Containment Ordinance (ContainO) of 1 June 2012

Commentary

1 INTRODUCTION

1.1 Preliminary remarks

Since the Ordinance of 25 August 1999 on the Contained Use of Organisms (Containment Ordinance, ContainO; SR 814.912) came into force on 1 November 1999, legislation on organisms has undergone further substantial development. To take full account of the changed legal basis and the advances in scientific and practical knowledge, a total overhaul of the ContainO became urgent. The total overhaul has been undertaken in close coordination with the "sister ordinances" of the ContainO, which were originally issued at the same time: the Release Ordinance (RO; SR 814.911) and the Ordinance of 25 August 1999 on the Protection of Employees from Dangerous Microorganisms (PEMO; SR 832.321). Previously, the objectives of legislation on organisms were to protect human beings and the environment from hazardous or undesirable effects. The protection of biological diversity and its sustainable use is now also a factor, as is respect for the dignity of living beings in the case of genetically modified organisms (GMOs). In addition, the various ways of handling organisms, particularly GMOs, and the specific requirements for this, have been differentiated.

Experience from the implementation of existing legislation on organisms have shown a need for some amendments. For example, the notification and licensing procedures for activities in contained systems have been simplified, and the safety measures have been brought into line with up-to-date science and technology, as the provisions of the Containment Ordinance (ContainO) were too often open to interpretation. At the same time, the scope of the ContainO was extended to include alien organisms, to counter, in coordination with the Release Ordinance (RO), the uncontrolled spread and proliferation of organisms with a high potential for invasiveness and damage. Finally, a new duty to report accidents and incidents, including those that fall outside the scope of the Ordinance of 27 February 1991 on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012), aims to tighten safety when handling organisms.

The notification and licensing procedures have been standardised and simplified, the safety measures have been brought into line with the latest state of science and technology, and the provisions on guaranteeing liability have been harmonised with those of the RO. Now, activities using Class 1 genetically modified organisms can be notified globally (instead of individually, as previously); even where work involves different organisms with similar properties, it is now possible to notify these activities as a single Class 2 activity. Such a reduction in procedures is possible without having an impact on biosafety only if the responsibility for risk determination and assessment is taken more seriously by all concerned. Incidents occurring in contained systems, involving an escape of organisms into the environment, or where there had been actual risk of such escape during Class 3 and 4 activities, must now be reported (to the Cantons, who then report it to the federal authorities), even if these incidents do not have to be reported under the MAO.

The tasks of the authorities remain essentially unchanged. The ContainO now explicitly requires the use of a database – already in existence as ECOGEN, which enables the Coordination Centre to transmit notifications and licence applications to the specialist agencies and parties involved to inform them of the status of the notification and licensing procedure. Another new possibility is the issuing of provisional licences, after an initial check of the risk determination and assessment and until the normal procedure has been

completed, for example when it is necessary to make rapid diagnosis of new types of microorganisms.
To simplify the introduction of the revised ContainO, accompanying measures are also planned. For example, the courses of the Curriculum Biosafety (training courses for Biosafety Officers) have been adapted to the new provisions of the ContainO, particularly those concerning the handling of alien organisms and the corresponding safety measures. Furthermore, the Federal Coordination Centre for Biotechnology will provide additional information and amended forms for notifying the handling of exotic organisms and for Class 1 global notifications.

1.2 Comparison with European legislation

Within the European Union (EU), handling in contained systems is obligatory for genetically modified microorganisms alone. The scope of this obligation is regulated by the recast Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Contained Use Directive)1. For risk determination and assessment in the occurrence of and handling of organisms, the Containment Ordinance relies on the Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (Biological Agents Directive)2.
Through the additional regulation of genetically modified macroorganisms and pathogenic and alien organisms, the ContainO goes beyond the Contained Use Directive, which refers only to genetically modified microorganisms (GMMs). For GMMs, the draft revision of the ContainO adopts, as before, the notification and licensing procedure of the Contained Use Directive. It now also comes closer to the EU regulation covering activities using Class 1 genetically modified organisms, as an establishment must now notify all its Class 1 activities globally. In derogation from EU law concerning first activities, however, the waiting period of 45 days that must be observed after notification for Class 2 activities using genetically modified organisms has now been dropped. This is justified because of the low risk of such activities, and to have a standardised procedure for all organisms, but it still guarantees that at any point the enforcement and regulatory authorities have a complete overview of activities subject to the ContainO.3

1.3 Effects on the Confederation and Cantons

Extending the scope of the ContainO to alien organisms means an increase in the cost of enforcement for the cantonal and federal authorities. Nevertheless, this extension of scope is urgent, as the ContainO must be harmonised with the revised Release Ordinance. In addition, by making some safety measures more flexible, increased demands are made on the authorities to evaluate applications for the omission of safety measures. Moreover, the revised Ordinance stipulates that Class 1 notifications can in future be made globally. Up to now Class 1 notifications have made up more than 40% of all notifications, so that after a transitional period we should be able to see a considerable reduction in workload. But the bottom line is that we should assume not only the total number of notifiable or licensable

1 OJ L 125 of 21.5.2009, p. 75.

2 Seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC, OJ L 262 of 17.10.2000, p. 21.

3 Cf. explanation of individual provisions, Article 8.

activities in contained systems will continue to increase, but also that there will be more stringent requirements for their evaluation.

1.4 Effects on research and industry

As a consequence of increased notifications and licence applications, the extension of scope will place increased burdens on some establishments. At the same time, however, legal certainty will be increased, as the current legal situation – where under the RO, an organism may not be handled in the environment, but where the ContainO gives no regulations for this organism in a contained system – is producing uncertainty and confusion.

The global notification of Class 1 activities using genetically modified organisms will considerably reduce the costs and time needed for these notifications. And a more flexible management of safety measures will reduce costs, for example by making it no longer necessary to purchase an autoclave if the inactivation of organisms can be achieved in another way (e.g. chemically). Substantial simplifications have been introduced for waste disposal as well. Some wastes arising from Class 2 activities can now be disposed of externally as special waste, and need no longer be inactivated on site. This will make things easier for hospitals in particular, as the laboratory wastes can now be disposed of together with hazardous hospital waste.

2 EXPLANATION OF THE INDIVIDUAL PROVISIONS

Ingress

The Ingress of the ContainO now also refers to the Convention on Biological Diversity of 5 June 1992 (CBD; SR 0.451.43). Article 8 CBD obliges the Contracting Parties to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology (letter g); prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species (letter h); and where a significant adverse effect on biological diversity has been determined, regulate or manage the relevant processes and categories of activities (letter l). In addition, Article 19 CBD regulates the transmission of information about the use and safety regulations required by that Contracting Party in handling such organisms (para. 4).

Chapter 1 General provisions

Art. 1 Aim

The substantive content remains unchanged, but the formulation has been harmonised with that of Article 6 Gene Technology Act (GTA; SR 814.91), Article 29a EPA and Article 1 para. 1 RO. Further, the Ordinance limits itself essentially to the “normal” operation of biotechnological establishments. Metabolic products and wastes, which if viewed in isolation from organisms would not fall under the scope of the ContainO, are now mentioned. The metabolic products themselves (e.g. purified toxins, antibodies, antigens etc.) do not fall under the scope of the ContainO. It should also be noted that plants and soils come under Article 1, although they are not explicitly mentioned alongside human beings and animals. The term “environment” should be interpreted broadly.

Art. 2 Subject matter and scope of application

Para. 1:
Alien organisms have been added to the subject matter.

Para. 2:
The term “placing on the market” has been replaced by “transport”. Placing on the market, in accordance with Article 3 para. 1 letter k RO, refers to the marketing of organisms for handling in the environment, and should therefore not be used for their handling in contained systems. Much as before, transport comes within the ContainO’s scope only in terms of the duty of care (Art. 4), the duty to inform recipients (now in Art. 15), specific provisions on transport (Art. 15), and the provisions on monitoring transport (Art. 25).

Para. 6:
This paragraph is substantively the same as Article 2 para. 6 Letter a RO. Experimental compounds that are used on humans in clinical trials may contain genetically modified organisms. Under the ContainO these must be produced in a contained system (Art. 16 para. 2 letter a of the Ordinance of 17 October 2001 on Clinical Trials of Therapeutic Products, ClinO; SR 812.214.2). The conduct of a clinical trial is assessed under the ClinO (Art. 16 para. 2 letters b and c) and not under the ContainO.

Art. 3 Definitions

Letter a:
The definition of “organisms” is in line with current Swiss legislation and is harmonised with the provisions of Article 5 para. 1 GTA, Article 7 para. 5bis EPA and Article 3 para. 1 Letter a RO (explicit mention of “products”). The term “organisms”, meaning biological entities that are capable of replication, also covers primary differentiated cell cultures that are now no longer replicating. It does not, however, cover e.g. blood plasma or cell organelles.

Letter b:
The definition of “microorganisms” remains unchanged, with the exception of parasites, which have been deleted from this definition, as parasitism describes a mode of life and not a classification (bacteria, viruses etc.). This amendment is also being made to the RO. For the ContainO, it is the pathogenicity of microorganisms that is relevant and not whether they are parasitic. Although macroparasites, such as broomrape, mistletoe and yellow rattle (plant macroparasites), or tick, tapeworm and liver fluke (animal macroparasites) may be parasitic, they are not microorganisms but macroorganisms, and as plants or animals the ContainO’s definition of “organism” already covers them. There is thus a duty to handle macroparasites in a contained system if they are themselves pathogenic (e.g. fox or pork tapeworm), or if a planned activity cannot rule out these organisms being infected with pathogenic microorganisms (see diagram below for explanations of Art. 3 letter i ContainO).
Biologically active genetic material continues to be regarded as microbiological entities. Biologically active genetic material describes DNA and RNA sequences that are incapable of replicating independently (e.g. plasmids), but can be transmitted, have a pathogenic effect, or are infectious, genetically modified or generally capable of causing a targeted or foreseeable effect in an organism, such as protein expression, immune response or inhibition

of cell division. For example, siRNA, which inhibits the expression of a particular gene sequence and thus causes a specific effect in an organism (e.g. inhibition of tumour suppressor genes), would be regarded as an organism pursuant to the ContainO, while fluorescence-tagged oligonucleotides, which *in vivo* are used only to detect a specific sequence, or PCR primers and products, would not come under this legal definition of an organism. Note that this definition is also applied to organisms produced using synthetic biology and/or nanobiotechnology.

Letter c:
The extension of the ContainO's scope to cover alien organisms, particularly small invertebrates, requires the definition to be amended accordingly. The definition is now the same as that in Article 3 para. 1 Letter c RO. The term "small invertebrates" is deliberately broad, as it is then possible to include additional, "problematic" species without having to amend the Ordinance each time, as would be the case for an explicit list. The definition is also intended to cover only those organisms that may be a potential hazard to the environment due to their invasiveness, but which are not otherwise regulated. For example, the definition does not cover land snails, as there are currently no known potentially invasive alien species. The species in question can be included in Annex 2 RO as required. Other invasive alien species (e.g. molluscs) would be treated similarly, as required.

Letter d:
In line with Article 3 para. 1 Letter d RO, "genetically modified organisms" also include pathogenic or alien organisms that have been genetically modified. Adopting this cascade from the RO supports the principle that wherever there are overlaps, the stricter procedure shall apply (e.g. concerning the duty to notify Class 1 activities).

Letter e:
The ContainO now also defines pathogenic organisms (PO), putting Article 7 para. 5^{quater} EPA into concrete terms and by analogy with Article 3 para. 1 Letter e RO. PO are understood to be organisms that can cause (infectious) diseases in human beings, domesticated animals and plants. They are typically microorganisms; predators, pests, macroparasites and poisonous animals are in general not regarded as pathogenic (except for certain endoparasites, such as fox or pork tapeworm, which are pathogenic per se). The delimitations of the three properties is not always clear and the transitions are sometimes fluid, especially in regard to microorganisms. In the case of macroorganisms infected or contaminated with PO, the PO should be taken into account when determining the risk of activities using these infected organisms. This may mean that domestic ticks, which do not normally count as PO and thus do not come under the containment obligation of the ContainO, may be regarded as Group 2 PO in the case of a suspected or proven infection, e.g. with *Borrelia*. It is thus the pathogen contained within the tick and not the vector (the tick itself) that determines its Group.
Instead of referring to livestock and crops, the definition now refers to domesticated animals and plants, so that pets will be covered; this amendment will also be made to the RO (cf. Annex 5 ContainO).

