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COMMISSION STAFF WORKING DOCUMENT

Details from individual Member States on their experience with Directive 2009/41/EC of the European Parliament and of the Council of May 2009 on the contained use of genetical modified micro-organisms (recast) for the period 2006 - 2009

Accompanying the document

COMMISSION WORKING DOCUMENT

Report on the experience of Member States with Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2006 – 2009

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COMMISSION STAFF WORKING DOCUMENT

Details from individual Member States on their experience with Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2006 – 2009

Annexes

1. ANNEX I – DETAILS FROM INDIVIDUAL MEMBER STATE THREE-YEAR REPORTS

1.1. An overview of activities and installations

Austria

During the reporting period the two competent authorities, the Ministry of Health or the Ministry of Science and Research, acknowledged or authorised a total of 491 activities involving genetically modified microorganisms and other genetically modified organisms. In 129 cases these were first-time activities in genetic engineering facilities.

Belgium

Since 1993, Belgium has fully implemented the Directive on the contained use of genetically modified microorganisms (at that time: Directive 90/219/EEC) in three regional decrees thereby. This means that, among the 750 notifications, 270 of them exclusively concerned non-GM pathogens and 310 notifications concerned GMMs and/or GMOs only. The rest of 130 notifications concerned contained uses of both GMMs/GMOs and non-GM pathogens. 381 notifications of GMM and 117 notifications of GMM/GMO combined were registered for the reporting period.

From 2006 to 2009, the subsequent use notifications represented 59% which is a high increase compared to the previous 3 year reporting period, when they represented only 31% of the total number. Since 2002, the Walloon decree of 04/07/2002 regarding the contained use of GMOs and/or pathogens did not distinguish anymore between first and subsequent contained uses. In consequence, all notifications for this region were treated as new activities (or first contained uses).

With respect to the type of exploitations, the large majority of GMMs were used for fundamental research by university research laboratories (70%). GMMs were handled in pharmaceutical companies (20%) for research purposes or production of enzymes, vaccines and therapeutic molecules. Rarely, GMMs were also used for teaching (2%) and diagnostics (5%).

Bulgaria

During the reporting period 2006-2009 neither installations nor activities involving the contained use of GMM were approved in Bulgaria.

Czech Republic

Most institutions that had intended to use GMMs submitted their notifications during the previous reporting period 2003 – 2006. Therefore, the number of new subjects starting to use GMMs in the period 2006 – 2009 was comparatively small. Prevailing notifications concerned new activities with GMMs in previously notified premises and in consequence mostly amendments to earlier notifications were submitted. The purpose of the 60 notified GMM activities was almost entirely research and education.

During the reporting period, the competent authority from Czech Republic authorised 68 installations for research purposes, 8 for commercial uses and 9 for another purposes like laboratories for detection, transport and storage. In this context 46 activities were approved for Class 1 and 39 for Class 2.

Cyprus

During the reporting period 2006-2009 no activities involving the contained use of GMM were identified in Cyprus. No installations were notified.

Denmark

During the reporting period 694 installations for research and 63 installations for commercial purpose were approved. 664 activities were classified as Class 1, 115 as Class 2 and 165 comprised GMO.

Estonia

During the reporting period 2006-2009 no activities involving the contained use of GMMs were identified in Estonia. No installations were notified.

Finland

During the reporting period 123 notifications of GMMs, GM animals and GM plants were submitted, of which 115 were in respect of GMMs. Most notifications concerned class 1 and class 2 contained use activities; one notification included the use of Class 3 GMMs.

A further 6 notifications involved both GMM and GM plants while 2 involved GMM and GM animals. 90 installations for research purposes, 13 installations for commercial use and 5 installations for other purposes have been notified over the period covered by this report.

France

During the reporting period 1167 activities were approved as follows: 919 installations for research, 20 for commercial purposes and 228 for gene therapy for GMM and GMO under contained use framework. The number of activities approved under each class was not provided. Compared to the previous reporting period 2003 - 2005, the overall number of notifications increased by 151.

Germany

In Germany 5408 installations for research and 129 for commercial purposes were notified. The majority of activities concerned class 1 and 2 uses, with some notifications for class 3 uses and 3 for class 4 uses. In terms of activities correlated with the above mentioned installations, 5813 activities were approved which belong to Class 1, 4722 to Class 2, 252 to Class 3, and 3 activities to Class 4.

1939 notifications were received (746 from Class 1, 1146 from Class 2,46 from Class 3 and 2 from Class 4).The number of notifications had decreased as during the previous report period there were 2434 notifications. 28 notifications involved GMM in combination with GMO (10 for GM plants and 18 for GM animals), all of them concerning class 2 uses.

Hungary

Compared to the previous period, when eight installations for the contained use of Class 1 GMMs and GMOs were authorised for research purposes and one authorisation was issued for the contained use of a Class 1 GMM for commercial purposes, there was an increase in applications for contained use as a result of growing research activities. 20 installations were approved for research and 2 for commercial purpose. During the reporting period, the number of class 1 activities approved increased from 1 to 13 and Class 2 activities emerged at 10 notifications approved.

Ireland

During the reporting period 73 notifications for GMM were approved. 12 installations for research purposes and 7 installations for commercial uses were notified over the period covered by this report. In terms of operations, 43 activities were notified for class 1, 30 activities for Class 2, and 36 activities involved GMO.

Latvia

No notifications for the contained use of the GMM were received by the competent authority during the reporting period.

Lithuania

Two notifications relating to class 1 activities were submitted to the Ministry of Environment during the reporting period. The activities were for research purposes.

Luxembourg

Two notifications relating to class 1 activities were reported during the reporting period. One notification was for GMM and GM plants.

Malta

No notifications for the contained use of the GMM were received by the competent authority during the reporting period.

Netherlands

In the Netherlands, during the reporting period 195 institutes and companies were actively involved in contained use activities with genetically modified organisms. 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 GMOs, i.e. not exclusively with GMMs. 33 new installations were forwarded notifications. In total 413 notifications and 2033 amendments on earlier notifications were received during the 2006-2009 period. In general more than one containment level was prescribed per notification.

Poland

In Poland, 54 notifications for GMM were submitted. In comparison with the previous reporting period, the number of installations and contained use activities increased. 47 activities were classified as class 1, 6 as class 2, and 1 as class 3. The majority of these activities took place in universities or research institutions.

5 installations were approved, all for research and development purposes.

Portugal

One installation for research comprising two activities for the contained use of Class 1 and Class 2 GMM were notified and approved in Portugal during the reporting period 2006-2009. One activity was classified as Class 1 while the other was classified as Class 2. Four activities were approved for GMO.

Romania

During the reporting period 2006-2009 no activities involving the contained use of GMM were identified in Romania. No installations were notified.

Slovakia

In Slovakia 42 notifications relating to Class 1 activities, 10 notifications for Class 2 as well as an overall of 52 activities for GMO were approved during the reporting period. 49 installations for research purpose and 3 installations for commercial use were authorised.

Slovenia

In Slovenia 41 installations were approved for research activities and 17 installations for commercial purpose, and one installation for educational purpose. 45 activities

were notified and approved, 41 being assigned to Class 1 with the remainder in Class 2.

Spain

Spain approved 21 notifications, all of them belonging to class 1 and 2.

During the reporting period 2006-2009, 50 installations were notified for the contained use of GMMs and/or GMOs in Spain. Thirty five research and development related activities were notified and fifteen for commercial purpose. Under the scope of the Spanish law on GMOs, all kind of genetically modified organisms were included for contained use purposes as well. Thus, during the reporting period Spain has received 15 notifications of GM plants (all of them class 1) and 9 notifications of GM animals, and 26 notifications of GMM and in combination with another GMOs.

