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Swiss Expert Committee for Biosafety SECB

## **Recommendation of the SECB**

# on the treatment and disposal of waste produced when handling genetically modified or pathogenic organisms in contained systems

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## 1. Purpose and field of application

Handling genetically modified or pathogenic organisms generates waste that, according to statutory requirements, must be inactivated and disposed of in such a way that it cannot harm either humans or the environment.

In this Recommendation, the SECB puts into concrete terms the statutory requirements for the inactivation and disposal of such waste, to simplify practice and to harmonise enforcement. This is based on the state of knowledge, technology and international best practice.

The Recommendation covers the types of waste and waste categories, listed below, produced in all institutions deemed to be contained systems as defined by the Ordinance on the Contained Use of Organisms (ContainO)<sup>1</sup>, especially research and diagnostics laboratories, animal facilities, greenhouses and production facilities. Waste that does not contain, or could not be contaminated with, pathogenic or genetically modified microorganisms does not fall within the scope of this Recommendation.

## 2. Types of waste, waste categories and definitions

## 2.1 Types of waste

The following types of waste may be produced during the contained use of genetically modified or pathogenic organisms:

- Liquid and solid cultures of pathogenic or genetically modified microorganisms;
- Cultures of primary cells and cell lines;
- Cultures of genetically modified cells and cell lines;
- Human or animal tissue samples, and potentially organs and body parts; human or animal blood and blood products as well as components thereof; and excretions and secretions of human or animal origin;
- Prions;
- Genetically modified animals;
- Animals infected with human- or animal-pathogenic or genetically modified microorganisms;
- Genetically modified plants and plant parts;
- Plants and plant parts infected with plant-pathogenic or genetically modified microorganisms;
- Mixed waste that could, in addition to biological material, contain hazardous chemicals or radioisotopes;
- Consumables contaminated with the biological material mentioned above;
- Waste posing a risk of injury (sharps).

## 2.2 Waste categories

In the present Recommendation, waste is subdivided into different categories according to its origin and composition:

- Waste from activities using genetically modified microorganisms in safety level 1 facilities (BSL-1);
- Waste from activities using microorganisms in safety level 2 facilities (BSL-2);
- Waste from activities using microorganisms in safety level 3 and 4 facilities (BSL-3 and BSL-4);
- Waste that contains prions;

Ordinance on Handling Organisms in the Contained System (ContainO), SR 814.912, <u>http://www.admin.ch/opc/en/classified-compilation/20100803/index.html</u>

- Medical waste;
- Animal carcasses from animal facilities, genetically modified or infected with pathogenic or genetically modified microorganisms;
- Plants and plant parts from greenhouses and growing rooms, genetically modified or infected with pathogenic or genetically modified microorganisms;
- Mixed waste containing biological materials and hazardous chemicals and / or radioisotopes.

The treatment and disposal of these waste categories is discussed in detail in Chapters 4 and 5. Special waste and municipal waste are essentially differentiated in terms of type of disposal.

#### 2.3 Definitions

In this Recommendation:

Infectious waste:	Waste that contains or comprises pathogenic microorganisms.
Medical waste:	Waste from the medical and veterinary sector, such as blood, blood products, diagnostic samples of all kinds, tissues, organs, excretions and secretions etc.
Sharps:	Waste posing a risk of injury (needles, cannulae, inoculation loops, glass vessels, shards, Pasteur pipettes, scalpel blades etc.).
Sharps containers:	Tested, puncture-proof, watertight disposal containers that can- not be reopened after locking.
UN transport containers:	Containers that comply with the packaging regulations for dan- gerous goods in line with international transport rules (see Sec- tion 3.3). The packaging and containers must be type-tested if required under ADR Section 4.1.4 <sup>2</sup> . Further information in Ap- pendix III.
Triple packaging:	Triple packaging <sup>3</sup> should be used for genetically modified organ- isms (UN 3245) packed in accordance with packing instruction P904. Such packaging does not require type-testing. Further information in Appendix III.
Special waste:	Any type of waste that, due to its composition, chemical-physical or biological properties, requires special measures for its envi- ronmentally sound disposal.
Municipal waste:	Waste that contains no genetically modified or pathogenic (mi- cro)organisms that are capable of reproducing, no hazardous chemicals or radioactive materials, and no other hazardous ma- terials or materials that are disgusting or foul-smelling.
	According to the Federal Office for the Environment's enforce- ment aid, "Entsorgung von medizinischen Abfällen" (Disposal of medical waste) <sup>4</sup> , municipal waste is:
	a) Waste that is converted by sterilisation, disinfection or inacti- vation into essentially dry, unrecognisable, stable material

<sup>&</sup>lt;sup>2</sup> European Agreement concerning the International Carriage of Dangerous Goods by Road, ADR, SR 0.741.621, Section 4.1.4, List of packing instructions <u>http://www.unece.org/trans/danger/publi/adr/adr2019/19contentse.html</u>

<sup>&</sup>lt;sup>3</sup> Triple packaging is also used for infectious materials that according to international transport regulations are classified under UN numbers UN 3373, UN 2814 and UN 2900.

<sup>&</sup>lt;sup>4</sup> Enforcement aid "Entsorgung von medizinischen Abfällen" (Disposal of medical waste, in German or French), FOEN 2004 (revision in 2017). <u>http://www.bafu.admin.ch/publikationen/publikation/00453/index.html?lang=de</u>

	that is neither disgusting nor foul-smelling (e.g. a granulate).
	<ul> <li>b) Consumables, such as disposable gloves, plastic pipette tips, gelatine, Petri dishes, agar plates, that neither fall into the category of waste that poses a risk of injury (sharps), nor are disgusting or foul-smelling.</li> </ul>
Inactivation:	Physical or chemical process that kills microorganisms.
Disinfection:	Physical or chemical process that reduces the number of micro- organisms.
Disinfectant:	Chemical capable of reducing the number of microorganisms.
Sterilisation:	Process that kills or removes microorganisms.
Validation (only BSL-3 and BSL-4)	Confirmation using objective evidence that a defined process (e.g. steam sterilisation) under defined conditions (e.g. batch size and composition, temperature, time, pressure) can repeatedly achieve the desired result <sup>5, 6, 7</sup> .
Evidence of effective- ness:	Evidence and monitoring to ensure that the process (e.g. steam sterilisation) achieves the intended result for each batch (e.g. time and temperature control for each batch, as well as periodic checking using temperature data loggers and biological indicators) <sup>8</sup>

#### 3. Statutory requirements

The regulations governing the treatment and disposal of waste arising in contained systems are the Ordinance on the Contained Use of Organisms (ContainO)<sup>9</sup> and the Ordinance on Occupational Safety in Biotechnology (OOSB)<sup>10</sup>. Further measures may need to be taken in order to ensure full protection of employees; these are not considered here in more detail.

Waste disposal is governed by the Ordinance on Movements of Waste (OMW)<sup>11</sup>, as well as other specific ordinances for particular waste categories, which will be detailed in Chapter 4. National and international transport regulations apply to the transport of waste.<sup>12, 13, 14, 15</sup>

#### 3.1 ContainO and OOSB

Appendix 4, No. 2.1 of the ContainO, and Appendix 3, No. 2, Table 1 of the OOSB stipulate measures for the treatment and disposal of waste that contains or is made up of genetically modified or pathogenic organisms.

- for Safety level 1 facilities (BSL-1) the harmless disposal of contaminated materials, equipment and waste;
- for Safety level 2 facilities (BSL-2) the inactivation of contaminated materials, equipment

<sup>&</sup>lt;sup>5</sup> ISO 9000:2005, Quality management systems - Fundamentals and vocabulary <u>http://www.iso.org/iso/iso\_catalogue/catalogue\_tc/catalogue\_detail.htm?csnumber=42180</u>

<sup>&</sup>lt;sup>6</sup> Process Validation: Moist Heat Sterilization for Pharmaceuticals <u>http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/validation/mhsp-schpp-eng.php</u>

<sup>&</sup>lt;sup>7</sup> ISO 17765-1:2006, Sterilization of health care products - Moist heat - Part 1: <u>http://www.iso.org/iso/search.htm?qt=ISO+17665-1%3A2006&searchSubmit=Search&sort=rel&type=simple&published=on</u>

<sup>&</sup>lt;sup>8</sup> ISO 9000:2005, Quality management systems - Fundamentals and vocabulary <u>http://www.iso.org/iso/iso\_catalogue/catalogue\_tc/catalogue\_detail.htm?csnumber=42180</u>

<sup>&</sup>lt;sup>9</sup> SR 814.912, <u>http://www.admin.ch/opc/en/classified-compilation/20100803/index.html</u>

<sup>&</sup>lt;sup>10</sup> SR 832.321, <u>http://www.admin.ch/opc/de/classified-compilation/19994946/index.html (in German)</u>

<sup>&</sup>lt;sup>11</sup> SR 814.610, http://www.admin.ch/opc/de/classified-compilation/20021080/index.html (in German)

and waste;

- for Safety level 3 facilities (BSL-3) the inactivation of contaminated materials, equipment and waste using validated processes;
- for Safety level 4 facilities (BSL-4) the inactivation of contaminated materials, equipment and waste in the laboratory, using a pass-through autoclave and validated processes.

