

CONCORDAT ON THE IMPLEMENTATION OF DIRECTIVE 2001/18/EC and REGULATION 1946/2003/EC

**An agreement between the Department of the Environment in Northern
Ireland, the National Assembly for Wales, the Scottish Executive and the
UK Government**

Introduction

1. This Concordat (“the Concordat”) sets out the agreed framework for co-operation between the Department of the Environment in Northern Ireland (DoENI), the Department for Environment, Food and Rural Affairs (Defra), the Welsh Assembly Government (WAG), as the executive of the National Assembly for Wales, and the Scottish Executive (SE), on the administration and coordination of the regulatory frameworks established under:
 - Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms; and
 - Regulation (EC) No.1946/2003 on transboundary movements of genetically modified organisms
2. The Concordat is not a legally binding agreement or a contract. It does not override the legal duties and powers of the four parties, each of which is responsible for discharging as it considers appropriate. Nor is it intended to cover every detailed aspect of the relationship between them. Rather, it is a statement of the principles that will guide relations between the four parties.
3. The Concordat is drawn up in accordance with the principles outlined in the *Memorandum of Understanding and supplementary agreements between the UK Government, Scottish Ministers, the Cabinet of the National Assembly for Wales, and the Northern Ireland Executive Committee* (December 2001). This sets out the broad understanding of the UK Government and the devolved administrations for Scotland, Wales and Northern Ireland of the principles and practices that underlie relations between them. The Concordat is also intended to be consistent with the overarching concordats between those administrations, particularly the *Concordat on Co-ordination of EU Policy Issues* and the *Concordat on International Relations*.

Legislative framework

4. Directive 2001/18/EC sets out a harmonised and generic EU framework for the regulation of deliberate releases into the environment of genetically modified organisms (GMOs). The Directive entered into force in October 2002. Regulation (EC) No. 1946/2003 introduces, for the first time, requirements relating to exports of genetically modified (GM) products from the Community, to international transboundary

movements of GMOs, and to information exchange with the Biosafety Clearing House established under the Cartagena Protocol on Biosafety. It completes EU implementation of the Protocol, which the UK ratified on 19 November 2003.

5. In the UK, responsibility for the regulation of GMO deliberate releases and transboundary movements of GMOs in Northern Ireland, Wales and Scotland has been devolved to the administrations responsible for those territories¹. Defra has responsibility for the regulation of these matters in England. Defra and the devolved administrations are each responsible for implementing the Directive and the Regulations in their respective territories.
6. The UK has four **territorial competent authorities** (TCAs) with responsibility for implementing the regulatory frameworks in Northern Ireland, England, Wales and Scotland respectively. These are the Secretary of State for Environment, Food and Rural Affairs in England, the Deputy Minister for Environment and Rural Development in Scotland, the Minister of State with responsibility for the Department of the Environment in Northern Ireland, and the National Assembly for Wales in Wales. In terms of the practical working arrangements in this document the term “territorial competent authority” or “TCA” also applies to officials acting on behalf of the TCA.

Relations with the EU and other states

7. Aspects of Directive 2001/18/EC that take place at the European level require the UK Member State to negotiate and act as a single entity. In these cases the Secretary of State for Environment, Food and Rural Affairs acts on behalf of the UK Government and Member State, and is responsible for communications at EU level which represent, or relate to, the agreed UK line.
8. Similarly, Regulation 1946/2003 requires each Member State to nominate a single “focal point” to engage in aspects of the 1946/2003 regime that occur at the EU and international levels. The Secretary of State for Environment, Food and Rural Affairs is the UK focal point on behalf of all territorial authorities². The Regulation also requires the designation of one or more competent authorities which are responsible for performing the administrative functions required by the Protocol. In

¹ Powers to regulate the deliberate release of GMOs under Part VI of the Environmental Protection Act 1990 were devolved to the devolved administrations for Scotland and Wales in 1999. Similar powers for Northern Ireland were established under the GMO (Northern Ireland) Order 1991. Powers under section 2(2) of the European Communities Act 1972 (which allows the holder of such powers to amend and introduce legislation in order to implement EC legislation) have also been devolved to Scotland (Section 53 of the Scotland Act) and Wales (SI 2003/2901). Northern Ireland was already designated under the Act.

² See regulation 3(1) read in conjunction with regulation 1(3) of the Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 (SI 2004/2692).