Letters f and g:
Because the ContainO's scope has been extended to include alien organisms, the corresponding definitions must be adopted into the ContainO, by analogy with those of

Article 3 para. 1 letters f–h RO. The definition of alien organisms (letter f) is slightly modified from the wording in the RO (cf. also the amendment to the RO via Annex 5 of the ContainO). To define the term “alien” unambiguously, we now refer to species, sub-species or lower taxonomic levels, as well as to the area in which the organisms naturally occur in their wild form, rather than starting from the assumed natural occurrence of organisms. An animal, a plant or another organism is thus regarded as being alien if the organism itself, as a sub-species or lower taxonomic level, is imported from areas outside the EU/EFTA area, even if the species in question may occur within these countries. Furthermore, an organism is regarded as alien if the area in which it occurs in its wild form lies outside Europe, even if the species has established and spread within Europe (cf. the example of the harlequin ladybird, Annex 2 RO). In contrast to the legislation on animal protection, the essential criterion for the ContainO and the RO is survivability in the wild and not a function as livestock or domestic animal. For considerations of commercial law, the primary focus is on European origin rather than on biogeographical regions. Organisms are not considered to be alien if they originate outside Switzerland and the EU/EFTA countries, but have been bred for use in agriculture or commercial horticulture in such a way that their ability to survive in the wild is reduced.

Letter i:
A deliberate activity involving organisms is regarded under the ContainO and PEMO as handling, and thus comes under the provisions of these two Ordinances. The PEMO also regulates work that involves handling microorganisms unintentionally, and in which contact with microorganisms is possible (Art. 2 letter e PEMO). This is not considered to be a handling of a microorganism, but an exposure to it. However, more than 10 years of practical implementation of the existing Ordinances have shown that these distinctions are not always clear to the establishments involved. Figure 1 therefore shows the relevant considerations, particularly with reference to the scope of the ContainO, as a diagram with a series of key questions.
If GMOs are being used for an activity (Question 1, answer yes / cannot be ruled out), it should be assumed, at least at the moment, that this is handling pursuant to the ContainO, as GMOs do not occur naturally but are made by human beings, and activities using them are by definition deliberate. It is not considered to be handling if the presence of GMOs can be ruled out. Thus, each analysis of samples for the presence of GMOs counts as handling, even if there is only a slight suspicion of their presence. Testing of environmental samples, e.g. in connection with an experimental release of GM plants, would be considered as handling, while GMO environmental monitoring across Switzerland would not, because the current moratorium should actually rule out the presence of GMOs in the environment. In both cases, however, such handling would still be subject to the PEMO, if the GMO is a microorganism by the PEMO definition.

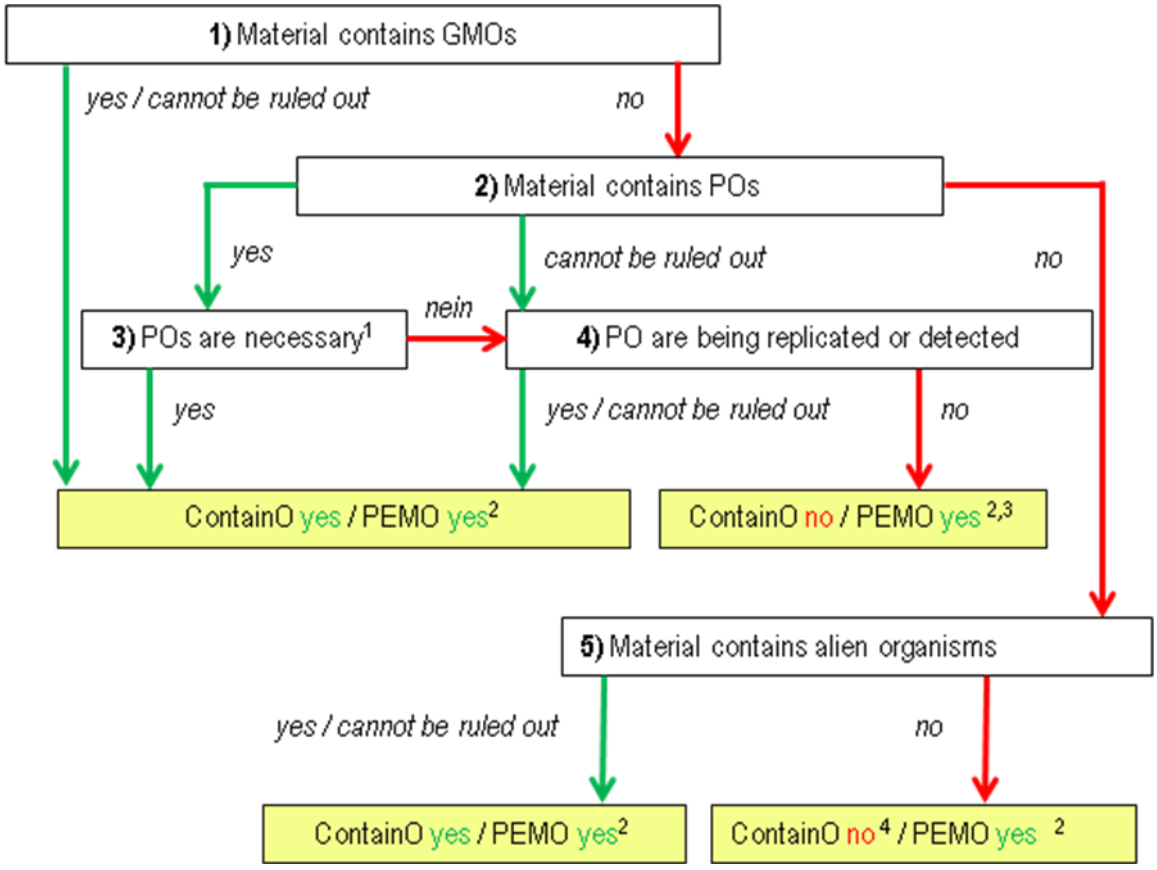

Fig. 1. Decision tree to distinguish the scope of the ContainO and PEMO
[1] The presence of POs is essential for the objective of the activity because of their (in)direct effects, even if the PO itself is not the direct subject of the activity. [2] If microorganisms according to the PEMO are present. [3] Exposure according to the PEMO; the duty of care pursuant to the ContainO shall apply. [4] The duty of care pursuant to the EPA shall apply.

If no GMOs are present and it should be assumed that POs are present (for example, if a positive primary and/or confirmed test result is available; Question 2, answer yes), the issue is whether the presence of this PO is necessary to achieve the research aim (Question 3). If yes, this counts as handling. An example would be the blood of a patient with HIV, which is being tested e.g. for HIV-related changes in cytokine concentrations with the aim of understanding the immunological reaction of the human body to HIV better. Although here the PO (HIV) is being neither detected nor cultivated and thus there is no direct activity involving HIV, this test still represents a deliberate activity and is thus handling under the ContainO.

If the POs are not necessary to achieve the research aim (Question 3 no), we go straight to Question 4. The possibility of POs being present also leads to Question 4 (Question 2, answer cannot be ruled out): it must now be clarified whether there actually is handling or whether “only” exposure should be anticipated. If HIV is to be detected in the blood of the above-mentioned patient either directly (e.g. detection of the pathogen’s nucleic acids or its antigen) or indirectly (e.g. through the serological detection of antibodies to the virus), these activities again represent handling under the ContainO (Question 4, answer yes / cannot be ruled out). On the other hand, if the blood of the same patient with a confirmed disease is being tested as part of routine diagnostic investigations, e.g. for ferritin or C-reactive protein (CRP), Question 4 can be answered with “no”, as these tests neither detect nor replicate HIV. This would be a “classic” exposure, which is not covered by the ContainO but by the PEMO, which ensures the protection of employees. However, if the same blood, as part of

any diagnostic or research activity, is handled in such a way that POs could be replicated, this again is considered to be handling under the ContainO.
If the answer to Question 2 is no, the question then arises of whether alien organisms are present. If yes (Question 5), this activity in principle falls under the ContainO; if no (Question 5), it is not subject to the ContainO, but certainly to the general duty of care pursuant to Article 29 Environmental Protection Act (EPA; SR 814.01).

Chapter 2: Requirements for Handling Organisms in Contained Systems

Section 1: General Requirements

Art. 4 Duty of care

Paragraphs 1 and 2:
The scope of these two paragraphs remains unchanged. The wording of para. 1 has been amended so that it is now in harmony with Article 29a EPA, Article 6 para. 1 GTA, Article 6 para. 1 RO, and Article 29 of the Federal Act of 18 December 1970 on Combating Communicable Human Diseases (Epidemics Act, EpidA; SR 818.101).

Para. 3:
This new paragraph states explicitly that compliance with the duty of care must be clearly documented. This documentation may consist of routine records, such as a lab journal, that detail the risks associated with the organisms and the activities. Standard Operating Procedures (SOP) may also be used to ensure that the necessary processes and safety measures are complied with and documented. In parallel, the duty to keep documentation in Article 9 para. 1 of the previous ContainO has been formally repealed. Documentation of the duty of care is particularly relevant for class 1 activities since such activities with pathogenic or alien organisms need not be notified any more, and activities with GMOs need only be notified globally. Documentation of the duty of care applies generally to the handling of organisms in contained systems, i.e. to organisms that are not genetically modified, pathogenic or alien, e.g. when using an apathogenic strain of a basically pathogenic species. The period of obligation to keep and disclose records will be extended from 5 to 10 years, to take account of the absolute limitation period of 30 years (Art. 59c EPA, Art. 32 GTA). This increase appears proportionate when compared with the general ten-year obligation to preserve business records.

Art. 5 Containment obligation and prior assessments

Para. 1:
The obligation to handle GMOs and pathogens in contained systems applies as before. Based on Article 29f para. 2 letter b EPA, this obligation is now also extended to alien small invertebrates, the direct use of which in the environment requires a licence pursuant to Articles 17 and 25 RO; to invasive alien organisms in accordance with Annex 2 RO; to (non-pathogenic) quarantine organisms in accordance with Annexes 1, 2 and 6 of the Plant Protection Ordinance (PlantPO; SR 916.20), and to harmful organisms in accordance with Annex 12 PlantPO, against which protected areas have been established. In addition to the

RO, the Ordinance of 12 May 2010 on the Placing on the Market of Plant Protection Products (Plant Protection Products Ordinance, PlantPPO; SR 916.161) and the Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products, OBP; SR 813.12) are now explicitly mentioned in para. 1, as the placing on the market of pathogenic or alien organisms may be authorised under these Ordinances. For simpler reference, the term “alien organisms subject to containment” has been introduced under letter c.

Para. 3:
The containment obligation also carries a reminder of the specific provisions of the GTA for the genetic modification of animals and plants. Genetic modification of their genetic material may not lead to lack of respect for the dignity of living beings (Art. 8 para. 1 GTA); and genetically modified vertebrates may only be produced and marketed for purposes of research, therapy and diagnostics on/for humans and animals (Art. 9 GTA). On the question of the point at which species-specific traits, functions or habits are substantially impaired (Art. 8 para. 1 GTA), for both animals and plants the primary criteria are growth, reproduction and the ability to adapt to environmental conditions. For animals, freedom of movement, individual and social behaviours, and the ability to feel pain, fear, stress or other suffering, must also be considered. A genetic intervention is permissible only if economic, social, ecological or scientific interests in accordance with Article 8 para. 2 GTA are weighted more heavily than the severity of the impairment of animals and plants caused by the genetic modification. If it subsequently becomes clear that the impairment of the animals or plants has been wrongly estimated, the weighing up of interests must be repeated. If this re-evaluation shows that the dignity of living beings has not been respected, further genetic modifications should not be carried out, or the transmission of these genetic properties should be prevented. Animals whose dignity has not been respected and who are suffering as a result should be humanely killed. In other cases where suffering is not involved, care should nevertheless be taken not to use the genetic properties in question any further or to pass them on. If the production of genetically modified animals or plants has been commissioned, the client is responsible for evaluating the interests correctly beforehand. If existing genetically modified animals or plants are being obtained, proof should be supplied that this evaluation of interests has been carried out before production, and that it continues to apply to the use in question. If this is not the case, a new assessment should be carried out.

