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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 December 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2016) 445 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Details from individual Member States on their experience with Directive 2009/41 of the European Parliament and of the Council of May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2009-2014 *Accompanying the document* COMMISSION WORKING DOCUMENT Experience of Member States with Directive 2009/41 of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2009-2014

Delegations will find attached document SWD(2016) 445 final.

Encl.: SWD(2016) 445 final

EUROPEAN
COMMISSION

Brussels, 20.12.2016
SWD(2016) 445 final

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{COM(2016) 808 final}

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1. DETAILS FRO INDIVIDUAL MEMBER STATE THREE YEAR REPORTS (raw data translated and compiled)

1 Overview of activities and installations

1.1 How many notifications were submitted in your Member State under Directive 2009/41/EC on the contained use of GMMs during the **reporting period 6 June 2009 and 5 June 2014**?

Please provide as annex at your report, a table with all the information required by art 18(2) for each of the notifications received, under Directive 2009/41/EC.

AUSTRIA

GMMs	**No. of notifications**
Class 1	**74**
Class 2	**137**
Class 3	6
Class 4	0
Amendments to earlier notifications	20
Total	**237**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	6	**1**
GMM + GM animal	14	**1**
Amendments to earlier notifications	-	-
Total no. of notifications received	20	

BELGIUM

GMMs	**No. of notifications**
Class 1	**253**
Class 2	**273**
Class 3	69
Class 4	0

Amendments to earlier notifications[1] (Subsequent use notifications)	418
Total	**595**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	24	risk class 1 GMM: 20 risk class 2 GMM: 4 risk class 3 GMM: 0
GMM + GM animal	113	risk class 1 GMM: 25 risk class 2 GMM: 68 risk class 3 GMM: 20
Amendments to earlier notifications	122	GMM + GM plant: 19 GMM + GM animal: 93
Total no. of notifications received	**136 notifications of GMMs/GMOs combined**	

BULGARIA

GMMs	**No. of notifications**
Class 1	Two
Class 2	None
Class 3	None
Class 4	None
Amendments to earlier notifications	None
Total	Two

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	Two	Both class 1
GMM + GM animal	None	Not applicable
Amendments to earlier notifications	None	Not applicable
Total no. of notifications received	Two	

CROATIA

Nineteen (19) notifications were submitted in Croatia during mentioned period.

GMMs	**No. of notifications**
Class 1	17
Class 2	2
Class 3	0
Class 4	0
Amendments to earlier notifications	
Total	19

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	2	1
GMM + GM animal	2	1 and 2

[1] Subsequent use notifications: since 2002, the Walloon decree of 04/07/2002 regarding the contained use of GMOs and/or pathogens doesn't distinguish anymore between first and subsequent contained uses. In consequence, all notifications for this region are treated as new activities (or first contained uses).

Amendments to earlier notifications		
Total no. of notifications received	19	

CYPRUS

GMMs	**No. of notifications**
Class 1	1*
Class 2	1*
Class 3	0
Class 4	0
Amendments to earlier notifications	0
Total	1*

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	0	
GMM + GM animal	0	
Amendments to earlier notifications	0	
Total no. of notifications received	0	

* Please note that both Class 1 and Class 2 Activities were included in one notification for the same installation.

CZECH REPUBLIC

GMMs	**No. of notifications**
Class 1	14
Class 2	2
Class 3	1
Class 4	0
Amendments to earlier notifications	35
Total	**52**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	0	
GMM + GM animal	0	
Amendments to earlier notifications	21	1 and 2
Total no. of notifications received	**21**	

Explanation note: According to the current Czech legislation, a new notification is required in every case **a new GMO is to be used** (not only new premises). This rule applies even to **class 1** of contained use that means the national requirements are stricter than those set by the Directive. An amendment to the Czech Act of GMOs has been drafted with the aim to ease this administrative burden both for notifiers and for the Competent Authorities. The amendment is now in the legislative process.

DENMARK

GMMs	No. of notifications
Class 1	244
Class 2	57
Class 3	0
Class 4	0
Amendments to earlier notifications	440
Total	**742**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	31	1 and 2
GMM + GM animal	283	1 and 2
Amendments to earlier notifications		
Total no. of notifications received	**314**	

ESTONIA

GMMs	No. of notifications
Class 1	3
Class 2	3
Class 3	2
Class 4	0
Amendments to earlier notifications	0
Total	**8**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	0	
GMM + GM animal	0	
Amendments to earlier notifications	0	
Total no. of notifications received	**0**	

NOTE: Labour inspectorate of Estonia registers notifications only for GMO-s. There are no combined notifications in Estonia

FINLAND

GMMs	No. of notifications
Class 1	136
Class 2	104
Class 3	3
Class 4	0
Amendments to earlier notifications	?? (what does the question specifically mean?)
Total	**183** (an individual notification may contain activities from several classes)

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	12*	1-2
GMM + GM animal	12*	1-2
Amendments to earlier notifications	??	
Total no. of notifications received		

*) notified together, not necessarily used in combination; please also note that this answer does not cover situations where GMMs are used in combination with non-modified plants or animals or vice versa

FRANCE

3500 notifications

GMMs	No. of notifications
Class 1	1850
Class 2	1450
Class 3	180
Class 4	20
Amendments to earlier notifications	500
Total	**3500**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	250	1+2+3
GMM + GM animal	2500	1+2+3+4
Amendments to earlier notifications	400	
Total no. of notifications received	**3150**	

GERMANY

GMMs	No. of notifications
Class 1	1147
Class 2	2264
Class 3	106
Class 4	5
Amendments to earlier notifications	
Total	**3522**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	12	2
GMM + GM animal	22	2
Amendments to earlier notifications		
Total no. of notifications received	**34**	

Please provide as annex at your report, a table with all the information required by art 18(2) for each of the notifications received, under Directive 2009/41/EC.

Class 3/4: see attached summary report of class 3 and class 4 contained uses.

HUNGARY

GMMs	**No. of notifications**
Class 1	5
Class 2	20
Class 3	none
Class 4	none
Amendments to earlier notifications	
Total	**25**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	2	2
GMM + GM animal	3	2
GMM+GM animal + GM plant	2	2
Amendments to earlier notifications		
Total no. of notifications received	**7**	

IRELAND

GMMs	**No. of notifications**
Class 1	70
Class 2	75
Class 3	5
Class 4	0
Amendments to earlier notifications	0
Total	**150**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	6	**Class 1**
GMM + GM animal	10	**Class 1 and Class 2 GMMs**
Amendments to earlier notifications	0	
Total no. of notifications received	**67**	

ITALY

GMMs	**No. of notifications**		
	Installations	**Activities**	**Total**
Class 1	33	N.A.*	33
Class 2	50	144	194
Class 3	5	8	13
Class 4	0	0	0
Amendments to earlier notifications	18	13	31
Total	**106**	**165**	**271**

(*) Notification is not due for class1 activity

Note: the following table only refers to activities with GMM inoculation.

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	1	2
GMM + GM animal	39	2
GMM + GM animal	3	3
Amendments to earlier notifications	4	2
Total no. of notifications received	**47**	

LATVIA

GMMs	No. of notifications
Class 1	1
Class 2	
Class 3	
Class 4	
Amendments to earlier notifications	
Total	**1**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	1	1
GMM + GM animal		
Amendments to earlier notifications		
Total no. of notifications received	**1**	

LITHUANIA

GMMs	No. of notifications
Class 1	6
Class 2	
Class 3	
Class 4	
Amendments to earlier notifications	
Total	**6**

GMMs and GMOs combined	No. of notifications	Class of GMM
GMM + GM plant	1	1
GMM + GM animal	2	1
Amendments to earlier notifications	2	1
Total no. of notifications received	**5**	

MALTA

GMMs	No. of notifications
Class 1	6

Class 2	0
Class 3	0
Class 4	0
Amendments to earlier notifications	0
Total	**6**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	0	
GMM + GM animal	0	
Amendments to earlier notifications	0	
Total no. of notifications received	**0**	

NETHERLANDS

GMMs	**No. of notifications**
Class 1	---
Class 2	---
Class 3	---
Class 4	---
New notifications	519
Amendments to earlier notifications	3281
Total	

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant		
GMM + GM animal		
Amendments to earlier notifications		
Total no. of notifications received	**3800**	

In the Netherlands, during the reporting period 210 institutes and companies were actively involved in contained use activities with genetically modified organisms. At these 210 institutes a total of 2315 licensed active contained use activities take place. This contained use involved not only activities with micro-organisms but also with genetically modified plants, animals, viruses, etc. In addition, most companies/institutes carried out activities with combinations of GMO's, i.e. not exclusively with GMM's. 15 new installations were notified compared to the last reporting period. In total 519 new notifications and 3281 amendments on earlier notifications were received during 2009-2014. In general more than one containment level was prescribed per notification.
Overall in the Netherlands we encounter a rise of more than 60% in the amount of new and amended notifications in comparison to the figures of the last reporting period.

POLAND

GMMs	**No. of notifications**
Class 1	250
Class 2	34
Class 3	2
Class 4	0

Amendments to earlier notifications	
Total	**286**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	57	I
GMM + GM animal	98	I/II
Amendments to earlier notifications		
Total no. of notifications received	**155**	

PORTUGAL

GMMs	**No. of notifications**
Class 1	2
Class 2	5
Class 3	-
Class 4	-
Amendments to earlier notifications	-
Total	**7**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	-	
GMM + GM animal	-	
Amendments to earlier notifications	-	
Total no. of notifications received	-	

ROMANIA

GMMs	**No. of notifications**
Class 1	None
Class 2	None
Class 3	None
Class 4	None
Amendments to earlier notifications	None
Total	None

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	None	
GMM + GM animal	None	
Amendments to earlier notifications	None	
Total no. of notifications received	None	

SLOVAKIA

GMMs	**No. of notifications**
Class 1	55
Class 2	8
Class 3	0
Class 4	0

Amendments to earlier notifications	0
Total	**63**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	12	1
GMM + GM animal	16 (class 1) + 10 (class 2)	1&2
Amendments to earlier notifications		
Total no. of notifications received	**38**	

Since 1.1.2013 the users of genetic technologies and genetically modified organisms aren´t obliged to notify the start of the new activity classified to the risk class 1 to the Ministry of the Environment of the Slovak Republic (hereinafter referred to as "the ministry"). Once every 6 months, the users of GMOs submit a summary notification on all the GMOs classified in the risk class 1, which they have carried out activities with, including their storage in the reporting period.

SLOVENIA

GMMs	**No. of notifications**
Class 1	7
Class 2	36
Class 3	0
Class 4	0
Amendments to earlier notifications	24
Total	**74**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant		
GMM + GM animal	3	2 in class 1; 1 in class2
Amendments to earlier notifications		
Total no. of notifications received	**3**	

Information required by art 18(2) under Directive 2009/41/EC is available in the GMO Register at Slovene Biosafety Portal http://www.biotechnology-gmo.gov.si/.

SPAIN

GMMs + GMP + GMA= All GMOs (**)	**No. of notifications**
Class 1	101
Class 2	103
Class 3	22
Class 4	
Amendments to earlier notifications	
Total	**226**

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	35	32 (Class 1) 3 (Class 2)

GMM + GM animal	28	27 (Class 1) 1 (Class 2)
Amendments to earlier notifications		
Total no. of notifications received	**63**	

(**) Under the scope of the Spanish Law on GMOs, all kind of genetically modified organisms are included in the requirements for contained use purposes. So we have considered all the notifications received during the reporting period (GMMs + GM Plants + GM Animals) for the four classes of risk.

SWEDEN

Please note that one "notification" may include more than one GMM activity or new GMM use. Numbers in table are approved activities and the "notifications" are stated above the table.
Total number of notifications, applications and changes during the time period: 477
Notification (class 1 and class 2, including new class 2 uses): 411
Applications (class 3 and class 4): 18
Changes to already approved GMM-activities: 143

GMMs	**No. of notifications (numbers are activities notified/approved during the time period)**
Class 1	123 (7 were later closed during the time period)
Class 2	102 (3 were later closed during the time period)
Class 3	13
Class 4	2
Amendments to earlier notifications *	
Total	**240**

*Amendments to earlier notifications do not include new class 2 uses. Such uses are not included in this list but are a large part of the 411 "notifications" we have registered during the time period.

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant		
GMM + GM animal		
Amendments to earlier notifications		
Total no. of notifications received		

The list in the annex includes all active activities and uses within activities regardless of when it was notified. It is not possible to provide a list only covering 5 years. Please also note that one post in the list does not equal one activity or one GMM-use.

UNITED KINGDOM

GMMs	**No. of notifications**

Installation or premises notification	126 (125 from GB; 1 from NI)
Class 2	612 (602 from GB; 10 from NI)
Class 3	75 (all GB)
Class 4	2 (all GB)
Amendments to earlier notifications	197 (196 from GB; 1 from NI)
Total	**1012 (1000 from GB; 12 from NI)**

a) The figure for 'amendments to earlier notifications' includes changes to the contained use that may affect risk (55 significant changes), changes to required containment (6 derogations) and transfer of contained use to a different installation (135 transfers).

b) Please note, the Directive is only concerned with genetically modified microorganisms (GMM) and does not require collection of information on work with genetically modified organisms (GMOs i.e. animals and plants). Consequently, such information is not collected in a form that is amenable for reporting purposes. For completeness, figures on combined work with GMMs and either animals or plants (which may or may not be genetically modified) have been compiled by reviewing individual notifications of GMMs.

c) The figures in the table below represent a subset of the individual contained use notifications listed in the first table in section 1.1.

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + plant	18	class 1 (4); class 2 (9); & class 3 (5)
GMM + animal	194	class 1 (9); class 2 (161); class 3 (24);
Amendments to earlier notifications	data not available	data not available
Total no. of notifications received	**212**	

d) Annex 1 provides details of contained uses notified to the UK competent authorities during the period of this report.

1.2 Of the aforementioned notifications how many were notified for:

AUSTRIA

- Research purposes not applicable (see below).
- Commercial purposes not applicable.
- Other (please specify) not applicable.

Note ad 1.2 and 1.4
The former distinction of contained uses on the basis of the purpose (i.e. operations of type A and type B in Dir. 90/219/EEC) has been abolished by Dir. 2009/41/EC. In accordance with the current Directive notifiers are not obliged to specify the purpose of the contained use and therefore only the total number is available (total number of installations: 352).

BELGIUM

- Research purposes (Universities, research institutes): 313
- Commercial purposes: 150
- Other
    - Hospitals: 88
    - Education – Teaching: 12
    - Public institutions (diagnostic, reference lab, quality control): 32

BULGARIA

- Research purposes 4
- Commercial purposes 0
- Other (please specify) 0

CROATIA

- Research purposes FOURTEEN (14)
- Commercial purposes FOUR (4)
- Other (please specify) ONE (1)

CYPRUS

- Research purposes 1
- Commercial purposes 0
- Other (please specify) 0

CZECH REPUBLIC

- Research purposes 57 (incl. amendments to earlier notifications)
- Commercial purposes 7 (incl. amendments to earlier notifications)

- Other (please specify) 9 detection laboratories, transport companies (incl. amendments to earlier notifications).

DENMARK

- Research purposes 724
- Commercial purposes 60
- Other (please specify) 21 (large scale research)

ESTONIA

- Research purposes 8
- Commercial purposes 0
- Other (please specify) 0

FINLAND

- Research purposes 146 (estimation)
- Commercial purposes 27
- Other (please specify) 10 (education, core laboratory services)

FRANCE

- Research purposes 3000
- Commercial purposes 500
- Other (please specify)

GERMANY

- Research purposes _____
- Commercial purposes _____
- Other (please specify) _____

No information available (database cannot be evaluated concerning the above criteria)

HUNGARY

- Research purposes 25
- Commercial purposes 7
- Other (please specify) none

IRELAND

- Research purposes 190 } These figures are inclusive of
- Commercial purposes 21 } 67 GMO (GM plants and GM

- Other (please specify) i.e. State 6 animals applications
- TOTAL 217

ITALY

- Research purposes 149
- Commercial purposes 16

LATVIA

- Research purposes 1
- Commercial purposes _____
- Other (please specify) _____

LITHUANIA

- Research purposes 11
- Commercial purposes _____
- Other (please specify) _____

MALTA

- Research purposes 6
- Commercial purposes 0___
- Other (please specify) 0___

NETHERLANDS

- Research purposes ---
- Commercial purposes ---
- Other (please specify) ---

Remark: due to reporting mechanisms it is not possible for the Netherlands to differentiate the issued licences between commercial or research purposes.

POLAND

- Research purposes 260
- Commercial purposes 1
- Other (please specify) 25 clinical trials

PORTUGAL

- Research purposes 6
- Commercial purposes 1
- Other (please specify) _____

ROMANIA

- Research purposes None
- Commercial purposes None
- Other (please specify) None

SLOVAKIA

- Research purposes 92
- Commercial purposes 16
- Other (please specify) 0

SLOVENIA

- Research purposes 63
- Commercial purposes 11
- Other (please specify) 0

SPAIN

- Research purposes 200
- Commercial purposes 15 (products close to commercial development phases, control quality procedures, manufacture of diagnostics, veterinary or human medicines).
- Other (please specify) _____

SWEDEN

- Research purposes 221 (both commercial and academics)
- Commercial purposes 6*
- Other (please specify) 12 with education at both high school level and university level; 1 with destruction of GMM in waste, 1 with diagnostics.

*Where the commercial purpose is research or if the purpose is both research and commercialisation, the purpose is included as Research. Several small business companies have research as their main purpose for GMM use. Some also use GMM for production.

UK

- Research purposes 719 in GB and 6 in NI
- Commercial purposes 229 in GB and 4 in NI
- Other (please specify) 52 in GB and 1 in NI

Other in this case relates to Government Organisations.

1.3 Please comment on the overall trend compared to the previous reporting period (e.g. has the overall number of notifications received increased or decreased, has there been an increase/decrease in respect of certain classes, commercial or research sectors etc.)

AUSTRIA

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BELGIUM

From 6 June 2009 to 5 June 2014, 552 dossiers of installations covering 1150 notifications of contained uses of GMMs, GMOs and/or pathogens have been reviewed by the SBB acting as the advisory body for the competent authorities.

- It is not appropriate to compare two different reporting time period (3 years for previous report and 5 years for this one) but in general, the number of dossiers and notifications remained comparable if the average of notifications per year is considered.
- Since 1993, Belgium has fully implemented Directive 90/219/EEC in three regional decrees thereby extending the scope to GMOs and non-GM pathogens. This means that, among the 1150 notifications, 426 of them exclusively concerned non-GM pathogens (37%) and 482 notifications concerned GMMs and/or GMOs only (42%). The remaining 242 notifications concerned contained uses of both GMMs/GMOs and non-GM pathogens (21%).

Compared to the previous 3-year reporting period, the percentage of notifications for non-GM pathogens remains exactly the same. In contrast, there was a strong decrease of notifications concerning exclusively MGMs or GMOs in favour of combined operations with GM and non-GM organisms.

- Subsequent use notifications: In Belgium, from 2009 to 2014, the subsequent use notifications have steadily increased. They account for up to 82 % which is a high increase compared to the previous reporting period when they represented only 59 % of the total number.
- With respect to the type of exploitations, the large majority of GMMs are used by the university research laboratories (60 %) for fundamental research. Sometimes medical researches with GMMs are conducted in hospital labs (9%). GMMs are handled in pharmaceutical companies (23 %) for research purposes or production of enzymes, vaccines and therapeutic molecules. Rarely, GMMs are also used for teaching (2 %).

BULGARIA

All four notifications received concern initial approval of facilities of academic institutions for contained use of GMM class 1 (Article 6 of the Directive) and in addition two of them included request for work with GM plants class A (see answer to question 2.2). All four notifications were received after July 2012. We expect further notifications for initial approval of facilities from between two and five academic institutions. All will include work with GMM class1 and it is possible that up to two of them will include work with GMM class 2. Additionally we expect that between 2 and 5 of the notifications will include work with GM plants class A and one or two work with GM animals class A. Notification for initial approval of facilities should be updated at least every two years.

CROATIA
Not applicable. Croatia has been started with the procedure of notification of contained use of GMMs in the middle of 2012.

CYPRUS
There was an increase in the number of notifications received. The previous reporting period there was no GMMs notification received.

CZECH REPUBLIC
Most institutions submitted their notifications during the first years after the Czech Act on GMOs came into force in 2004. Since 2006, the number of new subjects starting to use GMMs has increased only moderately. Prevailing notifications concerned new activities with GMMs in previously notified premises - that means mostly amendments to the previous notifications have been submitted (see the explanation note to 1.1. above). The purpose of the notified activities has been almost entirely research and education (Universities).

DENMARK
There has been an increase in the number of notifications for class 1 and 2. Regarding the classifications of locations there has also been an increase.

ESTONIA
This number has been increased, especially in class 3. In the previous reporting period there were no any class 3 notifications.

FINLAND
The overall number of notifications has increased. This is probably due to the current policy that each university research group notifies independently its GMO activities instead of joint notifications covering whole departments or units.

FRANCE
Generally, in all cases, the notifications are increasing.

GERMANY
The overall number of notifications has increased with respect to all classes.

