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	<b>Electron Microscopy Unit (EMU)</b> Tel: 4387/6079
	<a href="mailto:imces-support@uk-essen.de">imces-support@uk-essen.de</a>

## IMCES Biosafety Application Form

<b>Applicant</b>			
<b>Title:</b>	<input type="checkbox"/> Dr.	<input type="checkbox"/> PD	<input type="checkbox"/> Prof.
<b>Surname:</b>			
<b>Forename:</b>			
<b>Email:</b>			

<b>PI</b>	<input type="checkbox"/> same as above
<b>Title:</b>	<input type="checkbox"/> Dr. <input type="checkbox"/> PD <input type="checkbox"/> Prof.
<b>Surname:</b>	
<b>Forename:</b>	
<b>Email:</b>	

<b>Project Number:</b>	
(just relevant for projects registered with the EMU)	

**Our work at the IMCES will include handling of living microorganisms and will be classified as work of biosafety level (BSL)...**

**targeted**

☐ **non-targeted R2**     
 ☐ **R2**     
 ☐ **S1**     
 ☐ **S2**


... based on a proper risk assessment according to §4 of the *German BioStoffV* and *TRBA 400* of the “Bundesanstalt für Arbeitsschutz und Arbeitsmedizin” and under consideration of potential genetic modifications.

- As R1/R2 we define work with wt organisms of BSL1/2.
- As S1/S2 we define work with genetically modified organisms (GMO) of BSL1/2.
- Non-targeted work is defined in German BiostoffV §2(8). In many cases, work with untested human material falls in the category “non-targeted R2” → please verify yourself (see also TRBA100 4.4.1)

Properly chemically/aldehyde-fixed samples are biologically inactive and therefore belong to the group “no risk”. Consequently, working with them does not have to be considered, in this form. The same is true for active R1 samples. If you are unsure about definitions, please contact us.

**No work of a biosafety level higher than 2 is possible at the IMCES.**

(see Appendix 1)

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## 1. What to declare to whom? *Your responsibilities in BSL declaration, summarized for your information*

**You are fully responsible for generating a proper BSL risk assessment according to the *German BistoffV* in compliance with the guidelines of *TRBA 400* for the work you wish to carry out at IMCES. Any change in the BSL status of your work to a higher level at a later date must be notified to IMCES before work commences.**

Depending on this BSL risk assessment, the different rules listed below must be followed. Further clarifications can be found in the *Appendix*.

In any case, be aware that for the conducted work at the IMCES, its proper documentation and the supervision of these parts you and competent people of your group/facility are fully responsible (see *Appendix 4*).

### **Rules for R1 work**

According to chapter 4 of the German BioStoffV, new wildtype work of BSL1 does not have to be actively announced to the responsible authorities (*defined in Appendix 2*). Furthermore, there is no legal requirement for a R1 laboratory to be initially approved by a competent authority. Consequently, you can start your R1 work at IMCES without further measures. Also, submission of this form to us is not required.

### **Rules for non-targeted R2 work**

For definition of non-targeted work ("nicht gezielte Tätigkeiten"), see *Appendix 3*.


The requirement of a BSL2-compliant laboratory environment for this type of work has been met at IMCES. Therefore, based on the legislation explained in the appendix, you can start your non-targeted R2 work at IMCES as soon as you have returned this form to us, with no further action required.

Please note that an appropriate BSL risk assessment is also mandatory for this type of work and that this assessment might be more complex than for other work as it must take all the (unknown) factors into account that could affect the BSL. Proper documentation and supervision of the experiments and their documentation lies in your hand!

### **Rules for (targeted) S1 work**

For S1 work at IMCES you critically need an officially registered genetic facility within your own lab space which can serve as host facility for your GMO work at IMCES (*see Appendix 4*).

According to legislation, new BSL1 work with GMOs in an approved BSL1/2 facility does not have to be actively announced to the responsible authorities (German GenTG, § 9 para. 1), but as an internal regulation you must inform the IMCES about the genetic components of your work by submitting this form to us. Right after we have received this notification, you can immediately start your S1 work at IMCES.

