

REGULATORY IMPACT ASSESSMENT FOR REVISED REGULATIONS ON CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS (GMOs)

PURPOSE AND INTENDED EFFECT

1. The current Genetically Modified Organisms (Contained Use) Regulations 1992 (as amended in 1996 and 1998) cover activities in which genetically modified organisms (GMOs) are used under containment, ie in conditions where specific controls are in place to limit contact between GMOs and humans or the environment. Laboratories, industrial production plants and glasshouses or plant growth rooms are examples of containment facilities.

(i) Background

1. To implement an amendment to Directive 90/219/EEC on the contained use of genetically modified micro-organisms, the Regulations have to be revised. The proposed new Regulations also modify provisions for the contained use of genetically modified non-micro-organisms (ie animals and plants).

2. At present the notification and consent procedures to be followed are determined by classification schemes for the genetically modified organism and the activity in which it is involved. Micro-organisms are classified into two hazard groups (Group I and Group II) and activities into a small scale non-industrial group (Type A) and "others" (Type B) in order to determine notification procedures. There is a separate requirement for risk assessment to determine containment and control measures. These schemes have been criticized for being over-complicated and troublesome to work with.

(ii) Outline of proposed changes

1. The revision to the Regulations:

- requires people working with GMOs to assess the risks to human health and the environment and provide control measures; and

- sets up a regime for notification and consent.

1. The main aim of the proposed changes is to simplify the notification process. The proposed new regulations would require the practitioner to carry out a risk assessment before starting an activity. The risk assessment would lead the activity to be classified for notification purposes into one of four classes corresponding to the appropriate containment level. Thus, the changes will allow notifiers to go straight from the risk assessment to the notification requirement. The proposed changes also alter the notification requirements for some types of activity. For some activities it would no longer be necessary to notify HSE and for some others the length of the notice period is reduced.

2. Furthermore, notifiers no longer have to complete public register forms, nor indicate the number of risk assessments in annual retrospective returns.

3. The current Regulations require activities involving genetically-modified animal and plants to be notified only if they fail to meet certain criteria. Those criteria relate to human health protection alone. The environmental aspects of activities involving GM animal and plants have to be taken into consideration in a risk assessment, but no environmental data have to be notified.

(iii) Organizations affected

1. There are approximately 473 centres which have notified HSE that they undertake genetic modification. Of these about 100 are industrial centres and the remainder are universities and other research institutions. HSE estimates that about 5,500 new projects are undertaken each year, 90% to 95% of which are Group I Type A. Genetic modification work has played an important part in medical, biological and chemical research. However, there is also a wide variety of applications in industry (for example biological washing powder, vegetarian cheese and some vaccines).

Risk Assessment

2. Genetically modified organisms may sometimes be modified in ways which make them potentially harmful to humans or the environment. It is, therefore, important that there are robust systems for assessing the risk of such harm occurring and ensuring that the necessary controls are in place to protect workers and humans and the environment outside the containment facility. Hitherto, there have been no cases of harm arising from contained use activities. This may be attributed to the stringency of existing controls.

OPTIONS

1. We are obliged to make provisions to implement the amended Council Directive on contained use of genetically modified micro-organisms. With regard to the control of risks to human health arising from activities involving genetically modified organisms that are not micro-organisms, ie animals and plants, there are three options:

- (i) maintain current controls;
- (ii) remove current controls; or
- (iii) add to current controls.

The second option of removing current controls in legislation on contained use would probably have little adverse impact on human safety given employers' general duties under the Health and Safety at Work etc Act 1974 and specific duties under the Environmental Protection Act 1990 to avoid release of genetically modified organisms into the environment without consent. On this basis, there is also no justification for the third option of adding to the current controls. Public confidence, however, would be likely to be seriously undermined if there were no longer any means of identifying where contained use of genetically modified animals and plants was being undertaken and whether effective controls were being applied. Against that background, therefore, it is proposed to adopt the first option of maintaining current controls for the protection of human health and safety. Environmental protection with regard to animals and plants is outside the scope of these Regulations, but covered by the Environmental Protection Act and Regulations made under it.