HUNGARY
Compared to the previous reporting period, there has been an increase in the number of Class 2 contained use/installation notifications in Hungary, mainly for research purposes. In our

view, the reason for that is that the Government sent detailed information to the universities, laboratories, and other contained use facilities on the obligatory to apply for consent for these activities.
In most cases, notifiers propose Class 2 for contained use activities or installations where Class 1 would be also appropriate. The notifiers' reasoning behind is that by applying stricter contained use measures a higher level human health and environmental safety can be ensured. The competent authority approves the proposed Class level in these cases. There is an increase in the number of GM animal notifications, too.

IRELAND

Compared to our submission for the 2006 – 2009 report, the number of applications received from research institutions is slightly down (87% compared to 90% during period 2006 - 2009) but the trend is the same in that the majority of applications were submitted by users in research institutions. That said the current reporting period is 5 years as opposed to the 3 year duration of the 2006 – 2009 reporting period which could account for this slight difference

Consistent with previous years the majority of the applications submitted during the period belonged to Class 1 (70). These were all applications in respect of first time use of premises. In contrast, 75 applications were received in respect of Class 2 GMM contained use activities, however 45 of these were in respect of first time use of a premises and 30 corresponded to 'subsequent Class 2 contained use', i.e. where the premises has been the subject of a previous notification to carry out Class 2 GMM contained use activities.

The number of applications received from commercial users during the reporting period 2009 – 2014 has increased by almost 50%. Again most likely the extended reporting period has had a bearing on this.

ITALY

The overall number of notifications remains stable (-2%, actually) with respect to the previous period (i.e. 6 June 2004 - 5 June 2009); some more "class 3" activities, fully balanced by the decrease in the "class 1" installations. The actual period is characterised by a significant number of amendments: 11% of the overall submissions have been due to revisions (minor, usually) of previous notifications. No relevant change has to be reported in terms of sector breakdown.

LATVIA

This is first notification regarding contained use in Latvia.

LITHUANIA

Compared to the previous reporting period 2006 - 2009, the overall number of notifications increased by 9 notifications for research purposes.

MALTA

There was an increase from the last reporting period since we received one application to register Class 1 laboratory premises and notification of six Class 1 experiments.

NETHERLANDS

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POLAND

The majority of these activities have taken place in universities or research institutions for fundamental research. The number of installations and contained use activities increased, in comparison with the previous reporting period.

PORTUGAL

The number of notifications received during the present report period, increased to more than the double of the number of notifications comparing with the previous report period, regarding the same classes (classes 1 and 2) and in the great majority of notifications for research purposes (only one notification for commercial purposes).

ROMANIA

Not applicable.

SLOVAKIA

Compared to the previous reporting period (2006-2009), the overall number of notifications on the contained use of GMOs has slightly increased. The similar trend is seen also when compared number of notifications on the contained use of GMOs classified in the risk class 1 and 2. During this reporting period, we haven´t received notifications on the higher risk classes 3 and 4. The number of notifications for the research and commercial purposes in comparison to the previous reporting period has slightly increased, as well.

SLOVENIA

The overall number of the notifications has slightly increased. However, number of installations for GMOs in the biosafety class 2 has increased significantly. Some of the installations were newly build and registered, but mainly the installations that were already registered in the biosafety class 1 are upgraded to the biosafety class 2. Consequently there were also more notifications of the activities in the biosafety class 2. Slight increase of the activities with GMMs in the biosafety class 2 for commercial purposes was also recorded.

At the moment there are no installations and activities with GMOs/GMMs in containment classified in biosafety class 3 or 4.

SPAIN

Compared to the previous reporting period the number of notifications of installations has increased significantly (from 50 for the last reporting period to 139 for this reporting period), but taking into account that the current reporting period is broader (5 years).
Especially, notifications of installations for class 2 activities are being increased.

SWEDEN

We have seen a small decline in the number of activities for contained use in the private sector. One reason is that a big company with many GM-activities has closed down most of its research in Sweden.

Each year some activities are closed down and some are new, while some moves to new locations. The number of new or moved activities decreased 2009 and there was a net increase between new and closed down GMM activities of only +1 GMM-activity. In 2010 there was a net increase of +13. For 2011 the increase was +6 with a more normal inflow of new activities. For 2012 the numbers were more normal with a net increase of +35. The trend is kept for 2013 with a net increase of +32 and, so far, 2014 has a net increase of +18.

UNITED KINGDOM

a) Comparison of the overall notifications between the reporting periods of 2006-2009 and 2009-2014 indicates that the average number of notification per annum is not significantly different (i.e. 170 notifications per annum compared to 177 notification per annum). Similarly, there is no significant difference across the notifications at the different risk classes.

b) Within the reporting period, there was a dip in the number of notifications received in 2010/11 (140 notifications), which then increased each year to a peak in 2013/14 (207 notifications). However, when taken as an average over the 5 year period, the average number of notifications is very similar to the previous reporting period.

1.4 Number of installations approved to date:

AUSTRIA

Research Commercial Other (please specify)

Research	Commercial	Other (please specify)
-	-	-

See Note ad 1.2 and 1.4.

BELGIUM

Research	Commercial	Other (please specify)
34	261	Hospitals: 138 Education-Teaching: 19 Public institutions: 40

BULGARIA

Research	Commercial	Other (please specify)
4	None	None

CROATIA

Research	Commercial	Other (please specify)
12	4	1

CYPRUS

Research	Commercial	Other (please specify)
1		

CZECH REPUBLIC

Research	Commercial	Other: detection laboratories, transport companies
82	7	8

DENMARK

Research	Commercial	Large scale
1272	211	29

ESTONIA

Research	Commercial	Other (please specify)
4		

FINLAND

Research	Commercial	Other (please specify)
information not available	information not available	information not available

679 in total

FRANCE

Research	Commercial	Other (please specify)

Use is associates to the project in an installation but not for research structure

GERMANY

Research	Commercial	Other (please specify)

No information available (database cannot be evaluated concerning the above criteria)

BSL1 installations: 4 594
BSL2 installations: 1 506
BSL3 installations: 107
BSL4 installations: 4 (2x in operation, 2x construction approval)

HUNGARY

Research	Commercial	Other (please specify)
14	7	

IRELAND

Research	Commercial	Other (please specify)
17	35	3

ITALY

Class	Commercial	Research	Other (Education)	Total
1	16	248	16	280
2	10	198	4	212
3	1	29		30
Total	27	475	20	522

LATVIA

Research	Commercial	Other (please specify)
1		

LITHUANIA

Research	Commercial	Other (please specify)
-	-	-

MALTA

Research	Commercial	Other (please specify)
1	0	0

NETHERLANDS

See remark under 1.2

Research	Commercial	Other (please specify)

POLAND

Research	Commercial	Other (please specify)
63	15	0

PORTUGAL

Research	Commercial	Other (please specify)
2	1	-

ROMANIA

Research	Commercial	Other (please specify)
0	0	0

SLOVAKIA

Research	Commercial	Other (please specify)
74	6	0

SLOVENIA

Research	Commercial	Other (please specify)
56	8	1 education

SPAIN

139

Research	Commercial	Other (please specify)
124	15	

SWEDEN

An "installation" is always included in an "F-, L- or R-activity". The "installation" may be identical for more than one "activity". An "installation" may be a laboratory, an animal department, a large scale facility or any other similar physical place with equipment suitable for the GMM-activity. In a building or at a "site", there may be one or several "installation". Sometimes there may be more than one user (employer) in the same building or site.

In Sweden, GMM-activities are notified from 113 users (employers) that are scattered at 32 cities and 157 sites. Today a total number of 624 GMM-activities are active:

23 users (employers) are universities or other research institutes with a total of 472 GMM-activities in class 1-4.

There are three hospitals and 14 schools with GMM-activities with GMM-activities in class 1.

73 users are commercial biotech companies, waste management companies or private schools with a total number of 115 GMM-activities in class 1 or class 2. But far from all activities are commercialisation; a large part is research.

Research	Commercial	Other (please specify)
23 users in academia, about 500 GMM activities (class 1-4) 3 hospitals (class 1, notified by country councils)	73 users are commercial, about 100 GMM activities (class 1 and 2)	Schools (high school level): 14 GMM-activities (class 1)

UNITED KINGDOM

a) 881 installations (871 in GB and 10 in NI) have been approved to date in the UK.

Research	Commercial	Other (please specify)
509 (507 in GB; 2 in NI)	327 (320 in GB; 7 in NI)	45 (44 in GB; 1 in NI)

Other in this case relates to Government organisations.

1.5 Number of activities approved to date:

AUSTRIA

Class 1	Class 2	Class 3	Class 4	GMO
1584	422	16	0	-

BELGIUM

Class 1	Class 2	Class 3	Class 4	GMO
983	972	120	0	794

BULGARIA

Class 1	Class 2	Class 3	Class 4	GMO
Four	None	None	None	Two for GM plants, both Class A (see answer to question 2.2)

CROATIA

Class 1	Class 2	Class 3	Class 4	GMO
15	2	0	0	0

CYPRUS

Class 1	Class 2	Class 3	Class 4	GMO
1[2]	1[2]			

[2] Please note that only one installation was approved by the Department of Labour Inspection for Class 1 and Class 2 Activities.

CZECH REPUBLIC

Class 1	Class 2	Class 3	Class 4	GMO
65	31	1	0	included

DENMARK

Class 1	Class 2	Class 3	Class 4	GMO
741	161	0	0	71

ESTONIA

Class 1	Class 2	Class 3	Class 4	GMO
Research	Research	Research		

FINLAND

Class 1	Class 2	Class 3	Class 4	GMO
528	312	7	0	876*

*) Notifications on activities + installations 876 in total, of which 197 notifications merely for activities. Please note that the total number includes notifications and applications also on GM-plants and GM-animals and their combinations with GMMs.

FRANCE

Class 1	Class 2	Class 3	Class 4	GMO
Cf 1.1/1.4	Cf 1.1/1.4	Cf 1.1/1.4	Cf 1.1/1.4	Cf 1.1/1.4

GERMANY

Class 1	Class 2	Class 3	Class 4	GMO
6959	6986	358	8	

HUNGARY

Class 1	Class 2	Class 3	Class 4	GMO
5	27			

IRELAND

Class 1	Class 2	Class 3	Class 4	GMO
255	152	5	0	130

ITALY

	Class 1	Class 2	Class 3	Class 4	GMO
Total number of authorisations (since Oct. 2001)	N.A.*	454	21	0	N.A.
Not-expired authorisations up to date	N.A.*	143	8	0	N.A.

(*) Notification is not due for class1 activity

LATVIA

Class 1	Class 2	Class 3	Class 4	GMO
1				

LITHUANIA

Class 1	Class 2	Class 3	Class 4	GMO
11	-	-	-	-

MALTA

Class 1	Class 2	Class 3	Class 4	GMO
6	0	0	0	0

NETHERLANDS

See remark under 1.1

Class 1	Class 2	Class 3	Class 4	GMO

POLAND

Class 1	Class 2	Class 3	Class 4	GMO
250	34	2	0	325

PORTUGAL

Class 1	Class 2	Class 3	Class 4	GMO
2	5	-	-	1 (field trials with maize)*

* - Notification submitted accordance with Directive 2001/18/EC

ROMANIA

Class 1	Class 2	Class 3	Class 4	GMO
0	0	0	0	0

SLOVAKIA

Class 1	Class 2	Class 3	Class 4	GMO
7052	5626	0	0	Total number 197 GMM, GM animals, GM plants **(See Annex 1)**

Number of activities was quantified according to the organisms, genes and vectors that were used.

Total number of submitted notifications to date:

Class 1	Class 2	Class 3	Class 4	GMO
90	18	0	0	Overall 108

SLOVENIA

Class 1	Class 2	Class 3	Class 4	GMO
56	27	0	0	

SPAIN

234 (The number of activities may not match with the number of notification pointed out above)

Class 1	Class 2	Class 3	Class 4	GMO
93	122	19		

SWEDEN

5 June 2014 (only still active; closed down are not included)

Class 1	Class 2	Class 3	Class 4	GMO
396	208	18	2	

UNITED KINGDOM

a) In the UK, class 1 activities are not notified as a separate activity. Information on class 1 activities is provided as part of a premises (installations) notification but this does not represent the overall number of class 1 activities being undertaken.

Class 2	Class 3	Class 4	GMO
1816 (1795 in GB; 21 in NI)	211 (210 in GB; 1 in NI)	12 (all GB)	3 (all GB)

1.6 Were there any particular difficulties you encountered in the notification process during the reporting period and what in your opinion could be done at EU or national level to alleviate these difficulties?

AUSTRIA

-

BELGIUM

Some problems are met in the interpretation of the terms “subsequent activity”: There is no definition of a subsequent “contained use” in the Directive. Although the regional legislation for Brussels-Capital Region defines a subsequent contained use as "any new contained use, modification or continuation of contained use in an installation which has been the subject of a previous notification or authorisation for a contained use of the same or a higher class of risk", the user does not always know when an activity is considered as a subsequent contained use, especially in case of a modification of the authorised activity. Moreover, it is impossible to distinguish the amendments to earlier notifications (see table point 1.1) with other types of subsequent contained uses (continuation of activity or new activity) as defined in the regional decrees.

In Brussels-Capital Region some problems were encountered in the notification process due to the Brussels legislation which has set up numerous different procedures regarding the class of risk (8 in total).

To solve this difficulty, the Brussels-Capital Region implements first use procedure when the subsequent notification is introduced after expiry of the first use authorisation. That way, the procedure is uniformly applied concerning the reception and the analysis of the notification, the visit on site, the expert advice reception and the authorisation delivery timeframe.

This difficulty is not encountered in Walloon Region because there is no separate procedure for a first and a subsequent contained use.

BULGARIA

Directive 2009/41/EC provides only for the contained use of GM microorganisms but not for GM plants and animals. It will be helpful if the scope of the directive is extended to all GMO and unified requirements for contained use of GM plants and animals are established.

In addition it will be useful if a list of Generally Regarded As Safe (GRAS) laboratory strains and cultivars is adopted at EU level, because they account for most of the work done at universities and research institutions.

CROATIA

-

CYPRUS
There was no difficulty in the notification process.

CZECH REPUBLIC
The current Czech legislation on contained use is stricter than the Directive 2009/41/EC: a new notification is required in every case a new GMO is to be used - even in Class 1 of contained use.

The Ministry of the Environment as the Competent Authority has elaborated an amendment to the Czech Act of GMOs with the aim to ease this administrative burden both for notifiers and for the Authorities. The amended Act will comply with the Directive and will not go beyond the EU requirements. The amendment is now in the legislative process and is expected to come into force next year.

DENMARK
Class 1 notifications make up most of the notifications and there is a lot of administrative work due to this. That is why we are currently working on a change in our procedures in order to make things easier for the companies as well as the authorities

ESTONIA
Was a question about approved installations. There is an enterprise with allowance in certain address. They want to move to another laboratory in the another building. Does they have to make new notification and get new allowance.

FINLAND
Problems are similar to the previous reporting period:

- A major problem has been the definitions of the directive 2009/41/EC for GMMs, as they are outdated in the present research environment with its new molecular biology techniques.
- Classification of viruses and cell cultures has also been problematic in some cases. A special problem has been the classification of pathogens that have been attenuated (= can an attenuated pathogen ever be considered non-pathogenic according to the directive, and if so, on what conditions?).
- Clinical trials with GM-viruses are a borderline case between contained use and deliberate release in cases where it cannot be completely ruled out that the patients' or animals' excretions may contain live viruses.
- Research groups move frequently from one institution to another which means they have to repeatedly send new notifications of their new premises

FRANCE
Implementation of the computing processing for projects.

GERMANY

-

HUNGARY

In most cases notifier's practice is lacking in the compilation of the notification dossiers, there are lots of consultations necessary between the notifiers and the Competent Authority regarding the required documentation prior to submission or after the notification in the form of asking for further information

IRELAND

The deregulation of Class 1 GMMs.

Class 1 GMM contained use activities are deemed to present negligible or no risk (article 4, Directive 2009/41/EC on the contained use of GMMs). Class 1 GMMs are usually crippled strains with a long history of safe use. Annex II Parts B and C of Directive 2009/41/EC provide for the exclusion of GMMs from the scope of the Directive. However, the requirements under Part B are very onerous given the 'not harmful' status of Class 1 GMMs.

Under Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, it is not required that Hazard Group 1 Biological Agents (defined as unlikely to cause human disease) be notified to the Competent Authority rather it is simply required that the principles of Good Occupational Safety and Hygiene be observed.

Class 1 GMMs should be similarly dealt with.

ITALY

None.

LATVIA

Latvia has a low activity in this field and therefore we do not have any difficulties at this moment.

LITHUANIA

There were no particular difficulties during the reporting period.

MALTA

No.

NETHERLANDS
No.

POLAND
-

PORTUGAL
No particular difficulties were found.

ROMANIA
Not applicable.

SLOVAKIA
During this period we didn’t experience any difficulties in the notification process.

SLOVENIA
The notification process in Slovenia is well established; however slight delays are caused in the notifications in which the external experts (Scientific Committee) or another CA (Veterinary authority) are involved.

SPAIN
Difficulties relating to:

- Interpretation whether the GMO obtained by new genetic techniques is under the scope of the Directive 2009/41/EC or not.

SWEDEN
We have not encountered any specific problems with the notification process. The Provisions were changed 2011 and the notification process was enhanced by much more detailed instructions of what information the Competent Authority needs. The notification forms were also updated and tested by some users before launched to public access. See point 2.3.

UNITED KINGDOM
a) The notification requirements under the GMO(CU) Regulations (the regulations which implement Directive 2009/41/EC) are well-understood by users and there is believed to be a high level of compliance with these requirements in the UK. The only area that has presented difficulties for users is in deciding when it is appropriate to notify the competent authorities when the contained use changes significantly.

b) This has been addressed by working with users (Institute for Safety in Technology and Research) to provide guidance on deciding when changes to the contained use require notification. The guidance is available on-line:

(http://www.istr.org.uk/docs/ISTR%20BSG%20Significant%20Change%20guidance%20v1.pdf).

c) Subject to comments in sections 4.1 and 4.2, the notification of contained use of GMM in the UK is working well.

2 Notification and approval systems (and relevant changes)

2.1 Who is the Competent Authority (CA) for Directive 2009/41/EC on the contained use of GMMs in your Member State? (Please expand where other authorities or ministries are involved or where authorities are established at national/regional level)

AUSTRIA

The Ministry of Science, Research and Economy is CA for contained uses in Universities and scientific institutions in its purview; the Ministry of Health is CA for all other contained uses.

BELGIUM

The regulatory framework concerning the contained use of GMMs is implemented and enforced in Belgium at the regional level. Three different regional decrees exist that have first fully implemented the Directive 90/219/EEC (extending the scope to GMOs and pathogens) and then transposed new provisions of Directive 98/81/EC. Directive 2009/41/EC is a recast of the European legislation on contained use and does not suppose the transposition of new provisions in the Belgian regional decrees.

A Cooperation agreement concerning biosafety[2] was set up to ensure that the transposition and practical implementation of the Directive 90/219/EEC are done in a harmonised way between the three Regions at the administrative and scientific level. This agreement is still in application for the recast Directive 2009/41/EC.
The competent authorities in charge of the regional decree on contained use of GMMs (and pathogens) application are:

- For the Brussels-Capital Region: Institut Bruxellois pour la Gestion de l'Environnement (IBGE) / Brussels Instituut voor Milieubeheer (BIM), Authorisation Service
- For the Walloon Region: Service Public de Wallonie, Direction Générale Opérationnelle 3"Agriculture, Ressources naturelles et de l'Environnement (DGARNE), Department of Permits and Authorisations – External directions.
- For the Flemish Region: Vlaamse Minister van Leefmilieu, Departement Leefmilieu, Natuur en Energie (LNE), Environmental permit service.

At the federal level, the competent authority in charge of emergency planning for the contained use of GMMs is the Federal Public Service Home Affairs.

BULGARIA

Ministry of Environment and Water is the Competent Authority for Directive 2009/41/EC on the contained use of GMMs and on contained use of other GMOs. Control activities are performed by the regional inspectorates of the ministry and laboratory analysis by Environmental Executive Agency.

CROATIA

[2] http://www.biosafety.be/COOPAG/COOPAGEN.html

Competent Authorities for the purposes and official control in this Directive 2009/41/EC on the contained use of GMMs are:

a) Ministry of science, education and sport. It is responsible for administrative procedure of contained uses.
b) Ministry of Health as coordinative body in field of GMOs in Croatia, at same time, it is responsible for conducting official control on the contained use of GMM. Ministry of Health ensures that users of contained use of GMM comply with this Directive.

Croatian Committee for contained use of GMO helps to competent authorities in procedure of assessing class of risk on activity in which microorganisms are genetically modified or, in which such as GMMs cultured, stored. Croatian Committee for contained use is independent scientific body made of 11 scientists' different knowledge and experience of GMO and GMMs. Croatian committee is giving opinion on application on contained use of GMM and reviewing risk assessment.

CYPRUS

The Competent Authority for Directive 2009/41/EC on the contained use of GMMs in Cyprus is the Minister of Labour, Welfare and Social Insurance through the Department of Labour Inspection.