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#### **Rules for (targeted) R2 work**

According to German BiostoffV, all targeted R2 work (“gezielte Tätigkeiten”) must be officially announced to the district government thereby also declaring the location of the BSL2 laboratories where work will be conducted (see *Appendix 5*).

Before start of your targeted R2 work at the IMCES facility we therefore expect you to announce it a) to IMCES by submitting this form to us **and in parallel also** to b) the Düsseldorf District Government, Department **56**. The announcement to the district government must take place via the “Sicherheitstechnische Dienst” of the UME, currently in person of...

**Dr. Nora Koll, email: [nora.koll@uk-essen.de](mailto:nora.koll@uk-essen.de), phone: +49 201/723-3397 (Cordless -85596).**

After the announcement has been received by the district government, you must wait **30 days before your work at the IMCES** can be started. In most cases, no approval letter will be sent by the district government.


#### **Rules for (targeted) S2 work**

Comparable to S1 work, you shift parts of the genetic project from your host facility to the IMCES facility. This must be announced a) to the IMCES **and in parallel also** to b) the Düsseldorf District Government, Department **53.5**.

The announcement to the IMCES is achieved by submitting this form to us. The announcement to the district government must take place via the “Sicherheitstechnische Dienst” of the UME, currently in person of...

**Dr. Nora Koll, email: [nora.koll@uk-essen.de](mailto:nora.koll@uk-essen.de), phone: +49 201/723-3397 (Cordless -85596).**

After the announcement has been undoubtedly received by the district government, you can immediately start **your S2 work at the IMCES**. In some cases, a recipient notification to this announcement and in most cases an approval letter for this project change will be sent by the district government, at a later time-point.

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## 2. Specification of intended work

*Declaration is **always** required*

**Organism(s) and BSL declaration according to a proper risk assessment according to *German BiostoffV***

*Declaration is **always** required*

**Short description of your intended BSL-relevant work at the IMCES**

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### 3. Legal declaration of your work

#### **Declaration required for S1 and S2-work**

As explained in *Appendix 4* it is a prerequisite that you run an own S1/2 facility to primarily host GMO-projects of which you then shift work parts to the IMCES S2 facility. If applicable, please enter the following information **for your host facility** (see *Appendix 7*)

**„Anlagennummer“:**

... of the host facility for your S1/2 work

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**„Aktenzeichen“:**

... of the „Anlagen-Genehmigungsbescheid“

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#### **Declaration required for S2 work and optional for targeted R2 work**

If you intend to shift work parts of an S2 project to the IMCES facility, the entire project must first have been registered with the district government at your host facility. If you have already received a letter of approval for this first S2 project application, please enter the following information (see *Appendix 6*). In some cases, such a letter of approval is also sent when a wild type R2 project with targeted work is registered. If applicable, please provide the details of your project.

**Full project name:**

---

**“Aktenzeichen”:**

...of the respective project approval letter for your facility

---

#### **Declaration required for S1 and S2 work**

For S1/2 work, please specify the “Projektleiter” (**not necessarily the PI!**) and the “Beauftragte für Biologische Sicherheit (BBS)” responsible for the work **at your host facility**, according to German GenTG.

**“Projektleiter”:**

according to §3(8) of the German GenTG


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**“BBS”:**

... of the host facility according to §3(9) of the German GenTG

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- I am aware that each time we work at S2 level at IMCES we must a) indicate the S2-machine usage via the respective checkbox in the online booking system **and** b) fill out an S2-usage form to ensure a reliable record of our S2 activities at IMCES.