Sweden

In Sweden approximately 530 involving the contained use of GMMs activities were notified and carried out by 93 users. Two thirds of the users that had notified a GMM activity were limited companies, having a small number of GMM activities. The majority of GMM activities were registered at universities, institutes of technology and other governmental research establishments. All GMM activities at containment levels 3 and 4 were at research establishments.
During the reporting period, the Swedish Work Environment Authority approved for the first time a GMM activity at containment level 4. In addition, there were 16 approvals in effect for GMM activity at containment level 3. Approvals were normally granted for three years, and sometimes for five years. Those GMMs notified for the higher containment levels involve viruses, bacteria, prions and human internal parasites.
There are 357 GMM activities notified at containment level 1 in Sweden. At containment level 2, 154 GMM activities were notified, involving a total of 540 different uses. The GMMs that occur most frequently in the uses notified at protection level 2 were virus and cell cultures, followed by various human pathogenic bacteria.

There were in total eight GMM activities with contained use of GMMs in or on plants. Four users notified activities of this type. Three of these were undertaken at containment level 2, and the remainder at level 1.
A total of 52 activities with contained use of GMMs in or on animals were notified by fifteen users. A number of these were in the same animal cage installation, but those responsible for the activity were based in different parts of the organisations. Three of the animal activities were at containment level 3, fifteen at containment level 1, and the rest at level 2.

3 new installations for the contained use of plants and 7 new installations for the contained use of animals were notified during the reporting period.

The Swedish Board of Agriculture decided on extended approvals in 47 cases at 15 different installations involving genetically modified animals. Three installations had

approvals from the Swedish Board of Fisheries for contained use of genetically modified fish. All of these cases related to zebra fish. In one of the installations there was also contained use of GMMs.

United Kingdom

Great Britain received 496 notifications mainly covering class 1 and 2. 42 notifications belonged to class 3, and 4 notifications to class 4. Northern Ireland has received 14 notifications for GMMs, all belonging to class 1 and class 2.

From 496 notifications, 355 were for research purposes and 141 for commercial purposes. Information for the 14 Northern Ireland notifications were not recorded in a way that made it possible to provide this information.

Regarding the installations, there were 746 approved premises (65% for research, 30% for commercial purpose).

The number following numbers of activities were approved: 1193 for class 2, 135 for class 3 and 10 for class 4.

During the reporting period, 5 notifications for GMM. In Great Britain, activities involving GM animals or plants are only notifiable under the Genetically Modified Organisms (Contained Use) Regulations if the activity involves an increased risk to human health compared to the unmodified animal/plant. Consequently, there are very few notifications for this type of work. However, the requirement still applies to notify the Competent Authority of the intention to work with any GMO at premises.

1.2. Notification and approval system (and relevant changes)

Austria

The Ministry of Science and Research received notifications or applications for authorisation for activities involving GMOs carried out in university science faculties or federal scientific institutions under the Minister for Science and Research; notifications or applications for authorisation for all other activities involving GMOs were submitted to the Ministry of Health.

There were no relevant changes with regard to administrative practice since the last report in 2006. The operator of each genetic engineering facility must appoint a person responsible for biological safety and establish a Biological Safety Committee, with members which were not bound by the operator's instructions in carrying out their tasks. For all activities involving GMOs at Level 2 and above, the operator had to appoint a project leader, who is responsible for planning, directing and supervising activity involving GMOs.

Before beginning an activity involving GMOs, the operator had to classify it and determine the safety measures required, taking into account the risks associated with such activity. The biological safety committee had the task of reviewing the operator's safety classification and proposed safety measures, and publicising them internally if it agreed he or she agreed with them. The operator had to notify

activities involving GMOs to one of the two competent authorities or apply for authorisation.

Belgium

The regulatory framework concerning the contained use of GMMs is implemented and enforced in Belgium at the regional level. A Cooperation agreement concerning biosafety was set up to ensure the transposition and practical implementation of the Directive 2009/41/EC in a harmonised way between the three regions at the administrative and scientific level.

Bulgaria

No information provided.

Cyprus

No information provided.

Czech Republic

Czech legislation on contained requires a new notification in case a new GMO is to be used. This rule applies to all classes of contained use.

No relevant changes since the previous report.

Denmark

No relevant changes since the previous report.

Estonia

No information provided.

Finland

No relevant changes since the previous report.

France

No relevant changes since the previous report.

Germany

No relevant changes since the previous report.

Hungary

The Competent Authorities in Hungary are the Ministry of Agriculture and Rural Development in case of agricultural/commercial notifications and the National

Institute of Pharmacy in case of clinical trial notifications. As part of the authorisation procedure, the Genetic Engineering Advisory Board is consulted. The Board is a 17-member advisory body composed of representatives of the Hungarian Academy of Sciences, the relevant government ministries and civil society organisations in the field of environmental protection, health, biotechnology and consumer protection. Environmental concerns and impact on human public health are discussed with the eligible experts of the Ministry of Environment and Water and the National Institute of Pharmacy, respectively.

Ireland

The Competent Authority is the Environmental Protection Agency. The Minister for the Environment Heritage and Local Government has overall responsibility for policy matters in relation to the contained use of GMMs/GMOs.

Latvia

The Ministry of Agriculture is the Competent Authority for Directive 2009/41/EC. The Food and Veterinary Service is the competent authority to issue a permit for contained use of GMOs. On the other hand the State Labour Inspectorate, in conformity with the regulatory enactments regarding labour protection when coming into contact with biological substances, ensure the supervision and control of such safety and labour protection measures which are related to the contained use of GMOs.

Lithuania

The Ministry of Environment is the Competent Authority responsible for implementation of the Council Directive 2009/41/EC. Notification and approval systems are determined in the Order on Regulation on Contained Use of Genetically Modified Micro-organisms.

Luxembourg

The Ministry of Health is the Competent Authority responsible for Directive 2009/41/EC. Advice is obtained from different administrations (Administration of Environment, Inspection Travail et Mines) and the Inter-Ministerial Committee. Contained use facilities have to get an
Authorisation according to the legislation "Loi du 10 juin 1999 relative aux établissements classées".

Malta

The Malta Environment and Planning Authority is the Competent Authority for Directive 2009/41/EC.

Netherlands

No relevant changes since the previous report.

Poland

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 Commission on GMOs for assessment by scientific reviewers.

Portugal

The Competent Authority for Directive 2009/41/EC is the Portuguese Environment Agency (previous Environment Institute), belonging to the Ministry of Environment and Spatial Planning. Now according with national legislation the final approval of a notification is granted by the Ministry of Environment, after receiving a favourable opinion approval from the Ministry of Health.

Portugal is in the process of reviewing Decree Law n. 2/2001, which is the law that transposes Directive 98/81/EC in order to have a broader experts involvement and also to establish fees for notifications analysis, as already foreseen in the GMO legislation.

Romania

Starting with July 2007 the National Environmental Protection Agency (NEPA) is the Competent Authority for contained use of genetically modified microorganisms. The Biosafety Commission is the scientific authority with advisory role in the process of decision making by the NEPA.

Slovakia

For contained use of GMMs, two national authorities are involved, the Ministry of Environment of the Slovak Republic as the Competent Authority and the Slovak Environmental Inspection.

Slovenia

The Ministry of Environment and Spatial Planning of Slovenia (MESP), is the Competent Authority to decide upon registration of the premises for contained use of GMOs and upon approvals for the work with GMOs in containment.

The biosafety framework in Slovenia includes also contained use of GMO and 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 from Directive 2009/41/EC and includes also GM plants and animals.