CZECH REPUBLIC

The Ministry of the Environment is the CA for contained use of all GMOs in the Czech Republic. The Ministry of the Environment cooperates closely with the Ministry of Health and Ministry of Agriculture regarding the health and agricultural aspects of the use of GMOs.

DENMARK

The WEA is CA for the contained use of GMM's. For notifications with plants and animals the EPA is involved too. This also applies for productions.

ESTONIA

Competent authority is The Labour Inspectorate of Estonia. Labour Inspectorate has to ask opinion from Committee of Gene Technology of Estonia. This Committee makes their sessions 4 times in the year. This Committee works under Ministry of the Environment of Estonia.

FINLAND

For notifications and approval the CA is the Board for Gene Technology. The supervisory authority responsible for the inspections is the National Supervisory Authority for Welfare and Health, Finland (Valvira).

FRANCE

Ministère de l'Education Nationale, de l'Enseignement Supérieur et de la Recherche. Direction Générale de la Recherche et de l'Innovation.

GERMANY

The CAs for Directive 2009/41/EG in Germany are the Federal state (Bundesländer) authorities.

HUNGARY

In Hungary, there are two Competent Authorities established at national level, depending on the main goal of the application: one is the Ministry of Agriculture in case of agricultural/commercial notifications, the second is the National Institute for Quality and Organizational Development in HealthCare and Medicine in case of clinical trial notifications. As part of the authorisation procedure, the Genetic Engineering Advisory Board is consulted. The Board is a scientific advisory body composed of 19 representatives delegated by the Hungarian Academy of Sciences, the relevant government ministries and civil society organisations in the field of environmental protection, health, biotechnology and consumer protection.

IRELAND

The Environmental Protection Agency has responsibility for the implementation of the legislation. The Department of the Environment, Community and Local Government (DECLG) has responsibility for policy.

ITALY

According to the Italian Legislative Decree 206/2001, CA is the Ministry of Health, which authorises GMM installations and activities "in accordance with the conclusions of the Inter-ministerial Commission for the GMM Evaluations (further on CIV)".

LATVIA

During the reporting period 6 June 2009 and 5 June 2014 the Competent Authority (CA) for Directive 2009/41/EC on the contained use of GMMs in Latvia was the Food and Veterinary Service of Republic of Latvia. In order to achieve the scientific integrity and independence, the Scientific Expert Committee was established. The role of the Scientific Expert Committee is to provide the CA with the scientific advice.

Further CA for Directive 2009/41/EC on the contained use of GMMs in Latvia will be State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR".

The State Labour Inspectorate, in conformity with the regulatory enactments regarding labour protection when coming into contact with biological substances, shall ensure the supervision and control of such safety and labour protection measures which are related to the contained use of genetically modified micro-organisms.

LITHUANIA

There were no relevant changes since the last report in 2009. According to the Law on Genetically Modified Organisms the Ministry of Environment is a Competent Authority for Directive 2009/41/EC on the contained use of GMMs. The GMO Experts Committee was established by the Order on Genetically Modified Organisms Experts Committee and consists of 9 scientists with different scientific background. They analyze the report of risk assessment prepared by the notifier and makes scientific proposals and conclusions to the Competent Authority. The GMO Steering Committee was established by the Order on Genetically Modified Organisms Steering Committee and is a political advisory body for the development and enforcement of national regulatory system with respect to biosafety issues including contained use of GMMs and GMOs. This Committee consists of 21 members appointed by relevant state authorities (e.g. The Ministry of Health, The Ministry of Agriculture, State Food and Veterinary Service), the subordinated organizations, national biotech industry, non-governmental organizations and scientific institutions. The State Environment Protection Service is responsible for inspection of contained use of GMMs and GMOs.

Notification and approval systems are determined in the Order on Regulation on Contained Use of Genetically Modified Micro-organisms and the Order on Criteria for Genetically Modified Micro-organisms Classification in conformity to Directive 2009/41/EC.

MALTA

The Malta Environment and Planning Authority

NETHERLANDS

-

POLAND

The regulatory framework concerning the contained use of GMMs is implemented and enforced in Poland at the national level. The Ministry of the Environment is the competent authority in Poland. After receipt and verification of the notification, the Ministry forwards the notification to the National Commission on GMOs (advisory body) for assessment by reviewers. The consent for contained use of GMOs shall be issued within three months of receipt of the notification.

PORTUGAL

The Competent Authority for Directive 2009/41/EC is the Portuguese Environment Agency, just as it was for Directive 98/81/EC. We belong to the Ministry of Environment, Spatial Planning and Energy.

In the present national legislation - Decree Law n.2/2001, the final approval of a notification is granted by the Portuguese Environment Agency, after receiving a favourable opinion approval from the Directorate General of Health.

ROMANIA

The Romanian legislation provides for a procedure at the national level for notification and authorization in accordance with the provisions of this Directive, established through the Emergency Government Ordinance No 44/2007 on the contained use of genetically modified microorganisms (GMMs) as amended by Law No 3/2008.

Under these legal acts, the institutional framework for the implementation of the GMMs contained use legislation is ensured by the National Environmental Protection Agency, as competent authority, and the following authorities with responsibilities in the field of GMMs:
- The central public authority for education and research, which assesses and analyses the notification dossier of contained use activities in research and development domain and issues a notice;
- The central public health authority, which assess and analyses the notification dossier of GMMs that may have adverse effects on human health, issues a notice, develops and implements plans for inspection and control;
- The central public authority for labour, family, social protection and elderly, which assess and analyses all the notification dossiers with GMMs activities, issues a notice, develops and implements plans for inspection and control;
- The central public authority for agriculture, which evaluates and analyses notification dossiers of contained use activities in the agriculture, forestry, live-stock domain and issues a notice;
- The Biosafety Commission - interdisciplinary scientific body, with an advisory role in the decisions making process by NEPA, independent in carrying out its scientific activity, which issues a scientific notice;
- The National Sanitary Veterinary and Food Safety Authority, which ensures the inspection and control of the facilities where contained use activities with GMMs are developed;
- National Environmental Guard, as the control body, subordinated to the central public authority for the environmental protection, ensures the inspection and the control of the contained use GMMs activities

National Environmental Protection Agency, as the competent authority, after the acceptance of the notification and subsequent to the achievement of the public information and public consultation procedure, based on the notices issued by the responsible authorities and by the Biosafety Commission, issues the authorization on the GMMs contained use activities.

SLOVAKIA

For the contained use of GMOs in our Member State, there are involved only two national authorities. The Ministry of the Environment of the Slovak Republic as the competent authority (policy making, policy implementation, national and international coordination) and the Slovak Environmental Inspection as the inspection organ (enforcement and control).

SLOVENIA

Ministry of the Environment and Spatial Planning of Slovenia (MESP), Dunajska 47, 1000 Ljubljana Slovenia, is a competent authority to decide upon registration of the premises for contained use of GMOs and upon approvals for the work with GMOs in containment.

Registration of the installations for GM animals requires a consensus of the Veterinary authority which operates under the Ministry of agriculture and forestry.

SPAIN

In Spain, Directive 2009/41/EC has been transposed in the domestic legislation through the Law 9/2003 and Royal Degree 178/2004 and the subsequent modifications. For the implementation in our country of this legislation there are two different CAs:

1) At national level, the Inter-ministerial Council for GMOs (CIOMG) and the National Commission on Biosafety (CNB) at the Ministry of Agriculture, Food and Environment (Madrid, Spain). They are CAs for the activities of contained use carried out by Government Public Research Institutes or for activities with GMOs focused on medical purposes (clinical trials, human and animal medicines/vaccines, etc.). The first one (CIOMG) is the CA for grating permits at national level and the CNB is the scientific body dealing with the risk assessment of activities and installations, which report to the CIOMG and also to the CAs of the Spanish regions.

2) At regional level, the Autonomous Communities (Spanish regions) are the CAs for granting permits for most of the activities carried out with GMOs (except in the cases mentioned above).

SWEDEN

Swedish Work Environment Authority is the CA for contained use of GMM. Other authorities are responsible for contained use of plants and animals which are not regulated by the Directive 2009/41/EC. Se point 2.2.

UNITED KINGDOM

a) In England and Wales, the Health and Safety Executive (HSE) and the Secretary of State for the Department for Environment, Food and Rural Affairs (DEFRA) form the Competent Authority. The functions are delegated to HSE and DEFRA officials.

b) In Scotland, the Competent Authority comprises Scottish Ministers and HSE and similarly these functions are delegated to HSE and Scottish Government officials.

c) In Northern Ireland, the Competent Authority is the Health and Safety Executive for Northern Ireland (HSENI) and the Department of the Environment[3], acting jointly. HSENI officials are provided with technical support from HSE, under an Agency Agreement.

[3] The Department of Environment has been replaced by the Department of Agriculture, Environment and Rural Affairs which was established on 9 May 2016

2.2 Has the scope of the transposing legislation been extended to the contained use of GM plants and GM animals in your Member State?

AUSTRIA

Yes

GMOs	No. of notifications
GM animals	797
GM plants	15
Amendments to earlier notifications	-
Total	**812**

Note ad 2.2

Austrian legislation requires notification of all (i.e. first and subsequent class 1) uses of GM vertebrate animals. Since Jan. 1, 2013 (transposition date of Directive 2010/63/EC) all uses including breeding of GM animal species protected under that Directive require specific authorizations.

BELGIUM

Yes

GMOs	No. of notifications
GM animals	170
GM plants	51
Amendments to earlier notifications[4]	183
Total	**221**

BULGARIA

Yes, Bulgarian legislation classifies GM plants and animals either as class A – no or negligible risk for the human or animal health and for the environment and class B – all other cases.

GMOs	No. of notifications
GM animals	0
GM plants	2, both Class A
Amendments to earlier notifications	2
Total	**2**

CROATIA

Yes

GMOs	No. of notifications
GM animals	2
GM plants	2

[4] Subsequent use notifications: since 2002, the Walloon decree of 04/07/2002 regarding the contained use of GMOs and/or pathogens doesn't distinguish anymore between first and subsequent contained uses. In consequence, all notifications for this region are treated as new activities (or first contained uses).

Amendments to earlier notifications	
Total	**4**

CYPRUS

No

There was no need because there were no activities and/or installations involving GMOs.

GMOs	**No. of notifications**
GM animals	0
GM plants	0
Amendments to earlier notifications	0
Total	**0**

CZECH REPUBLIC

Yes

GMOs	**No. of notifications**
GM animals	4
GM plants	3
Amendments to earlier notifications	38 (mostly lab. mice)
Total	**45**

DENMARK

Yes

GMOs	**No. of notifications**
GM animals	26
GM plants	4
Amendments to earlier notifications	
Total	**30**

ESTONIA

Yes: For GM animals No: For GM plant

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	Labour Inspectorate doesn't gather these data.

FINLAND

Yes

GMOs	No. of notifications
GM animals	17
GM plants	14
Amendments to earlier notifications	what does this question specifically mean?
Total	**31**

FRANCE

Yes

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	

GERMANY

Yes

GMOs	No. of notifications
GM animals	54
GM plants	30
Amendments to earlier notifications	
Total	**84**

HUNGARY

Yes

GMOs	No. of notifications
GM animals	**2**
GM plants	**none**
Amendments to earlier notifications	
Total	**2**

IRELAND

Yes

GMOs	No. of notifications
GM animals	**61**
GM plants	**6**
Amendments to earlier notifications	
Total	**67**

ITALY

Yes

According to 2001/18/EC directive, the contained use of GMOs (e.g. for testing/research purposes) should be carried out by implementing containment measures based on the same principles as laid down in 90/219/EEC: it is not expected any notification to CAs. Contained uses of GMOs are non-regulated activities, both to at EC and national levels.

GMOs	No. of notifications
GM animals	N.A.
GM plants	N.A.
Amendments to earlier notifications	N.A.
Total	N.A.

LATVIA

Yes

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	

LITHUANIA

Yes

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	

MALTA

Yes

GMOs	No. of notifications
GM animals	0
GM plants	0
Amendments to earlier notifications	0
Total	**0**

NETHERLANDS

Yes

See remark under 1.1

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	

POLAND

-

GMOs	No. of notifications
GM animals	
GM plants	
Amendments to earlier notifications	
Total	

PORTUGAL

Yes

GMOs	No. of notifications
GM animals	-
GM plants	-
Amendments to earlier notifications	-
Total	-

ROMANIA

No

Not for the time being. Romania limited the scope of the transposition legal act to the scope of the Directive on the contained use of GMMs.

GMOs	No. of notifications
GM animals	0
GM plants	0
Amendments to earlier notifications	0
Total	**0**

SLOVAKIA

Yes

GMOs	No. of notifications
GM animals	3
GM plants	4
Amendments to earlier notifications	0
Total	**7**

SLOVENIA

Yes.

The biosafety framework in Slovenia is covered by horizontal legislation based on Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010). The Act implements the provisions of the Directive 2009/41/EC and beside GMMs regulates also GM plants and animals.

GMOs	No. of notifications

GM animals	3
GM plants	
Amendments to earlier notifications	
Total	**3**

SPAIN

Yes.

GMOs	**No. of notifications**
GM animals	35
GM plants	28
Amendments to earlier notifications	
Total	**63**

SWEDEN

Yes.

GMOs	**No. of notifications**
GM animals Swedish Board of Agriculture: all other GM animals except water living organisms Swedish Agency for Marine and Water Management: GM water living organisms	Swedish Board of Agriculture: 59 permits (for premises) during the period June 2009-June 2014 of which 43 were valid in June 2014. Swedish Agency for Marine and Water Management: 5 permits (for premises) and 3 notifications (for GMO) during the period June 2009-June 2014
GM plants Swedish Board of Agriculture	Swedish Board of Agriculture: About 30 premises have a permit for contained use of GM plants. The permits are valid for five years and the number of premises has been steady for the last ten years. New activities and plant species are to be notified to the CA. An estimate of notified operations with plants since 2009 is about 10 per year.
Amendments to earlier notifications	
Total	**78 permits and 3 notifications**

UNITED KINGDOM

a) Yes. The legislation has been extended to require notification, risk assessment and application of control measures for contained use of GM plants or GM animals (referred to as larger GMOs in the UK legislation) that present a risk to human health greater than the unmodified parental organism. Such work is rare, and there has only been one such contained use notified in the reporting period.

GMOs	No. of notifications
GM animals	0
GM plants	1
Amendments to earlier notifications	0
Total	**1**

b) There is also complementary domestic legislation (Environmental Protection Act 1990, associated regulations and the Genetically Modified Organisms (Northern Ireland) Order 1991) that requires risk assessment and application of containment for the contained use of larger GMOs to ensure protection of the environment. HSE inspects premises working with larger GMOs on behalf of DEFRA, Scottish and Welsh Governments under separate Agency Agreements.

2.3 What % of notifications was not processed within the statutory timeframe?

AUSTRIA
0

BELGIUM
In Belgium, the procedure for the notification of contained use of GMOs and/or pathogens is a part of the general procedure for application of an environmental permit. Furthermore, the Brussels-Capital Region and the Flemish Region define two timeframes, one for the technical expert (the SBB) to write an advice, and one for the competent authority to deliver the authorisation.

The timeframe for the Brussels and Flemish competent authorities to deliver the authorisation is linked to the timeframe for delivering the environmental permit, which is longer than the contained use authorisation timeframe. The competent authorities can only respect the timeframe to deliver the authorisation if the user has already obtained an environmental permit.

An authorisation can only be delivered when the environmental permit has been obtained. For a small percentage of the dossiers, the delivery of the advice by the SBB to the competent authority was postponed, often due to a 'stop the clock' (awaiting further information from the user, visit of the facility…).

In the Walloon region, the user submits a biosafety dossier to the technical expert (the SBB) before any application for an environmental permit. Hence the timeframe starts only when the user submits his application for an environmental permit to the competent authority, to which the advice of the technical expert is joined. During this 5-year reporting period, all applications for contained use of GMOs and/or pathogens were processed within the statutory timeframe of the environmental permit.

BULGARIA
All notifications were processed within the statutory timeframe.

CROATIA
None.

CYPRUS
0

CZECH REPUBLIC
None. For notifications of Classes 1 and 2 contained use there are no authorisation procedures with set time limits for the CA.

DENMARK
0 %

ESTONIA
0 %

FINLAND
0

FRANCE
About 10%

GERMANY
No information available.

HUNGARY
In case of 3 notifications, approximately in 10% of all cases.

IRELAND
0 %

ITALY
It’s hard to estimate such a percentage for the whole reporting period. In fact, a time-monitoring system has been implemented only in April 2013; since then, we have calculated an average percentage of about 15%. However, in the first half of 2014, the figure has been significantly lower (less than 5%).

LATVIA
0

LITHUANIA
-

MALTA

N/A

NETHERLANDS
38%

POLAND
For 10% of the notification was postponed, often due to a “stop the clock” procedure (awaiting further information from the notifier, etc.).

PORTUGAL
0

ROMANIA
-

SLOVAKIA
-

SLOVENIA
30% of the notifications were not processed in the given timeframe. However, most of the delays were short and in all cases notifiers were approached with the ample explanation. We did not receive any complaint about it.

SPAIN
Generally statutory timeframe is fulfilled, although in the most of the cases the clock is stopped when additional information is required.

SWEDEN
We have not recorded this but it is not a significantly large percentage.

UNITED KINGDOM
3.7%.

2.4 What gave rise to such delays in the notification process and what efforts are being made to lessen or prevent such delays in the future?

AUSTRIA

-

BELGIUM

The reason for delay in delivering the advice, if any, was often the lack of pertinent information needed to perform a correct analysis of the contained use activity, requiring further information from the user. Hence the timeframe is generally longer that the legal one because of a “stop the clock” while the competent authority is waiting for some information.
To extend the timeframe, the Brussels competent authority implements most of the time a first use procedure when the subsequent notification is introduced after expiry of the first use authorisation.

BULGARIA

Not applicable, see answer to question 2.3.

CROATIA

Not applicable.

CYPRUS

Not applicable.

CZECH REPUBLIC

see 2.3
However, the CA often asks the notifiers for clarification of some data in the submitted notifications and/or for additional information. To prevent these delays, the Czech CA provides guidelines and there is a possibility of consultations with the notifiers in advance.

DENMARK

Not applicable.

ESTONIA

No answer.

FINLAND

Not applicable.

FRANCE
No modification in the future.

GERMANY
-

HUNGARY
The following efforts have been made to prevent the delays: consultation between notifiers and the Competent Authority prior to submission or asking for further information after the submission.
Furthermore, there have been some changes in the internal structure of the Ministry of Agriculture. This was the reason that in one case, the notification has been released after the authority's deadline. Since this case, there has not been any delay in the authority's work.

IRELAND
Not applicable.

ITALY
Dead time between CIV's meetings. Meeting frequency has been increased (now every three weeks); however, in urgent cases, CIV may be convened at any time. Moreover, we are studying an ICT solution which should allow to speed up the authorization process.

LATVIA
Latvia has a low activity in this field.

LITHUANIA
-

MALTA
N/A

NETHERLANDS
In the Netherlands all activities with GMO's and GMM's need a license, resulting in lots of work for the competent authority. In combination with related work, like development of new licensing software, discussions about new legislation and a shortage of personnel it was not possible to process al the licenses within the applicable timeframe of 45 days. The mentioned new legislation will, among others, change the license for class I and mostly class II into a

notification scheme, thus lessening the effort needed. It is planned to put this new legislation into force before the end of 2014.

POLAND

The duration of the procedure depends on the Commission on GMOs and the reviewers, whose opinion is necessary to grant consents for contained use of GMOs in Poland.

PORTUGAL

-

ROMANIA

-

SLOVAKIA

-

SLOVENIA

Most of the delays are short and are mainly caused due to a very short period (30 days only) for The Scientific Committee to evaluate and give an opinion on the risk assessment of the notifications. Slightly longer delays are caused by the Veterinary authority which operates under the Ministry of agriculture and forestry. MESP put a lot of effort to explain the situation to the Veterinary authority in order to acquire their consent sooner.

SPAIN

There are delays in the statutory timeframe by several reasons:

1) The administrative process is quite long taking into account the previous assessment by the National Commission on Biosafety, visits and control at the facilities and the different procedures, opinions or permits granted by the CIOMG and the different CAs (CIOMG or regions).
2) Request for additional information to the notifiers.
3) Timeframes between meetings of the National Commission on Biosafety (usually it held one a month)
4) Previous inspections to the facilities before granting permits.

SWEDEN

In the beginning of the time period the notification procedure was somewhat more time consuming. We got more incomplete notifications than now. With our new provisions which came into force from New Year 2012, the notification procedure has been simplified. We have developed new forms for notification of class 1 and class 2 which can be downloaded

and sent electronically to us. The notifications have become significantly better with the new forms, which simplifies our work.

UNITED KINGDOM

a) Requirement for further information from the user in order to assess the adequacy of the risk assessment (this involved 3 rounds of exchange of information); 2) Timescales for assessment of notifications were not met; and 3) Delay in issuing of the clearance letters to be sent to the notifiers. The performance of the notification process is monitored and improvements in procedures identified and remedied. The performance (which was of a high standard) has improved with all deadlines being met.

3. Inspection and enforcement issues

3.1 Outline the procedure undertaken for the inspection of contained use installations/activities during the reporting period providing details of the number and the overall percentage of installations/activities inspected. Please mention the number of specialised inspectors available for inspections under Directive 2009/41/EC.