From the SECB's point of view, various inactivation procedures may be considered. In addition to heat inactivation by autoclaving, they include chemical inactivation. Waste from BSL-1 (genetically modified microorganisms) may be taken directly to waste incineration plants. Contaminated material, animal carcasses and diagnostic samples from BSL-2, and in exceptional cases – if authorised by the Federal Office responsible – solid cultures from BSL-2, may be disposed of as special waste without prior inactivation. Suitable transport containers must be used and all containment measures must be observed during transport so that humans or the environment cannot be put at risk. Inactivation on site should however be preferred.

In addition, to protect employees from exposure to waste that contains microorganisms, OOSB Art. 8, para. 2, letter f stipulates that all waste be collected, stored and disposed of in such a way that staff are not endangered.

#### 3.2 OMW

The Ordinance on Movements of Waste (OMW) ensures that waste be delivered only to suitable disposal companies, and regulates which waste counts as special waste. For the purposes of this Recommendation it is waste that is infectious (cultures of pathogenic microorganisms), or that poses a risk of contamination or injury (medical samples, blood, contaminated consumables, body parts, organs, tissues etc.), as well as waste that is disgusting or foul-smelling.

According to Article 4 para. 2 of the OMW, special waste may be delivered only to facilities that possess an OMW disposal licence (Art. 8 OMW;<sup>12</sup> for special waste described in this Recommendation that is municipal waste incineration plants<sup>13</sup> or special waste incineration plants<sup>14</sup>).

Movement documents are required for the delivery of special waste in quantities of 50 kg or more per waste code and delivery (Art. 6 OMW). For small quantities of less than 50 kg, neither movement documents nor labelling as "special waste" in the three official Swiss languages is required (Art. 7 OMW). However, in these cases the documentation concerning the delivery must be stored for five years (Art. 6 para. 2 letter a, OMW).

Special waste can be taken to the special waste incineration plant by the facility itself using a dangerous goods transporter, or can be collected by a waste disposal company<sup>15, 16,17</sup>.

#### 3.3 Transport regulations

If waste containing pathogenic or genetically modified organisms is not inactivated before leaving the contained system, it must be labelled and packaged according to national and international transport regulations<sup>18, 19, 20, 21</sup> (see also Appendix III). This does not apply to ge-

<sup>&</sup>lt;sup>13</sup> Address list of waste incineration plants in Switzerland: <u>http://vbsa.ch/anlagegruppen/kva/ (in German)</u>

<sup>&</sup>lt;sup>14</sup> Address list of special waste incineration plants: <u>http://vbsa.ch/anlagegruppen/sonderabfall/</u> (in German)

<sup>&</sup>lt;sup>15</sup> Spiromed AG waste disposal company:<u>http://www.spiromed.ch/</u> (in German)

<sup>&</sup>lt;sup>16</sup> Remondis Schweiz AG waste disposal company: <u>www.remondis.ch</u>, <u>info@remondis.ch</u> (in German)

<sup>&</sup>lt;sup>17</sup> Valbenne SA waste disposal company, Giubiasco (TI): <u>https://www.abfall.ch/daten/table/CH/1/3840</u> (in German)

<sup>&</sup>lt;sup>18</sup> European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), SR 0.741.621, <u>http://www.unece.org/trans/danger/publi/adr/adr\_e.html</u>

<sup>&</sup>lt;sup>19</sup> Ordinance on the Transport of Dangerous Goods by Road (SDR), SR 741.621, <u>http://www.admin.ch/opc/de/classified-compilation/20022136/index.html</u> (in German)

<sup>&</sup>lt;sup>20</sup> Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) <u>http://www.otif.org/index.php?L=2</u>

netically modified plants or parts of plants with no reproductive potential. The applicable transport regulations and instructions on packaging, labelling, documentation and shipping are given on the SECB website under "Transport, import and export"<sup>22</sup>.

## 4. Methods of waste treatment and disposal

To minimise the risk when handling waste, following measures should be considered:

- Waste reduction
- Separate collection of the waste (by category)
- Packaging / labelling before and after inactivation
- Storage / transport before and after inactivation
- Inactivation of the waste:Aim for inactivation on site
  - Select inactivation method
    - Location of the autoclave
    - Provide disinfectant
  - $\circ\,$  Validation of inactivation (for BSL-3 and -4): work with validated standard batches.
- Final disposal:
  - Municipal waste: no longer requires a biohazard label
  - Special waste:
    - Requirements concerning packaging and labelling
    - Waste disposal company
- Personal protection
- Staff training
- Standard Operating Procedures (SOPs): Waste treatment and disposal must be specified for BSL- 3 and -4 – and ideally for BSL-1 and -2 as well – in SOPs or specific instructions.
- Responsibilities for waste management should be clearly defined and laid out in writing for all types of waste.

#### 4.1 **Processing methods**

Waste can be inactivated using physical or chemical methods.

#### 4.1.1 Steam sterilisation

The internationally recognised technical standard for handling, inactivating and testing waste from laboratories for research, development and analysis is European Standard EN 12740 of July 1999<sup>23</sup>. This Standard recommends steam sterilisation in an autoclave for all waste containing pathogenic microorganisms from safety levels 2, 3 and 4.

The sterilising temperature and time depend on the total volume and type of material being treated, as well as on the number and type of organisms and their resistance to heat. Standard procedures are generally given by the autoclave manufacturer.

EN 12461, the Standard for inactivation of waste on a large scale<sup>24</sup>, states the following:

<sup>&</sup>lt;sup>21</sup> DETEC Ordinance on the Transport of Dangerous Goods by Rail and Cableway (RSD), SR 742.412, <u>http://www.admin.ch/opc/de/classified-compilation/20121700/index.html</u> (in German)

<sup>&</sup>lt;sup>22</sup> Transport, import and export of substances consisting of or containing pathogenic or genetically modified (micro)organisms <u>https://www.efbs.admin.ch/index.php?id=462&L=3</u>

<sup>&</sup>lt;sup>23</sup> EN 12740 Biotechnology. Laboratories for research, development and analysis. Guidance for handling, inactivating and testing of waste, available from the Swiss Association for Standardization, <u>http://shop.snv.ch/en/home/?lang=1</u>.

<sup>&</sup>lt;sup>24</sup> EN 12461, Biotechnology - Large scale process and production - Guidance for the handling, inactivating and testing of waste, 1998, available from the Swiss Association for Standardization, <u>http://shop.snv.ch/en/home/?lang=1</u>.

- For most production microorganisms that do not form spores, temperatures of 60 to 70oC for 10 to 20 min. are generally sufficient.
- For most thermoresistant microorganisms (e.g. spore-forming microorganisms), a batch process<sup>25</sup> at 121oC for 20 min. at 2 bar or a continuous process<sup>26</sup> at 140oC for 30 to 60 sec. are suitable.

The autoclaving process should be monitored for each batch (evidence of effectiveness of the validated process, e.g. temperature / time control, periodic tests using biological indicators, or in simpler cases chemical indicators, e.g. test strips). Autoclaving of waste that contains BSL-3 or BSL -4 microorganisms should be validated by the use of standard batches, and documented. If the batches vary greatly for operating reasons, each batch should be thermally monitored (thermoelements and temperature data logger), particularly for large containers of semisolid or compressed waste. Instructions and help on the autoclaving procedure and validation methods are generally provided by the autoclave manufacturer. Validation requirements according to microorganism and type of waste must be defined by the user.

Autoclavable waste containers should be sufficiently stable and robust for autoclaving, and designed so that air can be fully drawn out of the container (vacuum cycles) and steam penetrate easily. Containers that fulfil these requirements are labelled as such by the manufacturer.

The materials to be sterilised must not be packed too tightly, as this may hinder the exchanges of air and steam.

In addition to thermoelements or temperature data loggers, biological indicators can be used for validation and evidence of effectiveness. Chemical indicators or heat-sensitive test strips and adhesive tapes are not suitable for validation and evidence of effectiveness procedures, but may be used to indicate that the material has been autoclaved.

#### 4.1.2 Chemical inactivation

Waste is chemically inactivated using chemicals with an antimicrobial effect. Chemical inactivation is employed if steam sterilisation is not appropriate, for example if waste is highly diluted, or for mixed waste that cannot be autoclaved. Or if permission has been given not to use autoclaving and it could be shown in an evidence of effectiveness procedure that using chemical means to achieve inactivation is comparable to autoclaving.

The efficiency of chemical inactivation depends on several factors, including the disinfectant itself, exposure period or exposure time, the effective concentration of the disinfectant, the concentration of organisms, temperature, pH, contamination with inhibitors (e.g. proteins) and the stability of the disinfectant. In addition, the microorganisms have different properties, which will affect the activity spectrum of the disinfectant (see Appendix II)<sup>27</sup>.

One further variant of chemical inactivation is fumigation. This should however be considered only for waste with surface contamination, if its size or bulkiness means it has to be removed from a BSL-3 or -4 laboratory through an airlock. These methods must also be validated and each individual batch monitored using evidence of effectiveness techniques<sup>28</sup>.

<sup>&</sup>lt;sup>25</sup> Batch processing: the entire volume is heated over a defined period and then cooled (discontinuous inactivation).

<sup>&</sup>lt;sup>26</sup> Continuous sterilisation: inactivation in a continuous flow process.