Spain

The General Directorate for Sustainable Development of Rural Affairs, Ministry of Environment, and Rural and Marine Affairs is the Competent Authority for contained use activities carried out by Government Public Research Institutes or for medical purposes (clinical trials, human and animal medicines/vaccines, etc.), and the

Autonomous Communities (Spanish regions) for most of the activities carried out with GMOs.

Sweden

The Swedish Work Environment Authority has commenced work on reviewing the Swedish National Board of Occupational Safety and Health's regulations on the contained use of genetically modified organisms with a view to clarifying and simplifying the procedure for notification of GMM activities. The Swedish Board of Agriculture modified its regulations on contained use of genetically modified plants in order to simplify the rules.

United Kingdom

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

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

In Northern Ireland, the Competent Authority is the Health and Safety Executive for Northern Ireland (HSENI) and the Department of the Environment, acting jointly. The Biological Agents Unit (BAU) of HSE provides technical support to HSENI, under an Agency Agreement.

1.3. Risk assessment and classification of contained uses (including effectiveness of the risk assessment guidelines)

Austria

Activities involving GMOs are classified in four safety levels and follow the four class system of Article 4 of Directive 2009/41/EC.

The reported activities involving GMOs related to activities involving transgenic plants and animals (primarily *Mus musculus*) were classified as level 1. Level 2 activities included cases where donor organisms were bacteria (e.g. *Staphylococcus* ssp.), viruses (e.g. influenza viruses A, B and C; polio virus vaccine strains; adenovirus type 5; HIV-1) or cell lines from *Homo sapiens*. Examples of level 3 are influenza virus A used to produce influenza virus reassortants, and influenza virus A (H5N1) to produce wild type H5N1 strains using reverse genetics methods.

Belgium

In accordance with the co-operation agreement concerning biosafety the Regional decrees classify human and animal pathogens into three classes of risk and plant pathogens into two classes of risk.

Bulgaria

No information provided.

Czech Republic

The Competent Authority checks the risk assessment provided by the notifier together with the resulting assignment of the containment level, before or shortly after commencement of the activities, preventing in this way potential errors in classification.

Cyprus

No information provided.

Denmark

No information provided.

Estonia

No information provided.

Finland

Despite existing guidelines, the classification of viruses and cell cultures was difficult in some cases. A special problem was the classification of pathogens that had been attenuated.

France

No information provided.

Germany

No changes since the last reporting period.

Hungary

No changes since the last reporting period.

Ireland

No new information.

Latvia

No new information.

Lithuania

The notification system is determined in the Order on Regulation on Contained Use of Genetically Modified Micro-organisms.

Luxembourg

No information provided.

Malta

No information provided.

Netherlands

Standards for risk-assessment and classification of organisms and activities are laid down in the Ministerial Regulation on genetically modified organisms.

There are several classifications possible for the containment level of activities: a) laboratory work ML-I (Safe Microbiological Practice), ML-II, ML-III and MLIV; b) microorganisms in association with plants in growth chambers: PCM-I, PCM-II, PCM-III and PCM-ĪV; c) microorganisms in association with plants: PKM-I, PKM-H, PKM-III and PKM-IV; d) microorganisms in association with animals: DM-I, DM-II, DM-III, DMIV, e) large scale productions MI-I, MI-II, MI-III and MI-IV. Lists of safe hosts and safe vectors are provided by a Ministerial Decision.

Poland

No new information.

Portugal

No new information provided.

Romania

The EGO no. 44/2007 transposes Council Directive No 98/81/EC.

Slovakia

No new information.

Slovenia

In Slovenia, the biosafety framework which includes also contained use of GMO is covered by horizontal legislation based on the Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010). The Act implements the provisions from Directive 2009/41/EC and includes also GM plants and animals.

Spain

No new information provided. Under the scope of the Spanish Law on GMOs, all kind of genetically modified organisms are included, for contained use purposes as well.

Sweden

The forms for risk assessment, notification and approval applications are subject to continual review and improvement. The guidance on contained use of GMMs on the Swedish Work Environment Authority's website will be reviewed in the near future.

United Kingdom

The Scientific Advisory Committee on Genetic Modification (Contained Use) which provides technical and scientific advice to the Competent Authority on all aspects of the human and environmental risks of the contained use of genetically modified organisms (GMOs) held two open public meetings during this reporting period.

1.4. Accidents

No accidents were reported by: Austria, Belgium, Cyprus, Portugal, Bulgaria, Germany, Romania, Estonia, Lithuania, Latvia, Slovenia, Slovakia, Hungary, Sweden, Republic Czech, Denmark, France, Germany, Malta, Poland, and Spain.

Finland

During the report period there was one accident with consequences and several accidental needle pricks without consequences (in the latter cases operators were advised of proper working practices during inspections). In case of the accident with consequences, an operator had received an *E. coli* strain with *Staphylococcus aureus* enterotoxin gene from another research group and taken it into use based on the records provided. The strain was supposed to contain partial enterotoxin gene and the operator incorrectly assumed it to be a class 1 GMM. When lysing the bacteria with pressure, a small amount of bacterial suspension burst onto the worker's face. No safety or protective clothing were used, and the worker encountered some health problems. It was later discovered that the GM *E. coli* strain contained an operational enterotoxin gene. The operator failed to report the accident to the authorities in due course, and it was later discovered during an inspection. As the strain originated from another Member State laboratory, the Finnish supervisory authority informed the respective supervisory authorities on the accident.

Ireland

One accident was reported to the Competent Authority during the reporting period. The user was carrying out a procedure involving the aspiration of supernatant from a trypsinised, genetically modified lentivirus-infected HeLa cell culture (Class 2 GMM) previously rendered inactive after fixing with Para formaldehyde. During the aspiration procedure, the glass end of the Pasteur pipette (attached to the aspirator)

broke, piercing the latex glove worn by the user and penetrating the skin of the hand. Subsequently, the use of glass Pasteur pipettes during the course of the procedure was stopped. Prior to the accident occurring, the cells containing the viral vector had undergone a series of steps that would, in the opinion of the researchers, significantly reduce the infectivity of the virus.

Netherlands

Nine 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. In the first incident 1800 liters of GM bacteria were released in the sewage system. Based on the risk assessment, it involved an *E. coli* strain that most likely could not have survived in the sewer (biological restriction). In the second incident during construction work the airflow was disrupted in a high containment level GMO laboratory in which work on an unmodified SARS-virus had just ended. Although the chances of contamination were small, people that might have been exposed were followed clinically. No health problems were detected. In the third incident during a blood extraction procedure in an animal experiment involving GM malaria, a puncture incident took place. Research showed that the pathogen was no longer present in the animal at the time of the incident. In the fourth incident GMO waste had been mixed with conventional company waste. The complete batch of waste was incinerated under supervision. In the fifth incident there was a fire in a laboratory with GM animal cell lines. In the sixth incident GM *E. coli* was disposed in a sink in a school. It involved a weakened *E. coli* strain where survival in the sewer was unlikely (biological restriction), based on the risk assessment. In the seventh incident, an unintended release of approximately ten litres occurred from a fermenter with GM yeast. Based on a risk assessment, it was unlikely that this yeast survived the water purification system of the company. In the eighth incident 100 litres of a bacteria suspension was accidentally released in the sewers. This involved a weakened *E. coli* strain, which was being used for vaccine production. Based on a risk assessment, survival in the sewer was unlikely. In the ninth incident a flooding of an ML-III laboratory was registered. At the moment of the incident no activities with GMO's were taking place, but activities involving wild-type pathogenic viruses and bacteria. Approximately 100 liters of water got into the sewers. Based on a risk assessment, it was concluded that even if all this water was contaminated with pathogens it would have been highly unlikely that they could have survived in the sewers.

United Kingdom

Seven accidents were reported to the Competent Authority during the reporting period. All accidents involve GMM belonging to class 2.