Art. 6 Grouping of organisms

Organisms are allocated to Groups according to the same criteria as previously, i.e. in line with the list provided by Article 26 or based on scientists’ own investigations in accordance with criteria given in Annex 2.1. Independently of any particular activity, organisms present a potential hazard arising from their natural properties e.g. their pathogenicity or invasiveness. The presence of organisms is thus accompanied by a particular probability, according to the current state of knowledge and experience, that the properties in question may have a harmful effect on human beings, animals, the environment and biodiversity. Differentiation of the risk into four Groups remains unchanged and continues to comply with applicable EU law, i.e. the Biological Agents Directive 2000/54/EC. Based on this Directive and on

international practice, however, Annex 2.1 (point 2) now describes when the risk should be considered as negligible, low, moderate or high.
The list of organisms is intended to be an aid to their grouping, but does not exempt scientists from reviewing or if necessary reclassifying particular strains or isolates on a case-by-case basis. The criteria for allocation to Groups have remained broadly the same (cf. explanations to Annex 2.1), but reference to them has been moved here from the previous Article 8 para. 2 letter a. If organisms have already been grouped according to the list in Article 26, the fact that certain strains or isolates of this organism may show a higher or lower potential hazard should be taken into account, in which case allocation to a Group should be in line with the criteria of Annex 2.1 (para. 3).
Extension of the ContainO's scope to include alien organisms has made it necessary to supplement the criteria for grouping in Annex 2.1 that cover invasive potential for the environment. The fact that handling particular organisms in the environment is restricted or prohibited according to the RO and PlantPO is at least an implicit indication of their potential hazard. Therefore those organisms deemed particularly hazardous harmful in accordance with Annexes 1, 2 and 6 PlantPO, as well as organisms prohibited by Annex 2 RO, should be regarded as belonging to Group 3 (organisms whose occurrence presents a moderate risk), while those organisms whose use is subject to authorisation are classified as Group 2 (organisms whose occurrence presents a low risk). This summary grouping is however merely a tool and does not remove the obligation to undertake a risk determination and assessment on a case-by-case basis. Equally, an alien organism that is to be considered invasive should be allocated to Group 3 even if it is not explicitly mentioned in one of these lists, if it is nevertheless acknowledged to be highly invasive or is listed in the IUCN's Global Invasive Species Database, in the ECDC or WHO Recommendations, or the CPS/SKEW Black List.

Art. 7 Classification of activities

Para. 1:
More detailed criteria for risk determination are contained in Annex 2, as before (Annex 2.2 Point 1, previously Annex 2.3). Starting from the risk determined from the Group of the organisms in question, the risk of a particular activity should be determined and assessed depending on the type of activities and environmental conditions. The text of the Ordinance adopts the generally recognised formula contained in the previous version of Article 8 para. 1, according to which a risk is the product of the extent and the probability of harmful effects. The type of activity will determine whether the risk involved in handling a particular organism is greater or smaller, i.e. the risk may be different for diagnostics, research, production or storage.
Consideration of environmental conditions includes how widely the organism in question is already spread in the environment, and what the consequences of additional spread would be. This applies particularly to alien organisms subject to containment. For example, the use of alien mosquito species, which are potentially vectors of notifiable diseases, is classed as an activity with low risk (Class 2), irrespective of whether the mosquito species in question are already present in the environment, as the simultaneous presence of vector and disease (people or animals who have become infected elsewhere) in the same area could cause an epidemic to break out. However, if in addition to its competence as a vector, this organism is also invasive, it belongs to Group 3, and handling it in a contained system is a Class 3

activity. However, if the organism in question is already widespread in the environment, the potential hazard of its use in a contained system is lower to begin with, and a lower classification can be justified, e.g. in the case of the tiger mosquito in those regions of Canton Ticino where it already occurs seasonally in large numbers. A lower classification would also be justified if the organism is not subject to control pursuant to Article 52 RO.

Para. 2:
After determining the risk, it must be assessed. This is done as before, based on the type, the extent and the probability of harmful effects. The greater the extent of a possible harm, the lower the probability of harm occurring must correspondingly be. The risk assessment is expressed as before in the classes “no risk / negligible risk”, “low risk”, “moderate risk” and “high risk”. The description of these Classes remains unchanged and continues to be in line with applicable EU law, i.e. the Contained Use Directive 2009/41/EC.
Reference to biological containment systems and the previous Annex 2.2 have been deleted, since they had no practical relevance for enforcement.

Risk determination: relationship between ContainO and MAO

The regulatory area of the Containment Ordinance (ContainO) partially overlaps with that of the Major Accidents Ordinance (MAO). Since according to its Article1 para. 2 letter b the MAO applies only to establishments where an activity involving microorganisms is carried out, this provision does not need to be supplemented with alien organisms subject to containment, which are all macroorganisms. The risk report of the MAO is distinct from that of the ContainO as it has a broader approach, or wider system boundaries: within the framework of the MAO, the establishment is considered overall, taking account of the site, all the activities and any possible interactions. In terms of extent, then, risk determination in accordance with the MAO therefore represents (c.f. Annex 4.2 MAO, especially Point 33) a sum of the results of risk determination and assessment under the ContainO, but additionally requires specific operational considerations of the possible causes of major accidents or release events. Further specifications for the practical implementation of the MAO, taking the ContainO into account, are laid down by the FOEN in the Handbook II on the MAO, which is currently being revised.

Section 2: Requirements for Handling Genetically Modified Organisms Pathogenic Organisms and Alien Organisms that require Containment

Art. 8 Notification of Class 1 activities

Establishments or institutions are now required to notify the authorities by giving general notice of where they wish to carry out Class 1 activities with genetically modified organisms, and who will be doing so. This general notification includes the person(s) responsible, the Biosafety Officers (BSO), the name and address of the establishment, the addresses and type of facilities (laboratory, production plant, animal facility, greenhouse), the confirmation that Class 1 activities are to be carried out in these facilities, and confirmation that an evaluation of interests under Article 8 GTA has been carried out for activities using genetically modified animals. This confirmation of the performance of Class 1 activities also

includes a summary of the activities; the authorities have provided an aid for this in the form of yes/no questions. Modifications of the activities still need to be notified, as before, although in a much reduced form. This global form of notification will make it unnecessary to report technical changes except in special cases. Administrative changes (persons, sites and type of facility) will still need to be reported within a reasonable period to the Federal Coordination Centre for Biotechnology. The cantonal authorities will thus receive the minimum information they need to carry out inspections, which guarantees some control. This procedure also continues to take account of the increased public interest in gene technology, although to a somewhat less significant extent than previously. The end of an activity must be reported only if it is not expected that the activity will be resumed within a foreseeable period.

Art. 9 Notification of Class 2 activities

Para. 1:
Class 2 activities subject to notification now include all activities using genetically modified or pathogenic organisms or alien organisms that require containment, and not just first activities. It was often unclear to users when a new activity signified a significant change in the risk involved for humans and the environment, with the result that users erred on the side of caution and often notified each new activity. In addition, if activities were interrupted, it was not always clear to the enforcement and supervisory authorities at what point and in which installations notifiable activities or those requiring a licence were being carried out.
To balance the extension of the duty of notification, the previous 45-day waiting period after notification of first Class 2 activities has been repealed. Now, all Class 2 activities can be commenced at the same time as their notification. In view of the low risk of these activities it appears proportionate that they may be carried out even before the responsible authority has made a decision. Of course, the enforcement and supervisory authorities can continue to monitor notified activities at any time for their risk determination and assessment, or their operation, and may demand further information or even prohibit the continuation of these activities.

Para. 2:
In the interests of legal clarity, the ContainO now states expressly that any technical or administrative change in the notified activity and its conclusion must be reported. Notification of the conclusion of the activity should be made only if further activities of the kind notified will not take place in the foreseeable future, and is unnecessary if resumption of the activities is planned within a foreseeable period.
Annex 3 now distinguishes between technical and administrative details. Technical changes are regarded as those that concern the content of an activity, such as if the activity is modified (e.g. new type of installation), or if further research questions are being pursued, or other organisms used. Distinctions should be drawn, in particular, between human, animal and plant pathogens, between aerogenically and non-aerogenically transmissible organisms, and between transgenic animals, plants and microorganisms. The new use, or the use of additional organisms, do not count as a technical change if the original notification or licence contains technical details for one organism as a representative of other organisms with similar properties, and if the activities in question are associated with similar risks (cf. Annex 3.2 point 1). Technical changes must be reassessed by the responsible authority, and

it may therefore be necessary to order the use of a different type of facility or other/additional safety measures. This is particularly likely if there is authorisation to omit safety measures.
Administrative changes concern the organisational/administrative details in the notification form, e.g. a change of address, a change of persons and responsibilities, or the use of new premises (cf. Annex 3.2 point 2). Such reports help the Coordination Centre to keep its database up to date.

Para. 3:
Because there is a duty to obtain a licence for activities using highly infectious animal diseases that are to be undertaken outside the Institute of Virology and Immunoprophylaxis (IVI), in accordance with Article 49 para. 2 of the Epizootic Diseases Ordinance of 27 June 1995 (EzDO; SR 916.401), activities using such organisms may not commence immediately, but only after a licence has been issued under the EzDO.

Art. 10 Licensing of activities in Classes 3 and 4

All Class 3 and 4 activities now uniformly require authorisation, which is also in line with the Contained Use Directive 2009/41/EC. This authorisation can be obtained by making a new application, or by applying for an existing licence to be modified. The previous exception, in which only a first activity need be authorised (in clinical microbiological diagnostics) is no longer possible. This extension and standardisation is justified by the recent increased occurrence of new pathogens, e.g. SARS, Chikungunya, West Nile Virus, H5N1, AH1N1 or other potential Influenza pandemic strains. A similarly broad application, corresponding authorisation and the possibility of requesting changes to licences, will enable a diagnostics laboratory in the future to operate with a single licence or possibly two (one each in Classes 3 and 4).
In terms of the licensing of technical changes and the notification of administrative changes, we refer to the explanations to Article 9. For the use of additional Group 3 and 4 organisms, an application to make technical changes must always be submitted to the Federal Coordination Centre for Biotechnology.
The diagram in Figure 1 can be supplemented with the provisions on the containment obligation (Art. 5), the grouping of organisms (Art. 6), the classification of activities (Art. 7) and on notification (Art. 8 and 9) and authorisation (Art. 10), making the practical implementation of the ContainO by the federal authorities evident at a glance.
If the answer to Question 1 is yes and to Question 2a is no, i.e. GMOs but not POs are present, this will generally result in a Class 1 activity, which is notifiable. If POs are present (Question 2a answer yes), it will be handling in Classes 2–4 depending on the risk of the activities.
If GMOs are not present (Question 1, answer no), but POs are, Questions 3 and 4 follow as in Figure 1. There is further differentiation if Question 4 is answered yes, i.e. POs are being replicated or detected. If they are being cultured but not exclusively in closed containers, or if Group 3 or 4 organisms are being cultured in closed containers, the resulting handling is also classified as Class 2–4. A distinctive case arises if Group 1 or 2 organisms are being cultured exclusively in closed containers (Question 5, answer yes, Question 6 answer no). Such activities are given a lower classification, provided the risk assessment shows that safety level 1 achieves necessary protection (cf. also Annex 2.2). Because no GMOs are present (Question 1, answer no), such an activity is not notifiable.