AUSTRIA

Inspections were based on the characteristics of the activity, e.g. risk class, large scale equipment, inoculation of animals, etc.. In the reporting period 147 inspections were undertaken in 61 installations, i.e. about 18 % of installations. The total number of inspectors available is 10.

BELGIUM

Procedure

Inspections were organised in the three regions by different inspectorates on a regular basis and concerned contained uses with GMOs as well as pathogens. In the Flemish Region inspections were done by 2 inspection bodies, the Flemish Agency for Care and Health of the Flemish Community and the Environmental Inspection Department of the Flemish Competent Authority, respectively concerning Public Health and Environment.

Failures or non-respect by the user of the applicable conditions delivered in the environmental permit may give rise to a criminal penalty or an administrative fine. In case that the offense is likely to cause a substantial and immediate harm to public health and the environment, the license may be suspended or revoked by the competent authority.

Number and the overall percentage of inspected installations

During the period from 6 June 2009 until 5 June 2014, the Flemish Environmental Inspectorate Division carried out 161 inspections controlling contained use at 131 different installations.

From these 131 installations, 67 were required to have an authorisation and 64 were not. This means that less than 30% of the installations having an authorisation were controlled. Over the last 5 years an average of 0,42 full time equivalents a year was spent on Directive 2009/41/EC inspections including preparation of the inspection, the inspection itself and the administrative consequences of the inspection (writing exhortations and official reports of infringement).

In the Brussels-Capital Region, 25% of the installations were controlled. For the Walloon Region, we do not have detailed information but it is estimated that 3% of the installations were controlled.

In summary, 177 inspections were carried out by the Environmental Inspection Departments in the three regions (161 inspections in the Flemish Region, 14 inspections in the Brussels-Capital Region and 2 inspections in the Walloon Region).

Number of inspectors

In the Flemish Region, the Environmental Inspectorate has 6 specialised inspectors involved in controlling contained use activities. In the Brussels-Capital Region, 5 inspectors received training in biosafety and are performing controls on the contained use activities. In the Walloon region, no specialized inspectors are appointed for biosafety. These inspectors are not spending their full time on controlling contained use of GMO's and pathogens. As inspectors fulfil several tasks covering multiple matters concerning the environment or public health, only a certain percentage of their time can be dedicated to inspection of contained use activities.

BULGARIA

Inspections are performed by the regional inspectorates of Ministry of Environment and Water. Representatives of Environmental Executive Agency and the Ministry are also present. Facilities to be inspected and the schedule of inspections are approved yearly by the Minister of the Environment and Water based on the list of actual or potential operators that might work with GMOs. Additionally, unscheduled inspections may take place when unauthorised use of GMO is suspected. After receiving notification for initial approval of facilities for contained use of GMO, inspections are performed to verify conformity with the requirements for safe work at given containment class. Approved facilities are inspected at least once every two years. Samples can be taken during the inspection if necessary and analysed for presence of GMOs.

The number of inspections during five year period is as follows: 2011 - 23 inspections; 2012 – 14 inspections; 2013 – 18 inspections; 2014 –14 scheduled inspections, ongoing.

Currently in each of the sixteen regional inspectorates there is at least one person appointed to undertake inspections for contained use and release into the environment of GMOs. In addition, there is an analytical laboratory (two people) in the Environmental Executive Agency that performs the necessary analytical work and whose staff participates in inspections and collection of samples.

CROATIA

Periodically sites visiting. In Croatia there are two specialised inspectors of Ministry of Health available for inspection under Directive 2009/41/EC.

CYPRUS

The Department of Labour Inspection during the reporting period has carried out inspections in the premises of the installation approved for the use of GMMs and in various premises in order to verify whether GMMs are used. About 20 Labour Inspectors were partially involved under the instructions of a specialised Labour Inspection Officer.

CZECH REPUBLIC

The Authority responsible for the state supervision of the use of GMOs is the Czech Environmental Inspectorate (hereinafter "CEI"). It co-operates with other state supervision

bodies in fulfilling this task. CEI undertakes inspections of subjects authorised for contained use of GMOs, in accordance with the yearly schedule based on:
- information from the Ministry of Environment on notifications and authorisations;
- results and findings of the previous inspections;
- information from other sources and ad hoc initiatives;

The inspections are targeted on compliance with requirements for the contained space, documentation, waste treatment, transport of GMOs, equipment of the premises, training of the personnel etc.

Totally 141 inspections were carried out in contained use premises within the reported period. All authorised facilities were checked, some of them repeatedly.

CEI consists of the Headquarters and 10 Regional Inspectorates. At each of them, one inspector has been trained for GMOs supervision, although it represents only part of their agenda, depending on the number of GMO facilities in the region (there are no GMO premises in 3 regions, nevertheless the inspectors have been trained there as well). That means 10 regional inspectors and 1 person at the Headquarters deal part-time with inspections under the Directive. An inspection is always carried out by 2 inspectors (either 2 regional inspectors or 1 regional plus 1 from the Headquarters).

DENMARK

When a location is notified the first time it is always visited to be approved. This also applies when changes are made to an already classified location. There are 5 inspectors in Denmark who spend part of their working hours with inspection.

This procedure is about to change. In the future we are planning to allow class 1 GMO work to start based on the notification. There does not have to be a visit to the locations before they can start. Instead there will be inspections afterwards at selected locations.

ESTONIA

There is one inspector for such inspections, but during reporting period there is no inspections made.

FINLAND

An inspector from the National Supervisory Authority for Welfare and Health, Finland (Valvira) contacts the operator before the inspection and prepares an inspection report after the visit. From 2007 it has also been possible to use a written inspection procedure for the inspection of earlier inspected activities and premises, if certain conditions are met.

The operators which commence the class 2 or 3 use of GMOs for the first time or start use of higher class are inspected within a year after the CA has handled the notification or the application. The inspection interval is risk based, so that class 3 use is inspected more often (at least every second year) than class 1 or 2 use. During the reporting period 135 inspections were performed (33 % of all valid notifications). With the exception of a ten month period when only one inspector was available, two full-time inspectors worked in control of GMO use.

FRANCE

25 visits/controls, 0, 7 %.
2 inspectors.

GERMANY

In Germany, the Federal state authorities are responsible for monitoring installations and work involving genetic engineering and for implementing the resultant enforcement measures.

Inspections are conducted when there is a need for them and also on a routine basis when there is no specific need for them.

Inspections conducted when there is a need for them to take place, for example, in the following cases:

- New installations (mainly before they are put into service),
- Significant alterations to installations,
- Requests or incidents.

The routine inspections are conducted at fixed intervals which are shorter the higher the safety level involved and also, in some cases, the more intensively the installation is used. The intervals may also be adjusted to take into account unusual circumstances and the lessons learned from previous inspections. Routine inspections are conducted at approximately the following intervals:

- S1 installations: every three to six years,
- S2 installations: every two to three years,
- S3 and S4 installations: annually.

During the reporting period almost all installations used for genetic engineering underwent at least one on-site inspection.

The number of inspectors varies depending on the size of the Federal state, their respective responsibilities and the number of installations located in the Federal states which are used for genetic engineering.

See also the extended scope of German legislation on genetic engineering: it covers not only installations where work involving GM micro-organisms is carried out but also installations in which work is carried out involving (exclusively) GM plants or GM animals.

HUNGARY

Laboratories complying with Class 1 and Class 2 containment level specifications also conform to the requirements of the quality assurance systems of Good Laboratory Practices (GLP). The GLP requirements themselves are stricter than what is needed to execute for Class 1 and Class 2 containment measures for GMOs. The audits are conducted once a year and the compliance with GLP is checked every two years. Every contained use has been verified in these schemes. Each contained use has been verified by 4 inspectors (on average).

IRELAND

As per our suggestion in our submission on report 2006 – 2009, we continue to believe that the wording in the Directive could be more explicit requiring the establishment of biological safety committees as well as the appointment of a biological safety officer particularly where large multi user centres are involved.

Each year a draft site inspection plan for GMO/GMM contained use activities is drawn up. During the site inspection we consult with a competent person on site (usually the biological safety officer). We use a checklist originally adopted by the European Enforcement Project (EEP). We do not charge for site inspections. The level of compliance within GMO/GMM contained use facilities is high.

Class 2 GMM, Class 3 GMM, GM Animal / Plant activities are inspected once every 3 years. Class 1 GMM contained use activities are inspected once every 6 years (given their history of safe use and negligible risk). The inspection of Class 1 GMM contained use activities on a less regular basis was deemed necessary give the small team of 2 persons with responsibility for both licensing and enforcement and both contained use and deliberate release.

Enforcement activities carried out during reporting period:

Year	**From 6th June 2009**	**2010**	**2011**	**2012**	**2013**	**Until 5th June 2014**
Number of installations inspected	9	17	16	8	16	4
% of installations inspected	17	33	31	14.5	29	73.

ITALY

According to the Italian Legislative Decree 206/2001, the inspection functions are exercised by officers identified by CIV (art. 17); moreover, if needed, CIV can request the inspection of a GMM installation/activity (art. 18). No inspections have been requested by CIV during the reporting period.

LATVIA

As there is only class 1 the State Labour Inspectorate is not involved.

LITHUANIA

There were no relevant changes with regard to control procedure requirements since the last report in 2009.

In the period 2009 – 2014 about 15 inspections were conducted by one specialised inspector.

MALTA

One inspection of the class one facility was conducted by the permitting officer prior to the permit being issued to check for compliance with the legislation for class 1 installations. There are no specialised inspectors on GMMs; one should note that Malta only had one application to date.

NETHERLANDS

Annually 50-60 contained use facilities have been inspected by ILT, which is about 20-25% per year. The task is carried out by 4 different inspectors, total about 2 FTE. ILT has the aim to contact each user at least every four year. Based on risk and compliance and complexity of work this frequency may increase. Prime concern is that the mandatory Biological Safety Officer (BSO) performs the annual audits. So the inspection for a great part focuses on the administrative obligations. The inspection always includes a random reality check of compliance including among others. The GMOs handled, the way of working and containment integrity. This latter aspect is also inspected by the inspectors of local authorities.

POLAND

Three authorities carry out inspections of contained use installations: The State Labour Inspection is in charge of the safety and hygiene of work; they inspect the labelling of facilities, the safety measures and the equipment used. The State Sanitary Inspection controls biological factors, whereas the Environmental Protection Inspection is in charge of the control of wastes from contained use activities. These three authorities can carry out inspections on their own initiative or upon request by the Ministry of Environment. The State Labour Inspection has conducted 13 inspections.

PORTUGAL

Until the present date, the Inspectorate-General for Agriculture, Fisheries, Environment and Spatial Planning (IGAMAOT) hasn't carried out inspections of contained use installations/activities.

ROMANIA

National Environmental Guard (NEG) is the control and inspection body under the Ministry of Environment and Climate Change. Within the Biodiversity, Biosecurity and Protected Areas of NEG Control Directorate, there are inspectors with responsibility regarding control and inspection activities for the entire domain of activities in the directorate, not strictly specialized in accordance with Directive 2009/41/EC. They also have other inspection and control duties in accordance with Directive 2001/18/EC, as well as on biodiversity and natural protected areas.

SLOVAKIA

The authority responsible for the state supervision of the use of GMOs is the Slovak Inspectorate of Environment (SIE). In total 9 inspectors have been trained on the supervision of GMOs, although inspections under Directive 2009/41/EC represent only a part of their agenda, depending on the number of GMO facilities in the region. SIE cooperates with other state supervision bodies in fulfilling this task. SIE regularly carries out inspections in accordance with a yearly schedule, based on the information provided by the own findings mainly previous inspection reports and scientific publications, information of the Ministry of the Environment and other authorities. Inspections are based by that date known information on the inspected facility involving maps of the facility, information about the used donor and recipient organisms, genes used for the genetic manipulation, plasmids as well as used techniques and risk assessment.

Inspections are targeted on compliance with the requirements for the premises, waste treatment, transport of GMOs, record keeping, training of personnel, etc. The requirements for safe work with GMOs are also inspected although laboratory safety is not the main task of the inspections.

The last day of the inspection there is a final meeting with the responsible persons, where the outcome and findings of the inspection is discussed in detail. It is common SIE practise that the responsible persons are informed about the outcome immediately and according to the Slovak law, a detailed protocol or report is written and sent to the head of the inspected facility. Detailed procedure of the inspection, based on the Slovak law, was issued by the publishing house of the Slovak Academy of Sciences in 2008, ISBN 978-80-224-1048-9.

During the reporting period through 141 inspections all the 467 registered installations were inspected, i.e. all the permitted activities were inspected (100%). In general, each permit holder is visited at least once every 3 years; but larger institutes are visited once or twice a year. Inspection visits were carried out also in the institutions for which permits for contained use of GMO were not issued

SLOVENIA

Installations and activities are inspected according to annual plan of inspections ensuring that each installation is inspected at least every four years, or more often depending on the outcome of the previous inspection. Newly registered installations are inspected as soon as possible. The inspections are undertaken according to the adopted procedure using checklists what ensures uniform proceeding at all installations. In the reporting period 47 inspections were performed.

Slovenia has two specialised environmental inspectors for GMOs. Each inspector has been available for 5% of full working time for inspections of GMMs, GM plants and GM animals under Slovenian MGMO Act what ensures regular and thorough supervision.

SPAIN

There is not an Official Body for inspection under Directive 2009/41/EC in Spain. Generally, the Spanish regions are the competent for the inspection actions.

Nevertheless, after the application of the notification by the users and before giving the consent, specialised member(s) of the National Commission on Biosafety (CNB) accompanied by a representative of the competent region where the installation is placed, regularly carry out visits and controls on the premises. They check the records of activities and the major objective of control is to confirm the effectiveness of the respective containment level and to evaluate compliance with relevant approval conditions.

100% of installations are visited and controlled.

There are 4 members from the Biotechnology Unit at the Ministry of the Agriculture, Food and Environment, as part of the National Commission on Biosafety (CNB), who participate at the visits and controls.

SWEDEN

In most cases we inspected activities as part of the process of accepting notifications for class 2 or give permits for class 3 work. The focus was on activities with the potential greatest risk.

17 installations/activities was inspected. The number of specialised inspectors is two who also have many other duties according to contained use of GMM as well as other, non-GMM related duties.

UNITED KINGDOM

a) In the UK, inspections are undertaken by HSE and HSENI. HSE carries out such inspections across Great Britain and applies the same inspection regime to all contained use work with high-hazard biological agents (including GMMs). Inspection is undertaken by HSE specialist microbiology inspectors. In Northern Ireland HSENI's inspections (mostly class 1 and 2 GMM contained uses) are carried out by a non-specialist inspector, who calls on HSE for specialist support, when required.

b) The inspection programme in Great Britain covers contained uses involving GMMs, larger GMOs, non-genetically-modified human pathogens (under domestic legislation implementing Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work) and non-genetically-modified specified animal pathogens (derived from domestic legislation and implementing Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease).

c) The inspection programme is prioritised according to a hazard and risk system that focuses on activities in CL3 and CL4 laboratories. Contained uses involving GMMs are not targeted *per se* but captured as part of this programme.

d) Higher hazard laboratories receive more frequent inspections. CL4 laboratories are inspected at least once per year, most being visited multiple times per year.

e) CL3 laboratories are inspected based on a prioritisation scheme that considers the inherent hazard of the work, the safety performance of the user and time elapsed since

last inspection. Those laboratories undertaking class 3 contained uses are generally inspected every 2-5 years.

f) Premises only working with class 1 and 2 GMMs are not inspected as part of a proactive inspection programme. However, many of the premises will be visited as part of other inspection or engagement visits. For example, HSE's Regulatory Compliance Officer (RCO) may provide advice on compliance with the legislation either through site visits or presentations at industry led events. Similarly, the lower containment laboratories may be scrutinised as part of a CL3 inspection or a larger GMO inspection at that specific premises. Furthermore, an inspection may be instigated should issues be identified from a contained use or premises notification, where in the view of the inspector further enquiries are merited.

g) Inspections are generally topic-based and cover containment and control, training and competence, audit and inspection and risk assessment. Preparation for an inspection will include a review of the notified GM contained uses at the site. The topic of risk assessment evaluates the correctness of final classification and considers compliance with the GMO (CU) Regulations.

h) As mentioned in para 2.2(b), HSE undertakes a programme of ~15 inspections of laboratories handling larger GMOs (e.g. animals, plants, insects) each year on behalf of DEFRA and the Devolved Administrations. This includes a review of the risk assessments and inspection of the premises used for the contained use work, to check the adequacy of the containment and control measures.

i) HSE has a specific team (Biological Agents Unit – CEMHD8), which implements the inspection regime and reviews the adequacy of notifications of biological agents (including GMMs). Currently the Biological Agents Unit comprises of 7 Specialist Inspectors, 4 Principal Specialist Inspectors and 1 Regulatory Compliance Officer. In Northern Ireland there is one part time inspector. A joint inspection with a Specialist Inspector from HSE of all the notified centres is carried out. Inspections are also carried out by the local inspector to deal with specific topics during this period.

j) Over the period of the report, there have been 645 inspections undertaken by HSE's Biological Agents Unit, of which 342 were at sites where work with GMMs and larger GMOs (e.g. animals, plants, and insects) is undertaken. This represents in the region of ~40% of all the GM premises notified and includes 100% of the CL3 and CL4 notified premises.

3.2 What were the problems most frequently encountered during the course of inspections carried out during the reporting period?

AUSTRIA

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BELGIUM

The most frequent or severe problems encountered were related to:
- Waste management : the inactivation method is non-adequately validated;
- Authorisation : absence or non-compliance for the use of non GM-pathogens;
- Risk signalisation: absence of biohazard signs;
- Storage of contaminated laboratory equipment: lack of measures;
- Accident prevention and emergency response plans;
- Biosafety cabinets: certification of the HEPA filtered closed system;
- Restricted access to the controlled area.

The inspectors of the Brussels-Capital region pay particular attention on the waste management. The principal control matters are: sufficient evacuation frequency, on-site inactivation, availability of disinfectants, and waste disposal by a certified waste collector.

BULGARIA

Most academic institutions were not aware that facilities for contained use of GMO should be approved and registered even when they work only with model organisms routinely used in scientific research (e.g. laboratory strains of *E.coli*, *Arabidopsis thaliana*, etc.).

CROATIA

One technical issue (floor surface).

CYPRUS

No problems have been encountered during the course of inspections.

CZECH REPUBLIC

Apart from one case of unauthorised GMM, most frequent deficiencies found by the Inspection were of an administrative character: missing updates or parts of the documentation etc. These imperfections did not mean any risk to the environment.

DENMARK

When examining the notifications for research projects the risk assessment is often not sufficient. During inspections some times the written material on working procedures does not always correspond to the way things are carried out in practise. Sometimes it also turns out that the company has forgotten to notify the research project and has just notified the

location where the project is going to take place. Companies don't always remember to give the information that a location is no longer being used for work with GMM's.
Examples of things that are not in order when inspecting could be a missing sign on the door or on a freezer, disorder in the laboratory, alterations in the room, that have not been notified, lack of maintenance making the laboratory less cleaning friendly.

ESTONIA

No.

FINLAND

In general, documents were available but could be outdated or inaccurate. Inadequate book-keeping or risk assessment and taking new premises into use without giving notice were the most frequent problems. Also, persons responsible for the notification had sometimes left for another job without informing the authorities.

In some cases, training of the staff was not recorded.

In several cases, the premises were not properly marked or there were minor problems with waste management. In some cases, protective measures in use needed adjustment or rarely used personal protective equipment was missing.

Sometimes it was unclear for operators that it is their responsibility to evaluate whether the waste management practice or equipment maintenance is appropriate considering the GMO use

FRANCE

Treatment of solid and liquid waste

GERMANY

During inspections inspectors look at the structural and technical characteristics of the installation, at organisational aspects and at the documentation relating to the work involving genetic engineering. The following problems have frequently been identified:

- Lack of or insufficient indication of access points,
- Protective clothing (overalls, etc.) not worn or insufficient,
- Lack of regular inspection/servicing of equipment, such as safety workbenches and autoclaves, or shortcomings in record-keeping concerning such inspections/servicing,
- Lack of appropriate transport containers,
- Failure to provide timely instructions, or inadequate instructions for staff or service personnel (cleaners, tradesmen, etc.),
- Cramped or untidy laboratories,
- Inappropriate or dirty surfaces (in the work area),
- No clear separation of areas used for writing, on the one hand, and laboratory work, on the other,

- Insufficient hygiene or disinfection measures.
- Imprecise operating instructions and hygiene plans,
- Imprecise or incomplete records on work involving genetic engineering,
- Insufficient or deficient internal risk assessment,
- Performance of further S2 work without prior notification,
- Lack of or late reporting of changes to responsible staff (project leaders, biosecurity officers) or of alterations to installations of relevance to safety,
- Incomplete records regarding persons involved in work at safety level 2 (or higher).

HUNGARY

Minor problems have been reported, as regards documentation

IRELAND

Violations are few and are not significant in terms of posing a risk to human health and the environment

ITALY

N.A.

LATVIA

Not relevant.

LITHUANIA

There were no specific problems carried out during reporting period.

MALTA

None.