The first accident involved the transfer of the seed bacterial culture *(E.coli* HMS174(DE3) genetically modified to express *Neisseria meningitidis* surface proteins) from a flask into the fermenter using a peristaltic pump. The pump was activated while the clamp closing the transfer tubing was still in place. Consequently, the tubing separated from the pump, resulting in the spill. Following the incident, the company's standard operating procedure was adapted to highlight the clamp removal stage.

The second accident involved genetically modified *Mycobacterium tuberculosis.* The accident occurred when the shaking platform of the middle one of three stacked Infors Multitron 2 incubators appeared to shake much faster than the speed it had been set to.).The overspeed caused some of the secondary containers to come out of their clamps and some broke. Some of the primary containers containing GM *Mycobacterium tuberculosis* cultures were also thrown out of their secondary containers and into the body of the incubator. Eight of these primary containers had broken. The user had the faulty circuit board replaced. However, in case another overspeed incident occurred they had changed their procedures. In order to further reduce the possibility of overspeed incidents, Infors UK (the distributors) developed further overspeed prevention software, which was to be installed on all existing machines in the UK, free of charge.

The third accident involved waste liquid from work with samples containing live but highly attenuated genetically modified H5N1 influenza virus and also contained small amounts of thiomersal, a mercury containing preservative. The estimated maximum titre of the virus present in the liquid waste which was spilled was approximately 1×10^5 EID_{50}/ ml. All microbiology staff was retrained in the use of the peristaltic pump. The operating procedure was changed.

The fourth accident involved egg waste from the pandemic influenza vaccine facility containing genetically modified pandemic vaccine influenza virus The pandemic influenza vaccine facility pumps waste fluid into an intermediate bulk container (IBC) waste vessel or diverts it to the stand-by unit. A blockage occurred in the steel pipe work, causing a rupture at a flexible rubber elbow joint. The cause of the blockage is unknown. The spillage went into the waste tank area in an external building. Some of the spilled material reached the outside of the building but did not enter any drains. The pandemic influenza production run ended 3 days after the accident and there were no plans to use this waste system again due to a move to a new facility with a different waste handling system.

The fifth accident involved a 4th year postgraduate student who was injecting pigs subcutaneously with a genetically modified mutant of *Actinobacillus pleuropneumoniae* (App). A pig kicked out and struck his hand (right) holding the syringe. This caused the needle to pierce the skin of the non-injection hand (left). A small amount of App entered the nail bed of his left thumb causing a severe reaction which ultimately resulted in hospitalisation and surgery with antibiotic treatment. It is estimated that the postgraduate student was exposed to approximately 1 µl ($\approx 1 \times 10^7$ CFU) of App. The incident involved a severe reaction to a pathogen that had not previously been known to cause this. The College amended the risk assessment to highlight the potential consequences of subcutaneous exposure when working with this pathogen.

The sixth accident involved a GM vaccinia virus construct. A researcher suffered a needlestick injury very superficial while inoculation a mouse with a GM vaccinia virus construct. Consequently a very small volume (not more than 10µl) could have penetrated the individual's skin. Particular training was performed to ensure employees were aware that needles should never be re-sheathed and that the needle and syringe should be safely stored between inoculations.

The seventh accident involved GM parasite *Leishmania mexicana*. A University researcher was using a 25 gauge needle attached to a 5ml syringe to lyse 2.5ml culture of mouse cells infected with a genetically modified (GM) version of the parasite *Leishmania mexicana*. The procedure was undertaken on ice on the open bench. The force of pressure caused the needle to disengage from the syringe which resulted in the researcher being sprayed on the forehead with a small amount of the culture containing the GM parasites. No health effects were registered. The University changed its procedures to minimise the likelihood of disengagement of needle from the syringe.

1.5. Inspection and enforcement issues

Austria

During the reporting period, both competent authorities carried out checks scheduled and unannounced random on activities involving GMOs in closed systems. These included checks on closed systems for Levels 1 to 3, with different applications (small-scale basic research, food testing and large-scale production) being inspected. These checks provided no grounds for administrative measures.

Belgium

During the period 2006-2009, inspections were organized 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. Exchange of information with other European inspectorates was achieved by participation in the activities of the European network of inspectors (EEP: European Enforcement Project on contained use and deliberate release of GMOs) since 2005. One of the actual concerns of inspection is sampling of pathogens and GMOs as a means to control the adequacy of containment and work practices. For this purpose the Flemish Environmental Inspection ordered a study on the methodology for sampling and analysis of GMOs and pathogens and in parallel the Flemish Health Inspection asked for a study on sampling inside the facility with the aim to help in discern situations where sampling could be necessary and to provide an answer on the relevance and univocal interpretation of the sampling method.

The enforcement actions taken were the following: a) if inspection reveals shortcomings in the application of containment measures the user is summoned to comply with the conditions of the authorization within a limited period of time: an exhortation is drawn up. b) If the notifier does not comply with exhortation within the required timeframe an official report of infringement is written. c) when the shortcomings represent a serious risk or when there is no environmental permit or authorization, an official report of infringement is written.

The most recurrent problems encountered were: no regular supervision and control of the biosafety equipment, no validation of the used waste inactivation methods, insufficient training and lack of biosafety procedures, and incomplete registration of

used and stored micro-organisms. Also, still a few installations did not posses the requested environmental licence or authorization for the concerned activities. The Inspectorates are also responsible for the control of the storage and transportation of hazardous medical waste. As this is often related to contained use, inspections on storage and transportation of hazardous medical waste were also done during routine contained use inspections. Concerning this issue, non- compliances with the Flemish regulations were often found.

Bulgaria

No procedure yet defined for the inspection of contained use and in consequence there were no actions that were taken during the reporting period.

Czech Republic

Czech Environmental Inspectorate co-operates with other state supervision bodies carries out inspections for contained use of GMOs, in accordance with the yearly schedule based on the information from the Ministry of Environment and other authorities. Inspections are targeted on compliance with the requirements for the contained space, documentation, waste treatment, transport of GMOs, equipment of the premises, training of the personnel etc. In total, 77 inspections were carried out in contained use premises within the reported period, some of the facilities were inspected repeatedly. About 75 % of all authorised subjects were inspected during these 3 years.

No serious breach of the rules was identified within the reported 3 years period. Most frequent deficiencies found by the Inspection were missing updates or parts of the documentation and in one case some of the specific requirements for containment level were not met. These imperfections in most cases did not lead to infringement of the law nor to any risk to the environment. Six remedial measures and one fine were imposed during the reported period.

Cyprus

The Department of Labour Inspection during the reporting period has carried out inspections in various premises in order to verify whether GMMs are used. No premise within the scope of the Directive was identified in Cyprus up to now. About 20 Labour Inspectors were partially involved under the instructions of a specialised Labour Inspection Officer.

Denmark

Inspections were always performed upon notification of new premises or changes of already classified location. There were 7 inspectors in Denmark who spent part of their working hours with inspection. The frequent errors were: the information submitted to support risk assessment was not sufficient, the notification of the location but not also of the activities etc. Companies did not always remember to give the information that a location is no longer being used for work with GMMs.

When a company had not notified e.g. a research project they were given an order with short notice to get the matter settled. Sometimes companies were 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

No information provided.

Finland

The National Supervisory Authority for Welfare and Health, Finland (Valvira) was in charge with inspection. The inspection procedure was based on risk, so that class 3 uses were inspected more often (at least every second year) than class 1 or 2 uses (at least every 5 years /4 years respectively). During the reporting period 201 inspections were performed by two full-time inspectors (54 % of valid notifications). Approximately 500-800 orders of correcting measures were delivered (about 1 to 6 corrective measures / inspection, no further statistics available).