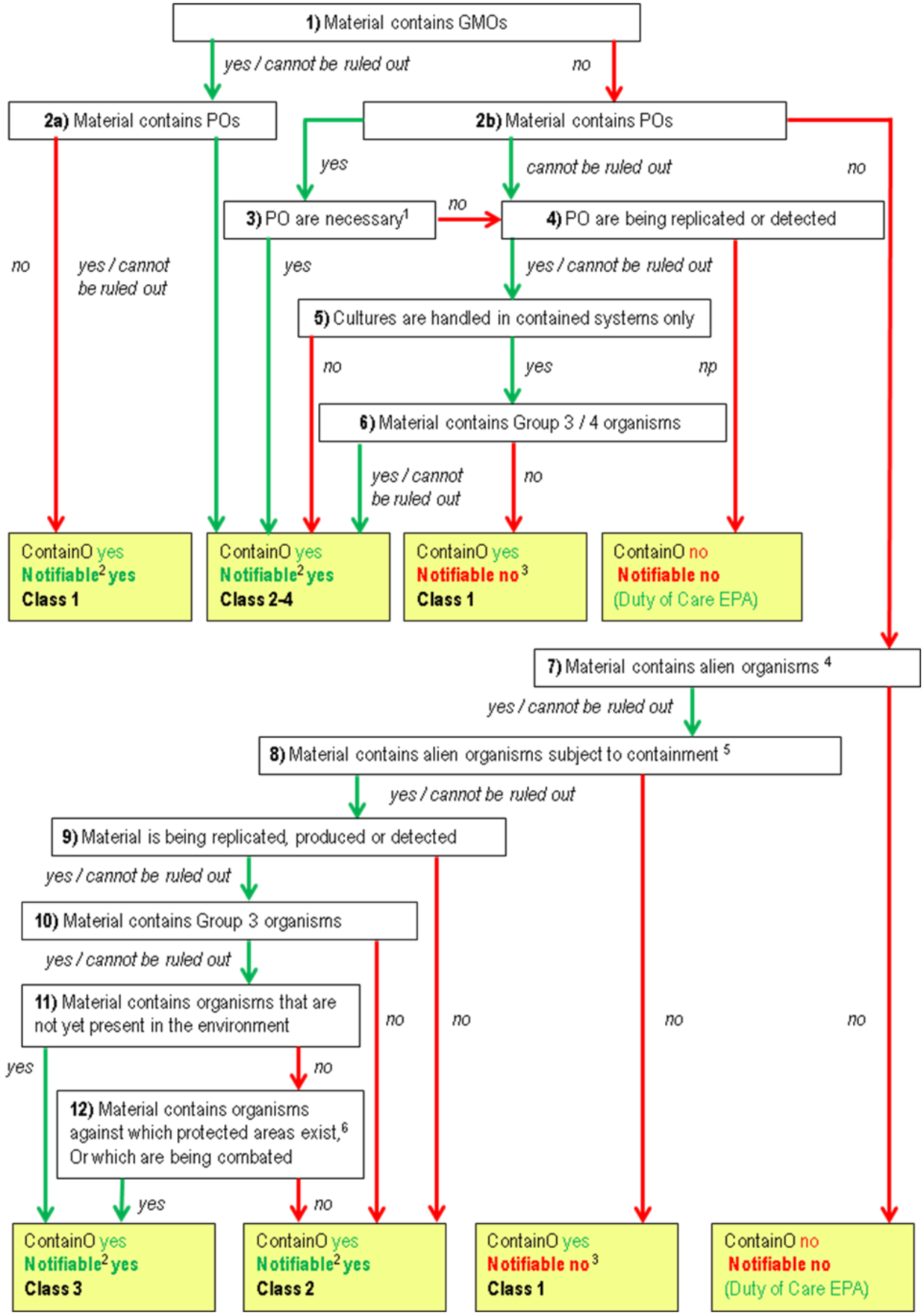
1) Material contains GMOs
yes / cannot be ruled out
no
2a) Material contains POs
2b) Material contains POs
yes
cannot be ruled out
no
3) PO are necessary[1]
no
4) PO are being replicated or detected
no
yes / cannot be ruled out
yes
yes / cannot be ruled out
5) Cultures are handled in contained systems only
no
yes
np
6) Material contains Group 3 / 4 organisms
yes / cannot be ruled out
no
ContainO yes
Notifiable[2] yes
Class 1
ContainO yes
Notifiable[2] yes
Class 2-4
ContainO yes
Notifiable no[3]
Class 1
ContainO no
Notifiable no
(Duty of Care EPA)
7) Material contains alien organisms [4]
yes / cannot be ruled out
8) Material contains alien organisms subject to containment [5]
yes / cannot be ruled out
9) Material is being replicated, produced or detected
yes / cannot be ruled out
10) Material contains Group 3 organisms
yes / cannot be ruled out
11) Material contains organisms that are not yet present in the environment
no
no
no
no
yes
no
12) Material contains organisms against which protected areas exist,[6] Or which are being combated
yes
no
ContainO yes
Notifiable[2] yes
Class 3
ContainO yes
Notifiable[2] yes
Class 2
ContainO yes
Notifiable no[3]
Class 1
ContainO no
Notifiable no
(Duty of Care EPA)

Fig. 2. Decision tree showing approximate classification of activities
[1] The presence of POs is essential to the objective of the activity because of their (in)direct effects, even if the PO itself is not the direct subject of the activity. [2] Notifiable for Classes 1 and 2, requires a licence for Classes 3 and 4. [3] The duty of care pursuant to the ContainO shall apply. [4] Material contains alien organisms or other organisms according to Art. 5 para. 1 letter c ContainO. [5] Containment is required for particularly hazardous harmful organisms in accordance with Annexes 1, 2 and 6 of the PlantPO, organisms listed in Annex 2 of the RO, and alien small invertebrates subject to authorisation, except for use as medicinal products, foodstuffs or animal feed. [6] If the activity takes place in an area that is protected against this organism, it must be carried out as a Class 3 activity (Art. 4 and Annex 12 PlantPO; SR 916.20). Unlike the ContainO, the PEMO does not classify the activities. Instead, the PEMO determines the appropriate safety level for handling each Group of microorganism (Art. 9 PEMO). Exceptions can be made only for clinical microbiological and veterinary diagnostics.

There is further differentiation if only alien organisms are present (no GMOs or POs Questions 1 and 2, answer no, Question 7, answer yes). If the organisms are alien but not subject to containment in accordance with Article 5 (Question 8, answer no), activities using such organisms come under the ContainO and thus the duty of care, but as handling is in Class 1 they are not notifiable. If Question 8 is answered yes, the risk-related Question 9 (reproduction of such organisms) follows. If Question 9 is answered no, such handling is generally allocated to Class 2 and is therefore notifiable. This also applies if the organisms are being replicated but they are already present in Switzerland (Question 9, answer yes, Question 10, answer yes, Question 11, answer no). If the answer to Question 10 is also yes, i.e. the organisms are not yet present in Switzerland, protected areas have been designated against these organisms (see above, footnote 6), or if the cantonal authorities are actively combating them, this handling comes under Class 3 and therefore requires authorisation.
The diagram in Figure 2 serves as a general aid to orientation and explanation. The specific constellations of each case always determine the group of the organisms and the classification of activities, with the consequent notification or authorisation obligation.

Art. 11 Submission to the authorities

Para. 1:
As previously, the dossiers on notifications and licence applications must be submitted to the Federal Coordination Centre for Biotechnology. This also applies to amendments to notifications and licences.

Para. 2:
Notifications and licence applications must include the information listed in Annex 3. Activities often encompass numerous work steps and methods that belong together in terms of type, scope and purpose, which can be summarised in one notification or licence application. This is in line with current practice, where self-contained projects can be notified or authorised as a single activity. Activities in different fields such as diagnostics, research and production cannot generally be summarised, as the risk associated with the activities will vary depending on the type of the activity or its field (cf. Art. 7).

Para. 3:

Notifications and licence applications may be entered directly in the electronic database and thus submitted to the Federal Coordination Centre for Biotechnology. The database can be accessed by the applicant, the competent federal office and the specialist agencies for particular fields only. Passwords for access to the database are issued by the Coordination Centre. The database system generates a signature form, which must be signed and sent to the Coordination Centre by post, together with any confidential documents. Notifications and licence applications may continue to be submitted on paper, although this may generate higher fees as more time is needed to process them.

Art. 12 Safety measures

Para. 1:
The first paragraph now expressly establishes general safety principles. For activities in contained systems, it must be ensured in the case of activities in Classes 1 and 2 that any escape by these organisms is limited to the extent that human beings, animals and the environment as well as biological diversity and its sustainable use cannot be endangered (Letter a); and in the case of activities in Classes 3 and 4 that these organisms cannot escape (Letter b).

Para. 2:
In addition to the previous principles, which require the general safety measures listed in Annex 4 to be taken, together with the special (previously “additional”) safety measures required according to the type and class of activity, the main body of the Ordinance now establishes the duty to devise an biosafety concept for activities of all Classes. Compliance with this plan was already stipulated in Annex 4. The operational safety plan is one of the key safety aspects when handling organisms in contained systems.

Para. 3:
The classification of special (previously “additional”) safety measures according to Annex 4 is retained. The role of the competent Federal Offices (FOPH and FOEN) is clarified, in that they will need to authorise (by means of an order) the modification, replacement or omission of individual special safety measures specified in Annex 4 for specific cases. This order may be issued in response to a substantiated request (Letter a).
Letter b now includes the possibility that the competent federal offices may order further special safety measures not listed in Annex 4 for the relevant type and class of activity if such measures have been recommended by international organisations (especially the WHO or the OIE) or the Swiss Expert Committee for Biosafety (SECB) and are regarded by the competent Federal Office as necessary for the protection of human beings, animals and the environment, and of biological diversity and its sustainable use. This may particularly be the case for new emerging diseases. This option should be used very sparingly, and the “downgrade principle” should be observed. In general, an activity should thus continue to be carried out at safety level 3- and not at a heightened safety level 2+.

Art. 13 Guarantee of liability

Based on Article 59b EPA and Article 34 GTA, the Federal Council may require the person subject to notification or authorisation to provide a guarantee for their liability. As before, this obligation to guarantee liability applies only to activities using genetically modified or pathogenic organisms of Classes 3 and 4; the provisions are now harmonised with those of Articles 11 and 14 RO. Damage to persons and property is now distinguished from damage to the environment, which requires a reduced guarantee of liability of CHF 2 million to take account of the low potential hazard. For damage to persons and property, the guarantee of liability of CHF 20 million continues to apply. The ContainO does not differentiate between GMOs and pathogenic organisms (in contrast to the RO), as the risk of an activity is already evaluated through its classification, which does not distinguish GMOs and pathogens. The way in which the obligation to guarantee liability may be fulfilled remains unchanged (para. 2). The Confederation, its public corporations and institutions are exempt from the guarantee of liability; this exemption is now extended to the cantons, and their public corporations and institutions, provided the cantons cover their liabilities and this is established in statute or in writing (para. 3).

Art. 15 Transport

Brief temporary storage during transit is considered to be transport and not storage. Actual storage should be clearly distinct from transport: while transport is covered only by Articles 4, 15 and 25 (cf. Art. 2 para. 2), the ContainO applies fully to storage in principle. One exception is the special safety measures according to Annex 4 Point 2.1, which under this Point's letter d could now apply only mutatis mutandi to the storage of organisms for reasons of practicability.
Transport within an establishment should also be understood as an activity or as part of an activity, to which in principle the ContainO applies fully. Like storage, the special safety measures according to Annex 4 Point 2.1 can apply only mutatis mutandi, which is now also laid down in letter d. Various situations can be distinguished:

- *Internal transport within laboratory:* Transport within a laboratory of the same safety level (1, 2 or 3), without crossing zones of a lower safety level;
- *Internal transport within building:* Transport within the building that does involve crossing zones of a lower safety level (e.g. transport of infectious wastes to the autoclave; transport from Lab A, safety level 2, via staircase, safety level 1, to Lab B, safety level 2);
- *Internal transport within establishment:* Transport within an institution's premises, including publicly accessible areas (e.g. in a university). This is regulated by the operational safety plan and should be carried out in accordance with the principles of safe transport (double packaging and appropriate labelling).

Para. 1:
Reference to the applicable national and international transport regulations, which are not specified in more detail, is retained. Please see the SECB's comprehensive information on this subject (http://www.efbs.admin.ch/index.php?id=146&L=3).

Para. 2:
This paragraph is intended to ensure, as before, that in the case of transport in a manner not covered by the national and international transport regulations but which according to the ContainO carries a potential hazard, the existing transport regulations should be applied in such a way that any escape of organisms is either limited or prevented. How this protection during transport is achieved is largely left up to the consignor.

Art. 16 Reporting incidents

Para. 1:
The obligation to report incidents during activities in contained systems in which organisms have inadvertently escaped into the environment, or if there is a risk that organisms could be released into the environment in the course of activities in Classes 3 and 4, has now been introduced. This provision applies to all Classes of activities in the ContainO and thus goes beyond the scope of the MAO or the notification it stipulates, since these apply only to installations in which Class 3 or 4 activities are being carried out. Knowledge of such incidents is essential in order for the competent authorities to optimise the safety measures.
Note that in the course of Class 1 and 2 activities, limited quantities of organisms may escape into the environment, but this would of course not trigger a reporting obligation. Thus, only serious incidents, in which the level 1 or 2 safety measures or those according to Article 12 and Annex 4 have seriously failed, must be reported.

Para. 2:
In line with the responsibilities within the scope of the ContainO, the report is addressed to the canton on whose territory the incident has taken place. The cantons then inform the competent federal office of any reports received. On the basis of these data, the Confederation may, if required, amend the enforcement procedures or the applicable biosafety legislation.