England this is the Secretary of State, for Environment, Food and Rural Affairs, National Assembly for Wales in Wales, Scottish Ministers in respect of Scotland and Department of the Environment in Northern Ireland is designated in respect of Northern Ireland.

9. UK lines on the development of EU policy matters or on applications presented by other Member States should be agreed between the four TCAs before EU level negotiations take place. Defra will represent the UK on the basis of this agreed line³. In agreeing UK lines, every effort should be made by the four TCAs to reach agreement, including (if necessary) embarking on the procedure set out in the *Concordat on co-ordination of European Union policy issues*⁴, providing that a common line can be agreed within the necessary timescales⁵. If this is not possible, the UK negotiating position should be set by the UK Government on the basis of expert scientific advice, and taking into account the views of the devolved administrations, in order that the UK can take part in EU level discussion and decision making.
10. Detailed descriptions of the coordination of certain aspects of the EU level regulatory process under Directive 2001/18 are covered in Annexes A-D.

Administration

11. The parties to the Concordat have jointly established the **Northern Ireland, England, Wales and Scotland GM Unit (NIEWS)**. NIEWS is a body consisting of scientists and administrators that serves the four TCAs in administering the GMO deliberate release regime in Northern Ireland, England, Wales, and Scotland. It provides for:

- *administration and technical support* – e.g. by processing Part B and Part C applications on behalf of the TCA to which the application has been made (i.e. subject to the instructions of that TCA acting in accordance with the Concordat). It will also undertake other work to assist the four TCAs to run the two regimes (e.g. providing scientific and procedural advice to TCAs);

³ In cases where a TCA has a particular interest in EU-level discussions (e.g. if it is the “lead competent authority” for a Part C application being discussed in Europe) a representative of that authority may accompany the UK representative to the discussion in accordance with the procedure set out in paragraph B4.15 of the *Concordat on co-ordination of European Union policy issues*.

⁴ Paragraphs B4.2-B4.11 of the *Concordat on coordination of EU policy issues* sets out a process by which the UK Government and the devolved administrations may discuss matters of mutual interest at the official, then ministerial, level leading to a formal discussion in the Joint Ministerial Committee.

⁵ The Directive sets clear timescales in which EU level discussion and decision making must take place (e.g. during the 1st stage of collective EU decision making on Part C dossiers, member states have 60 days to comment on, ask for more information on, or object to such dossiers after a positive assessment report has been forwarded by the lead member state). UK lines should be decided in time for the UK to use its voice in EU level discussions.

- *communication* – by ensuring that a high level of communication exists between the four TCAs on the function of the two regimes at the TCA, UK and EU levels. This includes being the “post-box” for correspondence flowing between the territorial/UK and UK/European levels;
 - *co-ordination* – by being the conduit through which the 4 TCAs discuss and agree UK positions (e.g. UK lines to be communicated by Defra at the EU level).
12. When NIEWS functions at the territorial/UK level it will do so on behalf of one of the TCAs – e.g. if NIEWS processes an application received by the Scottish TCA it will be working directly for the Scottish TCA. When NIEWS functions at the UK/European or UK/international level it will do so on behalf of the UK Government.

Expert scientific advice

13. The Directive requires that decisions taken by competent authorities on applications to release GMOs on their territories are based on sound scientific evidence. For the purposes of the Concordat the term “*expert scientific advice*” will be taken to mean the best available expert scientific advice on risks posed by a GMO (or GMOs) to human health or the environment in accordance with the requirements of Directive 2001/18/EC. This would normally be advice supplied by ACRE.
14. The **Advisory Committee on Releases into the Environment (ACRE)** is the statutory committee of independent scientific experts appointed by each of the UK’s four TCAs to provide them with expert advice on administering the deliberate release regime in Northern Ireland, England, Wales and Scotland respectively.
15. The four TCAs have also jointly established the **ACRE secretariat**, a body of officials that provides administrative and technical support to ACRE. In practice, NIEWS will undertake all functions of the ACRE secretariat jointly on behalf of the four TCAs.

Duration of the Concordat

16. This agreement takes effect from the date on which it is agreed by the four parties. It will run until its termination by any one of the parties giving six months’ notice in writing.