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

1. We requested information on the likely impact of the proposed revision of Directive 90/219/EEC. Twelve centres that use GMOs were contacted and we received information from ten of them. The type of centres that were contacted included industrial, academic and research-based establishments. Four that employed 75 people or less (of which two employed less than 20) were contacted in order to carry out a Small Business Litmus Test (SBLT). Since the revised regulations have a few implications outside the scope of the EC Directive, a similar sample of firms were contacted to elicit the additional information: 13 centres replied, of which two have fewer than 30 employees. During the consultation period, 14 centres provided further information by answering questions concerning the regulatory impact assessment.

2. The base year for appraisal is the year 2000, during which the new Regulations will be implemented. Costs and benefits are calculated in 1998 prices over a ten year period¹[HSE1].

BENEFITS

1. The main benefits of the proposed changes are expected to take the form of cost savings to centres using GMOs.

(a) Cost savings

1. Cost savings may arise from the following:

- (i) removal of organism and activity classification schemes;
- (ii) new provisions for exemption;
- (iii) reduction in the numbers of notifications;
- (iv) reduction in notice periods;
- (v) removal of annual returns forms;
- (vi) removal of public register forms; and
- (vii) application of containment and control measures to activities involving GMMs.

(i) Removal of organism and activity classification schemes.

1. The removal of the classification scheme allows notifiers to go straight from their risk assessment to the notification requirement and choice of controls. This could result in a cost saving in the form of a reduction in time spent on classification, although the extent of this is likely to be highly variable depending on the complexity of the case.

2. The responses from industry were mixed. Three centres did not believe that the changes would save time. Two others estimated a saving of two to three hours per project. Another stated that the time saving would be significant, but was unable to estimate it.

3. During the consultation period, one GM centre estimated a saving of 30 minutes per project, two centres estimated 5 minutes per project, and most of the centres stated that the time savings would be very small, or none.

¹In arriving at ten year cost figures (throughout this CBA) two adjustments are made. Firstly, earnings are assumed to rise by 1.8% per year in real terms - the observed increase for the whole economy over the past twenty-five years or so. Secondly, costs are discounted to present values using the Treasury recommended 6 per cent discount rate. Note that the first year total costs or benefits refer to year 2000, which is the first year of discounting. Totals are rounded to the nearest £100.

4. In view of the consultees' responses, HSE estimates that the amount of time saved in most cases will be less than 15 minutes. For borderline cases the amount of time saved will be more. It is assumed that there is, on average, a time saving of 15 minutes for each of the 5,500 new projects each year. On this basis, total cost savings would be about about £19,900 a year in the year 2000. It is estimated that the costs in terms of the staff time involved would be roughly £14² an hour. Over a ten year period this suggests total cost savings with a present value of £167,400.

(ii) New provisions for exemption.

1. The proposal includes modified and extended provisions for exempting GMOs and GM techniques. HSE considers that roughly 400 to 500 projects might be newly exempt each year. The large majority of these are likely to be Group I Type A activities that are not currently notifiable in advance. However, the exclusion will mean that those concerned do not need to undertake a special risk assessment, provide special controls or notify HSE as part of the annual return. One firm estimated that this could result in a cost saving of two hours per project. On average HSE considers that there could be a saving of one to two hours per project. This implies cost savings of £5,800 to £14,500 each year (again using the cost of staff time as £14 an hour). Over a ten-year period this implies cost savings with a net present value of between £48,700 and £121,800.

(iii) Reduction in the numbers of notifications

1. The proposed amendments would remove the notification requirement from most Group I Type B organisms. Most of those who commented on the RIA during the consultation period did not carry out Type B work. Estimates for the pharmaceutical sector (which comprises about 90 companies) indicated less than 5 such projects per company per year. In view of this, HSE estimates that there are about 300 such projects each year. This figure is expected to increase by about 10% each year as greater use is made of GMOs. The majority of the consultees indicated that there would be no activities currently classified as Group II Type A which would be freed from notification requirements. One GM centre stated that there would be 1 or 2 such activities per year. It is therefore assumed that only about 10 activities currently classified as Group II Type A would be freed from notification requirements. This figure is not expected to change significantly over time.