NETHERLANDS

Compared to other areas compliance is relatively high (> 80-90%). In about 10 % of the cases the BSO failed to perform a (complete) annual audit. Most problems encountered are new (technological) developments like single use bioreactors, the use of antibacterial coatings and the use of simple modification kits in secondary school biology teaching. Also the use of disinfectants that have not, or not yet been admitted as a biocide, is a point of concern. For the inspectors it's sometimes a challenge to meet the knowledge of the scientist working with the newest technology. See also the remarks under 4.1.

POLAND

Frequent offences detected were the lack of an emergency plan and the lack of signage on entrances to laboratories where GMO activities are carried out. In some installations, the formal requirements had been violated, e.g. waste produced was not properly recorded.

PORTUGAL

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ROMANIA

Not applicable.

SLOVAKIA

Shortcomings in fulfilment of the permit responsibilities mainly shortcomings in waste treatment, storage GMOs and record keeping. Also the use of GMO without permit due to ignorance of the law.

SLOVENIA

At the beginning, just after the MGMO Act had entered into force, the main goal of the inspections was to ensure that all installations for work with GMOs submitted a notification.

Later in the 3-year reporting period only minor infringements were disclosed with the documentation management (e.g. emergency action plans were not sent to the local authorities as required, yearly reports were not sent to the ministry, notifier failed to report the closure of the installation, etc.) The situation is similar up to the present, containment measures and good laboratory practice are well observed, so the inspection process only encounter minor administrative infringements.

SPAIN

Problems most frequently encountered are:

1) Deficiencies in Good Laboratory Practices (GLPs) or SOPs, and to use inadequate equipment, inappropriate contained measures and/or waste disposal procedures for the confined level notified.

2) Lack of Internal Biosafety Committees at the installations. The CNB always recommend establishing this kind of internal committees in order to implement properly the confined and control measures according with the class of risk and to have a Biosafety Officer in charge of these issues.

SWEDEN

There was not any specific problem that we encountered. If any it was mostly about who was responsible for different issues.

UNITED KINGDOM

a) The most frequently encountered issues (formally raised following inspections/investigations indicating GM activities) are:

- Validation of inactivation method for GMMs or contaminated waste;
- Risk assessments not sufficient to cover all the activities being undertaken;
- Adequacy of standard control measures (e.g. saleability; HEPA filtrations restricted access) with respect to on-going planned preventative maintenance;
- Training provision and training records – insufficient to demonstrate competence of the user; and
- Significant change notification or reclassification required – where the contained use has changed such that the risks are different or greater.

3.3 What were the corresponding enforcement actions taken?

AUSTRIA

The Ministry of Science, Research and Economy reports 8 improvement notices and 2 prosecutions.
The Ministry of Health: -

BELGIUM

If shortcomings were revealed in the application of containment measures an exhortation was drawn up and the user had to comply with these exhortations within a limited timeframe. Afterwards follow-up inspections have been carried out and if the user still did not comply an official report of infringement was written. Also if the shortcomings were that severe that a risk existed that the contained use could be breached a report of infringement was written. In general, shortcomings were quickly rectified so that no coercive measures, such as a cessation order or withdrawal of authorisation, have been taken.

BULGARIA

When it is found that GMOs are used or are about to be used in the near future in facilities that have not been approved and registered for such contained use regional inspectorate issues injunction ordering notification for initial approval to be submitted to the Ministry of Environment and Water within 40 days and prescribing that no work with GMOs should be carried out before the approval procedure is completed. So far, such injunctions have been issued on four occasions (see answers to Part 1 and questions 3.4 and 3.5).

Similar measures will be taken if work with Class 2-4 GMM or Class B GM plants and animals that has not been notified takes place.

When it is found out that facility for contained use of GMO or the activities taking place in them do not comply fully with relevant requirements, injunction will be issued prescribing measures than need to be taken and the timeframe. If observed issues of non-compliance could result in increased risk for human or animal health or for the environment all activities involving GMOs will be stopped.

CROATIA

Competent Authority has been given grace period of 1 year to improve conditions.

CYPRUS

No enforcement action was taken.

CZECH REPUBLIC

The deficiencies in the documentation were corrected either right at the time of the inspections or immediately afterwards. The CEI requirements were met within set time limits and without problems.

DENMARK

When a company has not notified e.g. a research project they are given an order with short notice to get the matter settled. Regarding the other problems experienced it depends on the situation. Sometimes companies are given advice on how to make things right. If the problem is more serious companies may be given an order with notice to get the matter settled.

ESTONIA

None taken.

FINLAND

No changes since the 2009 report. Most often the inspectors ordered correcting measures already during the inspection visit and discussed them together with the operator. The measures to be taken are always written down in the inspection report, and if necessary, the operator has to confirm in a written statement that the inspector's orders have been followed.

In more severe cases a written note of complaint is written to the operator and their superiors, and in very severe cases the issue is presented for the Board of Gene Technology, which has more authority in enforcement actions. Usually, however, the operators are very co-operative, and inspectors' orders and recommendations are followed without problems.

FRANCE

GERMANY

The Federal state authorities deploy a range of measures to deal with the complaints or shortcomings:

- Verbal indications and requests for remedial action during the inspection (in the case of minor measures which can be implemented immediately),
- Improvement notices or documented records with a request for remedial action, with a deadline being set,
- Inclusion of requirements in authorisation and approval decisions (in the case of new installations or substantial changes),
- decisions with instructions on remedial action or additional requirements,
- Initiation of proceedings for regulatory offences,
- In individual cases, a (temporary) ban on work involving genetic engineering, as well.

The operator or project leader has to report the implementation of the measures required to the authority. In individual cases the authority carries out an immediate, on-site inspection of the implementation of the measures. In most cases this takes place as part of the next routine inspection.

HUNGARY

Providing detailed information on what kind of documentation is required.

IRELAND

The compliance record for contained use of GMOs is high. The CA does not receive complaints and to date has been notified of few incidents. Violations are few and are not significant, and other than to request in writing resolution within a certain timeframe, more stringent enforcement actions (such as serve notices, prosecutions as specified under the national legislation) has not proved necessary.

ITALY

N.A.

LATVIA

Not relevant.

LITHUANIA

-

MALTA

No breach detected.

NETHERLANDS

In most cases a warning is given and the user is asked for an improvement plan. For serious cases a provisional order for penalty payment is issued.

POLAND

If there were any encountered problems during the course of inspection the CA would ask users for supplementing notifications and improving conditions in installations.

PORTUGAL

-

ROMANIA
Not applicable.

SLOVAKIA
Corrective measures and penalties.

SLOVENIA
Written warnings with a time limit were issued and in some cases the enforcing measure was only verbal communication with written minutes. All of the notifiers were keen to make good a deficiency, therefore we believe they understand the purpose of the biosafety system and want to contribute to adequate biosafety themselves.

SPAIN
Users have to correct the deficiencies before beginning the activities. If they not fulfil the requirements requested by the CNB, the favourable opinion is not released by the National Commission on Biosafety (CNB) and the permit is no granted by Competent Authority (the Inter-ministerial Council for GMOs (CIOMG) at national level or the CA of the affected Spanish region).

SWEDEN
In most cases we asked the inspected organisations to complete their notifications or applications for permits. In a few cases we sent an inspection notice where we presented the problem and asked them to correct the problem within a given time frame.

UNITED KINGDOM
a) Inspectors use a range of enforcement tools to ensure that users of GMMs comply with the legislation. These include:

- Verbal instructions to achieve required improvements (used where users are broadly compliant – minor issues);
- Providing written direction to achieve compliance e.g. letter (used where there is a material breach of the legislation);
- Serving statutory enforcement notices, requiring improvements to achieve the required level of compliance (Improvement Notices) within a specific timeframe or the immediate cessation of work where it poses an immediate risk to human health or the environment (Prohibition Notices);
- Withdrawal or variation of consent or addition of conditions to carry out the notified GM contained use; and
- Prosecution – where it is in the public interest to hold the user accountable for a failure to meet their legal obligations.

b) HSE's Enforcement Policy Statement sets out the factors that inspectors consider when deciding upon the most appropriate enforcement action (www.hse.gov.uk/enforce/enforcepolicy.htm).

3.4 How many enforcement actions were taken during the reporting period?

AUSTRIA

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BELGIUM

During this reporting period, on a total number of 177 inspections, 147 exhortations were written and 7 official reports of infringement were sent to users (3 because of a non-compliance determined by follow-up inspections and 4 because of the absence of environmental permit or an authorisation.

BULGARIA

4 (see answer to question 3.3).

CROATIA

One (1).

CYPRUS

0.

CZECH REPUBLIC

One fine was imposed for contained use of a GMM (Class 2) that had not been notified.

DENMARK

Approx. 10.

ESTONIA

0.

FINLAND

In inspection minutes approximately 700 orders of correcting measures were given (on average 5 corrective measures / inspection, no further statistics available). Valvira did not give notes of complaint during this reporting period as the operators followed the instructions given during inspections, according to their statement to Valvira.

In two cases Valvira informed the Board for Gene Technology about a possible violation of the gene technology legislation, and the Board gave the operator more accurate conditions for the GMO use for the future.

There were no issues taken to court.

FRANCE
0

GERMANY
An improvement notice or documented record is usually drawn up for each on-site inspection. The number of formal instructions and proceedings for regulatory offences is markedly lower, and varies according to need.

HUNGARY
None.

IRELAND
All site inspections are followed up with a letter to the user making recommendations in an effort to strengthen and harmonise containment measures

ITALY
N.A.

LATVIA
0

LITHUANIA
-

MALTA
0

NETHERLANDS
A provisional order for penalty payment has been used on average of once per year. None of these orders lead to the payment of the fine, as the offence was terminated after this first action. In total six such orders have been issued in the report period. Only once in this period a report was drafted for criminal law sanctions

POLAND

3

PORTUGAL

-

ROMANIA

Not applicable.

SLOVAKIA

26

SLOVENIA

Four written warnings with a time limit were issued in the reporting period.

SPAIN

Many enforcement actions were taken but the final checks have not given grounds for administrative action.

SWEDEN

Several inspections were performed as part of the notification/permission process, why the notifier/user was asked to deliver corrected information or documents that were missing.

UNITED KINGDOM

a) There were 0 statutory enforcement notices served and 0 prosecutions taken in relation to breaches of the GMO(CU) Regulations in the period of the report.

b) There were 0 withdrawals or variations of consent for contained use of GMMs in the period of the report.

c) There were 12 specific instances, where issues were raised by inspectors via verbal instruction/written direction, specifically referring to a failure to comply with the GMO(CU) Regulations.

d) Note that other enforcement action (including verbal, written, notices and prosecutions) have been taken at the same premises, however this action resulted from a failure to comply with other health and safety (e.g. requirements of Directive 200/54/EC on the protection of workers from risks related to exposure to biological agents at work, implemented by the Control of Substances Hazardous to Health Regulations 2002 and the

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 in the UK) or environmental legislation (Specified Animal Pathogens Orders 2008 and 2009 which is domestic legislation) and may have applied to the laboratories where users undertake GM contained uses.

3.5 What actions were taken by the user (and/or advised by the CA) in order to minimise the occurrence of these problems in the future?

AUSTRIA

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BELGIUM

In general, the user adjusts the operating procedures on his own or at the inspector's request. A toolbox meeting could be organised if needed.

For recurrent problems, the competent authority asks the user to be compliant to the environmental permit and authorisation within a limited timeframe.

BULGARIA

On all four occasions when injunction was issued, institutions submitted notifications for initial approval of facilities for contained use of GMO within the prescribed timeframe (see answers to Part 1 questions). Two more institutions have notified the Ministry that they are planning to register facilities in the near future in order to start contained use of GMO.

Ministry of Environment and Water submitted information letters to all actual or potential operators which might work with GMOs about legislation on contained use of GMO and their obligations under that legislation.

CROATIA

The laboratory was improved as Competent Authority suggested. The laboratory has been improved technical conditions in accordance to ordinance of Good laboratory practice.

CYPRUS

Not applicable.

CZECH REPUBLIC

Users often consulted potential problems with the Authorities (CEI and the Ministry of the Environment) in advance of the activity. Based on the experience gained, the Authorities provided guidance and formats for various aspects of contained use notifications and reporting (e.g. advice on equipment of the premises according to the containment level, formats for yearly reports and other documentation, guidance for notification of clinical trials with GM medicinal products, recommendations for transport of GM laboratory animals). Thanks to this approach, the number of deficiencies was low.

DENMARK

There have not been any big problems with this so no actions have been taking other than giving information to the companies that the CA has been in contact with.

ESTONIA

There was no need for actions.

FINLAND

The operators followed the instructions given during inspections, according to their statement to Valvira.

Apart from giving specific instructions to correct the observed deficiencies:

- Future plans of GMO activities were discussed with operators and inspectors gave instructions about the liabilities of gene technology legislation when starting new types of activities.
- Operators were advised to ensure that new or changed information related to GMO use is shared efficiently within the organization and (when needed) across organizational borders.

Importance of in-house control systems was emphasized to operators.

FRANCE

Corrective actions are organized by the users in the month even at the latest 3 months following the identified problem.

GERMANY

The shortcomings ascertained were usually rectified by the operators or users promptly or within the deadline set. Where necessary the frequency of official inspections was/is increased.

Internal procedures were improved by the following, inter alia:

- Discussion of problems and special safety measures as part of the annual instructions to staff,
- Circulars, updated operating instructions and SOPs,
- Improved consultation between operators, project leaders, biosecurity officers, occupational safety experts, works doctors, etc.

With regard to new/planned genetic engineering installations, or prior to substantial changes there was/is frequently

HUNGARY

Notifiers took account of the documentation required by the authorities.

IRELAND
To date the CA has dealt with such incidents by first and foremost giving seminars on the legislation in academic institutions thereby making both users and potential users aware of the legislation and the need to comply with it (and emphasising that it is the responsibility of the user to comply with it).

In addition, the CA has instructed institutions (in particular) on the need to have a Biological Safety Committee and a Biological Safety Officer who are aware of the research being carried out and who in turn can inform potential users of the need to comply with the legislation and to put appropriate containment measures in place for all GMM contained use activities. This has largely been achieved through correspondence with Heads of Department.

ITALY
N.A.

LATVIA
Not relevant.

LITHUANIA
-

MALTA
N/A

NETHERLANDS
Most users comply after a warning. If not, imposing sanctions always convinces them to do so.

POLAND
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PORTUGAL
-

ROMANIA
Not applicable.

SLOVAKIA

Inspections were to ensure
- increase the level of the scientific details of the proposal,
- Valuable regular contacts between the applicants and inspectors via telephone and e-mail,
- The renewal of certain equipment.

SLOVENIA

CA was always open to advise the notifiers during the preparation of the notifications and at the beginning we realised that a preparation of a vast documentation required for registration, including detailed risk assessment, posed a serious challenge even for bigger research groups.

The CA organised two Workshops for the notifiers. The main topics of the workshops were risk assessment and the preparation of the documentation. During the process we realised some notifiers needed more help and advice, so in the collaboration with the Scientific Committee CA regularly helps with the pre-notification/renovation visits of the premises and on-site discussion of the possible containment measures.

SPAIN

First of all, the main positive action in order to prevent problems is to clarify questions through previous consultations between the users and officials from the Biotechnology Unit before applying the final notifications to the Competent Authority.

On the other hand, the CNB makes several recommendations to users in order to improve their installations although the measure to implement wouldn't be compulsory.

SWEDEN

Correction of lacking or wrong information, providing documents that were missing. Every inspection is an opportunity to increase the knowledge of our rules and compliance of the rules to the persons we meet. Knowing that we are coming, is enhancing the notification rate as well as the update rate for older notifications.

UNITED KINGDOM

a) The user formally responds to the enforcement action in writing within a given timeframe setting out how the matters have been rectified. The information is used to inform the prioritisation for further inspection.

4. Problems with interpretation of the provisions

4.1 What aspects of implementation of Directive 2009/41/EC on the contained use of GMMs place the greatest burden on you as a Competent Authority?

AUSTRIA

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BELGIUM

1) The main problems which are met with the interpretation of the provisions of the Directive 2009/41/EC are related to the scope of the legislation:
- A question from the European Commission was addressed to the competent authority concerning the point of view for the status of a genetic modification of a *Lactococcus lactis* strain which produce Nisin V (consisting of polypeptides with an antibiotic action) such as defined by Directive 2009/41/EC. Advices from the Member States and the working group "New Techniques" were unanimous about the fact that it is concerning a genetic modified bacteria, but that the technique used for this activity (self-cloning) made it not falling under the scope of contained use of GMOs (Directive 2009/41/EC).
- A question from the European Commission was addressed to the competent authorities for Directive 2009/41/EC concerning the commercialisation of a commercial kit for the transformation of Bacillus subtilis (DIYbio kit). They were wondering if the use of this kit falls under the scope of contained use of GMOs (Directive 2009/41/EC) or not. Belgium considered the micro-organism transformed by means of this type of cloning kits as a GMM, due to the presence of the GFP gene. The contained use is of risk class 1 and according to the Belgian regional legislation it has to be notified to the competent authorities. In Belgium, the DIYbio kit is not commercialised but can be easily purchased via the internet and consequently be used by biohackers. However, it seems very difficult to control the use of this kind of activities. From a biosafety point of view, there is a need to improve the awareness of people potentially using those kits. On one hand through education in biosafety and on another hand by stimulating the distribution company to indicate the users they have to apply biosafety measures by adding a note in the user manual.
- A significant number of innovating therapies are actually being developed and applied. There is a need to evaluate these newly developed therapies in order to see whether they fall under the scope of contained use of GMOs as defined under Directives 2009/41/EC and 2001/18/EC. More specifically, a question from the European Enforcement Project (EEP) was addressed to the competent authorities concerning therapies based on synthetic naked DNA. We are of the opinion that plasmid DNA is a genetic material but that it should not be considered as a (micro)biological entity that is capable of replication or of transferring genetic material by itself. The injection of naked DNA in patients is therefore not submitted to the legislation of contained use or deliberate release of GMOs.

2) The too detailed reporting system and the complexity of the different procedures are also pointed out by the Brussels competent authority.

BULGARIA

There is no clear procedure to distinguish whether a clinical trial of products containing genetically modified organisms (both for human and for veterinary use) should be considered contained use and when release into the environment.

CROATIA

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CYPRUS

None.

CZECH REPUBLIC

New gene techniques: The question whether a specific technique and the resulting GMM fall within the scope of the Directive has to be resolved.

Clinical trials with medicinal products containing GMO: The decision whether a clinical study falls under the contained use or deliberate release legislative is difficult in cases when a minimal possibility of release of viable GMMs into the environment exists (e.g. shedding from the patient).

DENMARK

The class 1 notifications.

ESTONIA

Luck of knowledge for this inspector, not specific education.

FINLAND

1) The definition of a GMO is getting increasingly vague because new molecular biology techniques have evolved. The legal uncertainty caused by this is getting increasingly difficult for both the operators, CAs and the supervisory authorities, as it is no longer clear which organisms are actually covered by the directive.

2) As noted already earlier, research groups relocate quite frequently which increases the number of new notifications and subsequently the regulatory burden for both the operators and authorities.

FRANCE

Implementation of the controls.

GERMANY

This point is currently under discussion between the Federal and Land authorities; the results of these discussions are likely to be included in the next report.

HUNGARY

New techniques not considered to result in genetic modification can trigger interpretation problems.

Another problem is how to distinct between contained use and deliberate release (i.e. which directive to apply: Directive 2009/41/EC or 2001/18/EC) in case of clinical biotechnological applications. We propose to continue the discussions at EU level regarding this important issue.

IRELAND

The regulations of Class 1 GMM contained use activities (history of safe use and low risk) see section 1.6.

ITALY

We don't see any critical aspects.

LATVIA

The Competent Authority did not have problems with implementation of Directive 2009/41/EC on the contained use of GMMs.

LITHUANIA

No specific problems with the interpretation of the provisions were reported.

MALTA

The Authority did not experience any specific burden, although it has a lack of resources and training on the subject. However it should be also noted that the Authority only received one application.

NETHERLANDS

Although the directive is relatively recent, technological developments in this field are huge and lead to problems related to (1) definition of GMOs in relation to among others, synthetic biology, (2) new apparatus like single use bioreactor and cell sorters (FACS) in relation to the needed containment measures, (3) differences in interpretation of the annexes between the Member States. Next to that on a regular basis discussions about (4) whether or not a coating is sufficient antibacterial and (5) the use of disinfectants that have not, or not yet been admitted as a biocide, are signalled. Besides that, the Netherlands encounter differences in the (strict) GMO-regulations and the less strict regulation of wild type pathogens. This could

partially be explained by the implementation legislation of the Netherlands, but seems also be caused by a lack of harmonization at EU level.

POLAND

- It is unclear how activities involving plant and animal cells should be classified – as GMM activities or activities involving GM plants or animals.

- Several notifications involving the contained use of Saccharomyces have been submitted in Poland. So far, these activities have been classified as contained use. Poland also requests clarification as to the appropriate risk class for activities with GM higher plants and GMs.

PORTUGAL

No problems have arisen regarding interpretation of the provisions of Directive 2009/41/EC.

ROMANIA

Not applicable.