Financial and staffing issues

17. Defra agrees to fund and provide the staff for NIEWS (and thus for the ACRE secretariat)⁶. If Defra wishes to terminate or amend this aspect of the agreement it must give the devolved administrations at least six months notice in writing (unless the devolved administrations all agree to a shorter period of notice). If a devolved administration wishes to amend this aspect of the agreement (e.g. if it wishes to contribute money or staff in support of NIEWS) it should do so by agreement with Defra and the other devolved administrations.
18. The four competent authorities are entitled under the deliberate release regime to impose fees on applicants for costs incurred in processing their applications⁷. Any such moneys received by DoENI, WAG or SE will be forwarded to Defra to reimburse it for its funding of NIEWS. Charges imposed on consent holders to cover the costs of inspection and enforcement of GMO releases should either be forwarded to Defra or retained by the TCA, depending on who pays the bill for such work.

Liaison and review

19. Each of the four parties will appoint a liaison officer for the general purpose of ensuring the smooth running of the Concordat. The Concordat can be reviewed at any time at the request of one of the parties, and can be amended at any time with the agreement of all parties.

Public Register of Information

20. NIEWS will keep a statutory public register⁸ (in hard/paper copy) jointly on behalf of all four TCAs at its offices in London. The TCAs will be responsible for keeping and maintaining copies of the public register as it relates to their territorial interests. In addition to the maintenance of the statutory public register, NIEWS (on behalf of the four TCAs) will strive to make as much information as possible available via the Internet to the public of Northern Ireland, England, Wales and Scotland.

⁶ This is on the assumption that costs, in terms of money or staff time, incurred by NIEWS in working on behalf of a TCA are not excessively high compared to the normal cost of undertaking such work (e.g. as may be experienced if there are an abnormal number of responses to a public consultation). In such cases, Defra would expect the TCA to which the application has been made to contribute to costs incurred by NIEWS, at a level to be agreed by discussion with Defra.

⁷ For instance, under the "GMOs (deliberate release and marketing) fees and charges scheme 2001" in England.

⁸ As required by section 122 of the Environmental Protection Act 1990.

Annex A - Handling of Part B (non-commercial) applications

NB: *In all aspects of the Part B procedure set out below, NIEWS works directly for the TCA to which the application is made unless otherwise specified. NIEWS and the lead TCA (and the UK Government where appropriate) will work together to ensure that all specific requirements of the deliberate release regime are met.*

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| Stage 1(a) <i>Application</i> | <p>A Part B application is made to a TCA, which becomes the “lead TCA”. NIEWS drafts a letter of receipt for the lead TCA to send to the applicant. NIEWS checks that the application is in order and if necessary prepares a letter for the TCA to send to the applicant asking for more information. NIEWS forwards the application to ACRE, other relevant expert committees, the Health and Safety Executive, and the Food Standards Agency.</p> <p>Within 30 days of receipt of the application, NIEWS (on behalf of the UK Government) sends a summary of the application to the Commission, which is responsible for forwarding it to other Member States for information and comment.</p> |
| Stage 1(b) <i>Consultation</i> | <p>NIEWS checks that the applicant has met regulatory requirements concerning information/consultation (e.g. that the required organisations have been informed, and that the application and subsequent public consultation have been advertised correctly). NIEWS (and TCAs where appropriate) ensures that the required information on the application is placed on the relevant public register and that public representations are requested in accordance with the regulations.</p> |
| Stage 2 <i>Assessment and decision</i> | <p>When the public consultation is over, and ACRE has considered the application, NIEWS sends a summary of public representations, ACRE’s advice, and the views of other relevant organisations (e.g. the HSE and other Member States) to the lead TCA. If the lead TCA is content that there is sufficient information to make a decision, it decides either to grant or refuse a Part B consent and, if a consent is to be issued, the conditions that should be attached to it. NIEWS drafts the appropriate paperwork for the lead TCA to send to the applicant.</p> |
| Stage 3 <i>Information on decision</i> | <p>In accordance with the regulations, NIEWS (and TCAs where appropriate) ensure that the required information (e.g. a copy of any Part B consent issued and ACRE’s advice) is placed on the relevant public register.</p> |

Annex B - Handling of Part C applications (made in the UK)

NB: This procedure also applies to applications for renewal of Part C consents made within the UK. In all aspects of the procedure set out below, NIEWS works directly for the TCA to which the application is made unless otherwise specified.