<sup>&</sup>lt;sup>27</sup> Chemical inactivation of organisms in fluids, instructions as per the FOPH <u>https://www.bag.admin.ch/dam/bag/en/dokumente/biologische-sicherheit/chemische-inaktivierung-organismen-fluessigkeiten.pdf.download.pdf/wegleitung-chem-inaktivierung-11-2016-en.pdf</u>

<sup>&</sup>lt;sup>28</sup> Munro K. et al.: A comparative study of methods to validate formaldehyde decontamination of biological safety cabinets. Appl. Env. Microbiol. 65 (29): 873–76 (1999).

#### 4.1.3 Waste treatment at the industrial scale

The international technical standard for the treatment, inactivation and testing of waste produced on an industrial scale is the EN Standard 12461 of April 1998<sup>29</sup>. This Standard gives instructions for the determination of thermal and chemical treatment processes to be used on a production scale, particularly for the continuous sterilisation of liquid waste through a thermal inactivation system.

#### 4.2 Specific treatment and disposal procedures for individual waste categories

#### 4.2.1 Medical waste

If not inactivated, medical waste is classified as special waste (3.2). For its disposal, medical waste must be coded according to Appendix I (18 01 human medicine, 18 02 veterinary medicine). The Federal Office for the Environment's enforcement aid "Entsorgung von medizinischen Abfällen" (Disposal of medical waste<sup>30</sup>) contains detailed instructions. Further enforcement aids are available in certain regions (BL, BS<sup>31</sup>, VD<sup>32</sup>). For hospitals, doctors' practices and other institutions that handle medical waste, the handbook "Ökologie und Entsorgung" (Ecology and disposal)<sup>33</sup> is available from H+ (in German).

#### 4.2.2 Waste posing a risk of injury (sharps)

Sharps occur in various waste categories. They should be disposed of as special waste even after inactivation, to ensure the occupational safety and psychological wellbeing of staff tasked with disposal (including refuse collectors and staff who operate waste incineration plants)<sup>34</sup>.

The sharps containers must be labelled with the code 18 01 01 (18 01 human medicine) or 18 02 01 (18 02 veterinary medicine) (Appendix I). Sharps containers with non-inactivated material should also be labelled with a biohazard symbol.

#### 4.2.3 Contaminated consumables

After successful inactivation, consumables posing no risk of injury may be disposed of with municipal waste (without biohazard symbol). If, in justified exceptional cases, inactivation does not take place on site, consumables contaminated with pathogenic organisms should be disposed of as special waste in accordance with Appendix I (18 01 human medicine or 18 02 veterinary medicine) – labelled with a biohazard symbol.

#### 4.2.4 Animal carcasses

Animal carcasses that have not been intentionally infected with pathogenic microorganisms should be disposed of according to the provisions of the Ordinance on the Disposal of Animal By-Products (DABO)<sup>35</sup>. They are classed as category 1 animal by-products (Art. 5), and should be collected in tightly sealed packaging or covered, airtight, corrosion-resistant and easily cleaned containers, labelled with the colour black and the words "for dispos-

<sup>&</sup>lt;sup>29</sup> EN 12461, Biotechnology - Large scale process and production - Guidance for the handling, inactivating and testing of waste, 1998, available from the Swiss Association for Standardization <u>http://shop.snv.ch/en/home/?lang=1</u>.

<sup>&</sup>lt;sup>30</sup> Enforcement aid "Entsorgung von medizinischen Abfällen" (Disposal of medical waste, in German), FOEN 2004 <u>https://www.bafu.admin.ch/bafu/de/home/themen/abfall/publikationen-studien/publikationen/entsorgung-von-medizinischen-abfaellen.html</u>

<sup>&</sup>lt;sup>31</sup> CD-ROM "Entsorgung medizinischer Abfälle", Wegleitung für die Region Nordwestschweiz, Amt für Umwelt, Basel-Stadt, <u>http://www.bs.ch/publikationen/aue/CD-ROM-Entsorgung-medizinischer-Abfaelle.html</u> (in German)

<sup>&</sup>lt;sup>32</sup> <u>http://www.vd.ch/fileadmin/user\_upload/themes/environnement/eau/fichiers\_pdf/DCPE-572.pdf</u> <u>http://www.vd.ch/fileadmin/user\_upload/themes/environnement/eau/fichiers\_pdf/DCPE-572\_Annexe.pdf</u> (in French)

<sup>&</sup>lt;sup>33</sup> <u>https://www.vzk.ch/downloadcenter/dokumente-vzk/2018-oekologiehandbuch.pdf</u> (in German)

<sup>&</sup>lt;sup>34</sup> <u>http://www.bafu.admin.ch/publikationen/publikation/00453/index.html?lang=de (in German)</u>

<sup>&</sup>lt;sup>35</sup> Ordinance on the Disposal of Animal By-Products (DABO), SR 916.441.22, <u>http://www.admin.ch/opc/de/classified-compilation/20101486/index.html (in German)</u>

al/incineration only", kept chilled, and transported together with the appropriate movement documents (Art. 19, Art. 20 and Annex 4, DABO). Carcasses of genetically modified animals may not be used as animal feed (Art. 22 para. 2 letter b, DABO). They can be directly disposed of in a municipal waste incineration plant as hopper feed. Animals can be deposited at regional animal carcass collection points. In general, incineration must take place in a licensed plant (Appendix 1 DABO).

Disposal can sometimes be agreed with the animal supplier. Alternatively, transport can be carried out by the users themselves, or organised via the regional animal carcass collection point or directly with the animal carcass incineration plant.

Animal carcasses that have been intentionally infected with pathogenic microorganisms must, under the OMW, be incinerated as special waste, Code 18 02 98 (Appendix I). They may be disposed of only in licensed animal carcass incineration plants. If possible they should first be autoclaved on site. For larger animals, however, it may be difficult to achieve the temperature necessary for the inactivation of pathogenic microorganisms. The process must be validated for BSL-3 and BSL-4. After successful inactivation on site, disposal in accordance with the DABO is also possible (see above).

One effective, alternative inactivation procedure for animal carcasses is **alkaline hydrolysis**, in which the animal carcasses are heated with sodium or potassium hydroxide (pH 10–11) to 100–150°C for 3–6 hours in a pressure vessel. This process destroys all proteins (including the protein coats of viruses and prion proteins)<sup>36</sup>.

A further disposal procedure, particularly for bigger animals or larger quantities of animal carcasses, is **rendering**. This is the mincing and boiling (at 140°C) of animal material, and the dehydration (water can make up to 65% of the total weight) and the breakdown of the remaining dry material into fat and solid components<sup>37</sup>.

#### 4.2.5 Material containing prions

BSL-3 waste must be inactivated on site before disposal, either by autoclaving (1h, 134°C, 3 bar) or through chemical inactivation (1h, 2N NaOH or 2% hypochlorite solution at 20°C), and can then be disposed of as municipal waste. If inactivation does not take place on site, all waste must be collected and transported in UN transport containers and disposed of in accordance with OMW. Inactivated animal carcasses and recognisable animal parts must be disposed of in accordance with DABO (see also Chapter 4.2.4 and Tables 5.3 and 5.5). Incineration is currently considered to be a safe method of inactivation and disposal for material containing prions.<sup>38</sup>

#### 4.2.6 Plants and plant parts

#### Genetically modified plants

Standard EN13441 on containment of genetically modified plants<sup>39</sup>, and the "Practical Guide to Containment, Plant Biosafety in Research Greenhouses"<sup>40</sup> make recommendations on preventing the spread of genetically modified plants through pollen, fruit, seeds and vegetative plant parts. They recommend filtration and sterilisation of draining water and the inactiva-

<sup>&</sup>lt;sup>36</sup> Thacker H. L., 2004, Carcass disposal: a comprehensive review, chapter 6, National Agricultural Biosecurity Center, USDA APHIS Cooperative Agreement Project, <u>http://krex.k-</u> state.edu/dspace/bitstream/handle/2097/662/Chapter6.pdf?sequence=13&isAllowed=y

 <sup>&</sup>lt;sup>37</sup> The BSE inquiry report, volume 13, chapter 6, annex B: manufacturing process of rendering: <u>https://krex.k-</u> <u>state.edu/dspace/bitstream/handle/2097/662/Chapter4.pdf;sequence=15https://www.efbs.admin.ch/inhalte/dokumentation/e</u> <u>mpfehlungen/Empfehlungen\_aktuell/BSE\_Diagnostik\_EFBS\_E.pdf</u>

<sup>&</sup>lt;sup>38</sup> Recommendation of the SECB on BSE diagnosis: Classification and safety measures, 2013:

<sup>&</sup>lt;sup>39</sup> EN 13441:2001, Biotechnology. Laboratories for research, development and analysis. Guidance on containment of genetically modified plants, available from the Swiss Association for Standardization, <u>http://shop.snv.ch/en/home/?lang=1</u>

<sup>&</sup>lt;sup>40</sup> Adair D. and Irwin R., 2008, A Practical Guide to Containment, Plant Biosafety in Research Greenhouses, Information Systems for Biotechnology, <u>https://vtechworks.lib.vt.edu/handle/10919/78423</u>

tion of soil and plant material. Group 1 plant material<sup>41</sup> with no reproductive potential may be composted without prior inactivation. The compost must be re-used on site. Plant material with reproductive potential (seeds, pollen) must be inactivated before disposal, or taken directly to the incineration plant in appropriate triple packaging.