France

In May 2008 the Office for the Inspection of Contained Use Installations and Activities was created. Since, the proceedings initiated for control had been especially directed to a file review of application for accreditation. During the period May 2008 to late 2009, two major structures were visited, one private and one public structure. One part time inspector (biologist at CNRS) was available for control activities. The problems most frequently encountered in the sites visit were related to the application for decommissioning group of GMOs, the handling large volumes of lentiviral vector, the procedures for inactivation of liquid and solid waste.

Germany

After the notification of the consent the competent authorities regularly carried out the inspections on the premises. They checked the record of activities and in individual cases, took samples if needed. The inspection carried out during the reporting period revealed some negative points such us deficiencies concerning safety equipment, incomplete record keeping of genetic experiments, wrong or missing notes, detection of GMOs outside of the primary containment, e.g. in centrifuges. During the reporting period about 1600 enforcement actions were taken such as administrative offences, administrative fine, and written complaints, ordered tests of cell lines, administrative defences, and prohibition of genetic engineering operations. The users took different measures to minimise the occurrence of the problems, i.e. nomination of a dedicated person for dealing with legal and safety requirements and keeping in touch with competent authorities, training of biosafety officers and of project leaders etc.

Hungary

The authority regularly monitored the contained use activities, but no irregular activities were identified. The audits were conducted once a year and the compliance with Good Laboratory Practices was checked every two years.

Ireland

The CA is responsible for both the licensing and the inspection/enforcement of contained use activities. There were three inspectors available to carry out inspections. On balance the CA aimed to inspect all contained use activities once every three years. In carrying out inspections, inspectors used the checklist for contained use inspections devised by the European Enforcement Project.

Few aspects to be improved: users already actively engaged in the contained use of GMO/ GMMs without having first obtained the authorisation to do so, lack of knowledge regarding the consent conditions issued in respect of the contained use activity. Adequate training was provided by the CA. In specific cases it was recommended to have a Biological Safety Committee and a Biological Safety Officer. All site inspection activities were followed up with a letter to the user making recommendations in an effort to strengthen and harmonise containment measures.

Latvia

No comments due to lack of activities.

Lithuania

According to the Order on Regulation on Contained Use of Genetically Modified Micro-organisms, the Ministry of Environment inspects and examined the containment and other applied safety measures, at least every 3 years for Class 1 uses, every 2 years for Class 2, and every year for Class 3 and Class 4 uses. One specialised inspector is available for inspections under Directive 2009/41/EC.

The major objective for inspection was to confirm the effectiveness of the containment level and to evaluate the compliance with relevant approved conditions concerning the protection of the environment and human health.

The administrative penalties according to the Administrative Law Offence Code can be imposed on users, who carry out activities related to GMMs without or when the relevant requirements are not fulfilled. Approvals can be suspended or revoked where deficiencies with safety measures are discovered.

Luxembourg

Before planned contained use activities are started, inspections are held on a consultative basis with the applicant.

Malta

No facilities to be inspected.

Netherlands

No information provided.

Poland

Three authorities carried 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 of the Ministry of Environment. During the reporting period 71 inspections have been carried out. Frequently detected offences were the following: lack of an emergency plan and the lack of entrance signage in laboratories where GMO activities are carried out. There were 10 enforcement actions taken during the reporting period.

Portugal

The Portuguese Environmental and Spatial Planning General Inspectorate (IGAOT) is responsible for the inspection. During the reporting period there were no site inspections. There is one inspector, not specialised, who was involved with the OGM/MGM issues, among other issues not related with Biotechnology.

Romania

The National Environmental Guard (NEG) is a specialized control and inspection body under the co-ordination of the Ministry of Environment and Forests. The Directorate for Control of Biodiversity, Biosafety and Protected Areas in NEG is responsible for control and inspection activities in biosafety. Seven specialised inspectors were available for inspections under Directive 2009/41/EC**.**

Slovakia

During the reporting period 469 inspections were done with three specialised inspectors, which could impose fines for procedural offences. The most frequently encountered problems were related to the first time use of the premises and the lack of notifications. *15* enforcement actions were taken during the reporting period.

Slovenia

Slovenia had two specialised inspectors for GMOs. Each inspector was available for 10% of full working time for inspections under Directive 2009/41/EC and GM plants and GM animals. During the reporting period there were only minor infringements regarding 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 etc.).

In this context 11 written warnings were issued. The Competent Authority organised 2 workshops which focused on the preparation of the dossier and on risk assessment for potential notifiers.

Spain

Inspectors were from the Spanish Biosafety Committee and from the competent region. All installations were inspected. The problems most frequently encountered were: deficiencies in Good Laboratory Practices (GLP) and inadequate equipment, as well as the lack of internal Biosafety Committees at the premises of the user. The system was improved following a dialogue between the users and officials from the Biotechnology Unit before supplying the final notifications to the Competent Authority.

Sweden

Activities are inspected by Swedish Work Environment Authority (SWEA). Inspections were undertaken for various purposes: checking the information provided in the notification or regular inspection of premises. Inspection activity was at a relatively low level over the last two years. During the period inspections generally were triggered by notifications or approval applications.

United Kingdom

Great Britain had 13 Specialist Inspectors and 4 Principal Specialist Inspectors (managers). The inspection programme was a risk-based programme. Higher risk laboratories received more frequent inspections, for instances sites working at Class 2 were visited approximately every 5 years, sites working at Class 3 approximately every 3 years and sites working at Class 4 approximately every 1 year.

During the reporting period, 246 inspections were carried out on all sites working with GMMs in contained use.

Inspectors used a range of enforcement tools to ensure that users of GMM complied with the legislation such as: providing written advice and requesting improvements in certain areas; issuing of statutory Improvement Notices, requiring notifiers to remedy contraventions of the legislation within an agreed time period; issuing Prohibition Notices requiring the immediate cessation of work where it is considered by the inspector that it poses an imminent risk to human health; withdrawal or variation of consent to carry out GM work; and prosecution. Two enforcement actions were taken and involved the variation/suspension of consent to carry out GM activities until the problems were rectified. Note that this figure reflected formal enforcement specifically taken under the Regulations that implement Directive 2009/41/EC. Enforcement action had been taken under other health and safety legislation at premises that may have been carrying out GM activities.

In 2010, the implementation of a new rating system for all sites was started. This was be based on a rating for the inherent hazard (e.g. classification, complexity, scale and nature of the work) and a rating for the safety performance (e.g. safety management, maintenance, training/competence found during an inspection). The combined rating will be used to determine how often a site is revisited.

The most frequently encountered issues were related with: waste transport/storage/inactivation; insufficient/inappropriate risk assessment/standard operating procedures/local rules; poor laboratory equipment/fabric; and training/competence.

1.6. Problems with interpretation of the provisions

Belgium, **Czech Republic, Hungary** and the **Netherlands** encountered problems in assessing whether new techniques of genetic modification fall within the scope of Directive 2009/41/EC.

Also **Belgium** encountered problems related to clinical trials in humans submitted under the provisions of the Directive 2001/18/EC, part B, which also require in some instances an authorization based upon the contained use decrees (Directive 2009/41/EC), causing a double authorisation regime. In Belgium the term subsequent contained use caused problems for notifiers who had difficulties in determining what modifications of their activities constituted a subsequent contained use, i. e. whether the use of other genetically modified or pathogenic microorganisms or other techniques still fall under the scope of the authorized contained use activity or not.

Czech Republic encountered problems with new techniques for genetic modification, e. g. whether animals used for testing DNA vaccines could be considered genetically modified organisms as defined in the Directive. Problems also emerged regarding clinical trials.

For **Denmark** the increased number of class 1 notifications represented the greatest burden.

