Directive concerning the internal procedure for projects subject to notification/authorisation according to the ContainO, RO and OPTM Ordinances

LEX 1.5.3

12th September 2011, status as at 15th March 2021

This text is no longer in force

The Direction of the Ecole polytechnique fédérale de Lausanne,

based on the Ordinance of 9 May 2012 on Handling Organisms in Contained Systems (Containment Ordinance, ContainO),
based on the Ordinance of 10 September 2008 on the Handling of Organisms in the Environment (Release Ordinance, RO), and
based on the *Ordonnance sur la protection des travailleurs contre les risques liés aux micro-organismes (OPTM)* of 25 August 1999, the use of genetically modified organisms (GMOs) or pathogenic organisms in laboratories is, in most cases, subject to a notification or authorisation procedure,

hereby adopts the following:

Article 1 Introduction

[1] The objectives of the Containment Ordinance (ContainO), the Ordinance on Protection of Employees from Dangerous Organisms (OPTM) and of the Release Ordinance (RO) is to protect humans, animals and biodiversity against the risks inherent in the use of any biological material, such as e.g. (genetically modified or pathogenic) organisms, environmental samples containing microorganisms, cell cultures, biopsies or diagnostic samples. Activities involving biological materials may, depending on the nature of the material or environment in which the material is used, be subject to a notification or authorisation procedure.

[2] The aim of this Directive is to define the internal procedure at EPFL, in order to ensure that notification and authorisation application procedures are properly carried out. It particularly permits a distinction to be made between projects subject to a strict authorisation application and those for which the risk assessment means that temporary authorisation can be given for them to be carried out.

[3] It also defines the procedures allowing the Department of Security, Safety and Facilities Operations (hereinafter: DSE) to obtain information regarding the use of such biological material, in order to implement the necessary safety measures (infrastructure, interventions) and to provide medical monitoring of exposed persons.

[4] For authorisations required in accordance with the *Ordonnance sur la protection des animaux (OPAn)* (animal protection Ordinance), please refer to the instructions laid down by the EPFL Center of PhenoGenomics (CPG).

Article 2 Notification of a new activity

[1] The head of unit shall notify any use of biological material or organisms to the EPFL Biosafety Coordinator or a DSE staff member specialised in biosafety (hereinafter: EPFL Biosafety) and provide them with the information required under Art. 5 below. EPFL Biosafety determines, in cooperation with the head of unit, whether a procedure in relation to the Federal authorities is necessary.

[2] Where no procedure is required in relation to the Federal authorities, an in-house risk analysis shall nevertheless be conducted and documented so as to determine whether specific safety measures should be taken.

Article 3 Procedure for notifications and authorisation applications

[1] Procedure for activities in a contained system: EPFL Biosafety, with the support of the head of unit or Biosafety Officer (hereinafter: BSO), creates the notification or authorisation application dossier. The head of unit validates the dossier by email. The information is forwarded to the Federal Coordination Centre for Biotechnology, which verifies the completeness of notifications and requests for authorisation. Complete dossiers are then transferred to the relevant federal office. The relevant federal office communicates its decision within 90 days following the confirmation of the dossier's completeness. The procedure differs depending on the activity class (see Annex 1). Authorisations for Class 3 activities remain valid for a maximum of five years.

Additionally, if new infrastructures are required for Class 3 activities, they must be validated by the cantonal authorities, and then submitted to public enquiry. The criteria to be fulfilled are described in the Ordinance of 27 February 1991 on Protection against Major Accidents (Major Accidents Ordinance, MAO).

[2] Procedure for release into the environment: projects for release into the environment subject to authorisation may not start without the authorisation of the competent Federal authority. Prior to submission of the authorisation application, the appropriate procedure is defined on a case-by-case basis and the EPFL Direction is informed accordingly by the DSE.

[3] A copy of the reply by the competent federal office shall be sent to EPFL Biosafety.

Article 4 Modification of activity

[1] All significant modifications of an activity implying a risk reassessment must be announced:

1. A modification of the ContainO dossier is required as soon as:
   - a) new organisms[1] of Groups 1 and 2, with properties that are significantly different from those observed in the initially declared organisms, are used or generated;
   - b) new Group 3 organisms[1] are used.
   - c) new stages creating a new risk or an additional risk are introduced;
   - d) a new type of installation is required for working with the organisms (e.g. transfer of activities from the laboratory to a greenhouse).
2. If organisms tested in contained systems are planned to be used in a non-contained system, a new procedure shall be initiated and a new dossier opened according to the RO (see Article 3).