2. The respondents to the survey provided a range of estimates for the length of time that it takes to prepare a notification. In general the responses suggest that it takes between one and four hours to prepare a notification. In practice, in nearly all cases the notification will be cleared by members of a Biological Safety Committee (BSC) who might spend say up to an hour reviewing each notification. The BSC might typically consist of five to ten members. This would give a total of six to fourteen hours staff time involved in the preparation and clearing of each project. The cost of staff time involved would be similar to that as before (i.e. £14 per hour) since staff of the same level/grade would be involved. This would suggest total costs of between £87 and £203

2²The 1997 New Earnings Survey gives the average hourly wage (excluding overtime) of a laboratory technician as £8.74, and of "other natural scientists" as £12.54. Taking a figure near the middle of this range, adding a 30% allowance for non-wage costs, and uprating it to 1998 prices suggests that £14 is a reasonable estimate. It is thereafter assumed that earnings rise by 1.8% per year in real terms.

per project. There would also be the cost of the notification fee which in 1998 is £130³ per project. This would suggest total notification costs of £217 to £333 per project.

3. If there are 310 activities exempt from notification in the first year (three hundred Group I Type B, ten Group II Type A) then this would suggest a total cost saving of between £67,100 and £103,100. If the number of cases increases by 10% each year, over a ten year period total cost savings, in present value terms, are between £0.8 million and £1.2 million.

4. (iv) Reduction in notice periods.

1. When notification of the use of a GMO is required the project is subject to a notification period. The length of this is dependent on whether the notification is for the first use at premises for that category of organism or for a subsequent activity after first notice has been given. The proposed changes include reductions in the notification period.

2. For first use of premises the length of the notification period is currently 90 days for both Group I and Group II activities. The proposed changes would remove the notification period for Class I activities (such that work can begin as soon as notification has been given). HSE considers that about 30 Group I notifications a year would be affected by this. The proposed changes are also expected to reduce the notification period from 90 days to 45 days for about 15 Group II notifications.

3. For subsequent activities the removal of notification requirements as stated above for the estimated 10 Group I Type B activities is in effect a reduction in the notice period from 60 to zero days. HSE also considers that about 30 Group II activities might undergo the same reduction (i.e. from 60 to zero days). There is also expected to be a reduction in notification period from 60 to 45 days for about 10 Group II activities.

4. Eight centres stated that they are involved in projects that would have a reduced notification period. Five indicated that they would benefit from this. One stated that the reduction would give them a commercial advantage as they would be able to start projects more quickly. Another stated that the change would be very valuable and that the time saving would be of "great practical benefit". However four centres stated that the time saving would not be of significant benefit to them. One reported that it was unable to assess what the impact might be. Two small firms also stated that if they were to relocate they would benefit from the reduction in notification period for first use of Group I GMOs.

5. The centres interviewed more recently gave equally mixed responses, with a prevalence of respondents stating that there would not be much saving as a result of the reductions.

6. In the past, both industry and academic institutions have been critical of the current length of notification periods. For academic and research based institutions that have a rapid turnover of projects the notification period can be particularly disruptive in holding back work on new projects. For commercial centres the notification period may mean the loss of a project or a costly delay in a new project. The reduction in notice periods may enable earlier use of the GMO and therefore added benefits.

³ It is assumed that the charge increases by 1.8 per cent per year in real terms - in line with the assumptions for earnings.

7. Overall, the extent of the saving is likely to vary from project to project and centre to centre. Where the timetable of a project is determined by other factors or is not important, then the benefits might be limited. However for commercial centres in particular the benefit is likely to be more significant and may possibly outweigh the benefits (cost savings) derived from the other changes in the proposed revision. It is not, however, possible to quantify these potential benefits.