The volume of waste can be reduced by drying or mincing. Small volumes can be autoclaved. It may also be possible to compost larger volumes, although material from group 2 will require heat treatment for inactivation. Various studies have shown that transgenes cannot be detected after genetically modified plant material has been composted in combination with heat treatment<sup>42.43</sup>.

When incinerating dry plant material, care should be taken to ensure that there are no fire-resistant seeds (e.g. cotton seeds).

After successful inactivation, plant material can be disposed of together with municipal waste.

#### Infected plants

Plants infected with (genetically modified or pathogenic) microorganisms must be inactivated and can then be disposed of as municipal waste. Alternatively, infected plant material from BSL-2 may be disposed of as special waste without prior inactivation. Correctly packed plant material infected with genetically modified microorganisms from BSL-1 may be disposed of directly through bunkers in the incineration plant.

For plants infected with group 1 microorganisms, the duty of care in accordance with ContainO must be observed. This Recommendation does not cover these plants.

#### 4.2.7 Mixed waste containing biological material and hazardous chemicals

Information on the disposal of waste with hazardous chemical or physical properties can be found in the manufacturer's safety data sheet, in accordance with Article 70 of the Chemicals Ordinance (ChemO)<sup>44</sup>. The chemicals officer of the facility in question should be contacted for instructions on packaging, labelling and storage (Art. 74, ChemO).

The waste must be disposed of as special waste<sup>45</sup> with the appropriate waste code<sup>46</sup> (18 01 06 for waste from human medical research and diagnostics and 18 02 05 for waste from veterinary medical research and diagnostics; further waste codes may be appropriate for other chemicals, such as 20 01 13 for solvents, 20 01 14 for acids, or 20 01 15 for alkalis). Liquid waste, once it has been chemically inactivated, shall be disposed of in accordance with the instructions given by the manufacturer of the chemicals or disinfectants used. Such waste can be discharged into public sewers only if it fulfils the requirements of Annex 3.2 of the Water Protection Ordinance<sup>47</sup>, in particular those of No. 2.

<sup>&</sup>lt;sup>41</sup> Organisms are assigned to risk groups under Art. 6 and Annex 2.1, ContainO.

<sup>&</sup>lt;sup>42</sup> One study by the Canadian Food Inspection Agency shows that after composting shredded Bt176 maize plants and seeds above a layer of cow manure at over 50 °C for14 days, transgenes were no longer detectable by PCR. Guan J et al., 2005, The fate of the recombinant DNA in corn during composting, J. Env. Sci. Health, Part B. Pesticides, food contaminants, and agricultural wastes, vol. 40, pp. 463-473,<u>https://www.tandfonline.com/doi/abs/10.1081/PFC-200047595</u>.

<sup>&</sup>lt;sup>43</sup> One study by the Danish Research Centre for Organic Farming shows that after composting shredded transgenic Arabidopsis thaliana plants together with damp barley straw, plant material from conventional sugar beet, and white clover, at a temperature of 58 °C for 10–14 days and at 68 °C for 6–10 days, transgenes were no longer detectable by PCR. When plant material was mixed with soil, transgenes could still be detected after 77 days. Rasmussen L. D. et al., 2004, Composting rapidly degrades DNA from genetically modified plants, Newsletter from Danish Research Centre for Organic Farming, No 2 <u>http://orgprints.org/5858/1/5858.pdf</u>.

<sup>&</sup>lt;sup>44</sup> For a definition see the Ordinance on Protection against Dangerous Substances and Preparations; Chemicals Ordinance (ChemO), SR 813.11, <u>http://www.admin.ch/ch/e/rs/c813\_11.html</u>

<sup>&</sup>lt;sup>45</sup> OMW, SR 814.610, <u>hhttp://www.admin.ch/opc/de/classified-compilation/20021080/index.html (in German)</u>

<sup>&</sup>lt;sup>46</sup> DETEC Ordinance concerning the Lists for the Movement of Wastes, SR 814.610.1, <u>http://www.admin.ch/opc/de/classified-compilation/20021081/index.html#app1 (in German)</u>

<sup>&</sup>lt;sup>47</sup> Waters Protection Ordinance, SR 814.201, <u>http://www.admin.ch/opc/en/classified-compilation/19983281/index.html</u>

#### 4.2.8 Mixed waste containing biological material and radioactive substances

Waste containing radioactive substances should be disposed of in consultation with the collection point for radioactive waste of the Paul Scherrer Institut PSI (federal interim storage facility)<sup>46</sup>, in accordance with the Ordinance on Radioactive Waste subject to the Consignment Requirement<sup>49</sup>. The Federal Office of Public Health has issued instructions on this<sup>50</sup>. The facility's radiological protection officer should be contacted under Article 16 of the Radiological Protection Ordinance (RadPO)<sup>51</sup>. and the appropriate method of disposal, including packaging, labelling and storage, should be determined (Art. 75–87, RadPO).

Thermal inactivation or sterilisation of radiolabelled biological material is not appropriate, as this could lead to the radioactive contamination of the autoclave or even to the escape of radioactive steam from the autoclave. Mixed biological and radioactive waste should therefore be inactivated using a chemical process<sup>52</sup>, which should also avoid evaporation or volatilisation.

For waste containing radioisotopes:

#### Radionuclides with half-lives of more than 60 days

- <sup>3</sup>H, <sup>14</sup>C and others above the activity threshold (exemption limit) of the Radiological Protection Ordinance (→ radioactive waste):
  - Chemical inactivation of the biological material using disinfectants that are compatible with the radionuclides.
  - Disposal as low-level radioactive waste to the Federal Office of Public Health<sup>53</sup> or the federal interim storage facility at the Paul Scherrer Institut<sup>54</sup>.
- <sup>3</sup>H, <sup>14</sup>C and others below activity threshold (exemption limit) under the RadPO (→ non-radioactive waste):
  - Inactivation and disposal of the biological material according to Sections 4.1 to 4.2.6.

Radionuclides with half-lives of less than 60 days

- for example <sup>125</sup>I, <sup>131</sup>I, <sup>32</sup>P, <sup>35</sup>S
  - Storage for decay of the radioactivity.
  - Inactivation and disposal of the biological material according to Sections 4.1 to 4.2.6.

#### 4.2.9 Soil, water, air and food samples

Analyses of soil, water, air and food samples for pathogenic microorganisms are generally Class 1 activities. Waste from such activities can be disposed of together with municipal waste. Should a sample prove positive, waste should be disposed of in accordance with Sections 5.2. or 5.3 (waste from activities using microorganisms from BSL-1 and BSL-2, or BSL-3 and BSL-4 laboratories).

<sup>&</sup>lt;sup>48</sup> Collection point for radioactive waste (federal interim storage facility): <u>https://www.kernenergie.ch/de/bundeszwilag.html</u> (in German)

<sup>&</sup>lt;sup>49</sup> Ordinance on Radioactive Waste subject to the Consignment Requirement, SR 814.557, <u>https://www.admin.ch/opc/de/classified-compilation/20011820/index.html</u> (in German)

<sup>&</sup>lt;sup>50</sup> FOPH Information on the disposal of radioactive waste from medicine, industry and research: <u>https://www.bag.admin.ch/bag/de/home/gesund-leben/umwelt-und-gesundheit/strahlung-radioaktivitaet-schall/radioaktive-materialien-abfaelle/entsorgung-von-radioaktiven-abfaellen.html (in German)</u>

<sup>&</sup>lt;sup>51</sup> Radiological Protection Ordinance (RadPO), <u>https://www.admin.ch/opc/en/classified-compilation/20163016/index.html</u>

<sup>&</sup>lt;sup>52</sup> Statement of the German Central Committee on Biological Safety: <u>http://www.bvl.bund.de/SharedDocs/Downloads/06 Gentechnik/ZKBS/01 Allgemeine Stellungnahmen deutsch/06 Sicher</u> <u>heitsmassnahmen/Inaktivierung radioaktiver GVO.pdf? blob=publicationFile&v=2</u> (in German)

<sup>&</sup>lt;sup>53</sup> Radioactive waste from the medical, industrial and research sectors <u>https://www.bag.admin.ch/bag/de/home/gesund-leben/umwelt-und-gesundheit/strahlung-radioaktivitaet-schall/radioaktive-materialien-abfaelle/entsorgung-von-radioaktiven-abfaellen/sammelaktion-fuer-radioaktive-abfaelle-aus-den-bereichen-medizin-industrie-forschung.html (in German)</u>

<sup>&</sup>lt;sup>54</sup> Collection point for radioactive waste (federal interim storage facility):<u>https://www.kernenergie.ch/de/bundeszwilag.html</u> (in German)