[2] The OUC dossier must also be updated in the case of administrative changes such as:

1. a change concerning the management of the project or the BSO;
2. a change of address of the company or a move to a new site;
3. termination of the activity;
4. use of additional premises or other previously undeclared premises;
5. a request for the renewal of the Class 3 authorisation.

[1] In case new organisms are used while an authorisation has already been granted to omit one or several safety measures, it must be ensured that this authorisation is extended to the new organisms used, if the safety measures in question can also be omitted in handling these organisms.

Article 5 Information required to notify or apply for authorisation[2] of a new project in a contained system or to modify an existing project

The following information shall be sent electronically to EPFL Biosafety:

1. title of activity;
2. names of the head of unit and of the BSO;
3. description of the activity or activities (e.g. the description found on the project Web page or in the summary of a funding request submitted to the Swiss National Science Foundation), or of changes in the activity;
4. representative list of organisms used or newly used, with typical examples from the biological safety point of view. This list must cover the range of organisms used in carrying out the project. Any Group 3[3] organisms that might be used must be mentioned;
5. list of premises in which the activities will take place, or list of new premises or premises no longer used.

Article 6 Authorisation renewal for Class 3[2]

In order to renew the Classe 3 authorisation, the head of unit or BSO must contact EPFL Biosafety three months before the authorisation expiry date. The head of unit or BSOreassesses the situation with EPFL Biosafety in order to define the procedure to be followed (e.g. confirm in a document that the activity is still being carried out under the same conditions or submit a new dossier). The renewal application shall be forwarded to the Federal Coordination Centre for Biotechnology by EPFL Biosafety. A copy is given to the Safety Correspondent (COSEC) and the School Safety Coordinator (CSF). A copy of the reply received from the competent federal office must be sent to EPFL Biosafety.

Article 7 Entry into force

This directive entered into force on 12th September 2011, and was revised on 15th March 2021 (version 2.2).

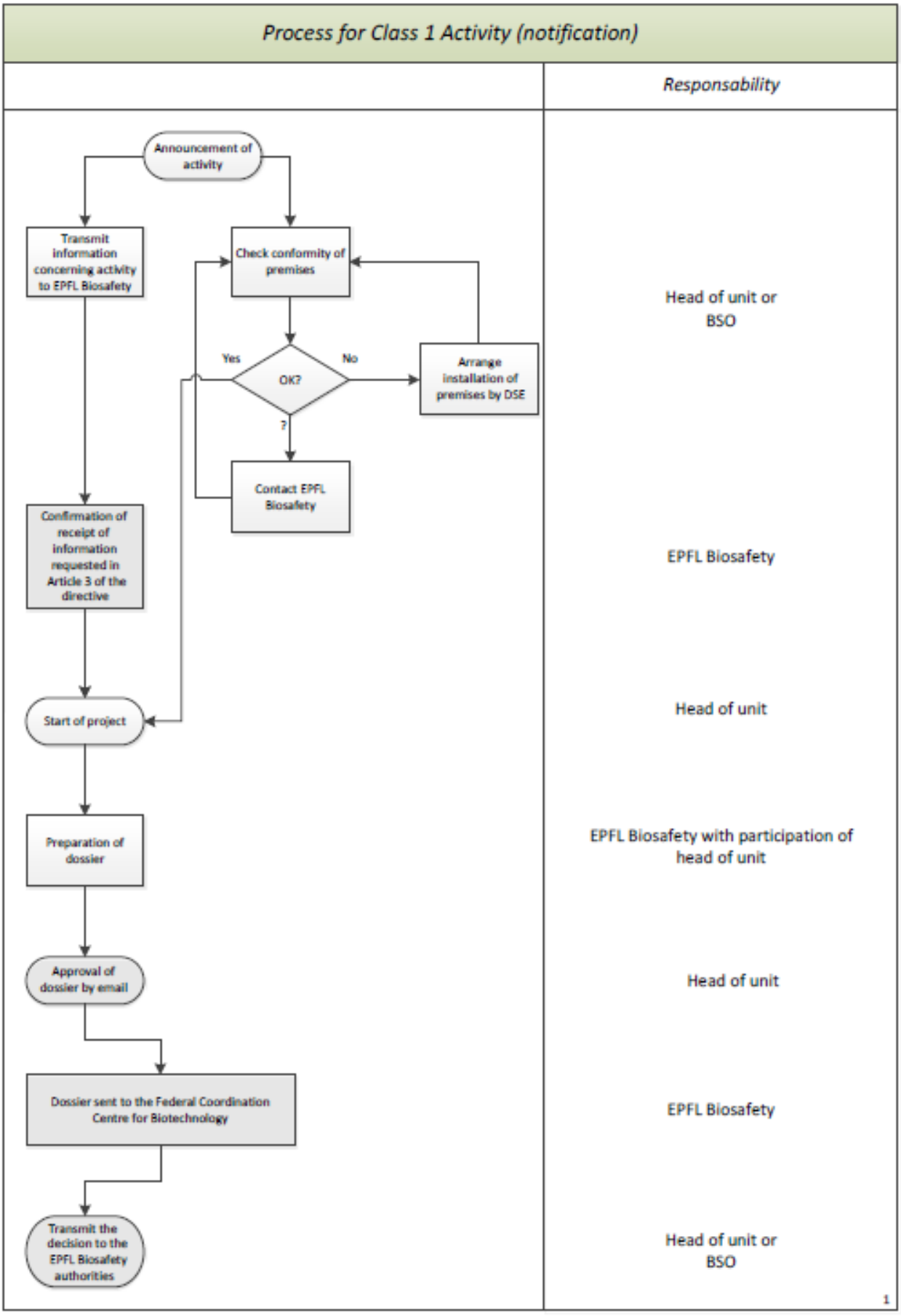
On behalf of the EPFL Direction:

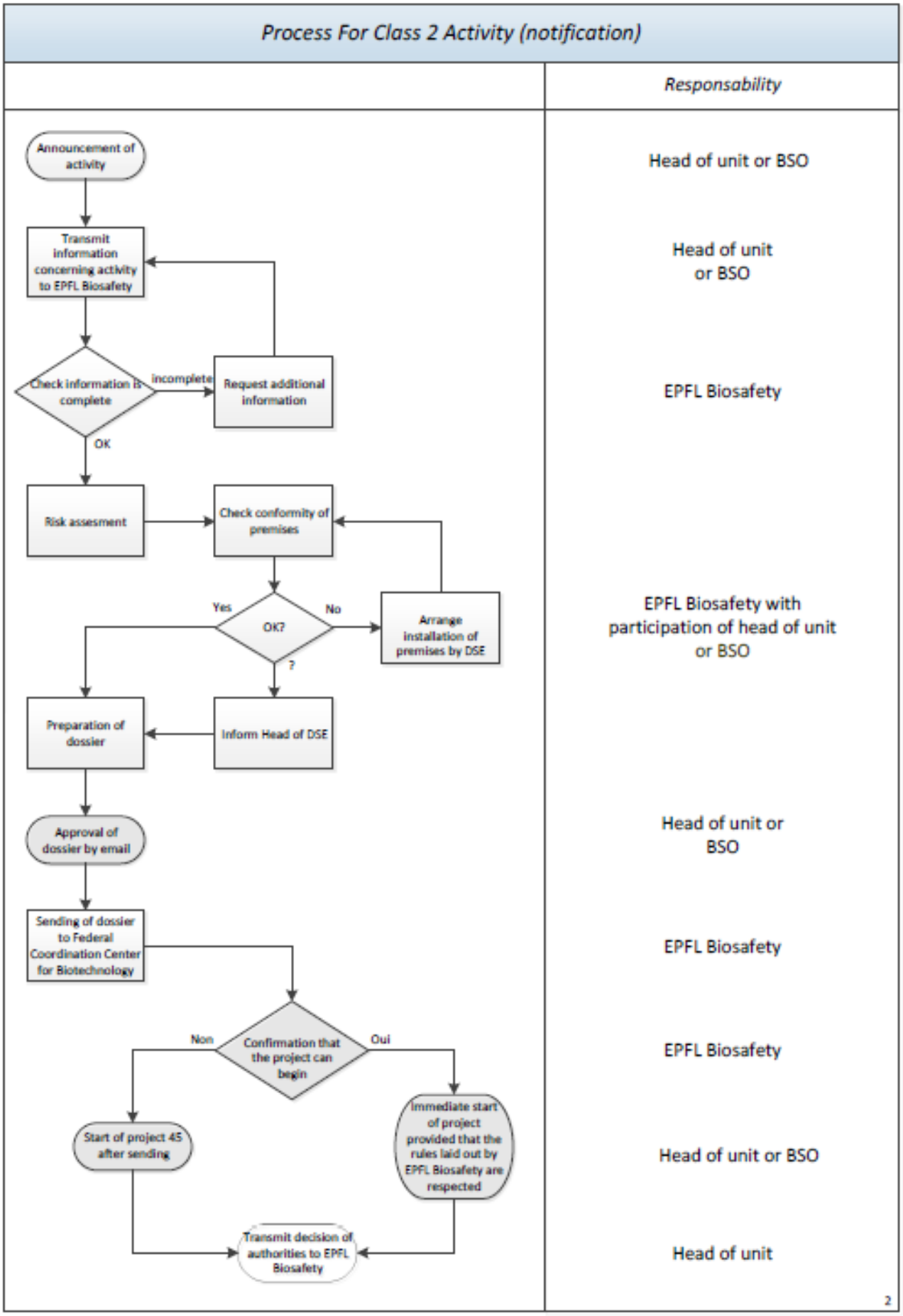
Martin Vetterli
President