SLOVAKIA

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SLOVENIA

The greatest burden for the CA are notifications which contain a lot of information, that need to be processed in the notification procedure. Assessing risks of the notified organisms is a very responsible task. On the other hand the notifiers complain that the preparation of the notifications and risk assessments are laborious and time consuming. There is a fine line between necessary and redundant information.

SPAIN

The main issues would be:

- A lot of visits to the installations,
- Problems in the interpretation if GMOs obtained by new genetic techniques, and whether they are under the scope of Directive 2009/41/EC or not.

SWEDEN

The notification procedure.

UNITED KINGDOM

a) The UK applies a hazard and risk-based approach to its regulation and inspection activities (see answer to question 3.1). The UK has recently consolidated the Genetically Modified Organisms (Contained Use) Regulations 2000 and its amending regulations, which transpose the Directive, to make them more risk based and proportionate and more closely reflect the requirements of the Directive. The UK is able to implement a regulatory framework that permits the risks from contained use of genetically modified micro-organisms to be controlled in a risk based and proportionate manner.

b) The greatest burden on the competent authorities in the UK, from the implementation of the Directive, is in the technical assessment of class 2 notifications. Whilst the UK ensures that all notifications are reviewed, and endeavours to ensure statutory timescales are met, the time spent reviewing lower-risk class 2 activities is disproportionate due to the amount of information required and the volume of notifications received (~90% of activity notifications are class 2). Furthermore, a large proportion of these notifications (~50%) involve work with multiply disabled viral vectors, the risks from which are well defined and the control measures established. The consequence of this is that majority of the competent authorities time spent on reviewing notifications is biased towards the lower risk work.

c) One further aspect of the Directive that places a burden on the competent authorities is the emphasis, within the definitions of genetic modification in the Directive, on the techniques used in the contained use to determine whether or not the Directive applies. Given the rapid nature with which techniques are developed and adapted, this can present challenges for interpretation and potential for disproportionate application of the legislation.

4.2 What could be done to improve the process at EU and/or national level?

AUSTRIA

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BELGIUM

1) A working group on New Techniques (NTWG) at the European level has been set up and started its work in 2008. Member States have each appointed scientific experts to participate in the NTWG, which is examining a range of new techniques to assess whether they should be considered to lead to GMOs or GMMs as defined under Directive 2001/18/EC or Directive 90/219/EEC, respectively. A final report has been published in December 2011, giving recommendations on editorial changes and further consideration on separate opinions per new technique.

We are of the opinion that the current risk assessment principles and methodology, and the GMO regulatory framework, seem robust enough to deal with the new techniques listed in the report. But because the science and technology developments in the field of synthetic biology evolve rapidly, those should be reviewed regularly. Action should be taken if voluntary codes or current regulatory procedures appear insufficient. In this regards, exchange between the research community, risk assessors and policy makers will be key to expand scientific and technical knowledge and to fill the potential gaps in risk assessment and regulation of evolving developments. Further approaches to reconsider effective risk governance should also be taken in a global perspective, allowing international coordination and dialogue. It is therefore important for the European Union to advance further in defining a harmonized view about safety and regulatory oversight of Synthetic Biology (Pauwels K, Willemarck N, Breyer D, Herman P (2012). Synthetic Biology. Latest developments, biosafety considerations and regulatory challenges. Ref: D/2012/2505/46.
http:// http://www.biosafety.be/PDF/120911_Doc_Synbio_SBB_FINAL.pdf).

2) As abovementioned and under point 1.3, the Brussels regional decree defines too many different procedures regarding the notification of contained uses of GMOs and pathogens. The Brussels Capital Region considers the possibility to make procedures more uniform.

BULGARIA

As applications for clinical trials of products containing genetically modified organisms (both for human and for veterinary use) are expected to increase it might be beneficial if guidance documents or legislation at EU level are adopted that harmonise the procedures for evaluation of the risks for the environment in these cases.

CROATIA

At EU level important process is to organize a meeting of contained use of GMOs emphases of conducting official control of contained use of GMO.

CYPRUS

No changes.

CZECH REPUBLIC

The evaluation of new gene techniques should be completed at EU level. It should be laid down whether a certain new technique of genetic modification and the resulting GMM fall within the scope of the existing legislative framework.

Legislative framework for clinical trials with GMM should be discussed at EU level. Current deliberate release notification formats are designed for field trials with GM plants, not for clinical trials with GMMs. Similarly, contained use formats are suitable for microbiological laboratories, not for hospitals.

Implementing rules for notifications of gene therapy clinical trials should be improved at national level.

DENMARK

The only suggestion is that the class 1 notifications are taken out of the Danish legislation.

ESTONIA

Specific training programme for this inspector with joint inspections with other member state authorities.

FINLAND

At the EU-level it would be important to update the definition of a GMO. Perhaps it would be even useful to evaluate the pros and cons of technology based regulation versus trait-based regulation when dealing with a rapidly developing technology. Also, the Commission could give more specific guidance on the classification of pathogenic organisms in cases where their pathogenicity has been attenuated. Moreover, guidance on the notification procedures concerning clinical treatments of patients with GMMs would be most welcome.

As to the regulatory burden caused by the frequent relocation of groups, institution level notifications could be a solution in principle. However, this has been already tried in Finland. Unfortunately institution level notifications led to a situation where neither the institution, CA, nor the supervisory authority were always fully aware which research groups were currently working in an institution, which premises they used and what GMOs were used. As a result, most notifications are nowadays made at the research group level.

At the national level there is a clear need for more education. Having Biosafety Officers in the major research institutes would be an option, but the concept of a BSO is unknown in Finland and not likely to be accepted in the present economic situation.

FRANCE
Financial means and number of inspectors.

GERMANY
This point is currently under discussion between the Federal and Land authorities; the results of these discussions are likely to be included in the next report.

HUNGARY
We propose to continue the discussions at EU level regarding these two important issues mentioned under 4.1.

IRELAND
See section 1.6.

ITALY
N.A.

LATVIA
At the moment and based on the experience we do not have any significant suggestions that could be done for the further improvements at EU and /or national level.

LITHUANIA
Organization of meetings for competent authorities and inspectors to share the experience gained under the Directive 2009/41/EC on contained use of GMMs and GMOs. Better explanation of gene therapy, Synthetic biology and other new techniques, their terminology would be valuable.

MALTA
Exchange of experiences/training would be deemed relevant.

NETHERLANDS
Simplify and harmonize the allowance of disinfectants as biocides in laboratories. Screen for new developments and give harmonized guidance in an early stage. Possibly look into the differences between EU legislation of GMO's and wild type pathogens in order to harmonize some of the provisions. It is suggested to call a meeting of the CA to discuss these items.

POLAND

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PORTUGAL

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ROMANIA

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SLOVAKIA

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SLOVENIA

Inclusion of safe organisms in Part C of the Annex II of Directive 2009/41/EC could contribute to reduction of the number and size of the notifications.

SPAIN

It would be desirable to have harmonised Guidelines at EU level (from the Commission) regarding:

1) Clinical Trials in order to clarify whether they have to be carried out under the scope of Directive 2009/41/EC or/and the Directive 2001/18 /EC (or both, “case by case”).

2) Problems in the interpretation if GMOs obtained by new genetic techniques, and whether they are under the scope of Directive 2009/41/EC or not.

3) It would be desirable to tackle new simplified procedures for Class 2 activities, which have increased a lot for the last years.

At national level, and in order to improve understanding of provisions and requirements for user, the National Commission on Biosafety (CNB) has developed a Guide for notifiers, which has been applied since the last year (2013).

SWEDEN

The notification procedure is of limited value for class 1 and 2. If there must be notifications, we think it is enough to give information on class and type of activity, organisation involved, contact information for the responsible persons and address to the workplace. In our view notification of class 1 and class 2 can be abolished altogether without problems. The risks in this field can be taken care of by the work environment legislation and the general environment legislation.

UNITED KINGDOM

a) The notification requirements for class 2 contained uses could be aligned with Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work which requires only the first class 2 contained use at a given premises is required to be notified. Subsequent class 2 contained uses could be carried out, following approval by an internal safety committee, without the need to notify the national Competent Authority.

b) Alternatively, the information requirements for class 2 notifications could be minimised (e.g. a description of recipient organism, donor material, evaluation of foreseeable effects and an indication of class). This would limit the requirement from users in providing the relevant information and the time spent by the Competent Authority in assessing compliance with the legislation. Similarly the EC could populate the Annex II Part C of the Directive with a list of multiply disabled vectors for class 1 contained uses - this would provide greater delineation of class 1 and 2 contained uses and minimise the degree of over classification.

c) This approach would allow the Competent Authority to divert more resource to the assessment of high hazard work, including reviewing notifications and inspections.

d) The definitions of genetic modification within the Directive should be reviewed to ensure they take account of technological advances, new fields or disciplines (e.g. synthetic biology) and there should be an effective means of implementing any revisions. Alternatively, consideration should be given to shifting the emphasis from the technique to the final product in determining whether the GMM is encompassed by the legislation.

5. Accidents

Provide details of accidents (including the identity of the GMM, the class of activity involved and quantities of GMMs concerned where the accident has involved a spillage) as defined under Article 2(d) of Directive 2009/41/EC, reported to the CA during the reporting period. In addition provide details of the measures taken by the user (and/or advised by the CA) to prevent the occurrence of similar accidents.

AUSTRIA

No accidents were reported.

BELGIUM

The three Belgian regional regulations mention that the user must declare immediately to the competent authority an accident that occurs in a contained use installation.

For the current reporting period, no accident has been declared in Belgium. However, in Brussels-Capital region one accident (fire) occurred in a biological waste storage room without the competent authority has been informed. Corrective measures have been taken.

BULGARIA

There were no accidents notified to the Ministry of Environment and Water during the reporting period.

CROATIA

None.

CYPRUS

No accidents were reported during that period.

CZECH REPUBLIC

No accident happened in the Czech Republic during the reporting period.

DENMARK

There have been no accidents.

ESTONIA

No accidents.

FINLAND
During the reporting period the Board received a few notices of mild accidents (needle pricks etc.) in class 2 with no consequences. The operators were advised of proper working practices.

FRANCE
0

GERMANY
No accidents as defined under Article 2(d) of Directive 2009/41/EC.

HUNGARY
No accidents occurred to date.

IRELAND
No accidents reported.

ITALY
No accidents have been reported.

LATVIA
0.

LITHUANIA
No accidents were reported.

MALTA
No accidents occurred.

NETHERLANDS
Thirteen incidents were reported. The Dutch authorities concluded in each of these cases that the incidents did not result in harm to people or the environment.

The first incident was caused by a small fire in a biosafety cabinet in a ML-I laboratory. No GMOs were present in the cabinet and the lab containment stayed undamaged. In a second incident GM cell lines had been mixed with wild type cell lines and subsequently handled as non-GMO samples. The inactivation procedure turned out to be similar to the procedure used

for GM cell lines. In a third ML-I incident a small amount (mL) effluent of GM cell lines had been accidently disposed in a sink. Survival of the cell lines in the sewer was unlikely (biological restriction).

A fourth incident concerns the transport of ML-I and ML-II waste. Due to a small collision in a corridor, the secondary containment was broken. A check on presence of GMOs showed that a class 2 micro-organism was present in the waste. The primary containment (Petri dishes and tubes) was still closed but cleaning had been carefully performed to prevent any further spread.

In the fifth incident a tube containing GM *Neisseria* had been broken in a centrifuge, which was located in a ML-I lab. The rotor was kept closed and moved to the ML-II lab for subsequent cleaning. People that might have been exposed were followed clinically. No health problems were detected. In the sixth incident a ML-II lab was flooded with a few cm water leaked from a broken ice machine. At the time of the flooding, no activities with GMO's were taking place and all the GMO material was present in incubators. The lab journal showed that no incidents concerning spoiling GMOs on the lab floor had been reported. It was concluded that no GMOs had been present in the water. In the seventh incident a needle accident with a low titre of GM Influenza occurred. The researcher was vaccinated on forehand, got a tamiflu prescription and was followed clinically. No health problems were detected.

Two incidents occurred with an isolator housing animals with GM Inluenza. In one incident the door of the lock was not tightly closed, under pressure was lost and the alarm went off. In the second incident a rip in a glove was detected. In both cases people were vaccinated on forehand, got a Tamiflu prescription and were followed clinically. No health problems were detected. In a tenth incident a glass wall of a ML-III laboratory was damaged. At the time of the incident activities with wild type HIV in a biosafety cabinet were ongoing. Loss of under pressure was minimal. It was concluded that release of a GMO or wild type had been very unlikely.

In the eleventh incident the under pressure in a DM-III facility was lost due to a technical defect. At that moment all animals were housed in isocages (HEPA filtered, under pressure) and no activities took place. It was concluded that a release of GMOs would have been highly unlikely. In the twelfth incident a mistake in a technical construction of a ventilation system was reported. Air from a ML-III could have been released, without Hepa filtering, into a ML-II laboratory when a power outage would happen. It had been concluded that no release of GMO’s from the ML-III to the ML-II laboratory could have been occurred, since all activities in the ML-III laboratory were performed in a biosafety cabinet and no incidents of spill had been reported. In the thirteenth incident it was reported that a cell line infected with GM SARS-virus was fixed with a presumably old fixative and the culture handled as fixed material. The researcher was clinically followed and the fixative was tested afterwards. It happened that the fixative was still fully active

POLAND

No accidents have been reported during the reporting period.

PORTUGAL
No accidents were reported in this period.

ROMANIA
Not applicable.

SLOVAKIA
2010 – The Institute of virology, Slovak Academy of Sciences, Bratislava – fire
The fire broke out during the building reconstruction of the northern facade of The Institute of virology building. The fire was localized in laboratories and offices on the third floor. Direct fire damaged installations approved for the contained use of genetically modified organisms on this floor. Other installations approved for the contained use of GMOs on the second and on the fourth floor were damaged by smoke and water during the extinguishing a fire. There was no leak of stored GMOs, because GMOs were stored in the deep freezer boxes in the corridors by the staircase at that time and they weren´t exposed to the fire. There were no activities carried out regarding GMOs in the approved installations at that time (holidays, moving of laboratories). The Institute of Virology works with GMOs classified in the risk class 1 and 2.

2010 – The Institute of Neuroimmunology, Slovak Academy of Sciences, Bratislava – fire
The fire from the Institute of Virology spread to the area of the Institute of Neuroimmunology, which is housed in the same building. The fire didn´t affect installations approved for the contained use of GMOs, although they were damaged by its effect (temperature, smoke, water that got there after extinguishing a fire on the fourth floor). Subsequently, these spaces were reconstructed. There was no leak of GMOs, because at that time, there were no GMOs in these installations. The Institute of Neuroimmunology works with GMOs classified in the risk class 1 and 2.

2013 – Slovak University of Technology, Bratislava – fire
In the laboratory approved for the contained use of GMOs was fire caused by the burning of the electrical socket. There were no GMOs in the laboratory at that time. Slovak University of Technology works with GMOs classified in the risk class 1.

SLOVENIA
No accidents involving GMMs/GMOs were reported in Slovenia.

SPAIN
No accidents were reported during this reporting period.

SWEDEN
A Ph.D. student was going to inject a mouse intravenously in its tail but instead she prickled herself in a finger. The syringe contained genetically modified vaccinia virus. After nine days

a blister appeared on her finger. Eleven days after the incident the finger was swollen and she had a fever. No treatment was needed and she recovered from her illness. The class of activity was 2.

UNITED KINGDOM

a) Annex 2 provides details of all the accidents involving contained use of GMMs or larger GMOs notified to the UK competent authorities in the reporting period. Whilst there were 12 accidents (12 in GB; 0 in NI) notified during this period 4 of these did not meet the accident criteria as set out in the Directive but are included for information.

6. Clinical Trials using the provisions of the Directive

6.1 How many gene therapy clinical trial applications were carried out under Directive 2009/41/EC on the contained use of GMMs during the reporting period?

AUSTRIA

Not applicable. In its "Gene Technology Act" Austria has a special legal regulation for applications concerning gene therapy in context with clinical trials. Therefore the regulations on contained use do not apply for these approvals.

BLEGIUM

From 6 June 2009 to 5 June 2014, 8 clinical trials were carried out.

BULGARIA

One application for clinical trial involving immunostimulatory product based on Vaccinia virus (not gene therapy as such) was filed. Positive opinion on the risk for the environment was issued in April 2014, but clinical trials were not conducted due to reasons unrelated to GMO.

CROATIA

None.

CYPRUS

None.

CZECH REPUBLIC

None.

DENMARK

There have been 7.

ESTONIA

0 applications

FINLAND

There were two on-going clinical trials.

FRANCE
12/year.

GERMANY
12.

HUNGARY
None.

IRELAND
None.

ITALY
4 class2 activities (class1 activities are not included / notifications are not due).

LATVIA
0.

LITHUANIA
No clinical trials were notified.

MALTA
No clinical trials took place.

NETHERLANDS
In the Netherlands gene therapy is regulated under directive 2001/18. A common interpretation of directives 2001/18 and 2009/41 in this respect is needed.

POLAND
25 clinical trials with GMMs were carried out in Poland. Clinical trials with GMMs also require decisions of the Minister of Health, the Ethical Committees and the Minister of Environment.

PORTUGAL
Regarding Directive 2009/41/EC, and for the period between 6 June 2009 and 5 June 2014, we confirm that there were no gene therapy clinical trials applications carried out.

ROMANIA

Only one clinical trial with TG4040 (MVA-HCV) in combination with pegylated interferon alfa-2a and ribavirin versus pegylated interferon alfa-2a and ribavirin in treatment-naïve patients with chronic genotype 1 hepatitis C.-2010, was carried (notified in 2010). Clinical trials were authorised under Directive 2001/18/EC.

SLOVAKIA

The Slovak scientists using genetic technologies and genetically modified organisms have tried to develop new medicines for the treatment of diseases, like for instance cancer, Alzheimer disease and others for several years. They have used a transduction altered genetically modified mammalian cells, which they applicate into the bodies of mice and watching their possible therapeutic effect on tumour cells that were transplanted to them before. By this way, genome of mice isn´t modified. For the period of years 2009 – 2014, the ministry has received 42 notifications on activities the results of which contribute to understand the cause and development of various serious diseases and their treatment. In 2013, there was submitted an application on consent for the first and every other introduction of combination of genetically modified organisms into the environment (PROSTAVAC-V/F +/- GM-CSF) to the ministry, which was submitted by the corporation PPD Slovak Republic s. r. o., SK in representation of BN ImmunoTherapeutics Inc., USA. Applicant didn´t submit necessary information to the application, and that´s why the ministry asked him to complete requested data. Whereas the applicant didn´t eliminate deficiencies of his application, the ministry stopped the process in this case

SLOVENIA

One gene therapy clinical trial on animals was notified in Slovenia.

SPAIN

Clinical trials with GMMs are assessed in Spain case by case, but in any case, most of them are dealt as Part B notifications (Directive 2001/18/CE), as usually patients don’t stay at the hospital for a long period and we consider that biosafety measures have to be taken in order to avoid accidental release of the GMM into the environment.

SWEDEN

In Sweden clinical trials with GMMs is performed under Directive 2001/18/EG. Three such trials have been applied for in Sweden during the period June 2009 - June 2014.

UNITED KINGDOM

a) In the UK, the GMO(CU) Regulations, allow clinical trials to be undertaken as contained use activities on a case by case basis. The competent authorities for contained use and deliberate release work collaboratively where there is uncertainty over which legislation should apply to the clinical trial.

b) The majority of clinical trials with GMMs in humans are class 1 activities hence would not individually require notification to the Competent Authority (other than the first use of the premises for work with GMMs). The total number of class 2 clinical trials notified during the reporting period is 9 (all in GB; none in NI).

6.2 Please comment on the overall trend compared to the last reporting period (e.g. has the overall number of gene therapy clinical trial applications carried out under Directive 2009/41/EC increased or decreased etc.)

AUSTRIA
Not applicable – see 6.1.

BELGIUM
Compared with the previous reporting period, there is a significant increase in the notifications for gene therapy clinical trials (4 times).

BULGARIA
The application for clinical trial mentioned above is the first that involves medicinal product containing or consisting of GMM. We expect the number of such applications to increase.

CROATIA
Not applicable.

CYPRUS
Not applicable.

CZECH REPUBLIC
The hindrance for clinical trials in the Czech Republic is lack of facilities that would meet very strict requirements for final preparation of gene therapy medicinal products.

DENMARK
There has been an increase since there was only 1 clinical trial in the last period.

ESTONIA
The same – no gene therapy clinical trial applications.

FINLAND
The number has increased. In addition to notifications, the Finnish CA has received several requests on whether clinical trials are considered in Finland as contained use or field trials under Directive 2001/18/EC.

FRANCE
Increased.

GERMANY
The number of clinical trials has decreased; in the last (three-year report) there were 14 clinical trials.

HUNGARY
Not applicable.

IRELAND
It has remained the same – No clinical trials are performed under the contained legislation rather they are performed under Part B of the deliberate release legislation.

ITALY
7 class2 activities during the last reporting period, i.e. 6 June 2004 - 5 June 2009. Class2 activities have been halved, probably because of the increase in the class1 activities; in fact, comparing the actual and the previous reporting period, new class1[class2] installations with inpatient rooms, - which are suitable for gene therapy clinical trial applications – increased[decreased] of 4[3].