Chapter 3: Duties of the Authorities

Section 1: Examination of Notifications and Licence Applications

Art. 17 Federal Coordination Centre for Biotechnology

The establishment of the Coordination Centre has proved valuable, and will be continued. The following new provisions will be introduced.

Para. 2 Letter b:
The competent federal office decides on a notification or licence application within a basic period of 90 days (Art. 19 para. 2, Art. 20 para. 2). Correspondingly, there is now an express deadline of 20 days in which the Coordination Centre must examine the notifications and licence applications and request any missing information. The person filing the notification or application receives confirmation that the completeness check has been concluded.

Para. 2 Letter f:
The Coordination Centre's responsibility to transmit decisions on notifications and licence applications will be repealed. This brings it in line with current practice whereby these decisions are communicated by the responsible Federal offices directly to the persons and specialist agencies concerned.
The Coordination Centre is now explicitly tasked with maintaining a database in which documents relating to the notification and licensing procedure and to enforcement are stored. This database already exists under the name ECOGEN. The amendment of this provision requires the Coordination Centre to receive complaints from the cantons that may have arisen in the course of inspections, and to transmit them via the database to the Federal Office responsible.

Para. 2 Letter g:
The database according to Letter f should be distinguished from the register of reported and licensed activities. Although this register is based on information stored in ECOGEN, it is limited to details that are always accessible to the public, pursuant to Article 28 para. 5. In accordance with the RO (Art. 38 para. 3) and the express wording of the Federal Act on Data Protection (Art. 19 para. 3^{bis}), the public register should be generally accessible by means of automated information and communication services (Internet). These regulations follow the freedom of information principle pursuant to the Federal Act of 17 December 2004 on Freedom of Information in the Administration (Freedom of Information Act, FoIA; SR 152.3).

Para. 2 Letter h:
The Coordination Centre does not just provide information, but also has an advisory function, which is now explicitly laid down in the ContainO. The advice may concern both technical or scientific matters in the completion of notification forms and the submission of licence applications.

Para. 2 Letter i:
In its capacity as an information and advice hub the Coordination Centre may, if there is a clear need, run courses and training sessions for the cantonal authorities or for establishments. This is in line with current enforcement practice. Under both Letter h and Letter i, the Coordination Centre's advisory function is restricted to its area of competence, i.e. the administrative side of enforcement. Advice on the scientific implementation of the Containment Ordinance, including implementing the conditions of Federal decrees, is a matter for the appropriate specialist federal and cantonal agencies. The cantons have an advisory role within their inspection activities, supporting the correct and efficient practical implementation of Federal provisions by establishments.

Para. 2 Letter j:
The complaints and reports that the cantons must submit in accordance with Article 22 must be forwarded by the Coordination Centre to the responsible federal offices. The Coordination Centre must also now issue an annual report on the supervisory activities of cantonal and federal authorities under the ContainO.

Art. 18 Competent federal office and specialist agencies

Competency to take decisions and the rights of participation are now set out in an Article. The FOPH and FOEN continue to be the federal offices competent to take decisions. The need for the consent of other federal offices is now laid down separately in para. 3, although consent is required only where the issue relates to compliance with the legislation enforced by these agencies. To ensure that decisions in accordance with Articles 18–20 ContainO and Article 49 of the Epizootic Diseases Ordinance, which requires an authorisation for handling potentially reproductive pathogens of highly infectious animal diseases according to Article 2 EzDO in a laboratory outside the Institute of Virology and Immunoprophylaxis (IVI), do not conflict, the federal offices in question are expressly required to coordinate their decisions in accordance with para. 4. Para. 2 now lists as specialist agencies those federal offices, institutes and committees that are invited to give an opinion on notifications and licence applications.

Art. 19 Notification procedure

In line with current practice, the deadline of 90 days in which a decision must be made, and the communication of this decision by the competent Federal Office directly to the person responsible for the notification, is now enshrined in law. Similarly, the specialist agencies should be informed directly of the decisions received by the competent Federal Office. In addition, according to para. 3, for notification of Class 1 activities (i.e. activities using genetically modified organisms) that pose non-existent or negligible risk, the competent Federal Office is free not to issue a decree as a response to the notification. In this case, after the maximum 90 days have elapsed from confirmation of receipt of the notification from the Coordination Centre, the notified activity can be deemed to be in compliance with the ContainO, and no further conditions need be expected. If relevant new findings are made, the competent Federal Office may however issue the necessary decree retrospectively.

Art. 20 Licensing procedure

Here, too, the direct transmission of licence decisions is stipulated. The time limit for processing licence procedures is now set at a uniform 90 days after examination starts (para. 2 sentence 1), which follows from the absence of the distinction between first activities and subsequent ones. Examination starts as soon as the application has been checked for completeness by the Coordination Centre and transmitted it to the competent federal office (cf. Art. 17 para. 2 letters a–c). The Coordination Centre's confirmation of receipt thus tells the institution applying when the examination has started. Treating all applications according to specific procedures justifies retaining the longer time limit. The Article also specifies, in line with current practice, that a licence may if needed be issued for a period of less than 5 years (para. 2 sentence 2), such as a transitional licence if a laboratory is being modified. The same deadlines apply to the licence extensions, i.e. the Coordination Centre must receive a (complete) application at least 110 days (90 days for the competent Federal Office) before the current licence expires.

Due to the emergence of new diseases and pandemics, a new para. 3 stipulates that in urgent cases, in particular if a rapid diagnosis for emerging pathogens is required, the competent federal office may grant a licence limited until the conclusion of the ordinary

procedure. This may be done following a provisional examination of the risk determination and assessment. The specialist agencies should be informed at the same time as the competent federal office, and should be granted an appropriate time limit for issuing their opinion (which may be hours or a few days).

Art. 21 Authorisation to modify, replace or omit certain special safety measures

The meaning of this procedural provision remains unchanged; it also takes over the new classification and the new terminology of (para. 1), and sets down the direct communication of decisions on applications (para. 2; see above, Art. 17 para. 2 letter f).

Art. 22 Standard deadlines

All standard deadlines in Section 1 are now subject to the same two rules. The first is in line with the general principle already stated in the previous ContainO, that deadlines shall be extended if additional documentation must be requested from the notifying person or applicant (para. 1). Para. 2 stipulates that the competent federal office shall inform the notifying person or applicant if it is unable to comply with the deadline for issuing a decision. The relativisation of standard deadlines in the previous ContainO (“as a rule”) has been eliminated.

Section 2: Monitoring in Establishments

Art. 23 Duties of the cantons

Para. 2:
Letter b has been added to state explicitly that cantonal spot checks should also monitor the risk assessment of activities that have not been notified or authorised, but which have been documented as part of the duty of care (Art. 4). The ContainO also applies to the cantons’ own monitoring activity: taking samples in the laboratory should be considered mere exposure, i.e. not handling, and no notification needs to be made nor an authorisation obtained. Analysis of samples in a cantonal laboratory, on the other hand, is subject to the notification or authorisation obligation.

Paragraphs 4 and 5:
If an activity that has only been documented should obviously have been notified or authorised, the cantons order the required measures to be taken and inform the Federal Coordination Centre for Biotechnology. This applies particularly if a suspension of the activity is required. If there are doubts concerning the need for notification or authorisation, it may be enough in the first instance for the canton to inform the Federal Coordination Centre for Biotechnology. The Coordination Centre then sends the information from the canton to the competent federal office (cf. Art. 17 para. 2 letter j).

Para. 7:
As before, the cantons are expected to send inspection reports that contain complaints to the Coordination Centre (Art. 23 para. 4). The Coordination Centre transmits these to the competent federal offices (Art. 17 para. 2 letter j). This information keeps the competent

federal offices informed of the current status of enforcement. If any further decisions are to be taken on an activity, this may be important to ensure that the cantonal and federal authorities do not make contradictory statements to the applicant. The cantonal authorities must now also send the Coordination Centre a brief annual report on their monitoring activities. Using a template provided by the Coordination Centre, this should give statistics on the type and number of inspections carried out, and on the proportions of inspections with and without complaints. A brief overview of the type of complaints should also be provided. The Coordination Centre again transmits this information to the competent federal offices, which allows the federal authorities to identify the precise problems associated with implementing the provisions of the ContainO in establishments, and to introduce suitable measures if necessary. In turn, the ContainO also lays down that the Coordination Centre should issue an annual report on cantonal and federal monitoring activities (Art. 17 para. 2 letter j).

Art. 24 Duties of the Confederation

Para. 1
If there is a risk to human beings and the environment due to an improperly conducted activity, and if the requirements for a notified activity or an authorisation are not met despite a complaint from the canton, the competent federal office prohibits the notified activity from continuing, or revokes its the licence. The federal office makes its decision to prohibit the continuation of the notified activity or to revoke the licence after consulting the canton concerned.

Para. 2
The competent federal office may conclude, according to information received from the canton concerned, that an activity that has only been documented does in fact require notification or a licence. In such cases, notification must be made immediately or a licence obtained, as otherwise the competent federal office can prohibit the activity.

Section 3: Monitoring Transport

In addition to genetically modified and pathogenic organisms, this provision now explicitly covers alien organisms subject to containment.

Section 4: Obtaining, Processing and Confidentiality of Data

Art. 26 List of classified organisms

There is no list of biological safety systems because it has no practical relevance in enforcement (see above, Art. 7); the duty to take account of existing lists of organisms is extended from the European Union to include its member states (para. 2), because the organism lists of European countries are sometimes more comprehensive than those of the European Union. In practice there will be no change, as these individual lists are already in use.

Art. 27 Surveys

The FOEN's responsibility for surveys remains unchanged except for its extension to cover alien organisms. As a competent authority, the FOPH is also explicitly empowered to carry out such surveys in future.

Art. 28 Confidentiality of information

The wording of this provision is harmonised with that of Article 54 para. 4 and Article 55 RO, but its material scope remains unchanged.

Section 5: Fees

Art. 29–31 Fees, level of fees, outlays

Article 25 GTA, Article 48 EPA, and Article 46a of the Federal Act of 21 March 1997 on the Organisation of the Government and the Administration (GAOA; SR 172.010) empower the Federal Council to set fees. These provisions allow substantial flexibility in setting the cost recovery level of each administrative sector. This margin concerns the core of each fee regulation, the level of fees. Because this matter is not insignificant, the level of fees should generally be set by the Federal Council (and not just by subordinate authorities). With the repeal of the Ordinance of 15 October 2001 on the fees for services under the ContainO (SR 814.912.35), originally issued by DETEC in agreement with the FDHA, the level of the fees should therefore now be regulated by the ContainO itself.

According to the principle that fees must be paid for services under the ContainO (para. 1), Article 29 now refers in para. 2 to the provisions of the General Fees Ordinance of 8 September 2004 (GFeeO; SR 172.041.1).
The levels of the fees, which in Article 30 para. 1 are now set by the ContainO itself, will be increased appropriately. The previous levels, i.e. for decisions concerning notifications a fee framework of CHF 100–500 and for licensing decisions of CHF 300–1500, is therefore opened up so that in specific cases cost-covering fees can be charged, while low fees can continue to be charged for less time-intensive modifications.

In view of this, the following levels appear appropriate:

- Examination of a notification CHF 100–2000
- Examination of a licence application CHF 300–4000
- Examination of a licence application for special safety measures CHF 100–4000

While Article 30 paragraphs 2 and 3 complies with existing law, fees for services without a fee rate (Art. 30 para. 4), which were previously regulated in the Departmental Ordinance, will now be adjusted for inflation from the end of 2001. The examination of administrative changes with minimal effort will remain free of charge. The cantonal agencies may not charge the competent federal office or the individuals concerned for providing opinions as

part of the notification or licensing procedure, as this procedure comes under the federal authorities' area of responsibility and the involvement of the cantonal agencies is optional.

Section 6: Guidelines, Basic and Continuing Professional Education

Para. 1:
Because the FOEN and the FOPH collaborate closely in the enforcement of this Ordinance, the guidelines will now be issued jointly by both Federal Offices, in line with current practice. The essential criterion for the publication of guidelines is a demand from cantons and users. The complex issue of transporting organisms is now explicitly mentioned as a possible subject for guidelines. As before, the safety measures and related quality controls are mentioned, as it is not just the safety measures themselves but also their validation and maintenance that are of vital importance.