## 5 Disposal of the different waste categories

## 5.1 Waste from activities using genetically modified microorganisms from BSL-1 facilities

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
- Liquid and solid cultures of genet-	- Liquid cultures	- Disinfectant-resistant containers	- Chemical inactivation	- Municipal waste water or special waste	<ul> <li>When inactivating chemically, observe application time and concentration.</li> </ul>
ically modified mi- croorganisms		- Autoclavable contain-	- Autoclaving	- Municipal waste water	- It is advisable to add a non-volatile, stable disinfectant to containers in which the waste is gradually accumulated e.g. suction bottles
ically modified cells or cell lines - Contaminated		er			<ul> <li><sup>A</sup>When using chemical disinfectants, the manufacturer's instructions on inactivation and disposal must be observed.</li> </ul>
consumables - Sharps	<ul> <li>Solid cultures</li> <li>Residues in culture vessels and tubes</li> <li>Contaminated consumables</li> </ul>	<ul> <li>Triple packaging: leak-proof bags / con-</li> </ul>	- None	- Direct transport to inciner- ator (bunker)	<ul> <li>Disgusting or foul-smelling waste is classed as special waste even after inactivation.</li> </ul>
		tainers, well sealed, no sharp objects			- Contaminated consumables should be collect- ed in leak-proof bags / containers, and well sealed.
					- If the waste has not been inactivated on site,
		- Disinfectant-resistant containers	- Chemical inactivation	- Municipal waste (or spe- cial waste <sup>∆</sup> )	the transport regulations (ADR) for the choice of container and transport must be observed (see Section 3.3 and Annex III).
		Autoclayable base /	Autoologing	Municipal wasta	- Disposal of special waste in accordance with
		containers	- Autoclaving	- Municipal waste	
	- Sharps	- Sharps containers	- None, or	- Special waste	- Sharps are still classed as special waste even
		(Section 2.2)	- Autoclaving		after inactivation.
Labelling / storage	Non-inactivated was ord / SOP of this pro	te may be taken directly to cedure must be kept. The d	the bunker for incineration in co uty of care must be kept in mind	ontainers (see Appendix III) in a I.	ccordance with transport regulations (ADR). A rec-
	Before inactivation, v period of temporary defined.	waste should not be compre storage, the waste should b	essed or otherwise compacted, be kept in leak-proof containers.	and if possible should not be st Waste should be removed reg	ored or stored for only a short period. For a longer ularly. Responsibilities for disposal must be clearly

## 5.2 Waste from activities using microorganisms from BSL-2 facilities

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
<ul> <li>Liquid and solid cultures of genet- ically modified microorganisms</li> <li>Liquid and solid cultures of path- ogenic microor- ganisms</li> </ul>	- Liquid cultures	<ul> <li>Disinfectant-resistant containers</li> <li>Autoclavable container</li> </ul>	<ul> <li>Chemical inactivation</li> <li>Autoclaving</li> </ul>	<ul> <li>Municipal waste water or special waste</li> <li>Municipal waste water</li> </ul>	<ul> <li>When inactivating chemically, observe application time and concentration.</li> <li>It is advisable to add a non-volatile, stable disinfectant to containers in which the waste is gradually accumulated, e.g. suction bottles.</li> <li><sup>Δ</sup>When using chemical disinfectants, the manufacturer's instructions on inactivation and disposal must be observed.</li> </ul>
<ul> <li>Cultures of genetically modified cells or cell lines</li> <li>Cultures of primary cells or cell lines</li> <li>Contaminated consumables</li> <li>Sharps</li> </ul>	<ul> <li>Solid cultures</li> <li>Residues in culture vessels and tubes</li> <li>Contaminated consumables</li> </ul>	<ul> <li>Autoclavable bags in solid containers, filled to <sup>3</sup>/<sub>4</sub>, or auto- clavable containers</li> <li>Disinfectant-resistant containers</li> <li>UN transport contai- ners (Section 2.2 / Appendix III)</li> </ul>	<ul> <li>Autoclaving</li> <li>Chemical inactivation</li> <li>None</li> </ul>	<ul> <li>Municipal waste</li> <li>Municipal waste (or special waste<sup>Δ</sup>)</li> <li>Special waste*</li> </ul>	<ul> <li>Solid cultures of genetically modified and pathogenic organisms can be collected, inactivated and disposed of together.</li> <li>Disgusting or foul-smelling waste is classed as special waste even after inactivation.</li> <li>Contaminated consumables should be collected in solid autoclavable, unbreakable and sealable containers.</li> <li>If the waste has not been inactivated on site, the transport regulations (ADR) for the choice of container and transport must be observed (see Section 3.3).</li> <li>Disposal of special waste according to OMW.</li> </ul>
	- Sharps	- Sharps containers (Section 2.2)	- None, or - Autoclaving	- Special waste	- Sharps are still classed as special waste even after inactivation*.
Labelling / storage	Before inactivation, *Non-inactivated wa sponsible. A record Before inactivation, period of temporary fined.	BSL-2 waste should be lal aste may be disposed of as / SOP of this procedure m waste may not be compre storage, the waste should	belled with a biohazard symbo s special waste in containers ir nust be kept. ssed or otherwise compacted, I be kept in sealed containers.	l. accordance with transport reg and if possible should not be s Waste should be removed reg	gulations (ADR), if authorised by the Federal Office re- stored or stored for only a short period. For a longer ularly. Responsibilities for disposal must be clearly de-

## 5.3 Waste from activities using microorganisms from BSL-3 and BSL-4 facilities

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions	
- Liquid and solid cultures of patho- genic and genet- ically modified mi-	<ul> <li>Liquid waste (cultures and samples)</li> </ul>	- Disinfectant-resistant containers (only BSL-3)	- Chemical inactivation (only BSL-3)	<ul> <li>Municipal waste water (or special waste<sup>∆</sup>)</li> </ul>	<ul> <li>Municipal waste water (or special waste<sup>Δ</sup>)</li> </ul>	<ul> <li>Inactivation (BSL-3) must be validated</li> <li>With chemical inactivation process, pay attention to exposure time and concentra-</li> </ul>
<ul> <li>croorganisms</li> <li>Cultures of prima- ry cells or cell lines infected with path- ogenic microor- ganisms</li> <li>Contaminated consumables</li> <li>Sharps</li> </ul>	<ul> <li>Autoclavable containers</li> <li>All waste, particularly cultures or enrichments of pathogenic microorganisms, including reference strains for validation of analytical methods, musbe autoclaved. The evidence of effect tiveness must be done for each batc</li> <li>BSL-4: Waste may not be transporter away from the laboratory without privi inactivation, but should be autoclave in a pass-through autoclave, from BS to the outside.</li> <li>BSL-3: Waste that cannot be autoclaved in the laboratory should be autoclaved in the laboratory should be autoclaved outside the laboratory in a controlled area using validated processes Secure transport must be guarantee</li> </ul>	<ul> <li>All waste, particularly cultures or enrichments of pathogenic microorganisms, including reference strains for the validation of analytical methods, must be autoclaved. The evidence of effectiveness must be done for each batch.</li> <li>BSL-4: Waste may not be transported away from the laboratory without prior inactivation, but should be autoclaved in a pass-through autoclave, from BSL4 to the outside.</li> <li>BSL-3: Waste that cannot be autoclaved in the laboratory should be autoclaved claved in the laboratory should be autoclaved in the laboratory should be autoclaved in the laboratory should be autoclaved outside the laboratory in a controlled area using validated processes. Secure transport must be guaranteed.</li> <li>Surface decontamination of consuma-</li> </ul>		<ul> <li>A non-volatile, stable disinfectant must be provided for containers in which the waste is generated gradually e.g. in suction flasks.</li> <li><sup>A</sup>When using chemical disinfectants, the manufacturer's instructions for inactivation and disposal must be observed.</li> <li>If required, add the necessary concentration of a disinfectant that is effective and suitable for autoclaving.</li> <li>Disposal of special waste according to OMW</li> </ul>		
	<ul> <li>Solid waste (cultures and samples)</li> <li>Contaminated consumables</li> </ul>	<ul> <li>Autoclavable bags in solid containers, filled to <sup>3</sup>/<sub>4</sub></li> <li>The surface of bags / containers should be de- contaminated before re- moval from the biological safety cabinet, and before transport to the autoclave.</li> </ul>	bles by fumigation in an airlock. - Or use a diving lock	- Municipal waste	<ul> <li>Solid cultures of genetically modified and pathogenic organisms can be collected, inactivated and disposed of together.</li> <li>Disgusting or foul-smelling waste is classed as special waste even after inactivation.</li> <li>Contaminated consumables should be collected in solid autoclavable, unbreakable and closed containers.</li> </ul>	
	- Sharps	- Sharps containers (Sec- tion 2.2)		- Special waste	<ul> <li>Sharps are still classed as special waste even after inactivation.</li> </ul>	
Labelling / storage	Before inactivation, Before inactivation, stored for only a sh possible. Waste sho	the waste should be labelled w waste may not be compressed ort period and under controlled build be removed regularly. Resp	ith a biohazard symbol. or otherwise compacted, and if possible shou conditions. For a longer period of temporary s ponsibilities for disposal must be clearly,/z/efin	uld not be stored in the storage, the waste shored in the storage.	BSL-3 or BSL-4 laboratory, or should be Ind be kept in sealed containers and cooled if	