LATVIA
This is first notification regarding contained use in Latvia.

LITHUANIA
-

MALTA
Remained constant – no applications.

NETHERLANDS
N.A.

POLAND
The number of applications on clinical trials has increased compared with previous period.

PORTUGAL

-

ROMANIA

See answer 6.1.

SLOVAKIA

For the period of years 2009 – 2014, the ministry hasn´t received any application (gene therapy clinical trial).

SLOVENIA

Since no clinical trial was notified in the previous reporting period, one notification may indicate a slight growth.

SPAIN

Clinical trials applications are increased since the last report but all of them are considered as deliberate releases.

SWEDEN

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UNITED KINGDOM

a) It is not possible to provide a comment on the overall trend as the numbers of class 2 notified clinical trials is small and there is no comparator from the previous EC report (2006-2009). However, the notified trials have been evenly spread over the period of the report.

7. Public consultation and information

7.1 Provide details of public consultations and/or information made publicly available under Directive 2009/41/EC during the reporting period.

AUSTRIA

Public consultation is foreseen only in cases of work with GMO in Safety Level 3 (large scale) and Safety Level 4. As we did not receive any such applications so far, public consultation was not carried out.

BELGIUM

Public consultation is performed, when relevant, through the general procedures established under the regional environmental laws. The procedures for public consultation aim at providing general information to the neighbourhood regarding the contained use of GMOs and/or pathogens.

In the Flemish and Brussels Capital Regions, this information is given via a "public dossier", which is a short summary of the full notification drafted by the user and containing information written in everyday language and without any reference to confidential information. A similar procedure of public consultation is established in the Walloon Region during the course of the environmental permit demand to the competent authority.

The consultation also gives the public the possibility to express comments, observations or objections regarding the contained uses. The competent authorities take these comments, observations or objections into account when drafting their final decision. All decisions are made available to the public for a time-limited period. Appeals against decisions may be submitted to the competent authority within that period.

In the Flemish and the Brussels Capital Region, public consultation occurs only in the frame of the environmental permit demand. To that purpose, a copy of the public dossier is joined to this demand. Public information is provided primarily in two ways. First, general information (in French and/or in Dutch) focusing on legal and administrative aspects can be found on the websites of the three regional competent authorities:

- Brussels Capital Region: http://www.ibgebim.be
- Flemish Region: http://www.lne.be
- Walloon Region: http://environnement.wallonie.be/

Second, scientific and technical information (in English, Dutch and French) is provided through the "Belgian Biosafety Server" (http://www.biosafety.be), a website managed by the SBB.

BULGARIA

During the reporting period no public consultations were conducted, as there is no such requirement when initial approval of facilities for contained use of GMO. Such public consultations should take place before permission is granted for work that involves contained use of GMM Class 2, 3 or 4 and GMO Class B.

A public registers of the premises for contained use of GMOs and permissions for work were established and are maintained in an electronic form (http://www.moew.government.bg/?show=top&cid=229&lang=bg). Information contained in notifications can be received from the Ministry of Environment and water upon request with the exception of confidential and personal data.

CROATIA

In first quarter of the year Ministry of Health has been published Annual report of the Council of GMOs from previous year. There is Annual report about submitted notifications of contained use. Annual report is performed on Ministry´s website.

CYPRUS

No public consultations and/or information were made publicly available under Directive 2009/41/EC during the reporting period because there was no need for that.

CZECH REPUBLIC

According to the Czech Act on GMOs, no public consultations are required for Class 1 and 2 contained uses. Notifications of Class 3 and 4 contained uses are made available to the public on the internet and announced via the relevant municipality. Public hearing is organised in the course of an authorisation process in case the Ministry of the Environment has received negative opinion and/or specific comments from the public, in which environmental risk assessment results are doubted or an objection to insufficient protection of the health and the environment is made.

During the reporting period, only one notification of Class 3 was submitted. The notification was published as required; no comments from the public were received. Therefore no public hearing was carried out.

In general, the public is informed on GMOs by different means: websites of the relevant Authorities, yearly public meetings of the Czech Commission for the use of GMOs (an advisory body of the Ministry of the Environment), seminars, publications etc.

The Ministry of the Environment has established and updated the register of subjects authorised for contained use of GMOs (“Register of Users”) on its website www.mzp.cz. The Register contains the name and address of a user, specification of GMO, purpose and class of the use. Summaries of emergency plans are published as well. Regarding Class 3 and 4, the full authorisation decision should be published.

Information in English is available at the Czech national Biosafety Clearing House webpage www.mzp.cz/biosafety including the legislation, notification formats and guidance documents.

DENMARK

All notifications are registered in a common database between the WEA and the EPA. Other authorities can get access to this database when needed. The public can apply for access following the rules laid down in the Law concerning Access to Public Records. Before the EPA makes a decision about an application for production the application is presented to the local authorities and if necessary other parties of interest. All of the approved notifications for production are published in a national and a local newspaper. When the approval is published you have 4 weeks to file a complaint against the decision to the Environmental Appeal Board.

ESTONIA

Specific information pages: http://www.envir.ee/et/gmo
http://www.agri.ee/et/eesmargid-tegevused/toiduohutus/toidugrupid/geneetiliselt-muundatud-toit
http://vm.ee/et/node/9868

Different brochures about GMO's are available in the printing form and in the pdf-form:
http://www.envir.ee/sites/default/files/gmoeesti.pdf

Introductions about different programmes:
http://www.voru.envir.ee/orb.aw/class=file/action=preview/id=1993/Bioloogilise+mitmekesisuse+kaitse+strateegia+ja+tegevuskava.pdf

FINLAND

None arranged for contained use.

FRANCE

200 for contained use level 3 and level 4.

GERMANY

Publication of the annual ZKBS activity report.
Publication of all general ZKBS position statements.
Publication of the list of classified microorganisms.

HUNGARY

The Biotechnology Advisory Board ensures that civil society organizations are involved in the authorisation procedure. The Registry Office appointed by the Competent Authority makes information concerning contained use available. Notifications are published on the internet. The notification of an activity has to include a short, easily understandable summary of the risk assessment for public information purposes, which can be consulted at the Secretariat of the Gene Technology Advisory Board.

IRELAND

Under the implementing legislation - (GMO (Contained Use) Regulations 2001 to 2010) - public consultation is required to be carried out for Class 3/4 contained use activities and it may be carried out at the discretion of the CA for Class 2 contained use activities. During the reporting period:

- notices were published in newspapers in respect of 4 x Class 3 GMM contained use activities.
- no public consultations were carried out in respect of Class 4 GMM contained use activities since no Class 4 GMM applications were received.
- With regard to applications for Class 2 GMM activities, the CA did not deem it necessary to consult the public on any of the applications received.

The GMO Register listing GMO users is made available for public viewing at the headquarters of the CA. Considerable technical guidance relating to the contained use of GMMs/GMOs is published on the CA's website (www.epa.ie).

ITALY

No public consultations have been carried out during the reporting period. The list of GMM authorised installations is publicly available on the Ministry of Health website, at the following address:
http://www.salute.gov.it/imgs/C_17_pagineAree_3377_listaFile_itemName_0_file.pdf

LATVIA

The relevant information (the summary of the information provided by the notifier, the documents that illustrate the procedures of decision taking) had been made publicly available. The information is published on web page of Food and Veterinary Service (http://www.pvd.gov.lv/lat/lab_izvlne/registri/darbbas_ar_mo).

LITHUANIA

During the reporting period The Ministry of Environment has published information about contained use of GMMs and GMOs to the public through the Competent Authority's Web Site **http://gmo.am.lt**, preserving confidentiality rights and intellectual property according the Order on Public Information and Participation and the Order on Genetically Modified Organisms Information System. The main tasks of the national GMO information system are to store, process and guarantee access to any available data about GMM and GMO, excluding confidential information

MALTA

Two Radio interviews on GMOs in general.

NETHERLANDS

In the Netherlands in the case of a large scale production the dossier was made public by means of an advertisement in a national newspaper in order to give the public the opportunity to make objections before the license was issued. All other dossiers were made public after

the license was issued. This was done by publishing the name of the notifier, title of the project and the issuing date of the licence on the Internet. In addition anybody could request to look into a specific dossier at the GMO office and the public concerned can object to an issued licence. Within the reporting period a public consultations was performed for 5 licenses for installations for large scale use of GMO's. In 2 cases comments were received, not leading to modifications of the license.

POLAND

Public consultation forms part of the approval procedure for all class notifications under the polish law on public information. All applications are available to the public. The consultation gives the public the possibility to express their comments or objections regarding the contained uses. The competent authority takes into account the comments before a decision.

The provisions for public participation in the authorization process require public access to the notification while restricting public access to confidential information. General information on contained use activities in Poland is provided on the website http://gmo.mos.gov.pl.

PORTUGAL

In the past the Competent Authority carried out public consultation, which had no public reaction. Therefore and although the legislation foresees that the competent authority could promote public consultation procedures when considered appropriate, no consultation procedures were carried out for the notifications presented in the current period.

ROMANIA

The national legislation transposing Directive 2009/41/EC includes provisions regarding public consultation and public information in the decision making process regarding the contained use of GMMs.

The approval procedure is public, National Environmental Protection Agency, publishes it on the website www.anpm.ro, within 10 days from acceptance of the notification and within 30 days from the display, receives comments from the public.

For the contained use classes 3 and 4, National Environmental Protection Agency holds public debates and elaborates a report that is send to the authorities that are involved in the notification procedure.

The public information at the national level is made in collaboration with county environmental agencies that are subordinated to the National Environmental Protection Agency.

All risk assessments submitted by the notifiers and the summary of all decisions taken by the competent authority are published on the NEPA website: www.anpm.ro and if necessary, public debates are held during the authorization procedure for contained use of genetically modified microorganisms.

Confidential information is treated in conformity with Directive 2009/41/EC. The CA ensuring the confidentiality of the information and of the intellectual property rights.

In no case the following information shall be kept confidential:
- The general characteristics of the genetically modified micro-organisms, name and address of the notifier, and location of the activity;
- The class of contained use and measures of containment;
- Any harmful effects on human health and the environment;
- The emergency plans;

SLOVAKIA

All the information is publicly available at our websites: www.enviro.gov.sk and www.gmo.sk. In 2009, the ministry published the publication "The national framework for using of the genetically modified organisms and products consisting of them in Slovakia". This publication is addressed to the professional public but also to the general public. It provides enough information on the processes, which are being applied in creating, testing and approving GMOs and products consisting of them.

SLOVENIA

GMO registry containing basic information on GMOs and installations is available at the ministry and also worldwide at the Slovene Biosafty Portal http://www.biotechnology-gmo.gov.si/.

SPAIN

Only notifications of class 3 and 4 activities are made available to the public through the Ministry Webpage.

Twelve activities of class 3 have been made public during this period through the publication of an information format of the activity on the Web of the Ministry of Agriculture, Food and Environment and the Web of the regional CAs or through others ways. No CBI is made public.

Other way to give information to the public is with a General Annual Report of the Ministry which includes data regarding activities under Directive 2009/41/EC.

SWEDEN

No public consultations have been done during the reporting period.

UNITED KINGDOM

a) The Regulations which transpose Directive 2009/41/EC in GB have been reviewed and consolidated and came into force on 1 October 2014. As part of this process, a public consultation was undertaken from 28 October – 20 December 2013. The consultation document, the public response to the consultation and the HSE response to the issues

raised are captured in documents (http://www.hse.gov.uk/consult/condocs/cd263.htm) on the HSE website. The equivalent Northern Ireland regulations are also being consolidated and it is anticipated that they will come into operation in 2015. A public consultation ran from 9 June to 15 September 2014 and the consultation document can be accessed on the HSENI site http://www.hseni.gov.uk/cd_gmo.pdf. A summary of the consultation responses and HSENI's response will be published in due course.

b) The Competent Authority maintains a public register of information on all notifications concerning contained use (with the exception of those withheld for reasons of national security). This contains information on premises and individual contained uses including the nature of the work to be carried out at the premises, the purpose of individual contained uses and the characteristics of the GMOs involved. The register can be found on the HSE website [http://www.hse.gov.uk/biosafety/gmo/publicregister.htm]. In Northern Ireland the Register is held at HSENI headquarters 83 Ladas Drive, Belfast.

c) The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)), which provides technical and scientific advice to the UK competent authorities on all aspects of the human and environmental risks of the contained use of GMOs publishes minutes of its meeting, annual reports and has in the past held open public meetings although no public meetings were held during this reporting period.

d) The Competent Authority in GB has received a number of requests for information relating to GMMs under the Freedom of Information Act/Environmental Information Act, all of which have been answered to deadline. No requests have been received in Northern Ireland.

7.2 Provide details of public reaction (if any) received in response to consultations and/or information made publicly available under Directive 2009/41/EC during the reporting period.

AUSTRIA
Not applicable.

BELGIUM
During the reporting period, no public reaction have been received in response to consultations and/or information made publicly available under Directive 2009/41/EC.

BULGARIA
No public reactions have been received so far about contained use of GMO.

CROATIA
No reaction to contained use reports.

CYPRUS
Not applicable.

CZECH REPUBLIC
No public reaction was received.

DENMARK
There have not been any public reactions.

ESTONIA
http://www.agri.ee/sites/default/files/public/juurkataloog/UURINGUD/eki_tarbijauuringud/OSTUEELISTUSED_2005___MAHETOIT.pdf

(There is no reported results about public reactions during reporting time).

FINLAND
Not applicable.

FRANCE
No response following the public consultation.

GERMANY
-

HUNGARY
No public reactions received to date.

IRELAND
No public reaction has been received in response to consultations and/or information made publicly available under Directive 2009/41/EC during the reporting period. However on one occasion the Agency received a letter from a member of the public, (June 2012), seeking additional information on the implications / risks associated with a Class 3 GMM contained use activity (GM strains of Hepatitis).

The Agency replied providing details of the nature and purpose of the Class 3 GMM activity, the containment measures to be employed, treatment of spillages and waste and protective clothing to be worn by those carrying out the activity.

ITALY
N.A.

LATVIA
There was no public reaction received in response to information made publicly available under Directive 2009/41/EC during the reporting period.

LITHUANIA
No specific reactions were received.

MALTA
None.

NETHERLANDS
Both cases mentioned above, the response asked for a total ban on GMO's.

POLAND
During the reporting period, there was no public reaction in response to consultations.

PORTUGAL
-

ROMANIA
Not applicable.

SLOVAKIA
-

SLOVENIA
Only one public hearing/consultation was organised in the processing of the gene therapy notification. Discussion proved to be on a very high expert level and no objections were filed.

SPAIN
No comments were received.

SWEDEN
To our knowledge there have been no public reactions during the reporting period.

UNITED KINGDOM
a) Overall users were content with the proposed changes to the GMO (CU) Regulations in the consultations mentioned in 7.1(a). The summary of responses to the GB consultation and the HSE response are captured on the HSE website (http://www.hse.gov.uk/consult/condocs/cd263.htm). on the HSE website. A summary of the NI consultation responses and HSENI's response will be published in due course.

8. Waste disposal

8.1 What are the means by which GM waste is inactivated and disposed of with particular reference to large volumes of waste material - (including large or large quantities of GM plants and/or GM animals, in particular where those plants and animals have been inoculated with GMMs)?

AUSTRIA

Waste from facilities using GMM must be treated as appropriate to the risk class in order to limit their contact with the general population and the environment and to prevent their replication in the environment. GMM of class 2-4 which are capable of replication under environmental conditions must be inactivated. Animals which have been inoculated with GMM in a non-survival project must be killed by an approved humane method and disposed of by incineration.

BELGIUM

In the Belgian Regional decrees implementing Directive 2009/41/EC, there is an explicit legal requirement to inactivate all types of GMOs - even of risk class 1 - by appropriate and validated means prior to disposal as waste. Inactivation can either be done on site, either after transport in biohazard containers to a waste processing company.

In each region, these requirements are completed by specific regulations on waste originating from medical care and dangerous waste in general, including waste from animal experiments, imposing rules for storage, for incineration and for collection by an certified or accredited company.

Steam sterilisation (autoclaving of solid waste) or chemical inactivation (fluids) is the predominant means of inactivation of large volumes of GM waste material in situ. Taking into account the broadened scope of the contained use legislation toward the intentional use of pathogenic organisms, waste streams are not limited to GM waste. This explains why other means, like high temperature and high pressure alkaline hydrolysis of animal carcasses, are evaluated on a case-by-case basis and are subject to validation.

Smaller amounts of waste material originating from contained use facilities are often treated by steam sterilisation, chemical inactivation or are collected by specialised companies for incineration of hazardous waste in authorised waste-processing firms.

A new type of autoclave has been presented by to the SBB. It is a combined system for treatment of infectious waste in which the waste is crunched, as well as autoclaved. The crushing reduces the waste to pieces of 8mm and diminishes the waste volume of 80%. Afterwards, the crunched waste is autoclaved during 20min at 135°C.

Regarding waste management, the Brussels-Capital region notes that it is very complex to apply simultaneously the different existing legislations on animal waste, health care waste and dangerous waste.

BULGARIA

All kind of waste must be inactivated and disposed in appropriate manner. The manner of inactivation and disposal is described in notification for approval of the facility as information for waste management and processing.

During the approval process is ensured that the relevant European and national requirements are strictly followed. All approved facilities are part of academic institutions and only small to moderate amounts of waste are produced at any given time. The inactivation takes place on the premises and is done by autoclaving of the waste. Inactivated waste is disposed following the general requirements for such material.

CROATIA

GMM materials waste treated: autoclaves/chemical inactivation, incinerators. Big question is a quantity of volume of waste (it is different from plant, GMM or and animal).

CYPRUS

There were no large volumes of waste material. For the inactivation of the GM waste, chemical disinfection and autoclave were used. For the final disposal inactivated GM waste was transferred to a facility authorised for treatment of clinical waste.

CZECH REPUBLIC

GMMs are inactivated and disposed of in the same way and by the same means as infectious waste containing pathogenic microorganisms (by chemical disinfectants, autoclaving etc.).

Likewise, GM laboratory animals and animals inoculated with GMMs are disposed of as other infectious animals.

GM plants are either autoclaved or in large volumes chopped, the seeds ground and the resulting material composted.

DENMARK

For class 1 the treatment of the waste is based on the risk assessment in each specific case. For class 2 the waste has to be inactivated with validated methods before final discharge. For class 3 the waste has to be inactivated before final discharge with validated chemical or physical methods. For class 4 only a validated physical inactivation is sufficient.

ESTONIA

There aren’t large quantities GM plants or GM animals activities in Estonia. All activities with GM animals are in the laboratories and they are in contained use. All waste will inactivate according good laboratory practise and safety rules. Waste will inactivated as dangerous waste.

FINLAND

For GM micro-organisms autoclaving or chemical inactivation (disinfectants chosen according to the organism). GM-vertebrates are first terminated with the appropriate method (depending on the species) and then frozen and incinerated or buried (burial not accepted if the animals were inoculated with pathogenic GMMs). *Cenorhabditis elegans* and *Drosophila* are usually autoclaved.

Most GM-plants are autoclaved, but there is a list of recommended methods for different species and their tissues, depending on whether the specific plant tissue is capable of reproduction. GM-plants inoculated with pathogenic GMMs must be autoclaved.

FRANCE

Process for inactivation: Chemical, thermal**.**

GERMANY

Waste disposal is carried out according to § 13 GenTSV (Genetic Engineering Safety Regulations); usually the waste is autoclaved for 20 min at 121 °C or 134 °C. There are two genetic engineering facilities in Germany where large animals can be disposed of with the help of a digestor (alkaline lysis).

HUNGARY

Waste from biotechnological activities (both hazardous and non-hazardous) is treated under the national legislation concerning hazardous waste.

IRELAND

The CA stipulates in consent conditions issued to the GMO user that all waste must be inactivated by validated means. In the event that the user does not have an autoclave on site[5], the CA may agree to the user sending the waste off site for inactivation and disposal – however, this only applies to waste arising from Class 1 GMM activities.

Waste arising from Class 2/3 or 4 GMM activities must be inactivated on site using validated procedures (autoclaving or chemical inactivation in the case of liquid waste). The only exception to this would be where GM and/or non-GM animals have been inoculated with Class 1 or Class 2 GMMs. In this instance the animal remains are transported off site to waste treatment facilities authorised for the inactivation of Class 1/2 GMMs, under the national legislation implementing Directive 2009/41/EC. The inactivation of large animals (where heat penetration in a laboratory sized autoclave would not be feasible) inoculated with Class 1/2 GMMs, or any sized animal inoculated with Class 3/4 GMMs, has not arisen to date and such a decision would be made on a case-by-case basis.

GM Plant waste is inactivated by autoclaving or off-site incineration.

[5] On the site of the GMO/GMM installation

ITALY

Basically, two methods are in use: thermal inactivation, by using dedicated equipment for biological waste sterilization (e.g. overkill thermal cycle with temperature > 121 ° C); chemical inactivation, by using sodium hypochlorite and/or soda.

After the inactivation, for their disposal, wastes are transferred to firms authorized in compliance with the Italian Legislative Decree n.152/2006 (ref. chapter IV).

LATVIA

All bacterial and plant material including petri dishes, liquid growth media, disposable plastic ware, plant material and soil are sterilized by autoclaving. Thereafter the waste is disposed as regular municipal waste.

