**CONCORDAT ON THE IMPLEMENTATION OF DIRECTIVE 2001/18/EC (as amended) AND REGULATION 1946/2003/EC**

An agreement between the Department of the Environment[1] in Northern Ireland, the Welsh Government, the Scottish Government and the UK Government (the four parties).

**Introduction**

1. This Concordat ("the Concordat") sets out the agreed framework for co-operation between the Department of the Environment in Northern Ireland, the Department for Environment, Food and Rural Affairs (Defra), the Welsh Government and the Scottish Government, 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 (GMOs), including the 2015 amendment; and
- Regulation (EC) No.1946/2003 on trans-boundary movements of GMOs;

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 United Kingdom Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive Committee* (October 2013). 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 GMOs. The Directive entered into force in October 2002.

i Directive 2015/412/EU amends Directive 2001/18/EC. It entered into force in April 2015 giving MS the power to restrict or prohibit the cultivation of a GM crop in all or part of their territory by either asking companies to change the scope of their applications for EU approval to exclude them or by implementing a national ban on non-safety grounds including those listed in the Directive. The scope of an application can only be changed while the crop is being authorised, but a national ban can be put on a GM crop at any point during the 10 year EU authorisation period.

ii Regulation (EC) No.1946/2003 introduces requirements relating to exports of genetically modified (GM) products from the EU, international trans-boundary movements of GMOs and to information

[1] With effect from May 2016 this will be the Department of Agriculture, Environment and Rural Affairs

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 regulating genetically modified food and feed and the deliberate release and trans-boundary movements of GMOs in respect of each of the devolution settlements is devolved. Defra and the devolved administrations of Northern Ireland, Wales and Scotland are each responsible for implementing the Directives 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. These are the Minister with responsibility for the Department of the Environment in Northern Ireland, the Secretary of State for Environment, Food and Rural Affairs in England, the Welsh Ministers and the Scottish Ministers respectively. 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 and 2015/412/EU 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. The Food Standards Agency (FSA) is the UK competent authority for GM food and feed including under Regulation 1829/2003/EC. Defra is the UK Competent Authority for decisions about deliberate release of GMOs, whether under 1829/2003 or 2001/18/EC. Where GMO cultivation is part of an application that is also for GM food and feed use, decisions on cultivation are subject to agreement under this Concordat.

8. Similarly, Regulation 1946/2003 requires each Member State to nominate a single "focal point" to engage in aspects of the 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 authorities. The Regulation also requires the designation of one or more competent authorities which are responsible for performing the administrative functions required by the Protocol. This is the Secretary of State, for Environment, Food and Rural Affairs in England, Welsh Ministers in respect of Wales, Scottish Ministers in respect of Scotland and the Department of the Environment 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. The relevant UK Competent Authority will represent the UK on the basis of this agreed line. 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, providing that a common line can be agreed within the necessary timescale. 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 due account of the policy views of the devolved administrations and any other advice that they consider relevant, in order that the UK can take part in EU level discussion and decision-making. If the UK voting position on regulatory matters (e.g. voting on part C applications) cannot be agreed in time, the UK Government will vote on the basis of expert scientific advice.

10. Detailed descriptions of the coordination of certain aspects of the EU level regulatory process under the Directive and Regulations are covered in Annexes A-E.

**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 consents on behalf of the TCAs 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 regimes (e.g., providing scientific and procedural advice to TCAs);
- *communication* - by ensuring that a high level of communication exists between the four TCAs on the function of the 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 the relevant Competent Authority).

12. When the Northern Ireland, England, Wales and Scotland GM Unit (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 European Food Safety Authority (EFSA) is responsible for the assessment process at the European level for applications to commercially cultivate GM, market GM or for GM food and feed.

14. The Directives and Regulations require 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 the Directives and Regulations. This would normally be advice supplied by ACRE.

15. 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.

16. 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**

17. 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**

18. Defra agrees to fund and provide the staff for NIEWS (and thus for the ACRE secretariat). 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.

19. The four competent authorities are entitled under the deliberate release regime to impose fees on applicants for costs incurred in processing their applications. Any such moneys received by the Northern Ireland, Welsh or Scottish Governments 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**

20. 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 the four parties.

**Public Register of Information**

21. NIEWS will keep a statutory public register (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.

**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)**<br><br>*Application* | A Part B application is made to a TCA, which becomes the "lead TCA". Northern Ireland, England, Wales and Scotland GM Unit (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 FSA.<br><br>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. |
| **Stage 1(b)**<br><br>*Consultation* | Northern Ireland, England, Wales and Scotland GM Unit (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 TCA 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. |
| **Stage 2**<br><br>*Assessment and decision* | When the public consultation is over, and the Advisory Committee on Releases to the Environment has considered the application, Northern Ireland, England, Wales and Scotland GM Unit (NIEWS) sends a summary of public representations, ACRE's advice, and the views of other relevant organisations (e.g. the Health and Safety Executive 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. |
| **Stage 3**<br><br>*Information on decision* | 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. |

**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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| **Step 1**<br><br>*Application* | 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. |
| **Step 2**<br><br>*Expert advice* | 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. |
| **Step 3**<br><br>*Assessment report* | Northern Ireland, England, Wales and Scotland GM Unit (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:<br><br>• 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.<br><br>• 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.<br><br>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. |
| **Step 4**<br><br>*EU decision making* | The dossier is considered at EU-level. During this process:<br><br>• 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;<br><br>• comments and objections from the Commission and other Member States are sent to NIEWS (as UK "postbox"), which forwards them to the 4 TCAs. |

