

Eeg/ checklist AO engels 9907

At the moment we are checking the administrative organisation of notifiers and licensees. This will also be the subject for joint inspections in the near future and therefore an attempt has been made to translate one of the checklists we use during these inspections.

## CHECKLIST ADMINISTRATIVE ORGANIZATION

### **Internal Organisation (article 4 and 4a)**

provide documentation of:

- 1 the appointment of the Biological Safety Officer (BSO) by the licensee (art. 6.1 and 4.1)
- 2 the appointment of Responsible Employees (RE) by the licensee (art. 6.1.a and 4a.1)
- 3 a description of the tasks of the BSO a.o. with respect to (artt. 4.2.a-f):
  - safety
  - internal control
  - accident/incident response and preparedness
  - internal counseling, advice and education
  - reporting
- 4 a description of the tasks of the ER a.o. with respect to (art 4.a.2):
  - everyday management
  - drawing-up and executing work-protocols
- 5 a clear description of the separation of responsibilities and tasks between the BSO and the RE (art. 4.a.3)
- 6 the discretionary powers/mandate that the BSO has received in order to fulfil his duty (art 4.3 juncto artt. 4.2.a, 4.2.b and 4.4.a).
- 7 the instructions that have been given by the licensee to the BSO (art 4.3 juncto artt. 4.2 a-f)
- 8 written guarantees for an independent position of the BSO that at least warrant (art. 4.4.a,b and c)
  - the possibility to report directly to the licensee
  - an independent position towards the people that should be controlled by him.
  - exclusion that the function of BSO is combined with that of ER (art. 4.4.c)
- 9 guarantees for sufficient presence/attendance of the BSO (art. 4.5)

### **Internal procedures and regulations for safe handling gmo's (art.5)**

provide written procedures for (art. 6.1.a):

- 10 a procedure for internal notification of incidents (art. 5.1.a)
- 11 a procedure for external notification in case of serious risk (art. 5.1.b)
- 12 a procedure for internal control on compliance with regulations and licence (art. 5.2.a)
- 13 a procedure for incident/accident response (measures, reporting, evaluation) art.5.2.b
- 14 a procedure for submission of a notification or application of a licence or proposed changes herein. (art. 5.2.c)
- 15 a procedure for assessment of expertise (art. 5.2.d)
- 16 a procedure for assessment and approval by the BSO of internal procedures and regulations or changes proposed herein (art. 5.2.e).

provide the following written safety regulations (art. 6.1a):

17 for inactivation of gmo's and disinfection of equipment that has been in contact with gmo's (art. 5.3.a).

18 for storage, transport and incineration of waste (art. 5.3.b).

19 for cleaning and disinfection of equipment and workingrooms/laboratories. (art. 5.3.c).

20 for transport of gmo's (art. 5.3.d).

21 for checking purity and identity of gmo constructs (art. 5.3.e).

22 for emergency preparedness actions and countermeasures in case of accidents or incidents (art. 5.3.f)

23 for testing , maintenance and control of proper functioning of containment equipment (art. 5.3.g)

24 for limiting accessibility to working places/laboratories (art. 5.3.h)

### **administrative records**

records that should be available on site central within the institution or establishment:

25.1 all documents mentioned previously covered by articles 4, 4a and 5.

25.2 a map of the institution or establishment indicating:

- workingareas and their containment level (art. 6.1a)
- any storage sites for gmo's outside these areas and the way of storage (art. 6.1.b)

25.3 results of periodical internal control on compliance as covered under point 12 of this list (art 6.1.c)

25.4 results of checks on proper functioning of the procedure for submission of a notification or application of a licence or proposed changes herein as covered by art. 5.2.c (art. 6.1.d)

25.5 data on and date of (artt. 6.1.e, 5.2.a, 5.1, 5.2.b and 4a.1):

- internal control
- incidents/accidents or violations of regulations including evaluation and reporting

25.6 on overview of all other relevant data and documents that allowed to be kept in various workingplaces or laboratories indicating their precise location within the institution or establishment.

records allowed to be available on several different sites within the institution or establishment:

26 accurate descriptions/characterizations of gmo's or groups of gmo's comprising at least (art. 6.2):

- a description of the host-organism and name of the gmo
- a description of the genetic material used to construct this gmo comprising at least the composition, and the donors it was derived from.
- in case of a group I gmo (requiring only reporting) gene functions should be documented.
- for gmo's requiring notification the number of notification/licence should also be mentioned.

27 relevant data on employees (art. 6.2.b) comprising at least:

- name
- education, training and experience
- containment level of the work they are allowed to
- for each individual employee a signed approval by the BSO indicating to which kind he or she is allowed.

28 a list of names (art. 6.2.c) of any other persons (students, guest workers, etc.) allowed to work with gmo's indicating at least period of work and name of responsible ER.

29 results and dates (art. 6.2.d) of execution of procedures for:

- for checking purity and identity of gmo's (art. 5.3.e).
- for testing , maintenance and control of proper functioning of containment equipment (art. 5.3.g)

30 working protocols drawn up by the ER (art. 6.2.e)

31 for all activities with gmo's in a certain workroom or laboratory a list the licence numbers under which these activities are covered (art. 6.2.f)

32 for each individual storage facility a list of stored gmo's (art. 6.2.g)

33 data on waste that contains or may contain gmo's comprising at least (art. 6.2.h and annex 8 under f): origin, composition, amount and date and period of storage.