(v) Annual returns

1. The current Regulations require practitioners to make annual retrospective returns indicating the number of risk assessments they have carried out. This requirement would be discontinued, implying some time savings for GM practitioners. The responses from centres were very mixed, ranging from 5/10 minutes to half a day. In view of the responses we assume the time saved will be between 10 minutes to 4 hours per year per centre, at the wage of £14 per hour. This gives a total of £1100 to £27,500 per year, and a present value of between £9,600 and £230,400.

(vi) Public Register

1. The current Regulations require HSE to maintain a register of notifications concerning premises and activities for which consent has had to be granted. The new Regulations would require the register to cover all notified activities. At present, notifiers have to complete a separate public register form, summarizing information from the notification. Under the new arrangements, notifiers would no longer have to complete such a form; the register entry would consist of the basic information from the notification itself minus the full risk assessment and any confidential information. All the respondents stated that the time saved was none or minimal.

(vii) Application of containment and control measures to activities involving GMMs.

1. There will be benefits to be gained from having more detailed indications of the control measures appropriate to different types of activities. For seven centres, this provision is beneficial because it avoids confusion. For three centres there are no benefits at all. For two centres it might induce some time savings, but only one centre attempted to quantify the benefits, in terms of one-two minutes per each risk assessment. In view of the responses, we have not attempted to quantify the cost savings, which are likely to be very small.

(b) Other benefits

1. Three respondents stated that there may be health and safety benefits arising from the proposed changes. One stated that the proposed system was easier to understand and as a result would promote better compliance and improve health and safety. The second stated that the proposed changes could improve health and safety by encouraging staff to undertake more risk assessments for "level two rather than simply submitting them to HSE as Group II". The third stated that the proposed scheme was simpler and would enable more "effort" to be spent on risk assessment as opposed to administrative arrangements. Four centres did not anticipate any health benefits arising from the proposed changes. Overall it is possible that there may be a slight improvement in health and safety at centres that use GMOs as a result of these proposed changes.

2. Finally, the new Regulations would bring benefits in terms of reduced environmental risks from activities involving genetically modified micro-organisms as a result of:

- improved containment and control provisions;
- targeting of notification requirements according to actual risk as opposed to inherent properties of micro-organisms; and
- a clearer risk assessment procedure.

It has not been possible to quantify these benefits.

Overall, benefits (cost savings) to employers are estimated to be £1,016,500 to £1,734,200 over a ten year period. There are also expected to be unquantifiable benefits relating to reductions in the notification periods, which could be significant in some cases. This is presented in Table 1 below.

Table 1 : Estimated cost savings

	Cost savings in first year £	10 year cost savings (present value) £ 1998 prices
Removal of organism and activity classification schemes	19,900	167,400
New provisions for exemption	5,800 to 14,500	48,700 to 121,800
Reduction in the numbers of notifications	67,100 to 103,100	790,800 to 1,214,600
Reduction in notice period	unquantifiable	unquantifiable
Annual returns	1,100 to 27,500	9,600 to 230,400
Reduced environmental risk	unquantifiable	unquantifiable
TOTAL	93,900 to 165,000	1,016,500 to 1,734,200

NB: these figures increase each year before discounting. Figures may not add up due to rounding

COSTS

Business sectors affected

1. The sectors affected are shown in paragraph 7. The proposed revision is not expected to impose significant costs on industry. However, firms were asked about possible costs in a number of areas. From the responses it seems likely that the main impact will be in respect of those employees that need to familiarize themselves with the new system.

(i) Familiarization with the new system

2. The number of employees needing familiarization will vary from centre to centre. Estimates from our survey ranged from 20 to 320 employees. For small firms estimates ranged from 3 to 8 employees. HSE estimates that on average 20 employees at each centre might need to become familiar with the new system. This suggests a total of 9,460 employees.

3. The responses suggest that internal training or instruction would be the common way in which familiarization is achieved. This would last between 1 hour and half a day. This would suggest total one-off costs of between £290 and £1161 per centre (assuming twenty employees

per centre, and again valuing the cost of staff time at £14 an hour). Total costs would be between £137,200 and £549,000.