Finland reported some problems with the definition of a GMO as well as with the classification of pathogenic organisms in cases where their pathogenicity has been attenuated. Finland saw the need for guidance on the notification procedures concerning clinical treatments of patients.

France encountered administrative problems when implementing the 45 days deadline in which the Competent Authority should examine the notification. The deadline was too short.

Germany encountered problems with the interpretation of Annex IV of the Directive 2009/41/EC and suggested a more precise wording of standards. The Directive would not specify acceptance criteria for technical demands (for example the term air tight). Germany also noted difficulties with the verification of the identity of GMO and with the detection of contamination of the working environment with GMO.

Hungary also encountered problems with a potential "overlap" between Directive 2009/41/EC and Directive 2001/18/EC in regard to gene therapy.

In **Ireland** the high number of site inspections and subsequent enforcement activities represented the greatest duty on the Competent Authority's resources. Ireland argued for a simplification procedure in as far as organisms falling into class I could be

exempted from the scope of the Directive (Part C of Annex II) if they had a proven and well established history of safe use.

Luxembourg proposes annual reporting of all authorized contained use activities by the authorization holder.

Malta recommended holding an EU training workshop dealing with what is required according to the Directive 2009/41/EC in order to have a co-ordinated approach in the whole EU.

The Netherlands calls for a common interpretation on the scope of directives 2009/41/EC and 2001/18/EC with respect to applicable legislation for gene therapy studies and trial notification.

Poland also encountered problems with clinical trials and potential "overlapping" between Directive 2009/41/EC or Directive 2001/18/EC as well as difficulties in classification of activities involving plant and animal cells (GMM vs GM plants or animals).

Slovenia suggested that inclusion of safe organisms in Part C of the Annex II of Directive 2009/41/EC could contribute to a reduction of the number and size of the notifications.

Spain has encountered difficulties to obtain feedback from the users of centres and institutions working with GMMs/GMOs in order to comply with the obligations derived from the contained use directive. According to the Spanish Competent Authority there were still some facilities which did no have notified installations or activities with GMM/GMOs. Spain suggested to have harmonised Guidelines at EU level regarding: a) clinical trials in order to clarify whether they have to be carried out under the scope of Directive 2009/41/EC or/and the 2001/18 /EC (or both, “case by case”); b) interpretation of Article 3 (2) of Directive 2009/41/EC (on transport).

Sweden considered that the yearly reports and three year report requested under Directive 2009/41 are sometimes redundant in terms of information provided.

The **United Kingdom** considered the work with viral vectors was at the low end of the risk spectrum, but because of the high number of notifications, took a disproportionate amount of time to review. The Competent Authorities from the United Kingdom suggested that the requirement to notify class 2 activities could be changed so that there is only a requirement to notify the first class 2 activity at premises. Subsequent class 2 activities could be carried-out, following approval by an internal committee, without the need to notify the Competent Authority. The Competent Authority could then commit more resources to the assessment of more hazardous work (including reviewing notifications) and to inspections of all classes of premises.

1.7. Clinical trials under the provisions of the Directive

Austria

Pursuant to the Austrian Genetic Engineering Law, clinical trials for the purpose of somatic gene therapy in humans are not subject to the legal requirements governing activities involving GMMs in a closed system. However, such trials only receive an authorisation from the Ministry of Health if various conditions under the legislation governing medicinal products are met, and if the somatic gene therapy causes no changes to the germ line and no harmful release of GMOs into the environment is to be expected.

Belgium

During the reporting period, two clinical trials were carried out and one more trial was authorised but withdrawn by the applicant before start.

Bulgaria

No clinical trials were notified to the Competent Authority during the period 2006-2009.

Czech Republic

Only one clinical trial with CEREPRO™ was carried out (notified in 2005). No other notification was submitted during the period. According to Czech Act on GMOs, the hospital participating in a clinical study and the company providing the product to be tested have to submit separate notifications, which constituted a considerable administrative burden.

Cyprus

The Department of Labour Inspection is not aware of any clinical trials with GMMs that take place in Cyprus.

Denmark

One clinical trial was notified.

Estonia

No clinical trials were notified.

Finland

No clinical trials were notified.

France

228 clinical trials were carried out in France between 2006 and 2009.

Germany

14 clinical trials were carried out in Germany between 2006 and 2009.

Hungary

No clinical trials were notified.

Ireland

No clinical trials were notified.

Latvia

No clinical trials were notified.

Lithuania

No information given.

Luxembourg

No clinical trials were notified.

Malta

No clinical trials were notified.

Netherlands

Clinical trials were handled under Directive 2001/18/EC.

Poland

Six clinical trials with GMM were authorised. Clinical trials with GMM require decisions of the Minister of Health, the Ethical Committees and the Minister of the Environment.

Portugal

No clinical trials were notified.

Romania

No clinical trials were notified.

Slovakia

No clinical trials were notified.

Slovenia

No clinical trials were notified.

Spain

Clinical trials with GMMs were assessed case by case and most of them are dealt as Part B notifications (Directive 2001/18/CE). Notifications of clinical trials increased since the last report but all of them were considered as deliberate releases.

Sweden

The Swedish Work Environment Authority and the Swedish Medical Products Agency reached the conclusion that clinical trials with GMMs on humans should be regarded as deliberate releases, as in Sweden it is required that there is physical containment of GMOs as well as biological containment. The Swedish Medical Products Agency deals with applications for clinical trials in accordance with Part B of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The procedure has also been incorporated into the Swedish Medical Products Agency's regulations and general advice is given on deliberate release into the environment of medicinal products that contain or consist of genetically modified organisms.

The United Kingdom

The regulations which implement Directive 2009/41/EC allow clinical trials to be undertaken as contained use activities. The Competent Authority does not collect this information. The vast majority of clinical trials were from class 1 as such, would not individually require notification to the Competent Authority (apart from first use of the premises for work with GMMs). Any class 2 clinical trial activities is included in the total number of class 2 activity notifications, and the information is not recorded in a way that readily allows retrieval of the number of this type of activity.

1.8. Public consultation and information

In **Austria** public information on the significance of genetic engineering and biotechnology was provided by the genetic engineering-related web pages of the Ministry of Health (www.gentechnik.gv.at) and the Ministry of Science and Research (www.bmwf.gv.at). There were no public consultations concerning activities involving GMMs as no applications for level 3 (large-scale) or level 4 were submitted. In addition, contact with operators carrying out activities involving GMMs or with petitioners was largely in electronic form.

In **Belgium**, public consultation was 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 generally

understandable information without any reference to confidential information. A similar procedure of public consultation was established in the Walloon Region for the environmental releases. 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 were made publicly available 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, the public was only consulted for environmental permit demands. Public information is provided primarily in two ways. Firstly, 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/. Secondly, scientific and technical information (in English, Dutch and French) is provided through the "Belgian Biosafety Server" (http://www.biosafety.be), a website maintained by the SBB.

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

In **Bulgaria** during the reporting period no public consultation was carried out. A public register of the premises for contained use of GMOs was established and maintained in an electronic form at the Ministry of Environment and Water. The public register was part of the information system in the framework of the Biosafety Clearing House.

In Czech **Republic** the public was informed in general by different means: yearly public meetings of Competent Authorities' advisory body, seminars, publications etc. No public consultation on any specific contained use notification was conducted during the period.
The Competent Authority keeps updated the register of subjects authorised for contained use (“Register of Users”) on its website www.mzp.cz. The Register contained the name and address of the user, the specification of GMOs, the purpose of the use and its classification. Summaries of emergency plans are published as well.
Information in English was made available at Czech Biosafety Clearing House webpage www.mzp.cz/biosafety including the legislation, notification formats and guidance document on the clinical trials notifications.
No specific reactions were received. The overall public attitude to biotechnology research and to the use of GMM in the health sector was positive in Czech Republic.