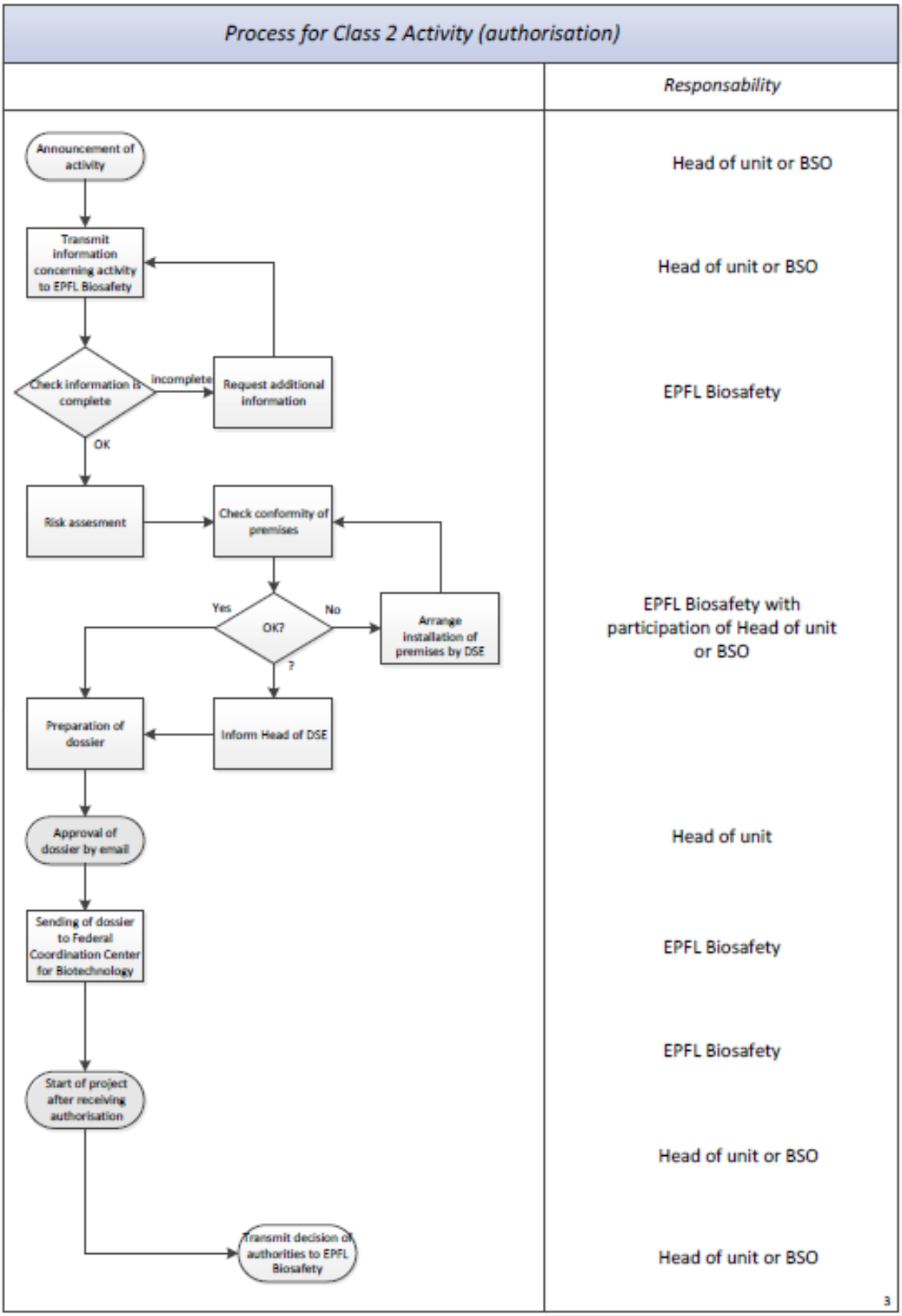
Françoise Chardonnens
Director of Legal Affairs