### 5.4 Waste containing prions

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
<ul> <li>Material contain- ing prions</li> <li>Cultures of ge- netically modi- fied microorgan-</li> </ul>	<ul> <li>Liquid waste (cultures and</li> </ul>	- Autoclavable containers	<ul> <li>All waste from BSL-3 facilities or above must be inactivated on site using a validated process. Each batch must show evidence of effectiveness.</li> <li>Autoclaving: 1 hour at 134 °C.</li> <li>Chemical inactivation: 1 hour in 2% hypochlorite solution at 20 °C or 2M NaOH.</li> <li>If inactivation is not carried out on site (applies only to BSL-1 and BSL-2 facilities), the waste must be collected in UN transport containers, transported according to regulations specified in Section 3.3 and disposed of as special waste (see Sections 5.1 and 5.2).</li> <li>All waste for BSL-3 facilities on the section at 5.2 for the section at 5.2</li></ul>	<ul> <li>Municipal waste water or special waste</li> </ul>	- If required, add the necessary concentration of a disin- fectant that is effective and suitable for autoclaving.
	samples)	- Disinfectant-resistant con- tainers			<ul> <li><sup>Δ</sup>When using chemical disinfectants, the manufactur- er's instructions for inactivation and disposal must be observed.</li> </ul>
genes	<ul> <li>Solid waste (cultures and</li> </ul>	- Autoclavable bags in solid containers, filled to <sup>3</sup> / <sub>4</sub>		<ul> <li>Municipal waste (or special</li> </ul>	- Disgusting or foul-smelling waste is classed as special waste even after inactivation.
<ul> <li>Sample material containing prion proteins</li> </ul>	samples) - Contaminated	- Disinfectant-resistant con-		waste∆	- Contaminated consumables should be collected in solid autoclavable, unbreakable and closed containers.
<ul> <li>Animal carcass- es containing prion proteins</li> <li>Contaminated consumables</li> <li>Sharps</li> </ul>	consumables	- UN transport containers (Section 2.2 / Appendix III)		- Special waste	<ul> <li>If inactivation does not take place on site, the appropriate transport regulations (ADR) must be adhered to when selecting containers and transport (see Chapter 3.3).</li> <li>Disposal of special waste in accordance with OMW.</li> </ul>
	- Animal car- casses and recognisable parts of ani- mals	- Autoclavable container		- Collection point or incineration plant for animal carcasses	<ul> <li>Disposal in accordance with DABO.</li> <li>For further information on the disposal of animal carcasses, see Sections 4.2.4 and 5.5.</li> </ul>
		- UN transport containers (Section 2.2 / Appendix III)		- Special waste	- Disposal of special waste in accordance with OMW.
	- Sharps	- Sharps containers (Section 2.2)		- Special waste	<ul> <li>Sharps are still classed as special waste even after inactivation.</li> </ul>
Labelling / stor- age	Before inactivation Before inactivation of temporary stora clearly defined.	, the waste should be labelled w , waste may not be compressed ge, the waste should be kept in s	ith a biohazard symbol. or otherwise compacted, and if p sealed containers and cooled if po	ossible should not be ossible. Waste should	stored or stored for only a short period. For a longer period be removed regularly. Responsibilities for disposal must be

#### 5.5 Medical waste

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
- Human or ani- mal tissue sam- ples, possibly	<ul> <li>Liquid and solid samples</li> <li>Contaminated</li> </ul>	<ul> <li>UN transport containers (Section 2.2 / Appendix III)</li> </ul>	- None	- Special waste	- Medical waste from BSL-3 and BSL-4 must be autoclaved on site. A validated process must be used. Proof of effectiveness must be shown for each batch (see Table 5.3).
also organs and body parts; - Humans or ani- mal blood and blood products and components	organs and parts; ans or ani- blood and d products components	- Autoclavable bags / con- tainers	- Autoclaving	- Municipal waste	- Medical waste from BSL-2 can be taken for incineration as special waste without prior inactivation, in line with current practice in hospi- tals, doctors' practices and diagnostics laboratories (authorisation not required). When choosing containers and means of transport, the appropriate transport guidelines (ADR) must be adhered to (see Chapter 3.3).
thereof; - Excretions and secretions of human or animal origin;		- Disinfectant-resistant containers	- Chemical inactivation	<ul> <li>Communal waste water (or special waste<sup>Δ)</sup></li> </ul>	<ul> <li>Medical waste that is special waste with contamination potential should be collected in the laboratory in UN transport containers. If small volumes of liquids are being disposed of with the sample ma- terial, sufficient absorbent material should be added so that all the liquid can be absorbed.</li> </ul>
<ul> <li>Contaminated consumables;</li> </ul>					- For chemical inactivation, see the remarks in Table 5.2 or Table 5.3, respectively.
- Sharps.					<ul> <li>Contaminated consumables should be collected in rigid, autoclava- ble, unbreakable, lockable containers.</li> </ul>
					<ul> <li>Disgusting or foul-smelling waste is classed as special waste even after inactivation.</li> </ul>
	- Sharps	- Sharps containers (Sec- tion 2.2)	- None	- Special waste	- Sharps are still classed as special waste even after inactivation.
- Cultures (liquid or solid)	<ul> <li>If the purpose has been to multiply pathogenic microorganisms, the sample material should be considered as material with cultures of pathogenic microorganisms and disposed of according to Section 5.2 (BSL-2) or 5.3 (BSL-3), depending on the safety level.</li> </ul>				
- Human waste from pathology	<ul> <li>Body parts, amputates, removed or- gans, foetuses</li> </ul>	- Suitable containers	- None	- Crematorium	<ul> <li>Pathological waste is not considered as special waste for ethical reasons.</li> </ul>
Labelling / stor- age	r- Before inactivation, the waste should be labelled with a biohazard symbol. Before inactivation, waste may not be compressed or otherwise compacted, and if possible should not be stored or stored for only a short period. For a longer period of temporary storage, the waste should be kept in sealed containers and cooled if possible. Waste should be removed regularly. Responsibilities for disposal must be clearly defined.				

#### 5.6 Animal carcasses from animal facilities

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
- Genetically modified animals (BSL-1)	- Carcasses and body parts	<ul> <li>Closed airtight containers or</li> <li>Covered airtight, corrosion- resistant and easy-to-clean con- tainers</li> <li>Should be black and labelled "for incineration only"</li> </ul>	- None	- Collection point or incineration plant for animal carcasses	<ul> <li>Disposal in accordance with DABO.</li> <li>Packaging requires particular movement documents (Art. 20 DABO).</li> <li>Carcasses of genetically modified animals may not be used as animal feed.</li> <li>Eurther information in Section 4.2.4</li> </ul>
	- Litter	- Suitable containers	- None	- Municipal waste	<ul> <li>Carcasses and body parts of animals that contain prions must be disposed of in accordance with Section 5.4.</li> </ul>
	- Cages	- None	- Chemical disinfection	- Recycling	- Carcasses and body parts of animals that are infected
- Animals infected with human- or animal- pathogenic or genetically modi- fied microorgan- isms (including deliberate infec	- Carcasses and body parts	<ul> <li>Closed and autoclavable con- tainers / slash-resistant bags in solid containers.</li> </ul>	- Autoclaving	- Collection point or incineration plant for animal carcasses	<ul> <li>Article 2 of the Epizootic Diseases Ordinance must be inactivated on site before disposal. The process must be validated.</li> <li>As of BSL3, a validated process must be used. Proof of effectiveness must be shown for each batch.</li> <li>Disgusting or foul-smelling waste is classed as special waste even after inactivation.</li> </ul>
tion) - Genetically modified animals (BSL-2 and BSL- 3)		<ul> <li>UN transport containers (Section 2.2 / Appendix III)</li> </ul>	<ul> <li>None (BSL-2; large animals in particular cannot be inactivated on site)</li> </ul>	- Special waste	<ul> <li>Disposal of special waste according to OMW.</li> <li>If the waste has not been inactivated on site, the transport regulations (ADR) must be observed for the choice of container and transport (see Section 3.3).</li> </ul>
0)	- Litter	<ul> <li>Closed and autoclavable con- tainers</li> </ul>	- Autoclaving	- Municipal waste	- Cages can be autoclaved in their racks.
	- Cages	- None	- Autoclaving	- Recycling	closed and autoclavable containers.
		- Disinfectant-resistant containers	<ul> <li>Chemical decontami- nation</li> </ul>	-	
Labelling / stor- age	Before inactivati If possible, anim storage, the was defined.	ion, containers of infectious animal ca nal carcasses should not be stored, or ste should be kept in sealed container	rcasses should be labelled v should be stored for only a s s and kept below 4 °C. Cont	vith a biohazard symbo short period, whether l ainers should be remo	ol and may not be compressed or compacted in any way. before or after inactivation. For a longer period of temporary by dregularly. Responsibilities for disposal must be clearly

### 5.7 Plants and plant parts from greenhouses and growing rooms

## 5.7.1 Genetically modified plants (Group 1)

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
<ul> <li>Genetically modified plants</li> <li>Genetically modified plants infected with Group 1 plant- pathogenic mi- croorganisms</li> </ul>	<ul> <li>Plant material not capable of propagation</li> </ul>	- Suitable containers	- None	- Composting on site	- Composting does not count as inactivation, unless it takes place using a heat-period and with vali- dated processes. Composting may be used only
	<ul> <li>Plant material capable of prop- agation (seeds, pollen, rhizomes, bulbs)</li> </ul>	- Triple packaging	- None	- Direct transport to incinerator (bunker)	The compost must be reused on site.
	- Soil, earth	- Autoclavable containers	<ul> <li>Autoclaving</li> <li>Steam treatment</li> </ul>	- Recycling	
	- Contaminated consumables	- Suitable containers	- Clean thoroughly	- Municipal waste	
Storage	Genetically modified	plants and plant parts should b	e stored and transported such that	no plant material capa	ble of propagation can escape into the environment.