Para. 2:
The FOEN and the FOPH are now expressly called upon to include the SECB in basic and continuing professional education events. This is in line with current practice and complies with the mandate to provide advice and information.

Chapter 4: Final Provisions

The previous ContainO will be repealed, as will the Ordinance on the fees for services under the ContainO (Art. 33). Activities that have been properly notified may continue to be carried out for a maximum of 5 years under the previous Ordinance; however, during this period the notifying person must verify that the activity complies with the new Ordinance, and provide notification if new provisions require changes in the activity or the safety measures (para. 2).
Notifications and licence applications for activities using alien organisms subject to containment must be submitted within one year of the new Ordinance coming into force (para. 3), to give the parties concerned and the authorities an appropriate timeframe for drawing up, submitting and examining the required documents. However, the obligation to handle certain alien organisms in a contained system will apply from the point at which the revised ContainO comes into force; this has effectively been the case since the licensing requirement of the RO, which has been in force since 1 October 2008.
Similarly, all notifications of activities using Class 1 genetically modified organisms in a single institution must be replaced within one year of this Ordinance coming into force by a general notification under Article 8 (see also Annex 3.1).

3 EXPLANATIONS CONCERNING THE ANNEXES

Annex 1 Definition of gene technology methods

The description of what should be understood by gene technology methods has not been materially altered, and complies with the EU's Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs and Directive 2009/41/EC. As in the RO of 2008, a clarification has been made to the effect that para. 1 Letter a now refers to "recipient organism" instead of "host organism".

Annex 2 Determination and Assessment of Risk

Risk management is regulated by the ContainO as closely to the revised RO as possible without changing the substantive content of the previous provisions. According to Article 5 para. 2, there should be four stages to the procedure. In analysing the risk, the inherent hazard of the organisms in question and the risk they actually present should be determined, based on their natural properties, such as pathogenicity or invasiveness, and the probability that these properties will have damaging effects. What is being protected here are human beings, animals, the environment, and biological diversity and its sustainable use. Then, the risk presented by the occurrence of organisms must be assessed, expressed in their allocation to four Groups. Based on these Groups, the planned specific activity and the specific environmental conditions should be considered to determine and assess the risk of handling these organisms, which results in the classification of the activity.
In parallel with the illustration of risk management in the main body of the Ordinance, which is more systematic than in the previous ContainO, Annex 2 has been redesigned in various ways although its content remains largely unchanged. Annex 2 has now been supplemented with criteria for determining and assessing the risk associated with the occurrence of and activities using alien organisms. Further, various criteria relating to GMOs have been brought forward from classification (previously Annex 2.3) to grouping (Annex 2.1). Finally, explicit details are given for how the risk is to be evaluated, for both the grouping and the classification. The four-stage procedure from risk determination and assessment in the occurrence of organisms, to the risk determination and assessment of activities using organisms (cf. above, on Art. 5–7), is given in four different sections, two in Annex 2.1 and two in Annex 2.2.

Annex 2.1: Assigning organisms to groups

Point 1: Risk determination

Para. 1:
The catalogue of criteria for assigning the organisms to Groups has largely remained the same (cf. previous Annex 2.1 para. 1). The following criteria have been added:

- Mutagenicity (letter k): The potential of active genetic material or of viruses to cause mutations through integration and thus e.g. activating or inactivating a gene must be considered in the risk determination.
- Potential contamination with pathogenic microorganisms (letter n): If organisms are being handled that could be infected or contaminated with pathogenic organisms, the latter

should be taken into account when determining the risk of activities using these possibly infected organisms. This may mean that ticks, which do not normally count as pathogenic organisms and thus do not fall within the scope of the ContainO, may be regarded as Group 2 pathogenic organisms because of a suspected or confirmed infection with e.g. *Borrelia*; by analogy, the same applies to primary cell lines that are not pathogenic in themselves but which could be suspected of containing pathogenic organisms. They are therefore in principle assigned to Group 2, unless there are concrete reasons that conclude that these cells are free of pathogens, e.g. cells of "Specific Pathogen Free" (SPF) animals. By analogy, tiger mosquitoes infected with Dengue virus are assigned to Group 3 due to the pathogen present and not because of the tiger mosquito's own capacity to be a vector, or its invasiveness.

- Environmental aspects and invasive potential (letters o and p): These criteria are particularly relevant for alien organisms, but also for pathogens and GMOs. Organisms that cannot survive the Swiss winter present a lower risk than those that can.
- The availability of suitable techniques to record, detect, identify, monitor and combat these organisms (letter q): The potential hazard depends not only on the properties of the organisms, but also on the feasibility of combating their spread into the environment. Here, the risk determination must also take account of techniques for identifying the organisms and if necessary monitoring and/or effectively combating them.

Point 2: Risk assessment

The ContainO now explicitly gives the cases in which the presence of organisms is associated with a negligible, low, moderate or high risk (para. 2–5). It also now explicitly states that when making a risk assessment, the effects of the organisms on healthy people, animals and plants must be considered (para. 1), as the assignment of organisms to groups is intended to give a broad indication of risk. Existing diseases in humans, animals and plants, however, should be taken into account in actual individual cases (cf. also the descriptors such as "normally", "rarely severe" etc.), particularly for personal protective measures or in the safety plan, which must define specific measures for particular situations. The risk assessment should also take account of the difference between humans, animals and plants. A severe illness in plants, for example, would mean that they die and that the disease can easily be transmitted to other individuals, or would result in severe crop failure. In accordance with current scientific knowledge, the highest safety level to employ when handling plant pathogens is level 3. Group 3 is therefore used for organisms whose use in the environment is prohibited (Annex 2 of the RO; Annexes 1, 2 and 6 of the PlantPO), and for alien organisms with known high invasive potential. The specifications of risk assessments for the individual Groups are closely based on the Biological Agents Directive (cf. its Art. 2). As a basic principle, in cases of doubt an organism should be assigned to the higher of two Groups.

Annex 2.2: Classification of activities

Point 1: Risk determination

The risk involved in handling a particular organism may be higher or lower depending on the activity, i.e. it may differ for diagnostics, research, production or storage. Account should also

be taken of the environmental conditions, e.g. the known or suspected geographical distribution of the organisms concerned. These criteria primarily cover the risk that the organisms may escape into the environment and cause damage there. All available data should be considered, even if the data can provide only a presumption and not complete confirmation.

Point 2: Risk assessment

Preliminary remarks: cf. also Figure 2 to Article 10. For the classification of activities, the first section (point 2.1) lists general criteria for risk assessment. For particular cases, a second section (point 2.2) gives special instructions for the risk assessment.

Point 2.1:
For classification, the ContainO now explicitly stipulates when a negligible, low, moderate or high risk should be assumed for activities using organisms. The starting point is always the group to which the relevant organisms have been assigned, although the Class of the planned activity will deviate from the Group of the organisms in question only if the activity and the environmental conditions will produce either a significantly higher or lower risk. The specifications of risk assessments for the individual Groups are closely based on the international standards (e.g. EPPO Lists, or WHO recommendations) and on the Lists of other countries, particularly European states and Canada. The risk assessment of the activities should expressly take into account the environmental conditions in Switzerland, or at the site of the activity. The classification of activities using small invertebrates subject to containment must include possible vector competence, particularly in the transmission of notifiable diseases, and this may lead to the activity being given a higher classification. On the other hand, an activity may also receive a lower classification if the organisms are already widespread in the environment, or if attempts to combat them have been discontinued (see Art. 6 and 7). The basic principle that in cases of doubt, an activity should be assigned to the higher of two Classes, remains unchanged.

Point 2.2:
The following activities are assigned to a particular Class based on a generalised prior risk assessment, which in some cases remains unchanged:

Para. 1 Letter a:
For further clarification, analyses of soil, water, air or food samples are assigned to Class 1 from the outset only if it can be assumed that the samples have not been contaminated with organisms subject to containment.

Para. 1 Letter b:

Diagnostic kits or tests based on replica plating are increasingly being used in medical practices and in food analysis to detect Group 1 and 2 organisms directly or indirectly. Detection takes place with or without the limited multiplication of the organisms by various methods, notably molecular biology (polymerase chain reaction), immunology and serology (detection of antigens and antibodies), or other methods (lateral flow assays, microscopy, biochemical analyses of signalling molecules etc.). Typical examples include Uricult, Urotubes, Hygicult, dip slides, rapid tests, and completely automated detection systems. The risks associated with such test kits are relatively low. If no replication takes place, any Group

1 or 2 pathogenic organisms present are generally inactivated through fixing, lysis or extraction buffers, or immobilisation on a matrix. If replication does take place, i.e. if cultures are grown in the test kits, the kits in question are generally sealed after inoculation, and after reading off the test result are either professionally disposed of directly or sent to an appropriately equipped diagnostics laboratory for further analysis. The reproduction of potentially pathogenic organisms should be regarded as handling under the ContainO, although an activity using such test kits can be assigned to Class 1 and does not require notification as long as no GMOs are used and the test kits are not opened. A risk assessment must be carried out for the classification of such activities, as for all other activities. The general safety measures and the special safety measures for level 1 in accordance with Annex 4 should nevertheless be observed.
Medical practices have not been considered by enforcement practice up to now, although under Article 29b EPA the handling of pathogenic organisms must be regulated irrespective of the site of their handling. At the same time, however, most of the activities in medical practices should be regarded as exposure and not as handling. Activities that represent actual handling are often conducted in a form that belongs under Class 1. A doctor may take on the role of BSO for such activities without further conditions, because his or her medical training has provided sufficient specialist knowledge to cover the safety aspects of the activities carried out in the practice. An autoclave can be omitted without the need for authorisation if the infectious material can be disposed of safely in other ways. A safety plan for a medical practice can be kept very brief, as there are only a few people to coordinate and instruct, and the activities are standardised.
If multiple medical practices operate a joint laboratory capable of conducting more complex analytical investigations, these investigations may constitute a Class 2 activity and thus be notifiable. This has been the case up to now. By analogy, the provisions of Letter b also apply to the detection of further organisms, e.g. animal or plant pathogens.

Para. 1 Letter c:
This provision has proved useful and remains unchanged.

Para. 2:
The principles for classifying clinical microbiological diagnostics have been supplemented with the above-mentioned exception according to para. 1 Letter b, and extended to cover more generally the analysis of organisms from clinical or other biological material for diagnostic purposes. Clinical microbiological diagnostics includes detection by culture of pathogenic organisms, further characterisation through resistance tests (antibiograms), serotyping and/or biochemical analyses, and the use of reference strains. These use open culture vessels, so that the risks may be low (Class 2) to moderate (Class 3) in line with the properties of the pathogenic organisms that may be present.
Here, too, the rules applicable to comparable situations outside human clinical diagnostics apply. This represents a relaxation of the ContainO of 1999, and reflects current practice by analogy with clinical microbiology.

Scope, grouping and classification of alien organisms

Scope

Alien organisms covered by the RO, but which may (without authorisation) be handled in the environment, are not subject to the safety measures of the ContainO as it would be inconsistent in such cases to have to limit or even prevent their escape from a contained system. Thus, all organisms that fall outside the scope of the RO, in accordance with Articles 15, 17 and 25, or whose use in the environment is permitted and not regulated elsewhere, are neither notifiable nor require a licence under the ContainO.

This includes the handling of:
- alien organisms approved as plant protection products or biocidal products;
- alien organisms approved as foodstuffs, animal feed or medicinal products;
- aquatic vertebrates, except for the species regulated otherwise in the Federal Act on Fishing (FishA; SR 923.0);
- alien plants, except for the species regulated otherwise in the Forest Act (ForA; SR 921.0) and the Forest Ordinance (ForO; SR 921.01);
- alien vertebrates, except for the species regulated otherwise in the Hunting Ordinance (HuntO; SR 922.01);
- alien plants that may be used pursuant to the Seeds Ordinance (SR 916.151);
- alien plants that are not prohibited in either Annexes 1, 2 and 6 of the PlantPO or Annex 2 of the RO;
- alien land snail species;
- alien small invertebrates kept as pets.

Conversely, all activities in laboratories or greenhouses using the following organisms fall within the scope of the ContainO:
- alien invertebrate animals and plants that are prohibited pursuant to Annexes 1, 2 and 6 of the PlantPO or Annex 2 of the RO;
- land-dwelling alien organisms that are not approved for direct use as plant protection products, biocidal products, or for classical pest control;
- alien fish and crustaceans that are not approved for direct use in the environment;
- alien small invertebrates, particularly those which may serve as vectors for notifiable transmissible diseases;
- alien vertebrates pursuant to Article 8 of the Hunting Ordinance.