4. A minority of firms might provide some of their employees with more formal training. This might enable these employees to instruct other staff. Three out of the six respondents (not including small firms) indicated that they would provide training lasting between 1/2 and 2 days and costing between £110 and £330 per person. (A third said that it would consider providing more formal training). If these responses are indicative of the sector as a whole then this would suggest that perhaps 1/2 of the 473 centres might provide formal training. It is assumed here that this might apply to 2 employees in each of these centres. This suggests costs of between £51,700 and £155,000.

5. Two centres also stated that there may be further costs incurred in the updating of internal paperwork but that these costs would be minimal.

6. Therefore total one off costs as a result of becoming familiar with the system are estimated to be between £189,000 to £704,000.

(ii) New notification requirements

1. The risk assessment for a particular activity may indicate that the appropriate containment measure falls between two points. According to the new Regulations, the classification should correspond to the higher of the two levels and notified accordingly. Some activities, currently Group I Type A and non-notifiable in advance, are likely to become notifiable under the new arrangements. Five respondents to the survey expected no, or few, such cases, whereas seven centres stated that some Group I/Type A activities currently non-notifiable may be classified as Class 2 and would therefore need to be notified under the new procedure. Their answers varied from between 3 to 5 notifications per year, up to 36 per year for one respondent.

2. During the consultation period, five centres replied that few (1 or 2) such activities a year are likely to become notifiable under the new arrangements. Two centres estimated no such cases, whereas four stated that around five per year would become notifiable. These replies suggest that between about 250 and 900 such activities per year may become notifiable. HSE considers that this may be an overestimate and, scaling down the previous range by about 20%, assumes that between 200 and 700 activities per year will become notifiable.

3. The notification period would be zero days and the preparation of the notification is likely to be simpler than for the Group I Type B and Group II Type A projects referred to earlier, given the nature of the activities that are affected (low-risk and small-scale non-industrial activities). During the consultation period, most centres stated that the notifications would take between 2 and 3 hours to prepare, whereas a few estimated a larger figure of up to 15 or 20 hours. Given the nature of these activities, and the wide range emerging from the responses, HSE considers that the notification on average may take between 2 and 10 hours and therefore cost between £29 and £145 in the year 2000 (assuming again that the cost of staff time involved is £14 per hour in 1998). This suggests annual costs of between £5,800 and £101,600. Over a ten-year period the costs are between about £48,700 and £852,400 in present value terms.

(iii) Notification of additional information

4. Regulation 10(4) of the current regulations provides for notifiers to notify significant changes to a notified activity or premises. Notifiers are also obliged to notify changes in

administrative particulars. The new Regulations would continue this requirement, but introduce specific charges for notifications of significant changes to cover current costs of re-evaluating the risk assessment. The charges are intended to re-distribute the costs amongst notifiers more fairly, so that those who use the 10(4) system heavily are not subsidized by those who do not. As such the costs to GM centres from these charges are shown as follows, but are not added to the total costs due to the new Regulations. The number of significant '10(4)' notification of changes typically made per year differs widely among the centres. For four respondents the number varies from 1 to 3 per year. Another six centres make none, whereas one centre makes 10 notifications of changes per year. As far as minor administrative changes are concerned, from the responses we obtain an average of about one per year. HSE estimates that there will be much fewer '10(4)' notifications per year than the current number (70) due to the fees being in place, and assumes a total of 30 notifications a year under the new Regulations. The estimated charge is currently (1998) £400, therefore the total annual costs due to the charge will be £12,400. In present value terms £104,400⁴.

(iv) Application of containment and control measures

1. Ten centres stated that the new tables of containment and control measures will not entail any, or only minor, additional measures to activities. The new tables are, in fact, closely related to those set out in the COSHH Regulations for the control of activities involving biological agents. In a great number of cases, the requirements for GMMs set out in the new tables should reflect what practitioners are already doing to fulfil their duties under COSHH.

