbillivirus)	4
H,A	Highly pathogenic human influenza virus (e.g. reconstituted 1918 strain)	3
H	Japanese encephalitis virus	3
H	Junin virus	4
H	Kyasanur Forest disease virus	4
H	Lassa virus	4
H	Louping ill virus	3
A	Lumpy skin disease virus	3
H	Lymphocytic choriomeningitis virus	3
H	Machupo virus	4
H	Marburg virus: all members of the Marburgvirus genus	4
H,A	Monkeypox virus	3
H	Murray Valley encephalitis virus	3
H,A	Nipah virus	3
H	Omsk hemorrhagic fever virus	4
H	Oropouche virus	3
A	Peste-des-petits-ruminants virus	4
H	Polio virus type 2 and 3[22]	3
A	Powassan virus	3
H	Rabies virus and other members of the Lyssavirus genus	3
H,A	Rift Valley fever virus	3
A	Rinderpest virus	4
H	Rocio virus	3

[21] In accordance with Art. 122 para. 2 EzDO

[22] Contrary to the data, the polio virus should be classified in group 3 of the viruses list. A modificaion of the list is planned.

	Viruses	Risk group
H	Sabia virus	4
H	Seoul virus	3
H	Severe acute respiratory syndrome-related coronavirus (SARS-MERS-related coronavirus)	3
A	Sheeppox virus	3
H	Sin Nombre virus	3
H	St. Louis encephalitis virus	3
H	Tick-borne encephalitis virus (Far Eastern and Siberian subtype)	4
H	Variola virus	4
HA	Venezuelan equine encephalitis virus	3
HA	Western equine encephalitis virus	3

	Bacteria	Risk group
HA	Bacillus anthracis	3
HA	Brucella melitensis	3
HA	Burkholderia mallei (Pseudomonas mallei)	3
HA	Burkholderia pseudomallei (Pseudomonas pseudomallei)	3
H	Chlamydia psittaci (Chlamydophila psittaci)	3
H	Clostridium, botulinum producing species	2
H	Coxiella burnetii	3
H	Francisella tularensis	3
H	Mycobacterium tuberculosis (extensively drug resistant M. tuberculosis; XDR)	3
HA	Mycoplasma capricolum subspecies capripneumoniae (Mccp)	3
H	Mycoplasma mycoides subspecies mycoides (Mmm)	3
H	Rickettsia prowazekii	3
H	Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi)	3
H	Shigella dysenteriae Serovar 1	3
H	Yersinia pestis	3

	Fungi	Risk group
H	Coccidioides immitis	3