## 5.7.2 (Genetically modified) plants infected with pathogenic (group 2 or 3) or genetically modified (group 1) microorganisms

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
<ul> <li>Plants infected with genetically modified Group 1 microorganisms</li> <li>Genetically modified plants infected with group 1 genet- ically modified microorganisms</li> </ul>	<ul> <li>Plants, plant parts, seeds, pol- len</li> <li>Soil, earth</li> <li>Contaminated consumables</li> </ul>	- Triple packaging: leak- proof bags / containers, well sealed, no sharp ob- jects	- None	- Direct transport to incinerator (bunker)	- Disposal as in Table 5.1.
<ul> <li>Plants infected with pathogenic or genetically modified micro- organisms</li> <li>(Group 2 or 3)</li> </ul>	- Plants, plant parts, seeds, pol- len	- Autoclavable containers	<ul><li>Autoclaving</li><li>Steam treatment</li></ul>	- Municipal waste	<ul> <li>Infected plants from BSL-3 must be inactivated on site.</li> <li>As of BSL 3, a validated process must be used.</li> </ul>
		<ul> <li>UN transport containers (Section 2.2 / Appendix III)</li> </ul>	- None	- Special waste	Evidence of effectiveness must be shown for each batch.
- Genetically	- Soil, earth	- Autoclavable containers	- Autoclaving	- Recycling	- For activities involving microorganisms from BSL- 3 facilities see Table 5.3.
infected with			- Steam treatment	- Municipal waste	- <sup>A</sup> When using chemical disinfectants, the manufac-
pathogenic or genetically modi- fied microorgan- isms (Group 2 or 3)		- UN transport containers (Section 2.2 / Appendix III)	- None	- Special waste	<ul> <li>turer's instructions for inactivation and disposal must be observed.</li> <li>Disposal of special waste according to OMW.</li> </ul>
	- Contaminated	- Autoclavable containers	- Autoclaving	- Municipal waste	
	consumables	- Disinfectant-resistant containers	- Chemical inactivation	(or special waste <sup>∆</sup> )	
Storage	Plants and plant part such that no pathoge	s infected with group 2 or 3 pat nic or genetically modified mici	hogenic microorganisms, or with ge oorganisms can escape into the en	enetically modified orga vironment.	anisms of all groups, should be stored and transported

## 5.8 Mixed waste containing biological material and hazardous chemicals and radioisotopes

Type of waste		Collection	Inactivation	Disposal	Special regulations / notes / exceptions
- Biological- chemical waste	<ul> <li>Biological mate- rial and hazard- ous chemicals</li> </ul>	- Disinfectant- and chem- ical-resistant containers	<ul> <li>Chemical inactivation</li> <li>Possible autoclaving</li> </ul>	- Special waste	<ul> <li>Disposal in accordance with the ChemO and the OMW.</li> <li>Further information in Section 4.2.7.</li> <li>When chemical disinfectants are used, it should be in accordance with the manufacturer's instructions for inactivation and disposal.</li> </ul>
- Biological- radioactive waste	- Biological mate- rial and radioac- tive substances	<ul> <li>Radioisotope-resistant containers, disinfectant- resistant</li> <li>Label: "radioactive"</li> </ul>	<ul> <li>Half-life &lt; 60 days:</li> <li>Chemical inactivation of the biological material</li> <li>Waste must be stored at the facility until the radiation has fallen to below the activity threshold (exemption limit) in accordance with the Radiological Protection Ordinance.</li> <li>Half-life &gt; 60 days:</li> <li>Chemical inactivation of the biological material</li> <li>Avoid evaporation / volatilisation</li> </ul>	<ul> <li>Municipal waste / special waste</li> <li>Radioactive waste to PSI</li> </ul>	<ul> <li>Disposal of radioactive waste in accordance with the Ordinance on Radioactive Waste subject to the Consignment Requirement.</li> <li>The Radiological Protection Ordinance lays down the activity threshold (exemption limit) for radionuclides.</li> <li>The Paul Scherrer Institut has a collection point for radioactive waste.</li> <li>The Federal Office of Public Health provides general instructions.</li> <li>Further information in Section 4.2.8.</li> <li>Thermal inactivation or sterilisation of radiolabelled biological material is not appropriate, as this could lead to the radioactive contamination of the autoclave or even to the escape of radioactive steam from the autoclave.</li> <li>Once the waste is no longer radioactive, disposal should be according to composition, in line with Sections 5.1 to 5.7.</li> </ul>
Labelling / stor- age	Before inactivation, the waste should be labelled with a biohazard symbol and may not be compressed or compacted in any way. Radioactive waste must also be labelled as such. Waste should be monitored and be stored for only a short period. For a longer period of temporary storage, the waste should be kept in sealed containers and cooled if possible. Waste should be removed regularly. One or two persons should be designated responsible.				
	be labelled as such.	Biological material must be c	hemically inactivated before tempor	ary storage.	usi be accessible only to authorised persons and must

## 6. Appendices

## Appendix I: Codes for special waste

## Extract from the DETEC Ordinance on Lists for the Movements of Waste, Chapter 1855

18 01	Waste from research, obstetrics, diagnosis, treatment or prevention of diseases in humans
18 01 01	Sharps (waste which poses a risk of injury), except for those that fall under 18 01 03
18 01 02	Waste with contamination potential (e.g. tissue wastes, waste containing blood, secretions or excretions, blood bags and blood preserves)
18 01 03	Infectious waste
18 01 06	Chemicals consisting of or containing dangerous substances
18 02	Waste from diagnosis, treatment or prevention of diseases in animals
18 02 01	Sharps (waste which poses a risk of injury), except for those that fall under 18 02 02
18 02 02	Infectious wastes
18 02 05	Chemicals consisting of or containing dangerous substances
18 02 98	Animal waste with contamination potential (e.g. tissue waste, waste containing blood, secre- tions and excretions, blood bags and blood preserves, contaminated animal carcasses)
20 01	Separately collected fractions
20 01 13	Solvents
20 01 14	Acids
20 01 15	Alkalis

<sup>&</sup>lt;sup>55</sup> SR 814.610.1, <u>http://www.admin.ch/ch/d/sr/814\_610\_1/app1.html (in German)</u>

#### Appendix II: Disinfectants and their spectrum of activity

The list below only gives a brief overview of active substances that can be used for chemical inactivation, decontamination and disinfection. Application must be adapted to each specific case.

In Switzerland, disinfectants are generally classed according to their application as medical products<sup>56</sup> or biocidal products<sup>57</sup>. Liquid waste that has been inactivated using chemical disinfectants must be disposed of in accordance with the manufacturer's instructions. Liquid waste may also need to be treated as special waste and disposed of under the OMW codes 18 01 06, 18 02 05, 20 01 13, 20 01 14 or 20 01 15 (see Appendix I).

Chemical active substance	Fungi	Bacteria			Spores	Viruses		
		Gram +	Gram -	Myco- bacteria		In blood	Envel- oped	Not en- veloped
Alcohols	++	+++	+++	+++	-	++	++	+
Chlorhexidines	++	+++	+++	+	-	+	+	-
Formaldehyde	+++	+++	+++	+++	+++	++	++	++
Glutaraldehyde	+++	+++	+++	+++	+++	++	++	++
H <sub>2</sub> O <sub>2</sub> and other O- radical emitters	+++	+++	+++	+++	++	+++	+++	+
Hypochlorite and other CI emitters	++	+++	+++	++	+++	++	++	++
Phenolic substances	+++	+++	+++	++	-	+	+	+
Quaternary ammonium salts (QAC)	++	+++	++	+	+	+	+	-

Data from:

- WHO Laboratory Biosafety Manual, Chapter 14, Disinfection and Sterilization, http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
- List of disinfectants and disinfectant processes as tested and approved by the Robert Koch Institut

http://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/des\_inf\_inhalt.html (in German)

- Antiseptics and Disinfectants: Activity, Action, and Resistance, Gerald McDonnell and A. Denver Russell, Clinical Microbiological Reviews, 1999, http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=88911
- Decontamination, sterilization, disinfection and antisepsis, Vesley D., Lauer J.L. and Hawley R.J.
   In: Fleming D.O. and Hunt D.L., *Biological safety principles and practices*. Washington, DC: ASM Press, 2000; 383-402.
- Principles and practice of disinfection, preservation and sterilization, Fraise AP, Lambert PA and Maillard JY (eds), Blackwell Publishing, 2004.
- CDC MMWR, Recommendations and Reports: Disinfectants and their properties, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5404a2.htm

A list of the spectrum of activity of disinfectants adapted for use on a production scale is given in the EN Standard 12461:1998<sup>58</sup>.