\_\_\_\_\_ , \_\_\_\_\_  
 Place Date Signature of applicant

\_\_\_\_\_ , \_\_\_\_\_  
 Place Date Signature of PI

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## Appendix for your information

1. The IMCES genetic S2 facility is officially registered with the Düsseldorf district government under the facility number 1410 (reference number of the approval notice 53.02.01-D-1.20/11). With this registration IMCES provides laboratory space that is generally suitable for work at the maximum BSL2.
2. The “Bezirksregierung Düsseldorf, Dezernat 56: Betrieblicher Arbeitsschutz in Mönchengladbach” is the responsible authority for BSL2 work with wt organisms and the “Bezirksregierung Düsseldorf, Dezernat 53.5: Gentechnik-Zulassungsbehörde”) for any work with GMOs.
3. In the BiostoffV §2(8) non-targeted work is defined as work with active organisms where at least one of the following conditions **does not** apply:
  - a. The activities within the work are directly targeted at one or a limited number of biosubstances.
  - b. The biosubstance(s) are known at least by species.
  - c. The exposure of employees during normal operation is sufficiently known or can be estimated.

As an example, non-targeted work includes activities with untested primary human material which might be contaminated with non-defined pathogens (i.e. FACS to isolate primary immune cells from human blood). According to TRBA100 4.4.1(1), isolated material of **healthy** human donors can generally be classified as work of BSL2. If at least one of the three above-mentioned points does not apply, this work is categorized as non-targeted R2-work.


§16(1)1.b) of the German BiostoffV stipulates that non-targeted work only must be reported to the competent authority if it focusses on biosubstances of BSL3 and if it is carried out regularly.

4. If you intend to work with GMOs (S1 or S2) at the IMCES it is a prerequisite that you run your own genetic facility in your independent lab space. This facility must be registered at the “Bezirksregierung Düsseldorf, Dezernat 53.5: Gentechnik-Zulassungsbehörde”.

The reason for this prerequisite is that, in line with legal regulations and with good biological practice, all BSL1/2 work, and its documentation require supervision by competent people. In case of genetic work, these responsibilities belong to the “Projektleiter’s” duties according to §3(8) of the German GenTG. For the IMCES S2 facility, several facility-internal “Projektleiter” have been officially registered with the district government. However, the IMCES is a service core facility hosting a variety of complex scientific projects. Therefore, the registered “Projektleiter” of the IMCES cannot provide individual supervision of the user’s work and its records. The IMCES “Projektleiter” care for providing proper lab conditions and routine processes at the IMCES to fulfill the requirements for safe BSL1/2 work. Further, the documentation of the daily machine usage via a) the online booking calendar and b) BSL2-usage protocols lie in the responsibility of the IMCES “Projektleiter”.

For the conducted work at the IMCES, its proper documentation and the supervision of these parts, you, and in case of GMO work the individual “Projektleiter” of your genetic host facility are



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responsible. In case of any project-related question by the authorities we will forward the officers to you and the people supervising your work.

5. For the performance of wild-type R2 work, there is no legal obligation to register defined associated laboratory rooms with the district government, in which only activities within the scope of the announced work can take place. Nevertheless, BSL2-compliant laboratory rooms in which BSL2 work can be carried out safely are mandatory for the performance of R2 work.

This requirement is checked in the mandatory process of registering all R2 work with the district government, in which the laboratory space is also declared. The department in charge for these issues is the “Bezirksregierung Düsseldorf, Dezernat 56: Betrieblicher Arbeitsschutz in Mönchengladbach”.

According to §4 of the BioStoffV, the supervision of wt BSL1/2 work, and its documentation lies in the responsibility of a not further defined “competent” person. As explained for GMO-work (see *Appendix 4*) this person cannot be provided by the IMCES. The IMCES staff cares for proper lab conditions to safely work under BSL1/2 conditions. For the work conducted at IMCES, its proper documentation and the supervision of these parts, you, and competent people of your group are fully responsible. In case of any project-related question by the authorities we will forward the officers to you and the people supervising your work.

6. From the initial announcement of your GMO project, **for your facility**, you potentially have received a project approval letter from the respective authorities with a unique “**Aktenzeichen**” on which also the “**Full project name**” is listed. If you had applied for establishing a new genetic facility with a particular project, the “Aktenzeichen” of the “Genehmigungsbescheid” for the facility and the project might be the same.
7. From the registration process of your genetic S1/2 facility at the district government you should have received an own “Anlagen” approval letter with a unique “**Aktenzeichen**” listing the unique “**Anlagennummer**” of your facility.