Grouping

In principle, an alien organism subject to containment must be assigned to Group 3 if it has high invasive potential or presents another potential hazard (e.g. agricultural pests), even if this hazard is only suspected or cannot be ruled out for lack of data. Invasive organisms according to Annex 2 of the Release Ordinance (RO) and organisms in Annexes 1, 2 and 6 of the Plant Protection Ordinance (PlantPO) are therefore basically assigned to Group 3, as handling them in the environment is prohibited.
If scientific data (experimental releases in other countries or in Switzerland pursuant to Art. 15 para. 2 RO) or experience demonstrate that the organism does not show invasive potential, it can be assigned to Group 2. Concerning host specificity, the rule that applies here is that the broader the host spectrum, the higher the Group. Alien small invertebrates

that must be licensed for direct handling in the environment pursuant to Articles 17 and 25 RO are therefore assigned to Group 2 across the board.

Classification

Research activities involving Group 3 alien organisms subject to containment that do not occur in Switzerland should generally be assigned to Class 3. Deviation from this rule may be possible if it can be proved that Swiss ecological conditions prevent the species from establishing itself in Switzerland. In addition, activities may receive a lower classification if the organism is already widespread in the environment, if attempts to combat it are not being undertaken, or if activities with a reduced risk, e.g. analysis or storage, are being carried out. Handling Group 3 species subject to containment, such as *Solidago* or *Reynoutria,* which are already widespread in Switzerland but which do not cause any further economic damage or impair the health of humans or animals, can be assigned to Class 2. Very careful handling, and observation of suitable safety measures, is nevertheless indicated in order to prevent further spread. On the other hand, if reproduction or spread of the organism in the course of the activity cannot be ruled out, it should always be assigned to Class 3 (e.g. *Crassula helmsii* or *Elodea nuttalli*).

A recognised invasive alien small invertebrate that is also a vector for a notifiable disease should be assigned to Group 3, even if it already occurs in the environment. However, if combating it has been waived, its use may also be assigned to Class 2 (see Art. 7 para. 1).

If an organism belongs to Group 2, the activity is assigned to Class 2, as long as the organism does not occur in Switzerland or is not yet widespread and its potential establishment cannot be ruled out. The most important criteria for classification, in terms of these categories of organisms, are Letters b and c in Annex 2.2 Point 1. To evaluate these points, Points 281–283 of Annex 3.3 RO should be considered, i.e. the natural spread of the organisms; the role and significance of the organisms in their original ecosystem; a description of the biology, in particular of their reproduction, generation time, paths of biological spread, and the host, habitat and climate requirements of the organisms and of their possible host range. For example, an alien tick used for research is assigned to Class 2.

Annex 3 Information for the Notification and Licensing of Activities

Annex 3.1

Annex 3.1 now specifies the requirements for the global notification of Class 1 activities involving GMOs. A single notification should be used to summarise all notifiable Class 1 activities taking place in a single institution or establishment. The administrative details of all the locations and persons involved are recorded; any subsequent changes in these should also be reported later (letters a and b). Confirmation that Class 1 activities with GMOs are being carried out should reflect all the activities carried out in one institution, so that the federal and cantonal enforcement authorities have at least a broad picture of the type of activities in this establishment. Similarly, conformation of a weighing of interests in accordance with Article 8 GTA is required. Note particularly that although this confirmation is of a summary nature, the weighing of interests must be conducted on a case-by-case basis for each activity.

Annex 3.2

Following the presentation of principles (point 1), a distinction is now made between administrative (point 2) and technical (point 3) information. This reflects Article 10 paragraphs 2 and 3, which state that for licensed activities administrative changes must be reported, but technical changes require a further licence.

The first principle establishes that the extent and the level of detail of the technical information required depend on the level of risk of the activity. This means that with increasing risk, the technical information provided must be increasingly detailed. For Class 2 activities, the technical information for one organism may be used for other organisms with similar properties, provided the activities concerned carry similar risks. This is why using new organisms of the type described in the original notification does not require a new notification. The information for different pathogenic organisms of Group 2 may be used for one another if the following criteria are fulfilled:

- the same host range in humans, animals and plants i.e. several organisms that are pathogenic to humans and animals can be notified together, but an additional plant pathogen cannot;
- the same transmission path;
- similar infective dose;
- the same catalogue of measures in the event of an incident (e.g. inactivation and cleaning with 70% alcohol).

Invasive alien organisms of Group 2 may be notified to represent one another e.g. under the following cumulative conditions:

- the same type of organism, distinguishing between plants, vertebrates, arthropods, nematodes and microorganisms;
- the same type of replication (sexual reproduction or cloning);
- the same type of dissemination (via the wind, through vectors etc.);
- the same catalogue of measures in the event of an incident.

For genetically modified organisms the following cumulative criteria are an example, although these may be added to the criteria mentioned above if the GMO is also a pathogenic or invasive alien organism of Group 2:

- comparable type of organism, e.g. bacteria, fungi, viroids, plants, vertebrates, nematodes, cell cultures etc.;
- comparable inserts: a distinction is made between basically unproblematic inserts (such as non-coding gene sequences), genes that code for marker proteins (e.g. GFP or luciferase), and genes that code for structural proteins. The more problematic inserts include oncogenes, interleukins and cytokines, and in general all genes involved in cell cycle regulation and cell growth. Other problematic inserts are those that code for toxins or allergens, or influence the expression of tumour suppressor genes, e.g. if they have mutated or are inhibited by siRNA.
- the same catalogue of measures in the event of an incident.

For organisms of Groups 3 and 4, each organism must be notified separately.

The list of administrative details remains largely unchanged. The qualifications of the person responsible for the activity no longer have to be stated, as the ContainO does not require evidence of training, and whether a responsible person has sufficient knowledge of both technical matters and safety issues will only be checked in the context of enforcement (cf. the more detailed requirements in Annex 4 point 1 letter c ContainO). For activities using

genetically modified animals, a confirmation that an evaluation of interests under Article 8 GTA has been carried out must now be submitted.

The list of technical details is essentially limited to a summary of the information to be submitted for the different Classes, with details concerning safety levels and measures for individual work steps.

Annex 4 Safety measures

To help make Annex 4 ContainO more readable, note that the general safety measures in Annex 4 Point 1 ContainO apply to all species and Classes of activities (letters a–j). The special safety measures under Point 2 are divided into two categories. Point 2.1 specifies the safety measures for activities using genetically modified or pathogenic organisms. The table given there is preceded by a key to the symbols used. The safety level corresponds to the Class of the activity. The text in small print beneath the symbols in the box of a safety level (e.g. “Airlock doors lockable on both sides” in safety measure 4, safety level 4) describes how the safety measure should be carried out, or the requirements that must be met even if the safety measure per se does not have to be taken (e.g. measure 33 “Inactivation of microorganisms in contaminated material and waste, and on contaminated equipment, from animals and plants and of process fluid in the case of “P” production activities”, level 1). The small print there (“In the work area”) thus gives specific descriptions for the general safety measure in question. Point 2.2 specifies safety measures for activities using alien organisms subject to containment, which are subject mutatis mutandi to the special safety measures of Point 2.1, in particular those of the Table, (Annex 4 point 2.2 para. 2 ContainO).

Point 1: General safety measures

Letter a (new):
It was previously considered self-evident that the generally accepted rules of building practice must be adhered to when erecting and maintaining buildings and installations, particularly in terms of their stability, the safety of persons and property, and fire protection. This is now stated explicitly under the general safety measures, as in the past there has been some defective maintenance of buildings and installations.

Letter c (previously b):
This specifies the tasks of the Biosafety Officer, because of his or her important position within the laboratory or establishment.

Letter i:
Decontaminants have been added to this requirement, as they are not necessarily the same as e.g. disinfectants used for a puncture wound.

Letter j (new):
Measures against any pests and vermin, if required, should be taken in all installations (previously only in growth rooms and greenhouses).

Point 2.1: Special safety measures for activities using genetically modified or pathogenic organisms

The specific safety measures to be taken according to the safety level are shown in a table, by type of installation and class of activity. This table combines the previous Tables 1–4 for the sake of clarity and comparability, helped by the use of suitable symbols (cf. key). The special safety measures must take account of the risk determined in the specific case (letter a). In particular, this means that the scope and quality of a measure must increase with increasing safety level, and must correspond to the state of technology (letter b). The information under the safety levels 1−4 correspond to the requirements for carrying out activities in Classes 1−4 (letter c).
For practical or technical reasons the special safety measures cannot always be taken when transporting or storing organisms within an establishment, and in these cases the special safety measures should be applied mutatis mutandi (letter d new). This means that the same protection targets as in the case of an immediate use should be achieved.
Table (new classification system): the planned safety measures are in basic alignment with Directive 2009/41/EC. However, there have been deviations from the Directive's provisions where this is required by the broader scope of the ContainO, or where applying a measure in practice has led to difficulties. Thus, the autoclave may now be omitted in cases where it can be justified, e.g. if inactivation can be carried out chemically to the same extent. Similarly, with the appropriate authorisation it will now be possible to use an autoclave outside the building in level 2; for example, if construction work causes temporary obstructions.
Key: This is to help with the correct reading of the Table. Thus, "P" stands for production, "L" for laboratory, "G" for activities using plants (greenhouse), and "V" for activities using animals ("veterinary"). Production activities include the culture of organisms in larger quantities. Large quantities require additional safety measures, e.g. facilities for trapping liquid cultures after a spill. However, since it is not just the quantity but also the species of the organism that is relevant for risk, it does not appear useful to lay down absolute thresholds here. Whether an activity is considered to be a production activity therefore depends on the intention behind it, and on the risk assessment carried out by the responsible persons. The enforcement authorities will then assess the activities again as part of the notification or licensing procedure. For activities in animal facilities, no distinction is drawn in terms of the species involved (exception: safety measure No. 3). Both vertebrates and invertebrates as well as other animals are covered. The safety measures should be applied by analogy, depending on the species of animal.
The safety measures that have changed from the ContainO of 1999, or that require clarification, are explained below.

No. 1: The work area is the space in which organisms are handled under the ContainO (e.g. laboratories, culture rooms, centrifuge rooms, cold rooms and deep freezes, microscopy rooms, rooms with FACS devices, rooms for inactivating organisms). Other areas are those in which organisms are not handled under the ContainO (e.g. office workstations).

No. 2: Access must be restricted from level 2. For level 2 itself this may mean that a list of persons permitted in the work area is affixed to the entry. There should be stricter (physical) access controls from level 3, such as locking systems or access monitoring, to prevent unauthorised persons from entry.

No. 3: Installations holding vertebrates must be separated by lockable doors irrespective of the safety level. For other animals, the premises must be separated by lockable doors only from level 3. These animals are often not kept in actual rooms, but in incubators located inside the laboratory. These incubators do not have to be lockable, provided the laboratory itself can be locked.

Nos. 4 and 5: In clinical diagnostic laboratories and research labs, it is not common practice to shower when leaving a safety level 3 laboratory. The use of a normal shower after an emergency or incident is generally not now considered suitable, although previously it was mandated. Normal showers do not decontaminate effectively, and the associated aerosolisation of any microorganisms still present could cause spread of the pathogens or increase the risk of infection of laboratory staff. If such an emergency shower is used in the event of an incident, the water must be collected so that it can be decontaminated before it flows into the drains. In accordance with Directive 2009/41/EC, the presence of a shower in the airlock is “optional” for level 3, i.e. it may be necessary depending on the risk assessment. Enforcement of the previous ContainO had always allowed showers to be omitted showers in level 3 laboratories (diagnostic, research) as long as emergency decontamination can take place in the laboratory; in this case, the release of microorganisms through wastewater must be prevented. In future, therefore, the need for authorisation to omit a shower will be waived. The shower should be regarded as part of the airlock, and will be present or not depending on the activity and on the organisms used. An applicant must judge whether an airlock shower is really necessary or appropriate for a specific activity.
By analogy to the rationale given above, and after the experience of building a level 4 diagnostic laboratory in Geneva, it is possible for level 4 facilities to omit the shower if authorised by the competent federal office. The applicant must judge whether the presence of a shower in the airlock really makes sense in terms of biosafety. Facilities for personal decontamination, e.g. automatically operated washbasins in the airlock or close to the exit, and eyewash or decontamination stations, must be available in the laboratory (new special safety measure No. 6; cf. also general safety measures pursuant to Art. 8 para. 4 PEMO), and any contaminated wastewater must be collected.
Nevertheless, a shower may well be sensible when handling non-human pathogenic organisms, to prevent humans acting as a vector to carry the organisms into the environment, as here other risks and protection targets – environmental protection – become paramount.