LITHUANIA

According to the Order on Regulation on Contained Use of Genetically Modified Microorganisms, the notifier has to provide information concerning the waste management, including the amount and type of waste, the methods of inactivation and the final form of the waste and destination. In all cases, all types of GMMs had to be inactivated prior to disposal.

Waste was mainly inactivated through thermal (autoclaving) or chemical means (e.g. sodium hypochlorite). In case of GM-vertebrates, their remains were transported to waste treatment facility for inactivation under the EU and national legislation.

MALTA

The only permitted Class 1 facility inactivates the small volume of waste it generates through autoclaving.

NETHERLANDS

A Ministerial Decision provides that all waste has to be inactivated by validated means. Waste storage must comply with the rules as laid down in an annex to the Ministerial Order. In general waste disposal and inactivation was performed in-house. If this was not possible, the waste had to be transported to dedicated waste facilities.

POLAND

The notifier must provide information about the foreseen quantity of aerosols and contaminated sewages resulting from the contained use activity. Information about storage and inactivation methods must be provided. All waste must be inactivated prior to disposal if it is not guaranteed that no harmful effects will occur otherwise. In case of class 3 and 4 activities, the water from sinks, showers, glass houses and animal houses must be inactivated as well.

PORTUGAL

In all cases, including activities at risk class 1 and 2, effluents, residues and wastes must be inactivated prior to disposal-autoclave.

ROMANIA

In national legislation, Emergency Government Ordinance 44/2007 as amended by Law NO 3/ 2008, regulates the necessary measures on waste management:

- Inactivation of genetically modified micro-organisms from materials and hazardous waste is optional for the contained use class 1 and binding for the contained use of classes 2, 3 and 4.
- Inactivation of genetically modified micro-organisms in effluent from hand washing sinks or drains, showers and similar effluents is not necessary for the contained use classes 1 and 2, is optional for contained use Class 3 and binding for the contained use of class 4.
-

These requirements are completed by regulations on waste from medical activities that require specific rules.

SLOVAKIA

As for the risk class 1, inactivation of GMOs is optional. There is required a minimal inactivation by a disinfectant solution of an adequate concentration and duration of action. In the risk class 2 - 4, there is required a sterilization at temperature 120 °C during 30 minutes. GM plants are being liquidated by crushing and ploughing on the land or by sterilization and GM animals by the killing in the installations for the contained use, moving into PVC covers, depositing in the fridge for cadavers and then they are transported to the incinerator.

Transport of GMOs is realized according to the European Treaty on International Road Transport of Dangerous Goods (ADR) and the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID). In case, the applicant of genetic technologies and genetically modified organisms is producing more than 10 tons of hazardous waste a year or 100 tons of other waste, he is obliged to work out a plan on the origin of waste according to the Act No. 223/2001 Coll. on the waste, as amended. If the applicant disposes more than 100 kg of the hazardous waste a year, or if the carrier transports annually more than 100 kg of hazardous waste, the consent for the management of hazardous waste including its transport is needed.

Waste management plan involves the collection, transport, assessment and liquidating of waste including supervising these activities and following care about the places, where the liquidation was carried out. The liquidation of waste is carried out in the special installation

SLOVENIA

In all cases special attention is given to the waste treatment. In the risk assessment, notifiers must elaborate a detailed plan for waste treatment, inactivation procedures and final disposal

of the wastes and waste waters in concord with *Regulation of risk assessment of work with genetically modified organisms in contained use* (OJ RS 45/2004) and *Decree of waste management* (OJ RS 34/2008 and 103/2011).

The waste disposal mode must be included in the risk assessment and is taken into consideration by the Scientific Committee before the premises for contained use of GMOs are registered or approval for work with GMOs in the contained system is issued. For the time being the biggest volume of biosafety class 1 GMMs is limited to semi-industrial reactors of 1000 l.

SPAIN

The waste material is treated and eliminated following the legal requirements for each type of waste. Usually autoclaves and chemical treatments are used for GMMs and incineration for GM plants and animals.

In Spain we follow the provisions according to Directive 2009/41/EC, so it means that, for laboratory activities the inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents was not required for containment levels 1 and 2, it was optional for level 3 and obligatory for level 4; however, for laboratory activities the inactivation of GMMs in contaminated material and waste was optional for level 1 and obligatory for levels 2, 3 and 4. Nevertheless, the CNB always recommends the inactivation of all GMOs in the cases of *'not required or optional'*.

Generally, there are waste treatment certified companies which collect the waste after the treatment is carrying out.

SWEDEN

In many cases the waste is autoclaved within the premises for contained use of GMM. Waste from contained use at BSL 1 and BSL 2 are sometimes sent to incineration plants. Dead monkeys with GMM from contained use BSL 3 are autoclaved to become sterilized on the surface. They are then sent to incineration plants in locked containers. Dead mice and rats with GMM from BSL 1 and 2 activities are frozen and transported to incineration plants.

Waste from GM plants, including soil, pots etc. are usually autoclaved. Premises with large volumes of waste gather this in a container, special for this purpose, that is send for incineration. The same container is brought back to the premises where it is kept in a locked area**.**

UNITED KINGDOM

a) The Regulations transpose the requirements of the directive in respect of GM waste. Contained uses will generate contaminated waste, which must be inactivated by a validated means at class 2, 3 and 4. Inactivation at class 1 is only not required where the following criteria are met:

   (i) do not have the potential to cause harm to human health or the environment;

(ii) Must be biologically contained (e.g. possess multiple disabling mutations or restrictive nutrient requirements that cannot be met outside the laboratory);

(iii) do not have the capacity to establish and multiply in the environment; and

(iv) Do not have capacity to transfer genetic material to other micro-organisms (e.g. non-mobilisable plasmid).

b) The risk assessment should conclude whether inactivation of waste at class 1 is required and the methods for achieving this. For the purposes of the Regulations, any of the following methods, i.e. disinfection, off-site treatment (e.g. autoclave, incinerator) or autoclave may be considered to be validated means and comply with the Regulations. This is provided appropriate steps are taken to confirm the efficacy of the method, the appropriate control measures are put in place for the safe transport and storage of the waste material and the process is completed in a safe manner. The level of compliance forms an important part of HSE's inspection programme of notified premises.

c) Autoclaving remains the most popular choice of method of inactivation. However, there has been an increase in the number of commercial waste disposal companies inactivating GM waste e.g. incinerators at GM registered sites deal with waste containing GMMs. These are primarily used for class 1 waste, for example, in animal bedding or clinical waste from gene therapy trials.

8.2 Are there waste treatment facilities in your Member State which are authorised to inactivate waste arising from GM installations and for what classes of activity? How is the transfer of waste from the GM installation to the authorised waste facility arranged/organised?

AUSTRIA

In Vienna there is one waste treatment facility that has submitted a notification for Class 1-GMOs in order to carry out the inactivation of GMO waste delivered by installations.

It is mandatory to inactivate solid and liquid waste from class 2 contained uses inside the installation.

BELGIUM

Biologically contaminated waste originating from contained use activities, which is not inactivated in situ, is collected for incineration in installations that are authorised for treatment of hazardous waste (authorised in an environmental permit). Both the specialised transport companies (certified for collection of hazardous waste) and the waste-processing firms have to comply with regional regulations regarding waste treatment, imposing rules for collection and storage prior to incineration. Transport of waste material follows the UN recommendations of dangerous goods.

In the Flemish region, an initiative aiming at authorising (in the environmental permit) installations for steam sterilisation operating at large scale may provide an alternative treatment method for infectious waste including GM waste originating from research facilities. According to the provisions of VLAREA (Vlaams Reglement voor Afvalvoorkoming en –beheer), infectious waste mainly consists of medical waste presenting a risk of infection. This initiative, which aims at reducing transport logistics costs of infectious waste intended for incineration, necessitates a revision of the Flemish waste regulations in order to create a regulatory framework for inactivation of infectious waste by wet heat sterilisation. Cost, benefit and environmental considerations will determine whether this alternative treatment method of infectious material will be preferred above incineration as hazardous waste.

BULGARIA

There are no waste treatment facilities in Bulgaria which are specifically authorised to inactivate waste arising from GM installations. There are installations authorised for treatment of hospital and other bio hazardous waste that can be used for treatment and disposal of GM material should a necessity arise. Inactivation of all GM waste is done by autoclaving on the premises of the approved facilities.

CROATIA

In Croatia GM waste is inactivated in autoclave or with chemicals (chemical inactivation). Inactivated waste GM materials are transported by authorising company for that kind of waste.

CYPRUS

There are no waste treatment facilities in Cyprus authorised to inactivate waste arising from GM installations.

CZECH REPUBLIC

There are no special waste facilities for material from GM installations. GMMs are inactivated at the premises where they have been used and the resulting waste is treated together with other hazardous waste from the premises (laboratories, hospitals etc.).

DENMARK

No, there are no authorised waste treatment facilities in Denmark. The companies take care of their GM waste themselves.

ESTONIA

There aren't specific inactivating GMO waste installations in Estonia. Every laboratory has its own equipment and rules for this. If the waste will send outside from laboratory, the waste is inactivated already.

FINLAND

Most of the GMO operators inactivate their GMO-waste themselves. However, there is one waste treatment facility, Ekokem, which has a long experience of GM-waste inactivation and treats class 1-2 GMO waste. For transferring the GMO waste to the Ekokem facility, the operators use the services of waste transport companies. Well-sealed and marked containers are required for transportation.

The Board for Gene Technology does not give separate authorisation to the problem waste facilities.

FRANCE

Yes for the containment levels 1, 2 and 3. The transfer of waste from the initial GM installation to the authorised waste facilities if the contained level is not broken. For the level 4 the waste was inactivated on site.

GERMANY

Two waste treatment facilities authorised to deal with waste arising from level 1genetic engineering facilities.

Two genetic engineering facilities carrying out biosafety level 2 genetic engineering work, which carry out only waste inactivation (the facilities are operated by universities and are used primarily for the autoclaving of safety post filters. The facilities consist of one or two high-volume pass-through autoclaves and the antechambers required as a 'black area').

Waste containing GMOs is transported in-house in closed and labelled containers protected from breakage in accordance with German genetic engineering law or, when transported on public roads outside the scope of the Genetic Engineering Act, in accordance with the provisions governing the transport of dangerous goods (GGVSEB).

HUNGARY

Some waste treatment facilities in Hungary are authorized to pursue such activities; however, they are not specialized solely to the treatment of waste arising from GM installations. The activity of inactivating waste arising from GM installations falls under a separate registration procedure. The transfer from the installation to the waste treatment facility can only be commenced possessing an authorization, under controlled conditions and specifying the route of transfer

IRELAND

Presently, there are two facilities in Ireland authorised to inactivate waste containing GMMs. One facility is authorised to accept waste containing Class 1 GMMs only, while the second facility is authorised to accept waste containing Class 1 and/or Class 2 GMMs. While the CA advises that the inactivation of Class 2 GMMs should take place on site, it is not always feasible to decontaminate GM or non-GM animal remains inoculated with GMMs in laboratory sized autoclaves (owing perhaps to large animal size).

In these instances, the animal remains are transported to the decontamination facility in accordance with the waste treatment facility's own procedures. Usually this entails that once killed, the animal remains are bagged, stored frozen while awaiting collection, transported frozen in refrigerated vans and cremated from frozen. GMM waste other than GMM inoculated animal remains is transported off site in sealed containers. Transportation is arranged by the waste treatment company.

ITALY

Inactivation is always done within GM installations and Italian CA has not authorised any waste treatment facility to inactivate waste arising from GM installations.

LATVIA

No.

LITHUANIA

There is facility authorized under the EU and national legislation to handle veterinary and environmental waste including GM-vertebrates. Transportation was arranged by the waste treatment company. There were no cases of contained use of GMMs or GMOs of class 2-4.

MALTA

Class 1 waste is disposed of in a landfill and is carried to the facility by licensed waste carriers.

NETHERLANDS

In the Netherlands there is one facility authorised for destruction of GMO-waste.

POLAND

In Poland there are not special waste treatment facilities authorised to inactivate waste arising from GM installations. The proceedings of hazardous waste are regulated by the Act on Waste from 2012.

PORTUGAL

There are several companies dedicated to inactivate biological waste, who operate mainly with hospital contaminated residues, and also with GM biological waste. Usually, the waste treatment company supplies proper collectors to the GM installation and, depending on the quantities of waste produced collects the waste and inactivates it in their facilities.

ROMANIA

Emergency Government Ordinance No 44/2007 as amended by Law No 3/ 2008, requires users of contained use of genetically modified micro-organisms, the endowment with equipment of autoclaving for the waste inactivation from such activities.

SLOVAKIA

In our Member state we have specialized facilities for processing organic waste. In the first place, before the transfer, the carrier is obligate to inactivate the waste arising from GM installations at the place and after it is possible to transport waste to a specialized facility. The transfer of waste from the GM installation to the authorised waste facility is organised according to the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Treaty on International Road Transport of Dangerous Goods (ADR).

SLOVENIA

Several waste incineration facilities are registered in Slovenia and often used by the notifiers for GMO final waste disposal. The notifiers make contracts for transport and destruction of GMO waste with the entitled companies.

SPAIN

Yes, the transfer of waste from the GM installation to the authorised waste facilities is arranged by the users. These treatment facilities are authorised by the Spanish Regional

Competent Authorities for the waste inactivation. They collect the waste which is conducted to their own facility where is inactivated by thermal, chemical or incineration methods.

SWEDEN

Incineration plants that incinerates waste with active GMM must notify their activity to us. Waste containing GMM from class 1 and class 2 activities can be sent to incineration in containers marked as waste class 9 or 6.2 according to the international transport regulations (ADR). The company that transports the waste and the incineration plant must be informed about the content of GMM.

Incineration facilities that accept waste from GM plants do not need any specific authorization.

UNITED KINGDOM

a) In Northern Ireland, all waste is treated at the site of origin, either by chemical means and/or autoclave. Inactivated waste then goes to land fill. There is no large scale production of GM waste in Northern Ireland.

b) There are currently 12 registered sites authorised to inactivate waste containing GMMs. Of these four are permitted to inactivate class 1 waste and eight are permitted to inactivate class 2 waste.

c) It is the waste producer's responsibility, in all cases, to ensure that the waste is inactivated or correctly packaged in approved containers and labelled appropriately. The waste producer completes a consignment note confirming the waste type and any specific precautions that need to be taken, sending a copy with the waste and retaining a copy for their records. This should all be verified before the driver removes the waste from site.

d) All drivers are required to have the appropriate level of training, which includes the transport of dangerous goods, the correct use of personal protective equipment and an appreciation of standard operating procedures, local rules and risk assessments. Additionally, drivers are trained in the use of waste spillage kits, which contain a surface disinfectant and are located in vehicles.

e) On arrival at the plant, the driver informs the plant manager that GM waste has been delivered, hands over the consignment note for verification and it is then passed back to the waste producer to confirm that the waste has been processed.

9. Other issues

Please provide comments on any other aspects of the Directive or on other related legislation.

AUSTRIA

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BELGIUM

No other issues.

BULGARIA

It is not entirely clear how the provisions of Directive 2009/41/EC will be applied together with the provisions of the proposed Regulation on clinical trials on medicinal products for human use.

If the contained use of GMO remains within the scope of the proposed Regulation on official controls, this may require changes in implementation of Directive 2009/41/EC on national level, with respect to competent control authorities in particular.

CROATIA

Croatia suggests:

a) In article 18 of the preamble to Directive 2009/41/EC word "CONSULT" to change in word "REPORT"

b) According to the article 23 of the preamble to Directive 2009/41/EC suggest EU Commission to establish a Register of accidents causing by GMMs. This information will be more applicable

During official control we noticed is necessary to uniform ordinance of the Annex of Directive 2009/41/EC with ordinance of Directive 2000/54/EC on the protection of workers related to exposure to biological agents.

CYPRUS

No other comment.

CZECH REPUBLIC

With the development of molecular biology and synthetic biology, questions are likely to emerge whether specific sub-cellular elements (modified or synthesized) fall under the definition of "micro-organism" or not.

DENMARK

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ESTONIA
None.

FINLAND
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FRANCE
Without comments.

GERMANY
This point is currently under discussion between the Federal and Land authorities; the results of these discussions are likely to be included in the next report.

HUNGARY
It would be a great help for us if an EU-level register would be established. This should not necessarily be a public register but an information source for Competent Authorities who could register the basic information (including the name of applicant, the general characteristics of the GMMs, protective measures to be taken, Article 18 (2) (c) issues, etc.) regarding the notification they have received. In this way, Member States could consult and cooperate more closely if there are similar facilities/activities or emerging questions. It would also speed up the preparation of the 3-year national reports.

IRELAND
None.

ITALY
Nothing to report.

LATVIA
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LITHUANIA
The information is provided in the item 4.2.

MALTA

No comment.

NETHERLANDS

No other comment.

POLAND

No comment.

PORTUGAL

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ROMANIA

Romania considers that it is necessary to clarify the scopes of Directive 2009/41/EC and Directive 2001/18/EC concerning clinical trials.

SLOVAKIA

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SLOVENIA

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SPAIN

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SWEDEN

Today we have a lot of experience of contained use of GMMs in science and technology. In most cases, there are no problems with GMMs for the environment or the human health. Gene technology is not by itself harmful. It can be used for illegal purposes, but this is not the scope of the legislation for contained use of GMM. Our view is that there is no reason to treat risks posed by GMMs differently than for microorganisms that have not been genetically modified.

The directives 2009/41/EC and 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work gives parallel legislations for contained use of GMM in the EU member countries. We think that the two directives can be merged to an efficient legislation that takes into account risks to the environment as well as the work environment. In our view, there is no need for special legislation for GMMs, except the demand to keep them contained if they have not been approved for deliberate release.

UNITED KINGDOM

a) Whilst recognizing that the opinion of the expert committees (SCHER, SCENIHR and SCCS) on a working definition of synthetic biology, has only recently been published, the EC should develop its position on the emerging topic of synthetic biology in relation to Directive 2009/41/EC, in a timely manner, to avoid individual Member States having to introduce separate and disparate legislation on this topic.

b) The EC should consider the need for a meeting of the Competent Authority of Member States for contained use. The Competent Authority has not met during the period of this report.

c) The EC should consider how best to use and share the information provided as part of the statutory reporting under the Directive (e.g. annual reports of class 3 and 4 contained uses) to inform development of policy and guidance.

d) The EC should consider whether the purpose of Annex II, Part C of the Directive is delivering its intended purpose, given that this annex has yet to be populated. The US National Institute for Health '*Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*'[6], specifically Section III-F-8 Appendix C, provides an example that may be useful in considering this matter.

[6] *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf

2. COMPETENT AUTHORITIES

AUSTRIA
Competent Authority Federal Ministry of Health

BELGIUM
Competent Authority[7] Biosafety and Biotechnology Unit (SBB), Technical expert for the regional authorities

BULGARIA
Competent Authority Ministry of Environment and Water

CROATIA
Competent Authority Ministry of Science, Education and Sports and Ministry of Health

CYPRUS
Competent Authority Department of Labour Inspection

CZECH REPUBLIC
Competent Authority Ministry of the Environment of the Czech Republic

DENMARK
Competent Authority Danish Working Environment Authority (WEA) and The Danish Environmental Protection Agency (EPA)

ESTONIA
Competent Authority LABOUR INSPECTORATE OF ESTONIA

FINLAND
Competent Authority The Board for Gene Technology

[7] art. 12, §2, 4° of the Cooperation Agreement between the Federal state and the Regions on the administrative and scientific co-ordination concerning Biosafety of 25 April 1997: "the SBB ensures the obligations relating to the exchange and the transmission of information and the reports imposed by the European regulations relating to the contained use of genetically modified micro-organisms…"

FRANCE
Competent Authority Ministère de l'Education Nationale, de l'Enseignement Supérieur et de la Recherche. Direction Générale de la Recherche et de l'Innovation

GERMANY
Competent Authority Coordinating Competent Authority: Federal Office of Consumer Protection and Food Safety (BVL)

HUNGARY
Competent Authority Ministry of Agriculture, Hungary

IRELAND
Competent Authority Environmental Protection Agency Ireland

ITALY
Competent Authority Ministry of Health

LATVIA
Competent Authority Ministry of Agriculture

LITHUANIA
Competent Authority The Ministry of Environment of Lithuania

MALTA
Competent Authority Malta Environment and Resources Authority

NETHERLANDS
Competent Authority Ministry of Infrastructure and the Environment

POLAND
Competent Authority Ministry of the Environment,

PORTUGAL
Competent Authority Portuguese Environment Agency

ROMANIA
Competent Authority NATIONAL ENVIRONMENTAL PROTECTION AGENCY (NEPA)

SLOVAKIA
Competent Authority The Ministry of the Environment of The Slovak Republic

SLOVENIA
Competent Authority REPUBLIC OF SLOVENIA MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING (MESP)

SPAIN
Competent Authority National Commission on Biosafety (CNB) and Interministerial Commission on GMOs (CIOMG), Ministry of Agriculture, Food and Environment

SWEDEN
Competent Authority Swedish Work Environment Authority

UNITED KINGDOM
Competent Authority Health and Safety Executive Great Britain (GB) and Northern Ireland (NI)