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| <p>Step 1 <i>Application</i></p> | <p>A Part C application is made to a TCA in the UK. This TCA becomes the “lead TCA” for all aspects of the process. Where this involves communications at the EU level the lead TCA should send all such communications through UK Government. NIEWS copies the application to the other 3 TCAs, to ACRE, and other expert committees as appropriate. NIEWS forwards a summary of the application and, subsequently, a copy of the application itself and any additional information to the Commission.</p> |
| <p>Step 2 <i>Expert advice</i></p> | <p>ACRE, as part of its statutory duty to advise TCAs under the EPA, will consider the application. Each of the 4 TCAs may ask for specific issues regarding potential risks posed by the proposed release to be considered by ACRE. ACRE will discuss the application and provide its advice to the lead TCA, copying to the other 3 TCAs.</p> |
| <p>Step 3 <i>Assessment report</i></p> | <p>NIEWS prepares an assessment report in line with ACRE’s advice, also taking account of other views expressed. If the lead TCA approves the report, NIEWS clears it with the other 3 TCAs (if a common line cannot be reached the final decision will lie with the lead TCA), after which:</p> <ul style="list-style-type: none"> • if the approved assessment report is negative, NIEWS will prepare the dossier and a letter, which the lead TCA will send to the applicant to inform them of the decision, copying to the other 3 TCAs. NIEWS (on behalf of the UK Government) will send a copy of the assessment report to the Commission. • if the approved assessment report is positive, NIEWS will prepare the dossier and a letter, which the lead TCA will send to the applicant to inform them that the assessment report recommends that a consent is granted, copying to the other 3 TCAs. NIEWS (on behalf of the UK Government) will send a copy of the assessment report to the Commission. <p>If the lead TCA does not agree with the assessment report or ACRE’s advice, or decides for other reasons to reject the application they must consult with NIEWS and the other TCAs on the way forward. Any decisions must be made by the lead TCA in accordance with the appropriate legislation.</p> |
| <p>Step 4 <i>EU decision making</i></p> | <p>The dossier is considered at EU-level. During this process:</p> <ul style="list-style-type: none"> • requests for further information from the Commission or another Member State are channelled through NIEWS (as UK “postbox”) to the lead TCA. NIEWS then requests information from the applicant, and the information flows back to the EU-level via the same route; • comments and objections from the Commission and other Member States are sent to NIEWS (as UK “postbox”), which forwards them to the 4 TCAs. Defra (via NIEWS) asks the Northern Irish, Welsh and Scottish TCAs for views which will be taken into account in preparing the UK line (which must be consistent with the assessment report); • DEFRA represents the UK in all dealings at the EU level, for instance in the initial 60(+45) day discussion and the Regulatory Committee. The UK line should be agreed in advance by the 4 TCAs, and should be in accordance with expert scientific advice. |
| <p>Step 5 <i>Granting or refusal of consent</i></p> | <p>Once the Commission and Member States make a decision on the dossier, Defra (via NIEWS) will inform the lead TCA and the other TCAs within the UK. NIEWS (on behalf of the lead TCA) will draft either (i) a Part C consent or (ii) a letter informing the applicant that consent has been refused, which the lead TCA will send to the applicant. NIEWS copies the consent or letter of refusal to the other 3 TCAs. NIEWS (on behalf of the UK Government) forwards a copy of the consent to the Commission.</p> |

Annex C - Handling of Part C applications (made in another Member State)

NB: This procedure will also apply to applications for renewal of Part C consents made in another Member State (as far as applicable).