No. 6: From level 2, facilities for personal decontamination must be installed in the work area. These may be in the form of disinfectant beside the washbasin, or an actual decontamination station. The methods of decontaminations or disinfection must be validated, and their effectiveness must be monitored periodically. It is important to decontaminate splashes and spills where they occur, before leaving the work area. From level 3, any contaminated wastewater (cf. No. 4 and 5) must be collected (e.g. in an autoclavable catch tank).

No. 9: This safety measure has been extended from animal facilities to cover all installations. Easily cleanable floors are universally important to ensure the hygiene of an installation.

No. 13: HEPA filters for the air supply to level 4 can now be replaced by other measures. For example, provided the level of risk allows, labs may use a combination of a primary contained system (microbiological safety cabinet, MSC) and gastight dampers on the air

supply side that close immediately if there is a power failure or impending pressure equalisation. It is vital that at level 4 there is a dual safety system to prevent the escape of organisms. When handling organisms in the MSC this may be achieved by the combination of the cabinet's HEPA filter plus the HEPA filter of supply and exhaust air to the work area, or through the use of a closed and appropriately secured container plus the HEPA filter of supply and exhaust air.

Nos. 15, 16, 17 and 25: These safety measures concern primary contained systems. This does not mean an MSC but systems such as fermenters, bioreactors or culture vessels (including all their component parts), which are used for large-scale culture.

Measures in the "Equipment" section are prescribed only for those work steps for which they provide effective protection, e.g. MSC for work involving microorganisms where aerosols may be produced.

No. 19: As in Directive 2009/41/EC, surfaces must now also be resistant to water. For example, greenhouses must not use wooden work benches, which could swell. Likewise, following Directive 2009/41/EC, resistance to decontaminants is required as well as to disinfectants.

No. 21: Samples in laboratories with MSC III (safety level 4) may enter through the pass-through autoclave or through the personal airlock. For airlock exit, two cases must be distinguished:

- The airlock exit of samples/wastes from the MSC III takes place through a fumigable material lock and/or dunk tank (surface decontamination, also used for airlock entry) attached to the MSC III. Installing a pass-through autoclave between the MSC III and the surrounding laboratory is not necessary.
- The airlock exit of surface-decontaminated but infectious material from the surrounding laboratory for further analysis should take place through a material lock (dunk tank or fumigation chamber) between the surrounding laboratory and the area around that.

These procedures, particularly airlock entry and exit of samples into and out of the MSC III and the surrounding laboratory, internal transport, and waste disposal, must all be validated. For activities using Class 4 animal and plant pathogens in MSC II, complete protection may not make sense, and may with authorisation from the competent federal office be omitted.

No. 23: An autoclave may be omitted for safety levels 1–3 provided other methods of inactivation with a validated and comparable effect can be used to inactivate cultures and enrichments of microorganisms and any contaminated waste where it occurs (levels 2 and 3), or to dispose of them harmlessly (level 1). For notifiable activities, authorisation should be obtained from the competent federal office (Art. 17). This measure may also be modified with the appropriate authorisation, if e.g. an autoclave in another building (level 2) or outside the work area (level 3) is used. It may be sensible to use an autoclave in another building, for example, if building work makes the lab's own autoclave temporarily unavailable. In both cases, the transport of contaminated material from the work area to the autoclave must be safe.

No. 27: Lab garments should be worn for activities in the laboratory. Suitable clothing for other activities should be specified according to the risk. This is to prevent employees from acting as vectors and transporting organisms into the environment on their clothes.

No. 28: Depending on the activity, employees should take personal safety measures. The particular measures to be taken (e.g. gloves, headgear, facemasks, protective goggles) are specified on the basis of the risk assessment. Personal protective equipment (PPE) not only protects the employees but also prevents them from acting as vectors.

No. 30: This safety measure is intended for the treatment of unavoidable residues in wastewater. The (deliberate) disposal of organisms directly through wastewater without appropriate prior inactivation is expressly forbidden! Minor contamination, e.g. of hands in levels 1 and 2, can be removed in washbasins without further decontamination if the risk allows. At levels 3 and 4, escape of microorganisms into the environment must be prevented. This requires an inactivation system for wastewater (e.g. installing autoclavable collectors under washbasins or in a decontamination station).

No. 31: The escape of wastewater must be minimised in levels 1 and 2, and prevented completely in levels 3 and 4. For levels 1 and 2, this safety measure may be modified, replaced or omitted, subject to authorisation.

No. 32: Escape of reproductive plant parts in the air or via vectors must be controlled. At level 2 the escape must be minimised to the extent that plants cannot outcross or establish a population in the environment. From level 3, escape must be prevented altogether. For levels 1 and 2, this safety measure may be modified, replaced or omitted subject to authorisation, and as long as substitute measures of equal value are taken.
This safety measure particularly concerns genetically modified and/or invasive alien plants. The escape of pathogenic microorganisms via inoculated plants into the environment is covered by safety measure No. 31 and by the use of primary contained systems such as a MSC and further technical, personal and organisational protective measures.

No. 33: As before, microorganisms in wastes from Class 1 activities must be disposed of harmlessly. Wastes from Class 2 activities should in principle continue to be inactivated within the building, unless an autoclave outside the building may be used for inactivation in accordance with safety measure No. 23. Contaminated material, animal carcasses and diagnostic samples can be disposed of as special waste, as has been the case up to now for medical wastes. In justified exceptional cases, and with authorisation from the competent federal office, it will now also be possible to dispose of solid cultures as special waste. In every such case proof of a functioning disposal chain of this type must be provided. Liquid wastes from Class 2 activities must always be inactivated on site.
Wastes from Class 3 activities must in general be inactivated inside the work area. If the wastes are to be inactivated outside the work area, the establishment must obtain authorisation from the competent federal office. All inactivation must nevertheless take place within the building. Any wastes from Class 4 activities must always be inactivated within the work area.
The method of choice for inactivating wastes is proper autoclaving. In general, alternative inactivation methods are permissible if they are considered equally effective and have been validated.

Point 2.2: Special safety measures for activities using alien organisms subject to containment

Alien organisms form an extremely heterogeneous group, whether in terms of their classification and size, their developmental stages, their reproduction, their distribution, or the ways in which they are used. Handling alien organisms subject to containment therefore requires a variety of special safety measures. The Table in Annex 4 Point 2.1 can only represent these varying requirements to a very limited extent. Therefore, the fundamental principle is that special safety measures apply by analogy, and special measures adapted to the specific organisms and uses should be taken to ensure equivalent protection. Here, too, the special safety measures must take account of the risk determined for individual cases; must correspond to the state of technology available for handling vectors of dangerous diseases, quarantine organisms and organisms used for classic pest control; and must increase with increasing safety level. In a first step, and on a case-by-case basis, the organism's possible escape routes in its relevant life stages into the environment should be defined (e.g. active escape, or passive escape via waste, wastewater, the air or vectors including employees). A second step then identifies safety measures that limit (Class 1 and 2 activities) or prevent (Class 3 and 4 activities) the escape of the organisms via these routes.

Annex 5 Amendment of Current Legislation

The following Ordinances will be amended in the course of the full revision of the ContainO:

- Ordinance of 20 November 1996 on the Swiss Expert Committee for Biosafety; SR 172.327.8;
- Animal Protection Ordinance of 23 April 2008, AniPO; SR 455.1;
- Transplantation Ordinance of 16 March 2007; SR 810.211;
- Ordinance of 17 October 2001 on Clinical Trials of Therapeutic Products, ClinO; SR 812.214.2;
- Ordinance on Biocidal Products of 18 May 2005, OBP; SR 813.12;
- Ordinance of 19 October 1988 on the Environmental Impact Assessment, EIAO; SR 814.011;
- Major Accidents Ordinance of 27 February 1991, MAO; SR 814.012;
- FOEN Fees Ordinance of 3 June 2005, FeeO-FOEN; SR 814.014;
- Ordinance of 1 July 1998 on the Pollution of Soil, SoilPO; SR 814.12;
- Release Ordinance of 10 September 2008, RO; SR 814.911;
- Cartagena Ordinance of 3 November 2004, CartO; SR 814.912.21;
- Ordinance of 25 August 1999 on Protection of Employees from Dangerous Microorganisms, PEMO; SR 832.321
  (in accordance with separate draft);
- Epizootic Diseases Ordinance of 27 June 1995, EzDO; SR 916.401;
- Ordinance of 23 June 2004 on the Disposal of Animal By-Products, DABO; SR 916.441.22.

These Ordinances will have the date of the effective Federal Council approval of the fully revised ContainO inserted into them; the references to Articles in the ContainO will be updated; and the boundary between the ContainO and other Ordinances will be made clear. Fields of application or references and reservations relating to alien organisms will be extended in some of the Ordinances listed, in accordance with the extension of scope of the ContainO.

In addition, material changes are linked to the following amendments:

Article 3 para. 1 Letters b, e and f RO will be amended in line with the definitions in Article 3 Letters b, e and f ContainO.

Article 3 para. 1 Letter g RO will be repealed in line with the non-adoption of the term "domesticated" by the ContainO.

Articles 11 and 14 RO will, in line with Article 13 ContainO, be supplemented with provisions on the start, suspension and termination of the guarantee (para. 6 and 7 will be new), which should ensure, as in the ContainO, that the competent enforcement authorities are informed at all times about the presence of the guarantee and are able to take the necessary measures before suspension or termination of the guarantee.

In Article 15 para. 2 RO, the previous specification "animals and plants" is replaced by "organisms". This corresponds to the title of Annex 2 RO (Prohibited invasive alien organisms) and ensures that if needed, organisms other than animals and plants can be included in Annex 2 RO.

The new wording of Article 15 para. 3 RO is intended to take account of knowledge and current practice that allows excavated soil and subsoil contaminated with invasive alien organisms as defined in Annex 2 RO, but free of chemical contamination, to be used at the place of excavation or stored in an inert materials landfill, and may now in addition be used in a gravel pit that is to be recultivated; these uses can be reconciled with the protection goals of the RO. Such use, however, requires specific prior measures, such as access control and adequate covering within a year. This more flexible wording does not exclude other sensible disposal solutions that ensure the protection of human beings, animals, the environment and biodiversity from alien organisms.

The supplement to Article 15 para. 4 RO ensures that the provisions of forestry legislation remain reserved. This is significant in view of the relationship between the RO and the Ordinance of 29 November 1994 on Forest Reproductive Material (SR 921.552.1), which makes clear that forestry provisions take precedence over those of the RO.

Articles 17 and 25 RO are restructured for clarification. Letters a (genetically modified organisms) and b (pathogenic organisms) of both provisions have not been materially altered, but for reasons of proportionality Letter c is limited to the licensing obligation for experimental releases or marketing of alien small invertebrates. Only alien small invertebrates that are intended for use in the environment and not as pets are covered. Thus, the indirect handling of alien small invertebrates – e.g. for use as medicinal products,

foodstuffs or animal feed – no longer requires a licence. Alien small invertebrates intended as pets, e.g. all zoo animals or exotic ants in private terrariums, are also exempt from licensing. These alien small invertebrates therefore do not have to be handled in contained systems. From the point of view of risk, restricting the licensing obligation to the direct handling of alien small invertebrates in the environment can be justified in that using such organisms as medicinal products, foodstuffs or animal feed is naturally of lower risk than using them directly in the environment, e.g. as part of classic biocontrol. In addition, the legislation on medicinal products, foodstuffs and animal feed shall apply as appropriate. In the case of pets, there is a relatively low risk of escape into the environment and the possibility of impairment of or damage to the objects to be protected, as keeping of such small animals as pets is geared to their not escaping. The general duty of care and the requirements for handling in accordance with Article 15 RO continue to be applicable.

Article 49 para. 2 EzDO on the coordination of procedures will be slightly amended. In line with the ContainO, under Article 49 para. 2 EzDO requires only the agreement of the cantonally designated specialist agency and not that of the cantonal veterinary officer, which takes account of cantonal differences in administrative competencies. The principle of Article 19 para. 2 ContainO, according to which a decision must be made within 90 days, is also included in Article 49 para. 2 EzDO.