In **Cyprus** no public consultation were carried out.

In **Denmark** all notifications were registered in a common database shared by the Danish Working Environment Authority and the Danish Environment Protection Agency. 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 Environment Protection Agency 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 were published in a national and a local newspaper. When the approval was published complaint against the decision could be filed to the Environmental Appeal Board within a four week period.

Estonia did not provide any information about public consultation.

In **Finland** there was no public consultation in connection with contained use activities.

In **France** there was no public consultation in connection with contained use activities.

The Central Committee on Biological Safety from **Germany** published annual reports concerning on-going activities as well as general recommendations and the list of classified microorganisms. All the data was available on BVL homepage.

In **Hungary** 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. The Biotechnology Advisory Board ensures that civil society organizations are involved in the authorisation procedure. The Registry Office appointed by the Competent Authority offers information concerning contained use.

In **Ireland** the Competent Authority notifies the public of class 3 and 4 activities in accordance with national Regulation 73/2001. Based on the same regulation the public consultation may be carried out at the discretion of the Competent Authority for class 2 contained use activities. No public consultations relating to class 3 and 4 contained use activities were carried out during the reporting period since no class 3/4 applications were received. With regard to applications for class 2 activities, the Competent Authority 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 Competent Authority. Considerable technical guidance relating to the contained use of GMMs/ GMOs is published on the Competent Authority's website (www.epa.ie). No public consultations were carried out during the reporting period. The Competent Authority received no public reaction or comment in response to the GMO Register or its guidance.

In **Latvia** no public consultation took place because no notifications were submitted.

In **Lithuania** according to the Order on Regulation on Public Information and Participation in Authorization of Consent for Use of GMOs, the Ministry of Environment has to organize use, storage and availability of information about GMOs to the public through the national GMO database. This database is available at the following address: http://gmo.am.lt and has a dedicated section for the direct public opinion presentation. Notification and information on contained use of GMMs are presented in this database.

In **Luxembourg**, public consultation is performed through the general procedures established under environmental law "Loi du 10 juin 1999 relative aux

établissements classes. According to the law "Loi du 13 janvier 1997 relative aux contrôle de l'utilisation et de la dissemination des organismes génétiquement modifiés", a public consultation is performed for first time moderate or high risk activities.

In **Malta** the Competent Authority published and disseminated a leaflet on contained use, which explained the legislation requirements and timeframes. It also organised a one day public awareness on this issue.

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. No objections were received during the reporting period.

In **Poland** public consultation is a part of the approval procedure for all classes of notifications under the Polish law on public information. The provisions for public participation in the decision making process require public access to the notification while restricting public access to confidential information. General information on contained use activities in Poland was provided on the web site http://gmo.mos.gov.pl.

In **Portuga**l, although the legislation foresees the option that the Competent Authority could promote consultation procedures when it considers appropriate, no consultation procedures were carried out for the notifications presented in the current period.

In **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. The National Environmental Protection Agency publishes notifications on the website www.anpm.ro. Within 10 days from the acceptance of the notification and within 30 days from the display, the public has the possibility to comment.

In accordance with national legislation for the contained use classes 3 and 4, the National Environmental Protection Agency (NEPA) should held public debates and report to the authorities involved in the notification procedure. The public information at the national level is made available to the public in collaboration with local environmental protection 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.

In **Slovakia** all the information are publicly available on the websites www.enviro.gov.sk and www.gmo.sk. Also during the reporting period 8 events were organized (workshops and seminars) for the general public, consumer associations, school teachers, environmental inspectors, researches and scientists.

Slovenia did not provide any data regarding public consultation.

In **Sweden** there were no changes since the last reporting period.

In the **United Kingdom** 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 register contains information on premises and individual activities, including the nature of the work to be carried out, the purpose of individual activities and the characteristics of the GMOs involved. The register can be found at
http://www.hse.gov.uk/biosafety/gmo/publicregister.htm.

Additional information is provided by The Scientific Advisory Committee on Genetic Modification (Contained Use). This committee provides technical and scientific advice to the Competent Authority on all aspects of the human and environmental risks of the contained use of genetically modified organisms (GMOs). It held two open public meetings during this reporting period.

1.9. Protection of confidential information

Austria

The operator may indicate in the application or notification submitted to the authority those data to be treated as confidential. In such a case, the authority decides which data are to be recognised as confidential in accordance with § 105 of the Genetic Engineering Law and may therefore not be made accessible to the public during the consultation process.

Belgium

As the elaboration of a public as well as a technical dossier is often a burden for the notifier, the competent authorities are willing to accept only one (technical) dossier. The Brussels Capital Region considers the possibility of a new single form with confidential information in an annex, if necessary. In the Flemish and Brussels Capital Regions, the information for public is given via a "public dossier" which is a short summary of the full notification drafted by the user and containing information written in every day language and without any reference to confidential information.

Bulgaria

No information provided.

Czech Republic

No information provided.

Cyprus

No information provided.

Denmark

No information provided.

Estonia

No information provided.

Finland

No information provided.

France

No information provided.

Germany

No information provided.

Hungary

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

Confidential information was submitted in connection with three Class 1 GMM applications received during the reporting period. All requests to keep information confidential were considered by the CA in the context of Article 18 of Directive 2009/41/EC and implementing Regulations. The information submitted and proposed as confidential was deemed by the notifier to be commercially sensitive and provided it did not impede the provision of an adequate description of the GMM on the GMO Register, the CA agreed that it should be treated and held as confidential.

Latvia

No comments due to lack of activities.

Lithuania

According to the Order on Regulation on Public Information and Participation in Authorization of Consent for Use of GMOs the Ministry of Environment has to

organize use, storage and availability of information about GMOs to the public through the national GMOs database (Internet address: http://gmo.am.lt), undamaging the rights of confidential and intellectual information. Notification and information on contained use of GMMs are presented in this database.

Luxembourg

No information provided.

Malta

No information provided.

Netherlands

When a notifier claims confidentiality it has to be made clear on what basis the risk assessment has been carried out. A general description of the confidential parts has to be submitted in order to give the public insight into the entire risk assessment. All confidential parts of notifications have to be submitted in confidential annexes. Only authorised personnel have access to the rooms where the dossiers are handled and stored.

Poland

No information provided.

Portugal

No information provided.

Romania

No information provided.

Slovakia

No information provided.

Slovenia

No information provided.

Spain

No information provided.

Sweden

No changes since submission of the 2003-2006 report.

United Kingdom

No information provided.

1.10. Waste disposal

Austria

GMMs of class 2 to 4 which are capable of proliferating under ambient conditions must be inactivated prior to disposal. Inactivation of GMOs was mainly carried out using validated thermal (autoclaving) or chemical (e.g. sodium hypochlorite) processes. Most inactivated GMO waste was thermally treated. The planned disposal of waste and waste water must be considered during the safety classification of the specific activity involving GMOs.

Belgium

In the Belgian Regional decrees implementing Directive 2009/41/EC, there is an explicit legal
requirement to inactivate all types of GMOs, class 1 included, by appropriate and validated means prior to disposal as waste. Inactivation can either be done on site, or 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 approved company. Transport of waste material follows the UN recommendations of dangerous goods.

Bulgaria

Bulgarian legislation requires that all kind of waste must be inactivated and disposed in an appropriate manner. The details regarding inactivation and disposal are given in the application under a specific point of information for waste management.There were no waste treatment facilities in Bulgaria which are authorised to inactivate waste arising from GM installations.

Czech Republic

There were no special waste facilities, GMMs were inactivated at the premises where they had been used and the resulting waste was treated together with other hazardous waste from the premises (laboratories, hospitals etc.).