<sup>&</sup>lt;sup>56</sup> Ordinance on Medical Devices (MepV), SR 812.213 <u>http://www.admin.ch/opc/de/classified-compilation/19995459/index.html</u> (in German)
<sup>57</sup> Ordinance on Biocidal Products (OBP), SR 813.12, <u>http://www.admin.ch/ch/e/rs/c813\_12.html</u>

 <sup>&</sup>lt;sup>58</sup> EN 12461, Biotechnology - Large scale process and production - Guidance for the handling, inactivating and testing of waste, 1998, available from the Swiss Association for Standardization, http://shop.snv.ch/en/home/?lang=1.

#### Appendix III: UN transport containers

The national and international transport regulations given in Section 3.3 apply to the packaging and transport of waste that contains or is contaminated with non-inactivated pathogenic or genetically modified organisms.

<u>Small amounts</u> of waste in the scope of this Recommendation that is disposed of as special waste without inactivation on site should be assigned to UN number 3291<sup>59</sup>, and must be packed according to packaging regulation P621<sup>60</sup>. Larger quantities of waste or larger animal carcasses may be transported in bulk material containers<sup>61</sup>. The UN transport containers must adhere to the following criteria and be type-tested:

- Rigid, airtight, unbreakable packaging that contains sufficient absorbent material to absorb all liquid substances contained in the packaging. The packaging must also be capable of retaining liquid substances, and must pass a drop test from a height of 1.2 m.
- Packaging intended for sharp or pointed objects such as glass or needles (sharps containers) must additionally be puncture resistant.
- The packaging must be labelled with a biohazard symbol.

Various national and international companies supply UN transport containers that may be used for the collection and disposal of waste. The list of addresses below gives some examples, but makes no claim to being complete:

- Milian: <u>http://www.milian.com/frontoffice/browse\_catalog?id=0N-17</u>
- Remondis Schweiz AG: http://www.remondis.ch/rmch/spektrum/sammelsysteme/behaelter/
- Servi-Medical (CH): http://www.servi-medical.ch/
- Spiromed AG (CH): http://www.spiromed.ch/index\_frame.html
- Semadeni Group: http://eshop.semadeni.com/
- Carepack Holland BV: <u>http://www.carepack.nl/</u>
- Inmark: <u>http://www.inmarkstp.com/products/</u>

Larger quantities of medical waste assigned to UN number 3291, may also be packed in accordance with packing instructions LP621 or IBC620<sup>62</sup>. LP621 describes rigid, leak-proof large packagings with a net weight of more than 400 kg or a capacity of more than 450 litres, but a maximum volume of 3 m<sup>3</sup>, and which is an outer packaging for (several) inner packagings. IBC620 also permits rigid, leak-proof IBCs with a capacity of up to 3 m<sup>3</sup>. Larger quantities of waste or large animal carcasses may also be transported in bulk containers<sup>63</sup>. These three packagings must also be type-tested.

<u>Genetically modified organisms</u> are assigned to UN number 3245 and must be packed in accordance with packing instruction P904. The following packagings are authorised:

- Triple packaging (does not need to be type-tested):
  - Primary receptacle(s) and secondary packagings must be leak-proof for liquids, and siftproof for solids.
  - For liquids, sufficient absorbent material must be placed between the primary receptacle(s) and the secondary packaging to absorb the entire quantity of liquid.
  - The outer packaging must be strong enough for its capacity, mass and intended use, and with a smallest external dimension of at least 100 mm.

<sup>&</sup>lt;sup>59</sup> ADR 2019, Sections 2.2.62.1.11.1. to 2.2.62.1.11.3, <u>http://www.unece.org/fileadmin/DAM/trans/publications/ADR\_2019\_vol1\_1818953\_E.pdf#page=227</u>

<sup>&</sup>lt;sup>60</sup> ADR 2019, Section 4.1.4, Packing instruction P621, <u>http://www.unece.org/fileadmin/DAM/trans/publications/ADR 2019 vol2 1818956 E.pdf#page=129</u>

<sup>&</sup>lt;sup>61</sup> ADR 2019, Section 7.3.2.6, <u>http://www.unece.org/fileadmin/DAM/trans/publications/ADR\_2019\_vol2\_1818956\_E.pdf#page=556</u> <sup>62</sup> ADR 2019, Section 4.1.4, List of packing instructions LP621

http://www.unece.org/fileadmin/DAM/trans/publications/ADR\_2019\_vol2\_1818956\_E.pdf#page=156 and IBC620 http://www.unece.org/fileadmin/DAM/trans/publications/ADR\_2019\_vol2\_1818956\_E.pdf#page=152

<sup>&</sup>lt;sup>63</sup> ADR 2019, Section 7.3.2.6, <u>http://www.unece.org/fileadmin/DAM/trans/publications/ADR\_2019\_vol2\_1818956\_E.pdf#page=556</u>

- Various packagings such as drums, boxes, canisters and bags made of different materials. The packagings do not need to be type-tested; various ADR requirements are sufficient, e.g. those relating to maximum capacity and maximum net weight:
  - Drums: 250 450 I (depending on the material)
  - o Canisters: 60 I
  - o Boxes: 400 kg
  - o Bags: 50 kg

Transport regulations and instructions on packaging, labelling, documentation and shipping are given in detail on the SECB's website, under Transport, import and export of substances consisting of or containing pathogenic or genetically modified (micro)organisms<sup>64</sup>.

<sup>&</sup>lt;sup>64</sup> Transport, import and export of substances consisting of or containing pathogenic or genetically modified (micro)organisms <u>http://www.efbs.admin.ch/index.php?id=462&L=3</u>

#### **Appendix IV: References**

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- Laboratory biosafety manual (3rd edition, 2004), Geneva, WHO: http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
- Safe management of wastes from health-care activities, Geneva, WHO (Second edition 2014): <u>http://www.who.int/water\_sanitation\_health/publications/safe-management-of-wastes-from-healthcare-activities/en/</u>
- Handling, storage and transportation of health-care waste, WHO 1999: http://www.who.int/water\_sanitation\_health/medicalwaste/061to076.pdf
- Biosafety in Microbiological and Biomedical Laboratories (BMBL; 5th edition, 2009) U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health: <u>http://www.cdc.gov/biosafety/publications/bmbl5/index.htm</u>
- Canadian Biosafety Standards and Guidelines (CBSG; First edition, 2013): http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php
- (German) Committee for Biological Agents (ABAS): TRBA 100 "Protective measures for specific and non-specific activities involving biological agents in laboratories": <u>http://www.baua.de/cae/servlet/contentblob/673098/publicationFile/48545/TRBA-</u> 100.pdf;jsessionid=DAA1450896982AB71E7814F4277FFC5D
- Recommandations en matière de gestion de déchets et/ou matières biologiques résiduelles dans le cas d'une gestion centralisée avec intervention d'une société extérieure de traitement des déchets: <u>https://www.biosecurite.be/sites/default/files/cl\_fr\_dechets\_2006\_e.pdf</u> (in French)
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- Verhütung von Berufskrankheiten in diagnostisch-mikrobiologischen Laboratorien SUVA (3rd, revised edition, 2003): <a href="https://extra.suva.ch/suva/b2c/download/(layout=6\_5\_59\_52\_10\_6\_1&uiarea=1&citem=4CA34C7\_20AA94329E10080000A63035B3B1E1F5ADC1B710CE10000000A63034B]/.do?doctype=pdf&d\_ocid=0000000000005450&file=2869\_27\_D.pdf</a> (in German)
- Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Guidance from the Advisory Committee on Dangerous Pathogens' TSE Working Group, Annex C: General principles of decontamination and waste disposal (2009) <u>http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod\_consum\_d</u> <u>h/groups/dh\_digitalassets/@dh/@ab/documents/digitalasset/dh\_108602.pdf</u>
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#### Appendix V: Ordinances and enforcement aids

- Ordinance on Handling Organisms in the Contained System (Containment Ordinance, ContainO), SR 814.912, <u>http://www.admin.ch/opc/en/classified-compilation/20100803/index.html</u>
- Ordinance on Occupational Safety in Biotechnology (OOSB), SR 832.321, http://www.admin.ch/opc/de/classified-compilation/19994946/index.html (in German)
- Ordinance on Movements of Waste (OMW), SR 814.610, <u>http://www.admin.ch/opc/de/classified-compilation/20021080/index.html (in German)</u>
- DETEC Ordinance concerning the Lists for the Movement of Waste, SR 814.610.1 http://www.admin.ch/opc/de/classified-compilation/20021081/index.html#app1 (in German)
- Ordinance on the Disposal of Animal By-Products (DABO), SR 916.441.22, http://www.admin.ch/opc/de/classified-compilation/20101486/index.html (in German)
- Water Protection Ordinance (WPO), SR 814.201, http://www.admin.ch/opc/en/classified-compilation/19983281/index.html
- Ordinance on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products, OBP), SR 813.12, <u>http://www.admin.ch/opc/en/classified-</u> <u>compilation/19983281/index.html</u>
- Ordinance on Medical Devices (MedDO), SR 812.213, <u>http://www.admin.ch/opc/de/classified-compilation/19995459/index.html (in German)</u>
- Ordinance of on Radioactive Waste subject to the Consignment Requirement, SR 814.557, https://www.admin.ch/opc/de/classified-compilation/20011820/index.html (in German)
- Radiological Protection Ordinance (RadPO), SR 814.501, <u>https://www.admin.ch/opc/en/classified-compilation/20163016/index.html</u>
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