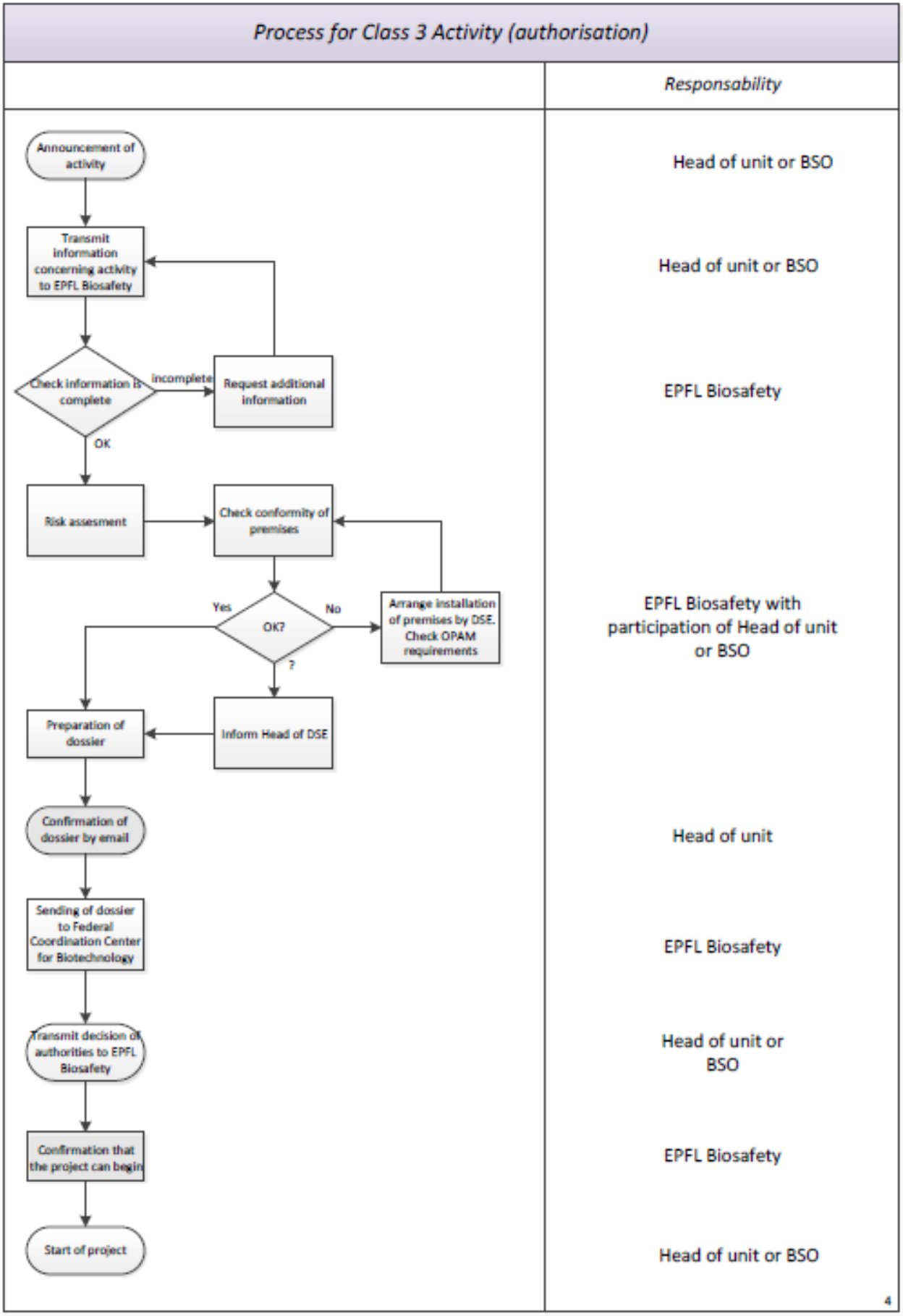
[2] Authorisation renewals for non-contained use are processed separately according to the schedule for the procedure applicable to this type of use.
[3] Storage and use of Group 4 organisms are strictly confined to biosafety level 4 infrastructure. EPFL has no such facility. Possession of this group of organisms is therefore prohibited.