(v) Other possible costs

1. In view of the extra detail that might be required in risk assessments to allow notifiers to go straight from the risk assessment to the notification requirement, the centres contacted were asked if they felt that there would be a need to increase the time spent on risk assessments. Eight of the respondents stated that this would not be the case. However, one respondent felt that under the proposed changes, the risk assessment and subsequent containment requirements for the lowest risk work (i.e. Group I Type A) might be made more complex in order to give the necessary protection for the more hazardous work. They estimated that if this was the case, risk assessments might take an extra hour to carry out. A second firm felt that if the associated guidance was not clear then risk assessments might take one to two hours extra to carry out. HSE considers that it is unlikely that firms would have to spend longer on risk assessments and some may need to spend less. In view of the this and that only two of the centres felt that there was the possibility of increased time spent on risk assessments such potential costs have not been included in the RIA.

2. Total one-off costs arising in respect of familiarization with the new system are estimated to be between £189,000 and £704,000. Over a ten year period, the present value of recurring costs relating to new notification requirements is estimated to be £153,100 to £956,800. Overall this gives total costs to industry of between £342,000 and £1,660,800 over a ten year period (1998 prices).

Impact on HSE

4 ⁴It is assumed that the notification fee increases by 1.8 per cent per year in real terms - in line with the assumptions for earnings - to cover full economic cost.

3. HSE considers that the revised Regulations will imply additional costs mainly due to the large number of activities (between 200 and 700), currently non-notifiable, which consultees suggest will be classified as Class 2 and will therefore need to be notified under the revised Regulations. Depending on the actual number of new notifications per year, costs to HSE per year may be between £8,000 and £28,000. Over a 10 year period, in present value terms, this equals £67,100 to £235,000.

SMALL BUSINESS LITMUS TEST (SBLT)

4. Four small centres that use GMOs were contacted from a list of small and medium-sized firms compiled by HSE about the expected impact of the proposed changes. Another two firms with fewer than 30 employees were contacted during the more recent survey.

5. The responses from the small firms were broadly consistent with the responses received from the other larger firms and have been incorporated into the main body of the RIA. The large majority of the projects use Group I Type A GMOs. All four stated that they would not provide formal training but would provide internal training lasting between one and ten hours per person. As a whole, two respondents felt that the proposed changes would have a beneficial impact. This was largely a result of expected reductions in the time spent on notifications (by two to three hours per project) and from the reduction in notification periods. Another two respondents felt that the proposed changes would have little impact on their work.

6. From the responses, the proposed amendments would therefore appear to have either very little or a small but positive impact on small firms.

7. ENVIRONMENTAL IMPACT

8. The proposed Regulations would have a positive environmental impact which was discussed in the Benefits section.

BALANCE OF COSTS AND BENEFITS

1. The responses received suggest that the costs arising from the proposed revision are mainly due to one-off familiarization costs for the uses of the new system, (although one respondent felt that costs may arise as a result of a need to spend a greater length of time on risk assessments), and, subject to the uncertainty captured by the wide range used, to the new notification requirements. Total costs are estimated at between £409,200 and £1,895,800 over ten years in present value terms. Over a ten year period total discounted cost savings are estimated to be between £1,016,500 and £1,734,200 in present value terms.

2. This comparison does not include the potential benefits arising from the reduction in notification periods which are unquantifiable but which may be significant in some cases and perhaps exceed the benefits (cost savings) that arise under other parts of the proposed changes.

3. Some responses suggest that there may additionally be a marginal improvement in health and safety although this is expected to be very much secondary to the cost savings and benefits relating to the reduction in notification periods.

Appraisal of Uncertainties

1. There is uncertainty concerning 1) the time currently spent by GM practitioners to make annual returns, 2) the time spent preparing a notification, and, in particular, 3) the number of activities per year likely to become notifiable under the new arrangements. If the actual figures are near the lower end of our ranges, benefits will significantly offset the costs, by almost 3:1. If, however, the figures are closer to the top end of the range, costs will broadly balance the estimated cost savings.

2.

ARRANGEMENTS FOR MONITORING AND EVALUATION

3. The impact of the new Regulations would be continually monitored by HSE in the course of scrutiny of notifications and inspection of containment facilities. A formal evaluation will be conducted after the Regulations have been in force for three years.

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