For the GMMs (class 1 and 2) which have been authorised in Czech Republic the waste was inactivated and disposed of in the same way and by the same means as infectious waste containing pathogenic micro-organisms (by chemical disinfectants, autoclaving etc.). Likewise, GM laboratory animals and animals inoculated with GMMs were disposed of as other infectious animals. GM plants were either autoclaved or in large volumes chopped, the seeds ground and the resulting material composted.

Cyprus

No data available.

Denmark

There were no authorised waste treatment facilities in Denmark. The users inactivated their GMO-waste themselves. For class 1 the treatment of the waste was based on the risk assessment in each specific case. For class 2 the waste had to be inactivated with validated methods before final discharge. For class 3 the waste had to be inactivated before final discharge with validated chemical or physical methods. For class 4 only a validated physical inactivation is sufficient.

Estonia

No data available.

Finland

Any viable organism in the waste must be inactivated. GM-vertebrates were incinerated or buried. Most GM-plants were autoclaved, but there was a list of recommended methods for different species and their tissues, depending on whether the specific plant tissue is capable of reproduction. One waste treatment facility in Finland, which had a long experience of GM-waste inactivation, was used to treat class 1 and 2 GMO waste. However, most of the GMO operators inactivated their GMO-waste themselves.

France

No data available.

Germany

There were two facilities in Germany authorised to inactivate waste containing GMMs, in North Rhine Westphalia and in Hamburg. Both facilities were authorised to accept waste containing Class 1 GMMs. The transfer of waste was organised by the operator.

Hungary

Waste from biotechnological activities was treated under the national legislation concerning dangerous waste.

The waste treatment facilities in Hungary authorized for such activities did not only treat GMO waste. The activity of inactivating waste arising from GM installations required a special registration procedure. The transfer from the installation to the waste treatment facility was done under controlled conditions and specifying the route of transfer.

Ireland

The Competent Authority stipulated in consent conditions issued to the GMO user that all waste had to be inactivated by validated means. Waste arising from Class 2, 3 or 4 GMM activities had to 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 had been inoculated with class 1 or class 2 GMMs. In the case of animals inoculated with Class 1/2 GMMs, the remains were 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, had not arisen and such a decision would be made on a case-by-case basis. GM Plant waste was inactivated by autoclaving or off-site incineration.

There were two facilities in Ireland authorised to inactivate waste containing GMMs. Transportation was arranged by the waste treatment company.

Latvia

No information available.

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 or chemical means.

Luxembourg

Waste inactivation is by autoclaving or by using chemicals.

Malta

The requirement for inactivation for Class 1 GMMs was 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 contaminated use activity. Information about storage and inactivation methods must be provided. All waste must be inactivated prior to disposal if 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, effluents, residues and wastes must be inactivated prior to disposal .There were several companies dedicated to inactivate biological waste, who operate mainly with hospital contaminated residues, and also with GM biological waste.

Romania

In Romania, Emergency Government Ordinance 44/2007, as amended by Law 3/2008, regulates the necessary measures on waste management. These requirements are completed by regulations on waste from medical activities. Emergency Government Ordinance 44/2007 as amended by Law 3/2008, requires users of contained use of genetically modified micro-organisms to have equipment to autoclave and inactivate waste from such activities.

Slovakia

In Slovakia, the holder of waste, who treated per year in total more than 100 kilos, or carrier, that transports annually more than 100 kilos of hazardous waste, shall have a waste management plan and approval from the Competent Authority. The applicant has to declare the amount of waste material to be produce and how the inactivation is performed. The carrier is obliged to inactivate the waste arising from GMO installations at the place before he can transport waste to a specialized facility. The transfer of waste from the GM installation to the authorised waste facility is organised according to the Treaty on International Railway Transport (COTIF) and the European Treaty on International Road Transport of Dangerous Goods (ADR).

Slovenia

In Slovenia according to the Regulation on risk assessment of work with genetically modified organisms in contained uses (OJ RS 45/2004) and the Decree of waste management (OJ RS 34/2008), the notification should submit a detailed plan for waste treatment, inactivation procedures and final disposal of the wastes and waste waters. The waste disposal procedure outlined in the risk assessment must be taken into consideration by the Scientific Committee before the premises for contained use of GMOs are registered or approved for work with GMOs. Several waste incineration facilities were registered in Slovenia.

Spain

The treatment facilities for the waste inactivation need authorisation from the Spanish Regional Competent Authorities. Usually autoclaves and chemical treatments were used for GMMs, and incineration for GM plants and animals. After waste treatment, the resulted waste was collected by certified companies. The transfer of waste from the GM installation to the authorised waste facility is the responsibility of the users.

Sweden

No change since the second report in 2006.

United Kingdom

In the UK the regulations that transpose Directive 2009/41/EC require that all waste, including waste from Class 1 activities, is "inactivated by validated means" prior to discharge/disposal. The Competent Authority has, in consultation with stakeholders, produced guidance on this subject. There are currently 9 registered sites authorised to inactivate waste, three at class 1 and six at class 2. 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.

2. ANNEX II – TABLE OF COMPETENT AUTHORITIES

Member States	Competent Authority	Other authorities involved
Austria	Federal Ministry of Education, Science and Culture (work at universities and scientific institutions) Federal Ministry of Health and Women (remaining activities)	
Belgium	Competent authorities in the three regions (Brussels Capital, Flemish Region, Walloon Region)	SBB (Section Biosécurité et Biotechnologie) as federal advisory body
Czech Republic	Ministry of the Environment	Czech Commission for the use of GMOs and genetic products (opinion), Ministry of Agriculture and Ministry of Health (may make comments or raise objections)
Cyprus	Department of Labour Inspection (Ministry of Labour and Social Insurance)	Licensing Technical Committee (advice)
Denmark	Forest and Nature Agency (under the Environment Ministry) and Working Environment Authority (under the Employment Ministry) in collaboration	
Estonia	Labour Inspectorate	
Finland	Board for Gene Technology	
France	Ministry of Research	Commission de genie génétique (Genetic Engineering Commission)
Germany	Länder authorities Competent federal authority: BVL (Federal Office for Consumer Protection and Food	Zentrale Kommission für die biologische Sicherheit (ZKBS, expert advisory body) (makes statements on classification)

	Safety)	
Hungary	Genetic Engineering Authority (Ministry of Agriculture and Rural Development)	Genetic Engineering Advisory Board (consulted)
Ireland	Environmental Protection Agency (EPA)	
Italy	Ministry of Health	Biotechnology Committee (positive opinion required)
Latvia	Food and Veterinary Service (Ministry of Agriculture)	
Lithuania	Ministry of the Environment	Steering Committee on GMOs (political advisory body), Ministry of Agriculture, Ministry of Health, State Food and Veterinary Service (opinions)
Luxemburg	Ministry of Health	
Malta	Malta Environment and Planning Authority (MEPA)	Biosafety Coordinating Committee (assessment)
Netherlands	Ministry of Housing, Spatial Planning and the Environment	
Poland	Ministry of the Environment	Commission on GMOs (assessment)
Portugal	Agence for the Environment (Ministry of Agriculture, Sea, Environment and Spatial Planning)	
Slovakia	Ministry of the Environment	Commission for Biological Safety (expert advisory body) (recommendation)
Slovenia	Ministry of the Environment and Spatial Planning	Scientific Committee for Work with GMOs in Containment (assistance)
Spain	Autonomous Communities Interministerial Council on Genetically Modified Organisms (activities representing a risk for human health, research programs)	National Commission on Biosafety (CNB) (evaluation, inspection, favourable or unfavourable report)
Sweden	Swedish Work Environment	

	Authority (SWEA)	
United Kingdom	Health and Safety Executive (HSE)	