Annexe 1 to the Directive concerning the internal procedure for projects subjected to notification/ authorisation according to the OUC and OPTM


Process for Class 1 Activity (notification)
Responsability
Announcement of activity
Transmit information concerning activity to EPFL Biosafety
Check conformity of premises
Head of unit or BSO
Yes
OK?
No
Arrange installation of premises by DSE
?
Contact EPFL Biosafety
Confirmation of receipt of information requested in Article 3 of the directive
EPFL Biosafety
Start of project
Head of unit
Preparation of dossier
EPFL Biosafety with participation of head of unit
Approval of dossier by email
Head of unit
Dossier sent to the Federal Coordination Centre for Biotechnology
EPFL Biosafety
Transmit the decision to the EPFL Biosafety authorities
Head of unit or BSO
1


Process For Class 2 Activity (notification)
Responsability
Announcement of activity
Head of unit or BSO
Transmit information concerning activity to EPFL Biosafety
Head of unit or BSO
Check information is complete
incomplete
Request additional information
EPFL Biosafety
OK
Risk assesment
Check conformity of premises
Yes
OK?
No
Arrange installation of premises by DSE
EPFL Biosafety with participation of head of unit or BSO
?
Preparation of dossier
Inform Head of DSE
Approval of dossier by email
Head of unit or BSO
Sending of dossier to Federal Coordination Center for Biotechnology
EPFL Biosafety
Non
Confirmation that the project can begin
Oui
EPFL Biosafety
Start of project 45 after sending
Immediate start of project provided that the rules laid out by EPFL Biosafety are respected
Head of unit or BSO
Transmit decision of authorities to EPFL Biosafety
Head of unit
2


Process for Class 2 Activity (authorisation)
Responsability
Announcement of activity
Head of unit or BSO
Transmit information concerning activity to EPFL Biosafety
Head of unit or BSO
Check information is complete
incomplete
Request additional information
EPFL Biosafety
OK
Risk assesment
Check conformity of premises
Yes
OK?
No
Arrange installation of premises by DSE
EPFL Biosafety with participation of Head of unit or BSO
?
Preparation of dossier
Inform Head of DSE
Approval of dossier by email
Head of unit
Sending of dossier to Federal Coordination Center for Biotechnology
EPFL Biosafety
EPFL Biosafety
Start of project after receiving authorisation
Head of unit or BSO
Transmit decision of authorities to EPFL Biosafety
Head of unit or BSO
3


Process for Class 3 Activity (authorisation)
Responsability
Announcement of activity
Head of unit or BSO
Transmit information concerning activity to EPFL Biosafety
Head of unit or BSO
Check information is complete
incomplete
Request additional information
EPFL Biosafety
OK
Risk assesment
Check conformity of premises
Yes
OK?
No
?
Arrange installation of premises by DSE. Check OPAM requirements
EPFL Biosafety with participation of Head of unit or BSO
Preparation of dossier
Inform Head of DSE
Confirmation of dossier by email
Head of unit
Sending of dossier to Federal Coordination Center for Biotechnology
EPFL Biosafety
Transmit decision of authorities to EPFL Biosafety
Head of unit or BSO
Confirmation that the project can begin
EPFL Biosafety
Start of project
Head of unit or BSO
4