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| <p>Step 1 <i>Receipt of summary and dossier</i></p> | <p>A summary of a Part C dossier (on which a CA of another Member State is leading) is forwarded to the UK by the Commission. NIEWS (on behalf of the UK Government) copies it to the 4 TCAs within the UK, ACRE, and others as appropriate. A similar process occurs upon receipt of the full application and the assessment report, which the Commission is required to forward later. Defra leads in agreeing a UK line and communicating on the EU-level.</p> |
| <p>Step 2 <i>Expert advice</i></p> | <p>ACRE, as part of its statutory duty to advise the 4 TCAs, will consider the application. Each of the 4 TCAs may ask for specific issues regarding potential risks posed by the GMO to be considered by ACRE. Requests for further information are channelled through Defra (representing the UK). When ACRE is satisfied they have sufficient information they discuss the dossier and provide advice to Defra (as the lead UK CA), copying to the other 3 TCAs.</p> |
| <p>Step 3 <i>UK line</i></p> | <p>Defra and the TCAs agree a UK line on the dossier, in light of expert scientific advice⁹.</p> |
| <p>Step 4(a) <i>1st stage of EU level discussion</i></p> | <p>DEFRA forwards the UK comments/objections to the Commission. Defra acts on behalf of the UK in any discussions that take place at EU-level during the initial 60(+45) day period in which dossiers are discussed at the EU level. Defra (via NIEWS) keeps the other 3 TCAs informed (e.g. copying them details of comments and objections raised by other Member States), invites comments, and reflects these views in the UK line as appropriate.</p> |
| <p>Step 4(b) <i>2nd stage of EU level discussion</i></p> | <p>DEFRA represents the UK in the Regulatory Committee in the event that there is no collective decision after the 60+45 day period. Defra (via NIEWS) keeps the other 3 TCAs informed, invites comments, and reflects these views in the UK line as appropriate.</p> |
| <p>Step 4(c) <i>3rd stage of EU level discussion</i></p> | <p>Defra represents the UK in the Council of Ministers in the event that there is no collective decision in the Regulatory Committee. Defra (via NIEWS) keeps the other 3 TCAs informed, invites comments, and reflects these views in the UK line as appropriate.</p> |
| <p>Step 5 <i>Consent</i></p> | <p>Defra (via NIEWS) informs the other 3 TCAs of the Commission and Member States' decision. If a consent is granted, Defra (via NIEWS) sends a copy to each of the other 3 TCAs when it receives it from the Commission.</p> |

⁹Subject to the procedure for agreeing UK lines set out in paragraph 9 of the Concordat.

Annex D - Handling of enforcement action relating to unauthorised GMO release or failure to comply with Part B or Part C consent conditions

NB: this procedure should be used by competent authorities considering or taking enforcement action under the EPA (or similar NI legislation) - e.g. to issue prohibition notices against unauthorised GMO releases taking place in their territories

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| Step 1 <i>Detection</i> | A TCA within the UK becomes aware that an unauthorised GMO release has taken place, or is about to take place, on its territory ¹⁰ . The TCA (using the support of NIEWS and GM inspectors as appropriate) makes an initial assessment of the situation and takes any immediate enforcement action it considers appropriate ¹¹ . The lead TCA (via NIEWS) should immediately inform the other 3 TCAs of the unauthorised release and of any immediate action that has been taken. The other 3 TCAs should each examine whether action may be necessary in their own territories. |
| Step 2 <i>Expert advice</i> | At the earliest opportunity ACRE (and other relevant experts) should be asked to provide advice to the TCA on the implications of the unauthorised release, and on the details of enforcement action (or further action) needed to deal with it. The TCA should take full account of ACRE's advice. |
| Step 3 <i>Coordination</i> | In all dealings on enforcement actions, the lead TCA (via NIEWS) should keep the other 3 TCAs fully informed of developments. In cases that affect more than one territory the affected TCAs should (via NIEWS) coordinate action in a way that best protects human health and the environment. They should also keep each of the other TCAs informed if any prosecution proceedings that may be taken against any person suspected of an offence under the Environmental Protection Act. |
| Step 4 <i>Europe</i> | NIEWS (on behalf of the UK Government) should inform the Commission and other Member States of any unauthorised release that has taken place within the UK, and any remedial action that has been taken by any TCA within the UK as a result. |

¹⁰ "Unauthorised GMO releases" may include:

- (i) releases of GMOs that have not been authorised under the Directive or other sectoral legislation – e.g. the growing of an unauthorised GM crop anywhere in a territory of the UK.
- (ii) release of GMOs authorised under Part B of the Directive, but being grown outside the conditions of the Part B consent. For instance, a Part B consent will specify when, where and how a GMO may be released, how it must be destroyed and so on. If any of these conditions is not followed, a TCA may take enforcement action.
- (iii) releases of GMOs that have been authorised under Part C of the Directive, but that are being used outside the conditions of their consents – e.g. if a Part C authorised GM crop is being grown commercially in a territory of the UK, but the conditions of the consent are not being followed. For instance, if the consent sets separation distances (e.g. that the crop must not be grown within a certain distance of a National Park) that are not being observed; if post-market monitoring conditions; traceability and labelling conditions; or any other condition placed on a consent was not being observed a TCA could use enforcement powers to rectify the situation.

¹¹ As a general rule, each TCA has the flexibility to use its enforcement powers to rectify situations where unauthorised releases have taken place in its territory according to its own discretion in accordance with the deliberate release regime.