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| | 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);<br>• 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 |
| **Step 5**<br><br>*Granting or refusal of consent* | Once the Commission and Member States make a decision on the dossier, Defra (via Northern Ireland, England, Wales and Scotland GM Unit (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. |

**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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| **Step 1**<br><br>*Receipt of summary and dossier* | 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. |
| **Step 2**<br><br>*Expert advice* | 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. |
| **Step 3**<br><br>*UK line* | Defra and the TCAs agree a UK line on the dossier, in light of expert scientific advice. |
| **Step 4(a)**<br><br>*1st stage of EU level discussion* | 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. |
| **Step 4(b)**<br><br>*2nd stage of EU level discussion* | 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. |
| **Step 4(c)**<br><br>*3rd stage of EU level discussion* | 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. |
| **Step 5**<br><br>*Consent* | 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. |

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

**NB:** T*his 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**<br><br>*Detection* | A TCA within the UK becomes aware that an unauthorised GMO release has taken place, or is about to take place, on its territory. 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. 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**<br><br>*Expert advice* | 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**<br><br>*Coordination* | 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**<br><br>*Europe* | 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. |

**Annex E – Applications to cultivate GM crops: handling in relation to the opt-out and ban provisions**

**NB:** *this procedure is to be used by Competent Authorities in respect of applications made to cultivate GM crops under (a) Directive 2001/18/EC or (b) Food and Feed Regulation 1829/2003[2], and the options 2015/412 provides to either: (i) be excluded from the scope of an EU authorisation for GM cultivation (Articles 26b(1)), or (ii) restrict or ban cultivation of an EU-authorised GM crop (Article 26b(3)) and (b) Food and Feed Regulation 1829/2003).*

Transitional measures: Directive 2001/18/EC, as amended by Directive (EU) 2015/412, provided transitional measures until 3 October 2015. The handling arrangements which apply for each application submitted or authorisation granted for cultivation before 2 April 2015 (as per Article 26c(1) of the Directive) were similar to those set out below.

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| *Adjusting the geographic scope of an application or existing authorisation Options for action under 2001/18/EC as amended by the 2015 Directive* | The TCAs for England, Wales, Scotland and Northern Ireland will consider whether they want all or part of their territory to be excluded from the geographic scope of each application for cultivation approval, including in respect of renewal of an existing authorisation (as per Article 26b(1) of the Directive).<br><br>Where a TCA decides to seek an exclusion it shall confirm its demand for this to Defra by e-mail at least 5 working days in advance of the relevant deadline for receipt by the Commission, as specified at Articles 26b(1). Defra, as the UK CA, will forward the demand to the Commission by e-mail by the relevant deadline.<br><br>The demand to Defra should include at minimum the following information:<br>• the application that adjustment request refers to.<br>• Each application should be treated separately – applications must not be grouped together in one e-mail;<br>• the geographic area that the exclusion request refers to; and<br>• the lead contact person in the TCA.<br><br>The demand should be submitted as a 'pdf' document.<br><br>Defra, as the CA, will forward one e-mail to the Commission per application that reflects the demands of all of the territories seeking a change to the geographic scope of an application. The Devolved Administrations will be copied into the e-mail.<br><br>The Commission will feed back to Defra the result of any demand made, either shortly after receiving the relevant reply from the applicant, or after the 30 day deadline (Article 26b(2)). Defra will relay the feedback as soon as possible to Northern Ireland, Wales and Scotland as appropriate. |

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| *Implementing national restrictions or bans – notifying intended measures* | As per Article 26b(3) of the Directive, the TCAs can also consider adopting measures to restrict or ban the cultivation in all or part of their territory of a GMO, or a group of GMOs defined by crop or trait, once EU approval has been granted.<br><br>If a TCA decides that it wants to implement a national restriction or ban, it shall set out its intended measures and the corresponding grounds being invoked in an e-mail to Defra. As the UK CA, Defra will forward the e-mail to the Commission as soon as possible.<br><br>It is the TCA's responsibility to ensure that:<br><br>• the proposed measures meet all the requirements at Article 26b(3) of the Directive (i.e. that they conform with EU law, are reasoned, proportional and non-discriminatory, and are based on compelling grounds that do not conflict with the relevant environmental risk assessment undertaken as part of the EU process); and<br>• the requirements of the 75-day standstill period specified at Article 26b(4) of the Directive are observed.<br><br>The e-mail to Defra should contain at minimum the following information:<br>• the GMO, or group of GMOs, that will be subject to the ban;<br>• the grounds for the national ban, as described in Article 26b(3) and the justification for those grounds;<br>• the intended start date of the ban; and<br>• the lead contact person in the TCA.<br><br>The demand should be submitted as a 'pdf' document.<br><br>If Defra receives comments on the measures from the Commission they will relay these as soon as possible to Northern Ireland, Wales or Scotland as appropriate. |
| *Implementing national restrictions or bans – communicating adopted measures* | Where a TCA adopts a national restriction or ban after the 75-day standstill period it shall e-mail the final measures to Defra without delay and make these public on their website. As the UK CA, Defra will communicate these without delay to the Commission, other MS and the relevant company or companies. |
| *Re-integration into the geographic scope of an authorisation and/or revoking national bans or restrictions* | Where a TCA's territory has been excluded from the scope of an EU authorisation and it wants to rescind that exclusion, it shall e-mail Defra, as the UK CA, asking to make an appropriate request to that effect to the Member State CA that issued the EU consent, or to the Commission if the GMO was authorised under Regulation 1829/2003. Defra will make the request as soon as possible.<br><br>Where a TCA revokes a restriction or ban it has put in place it shall e-mail Defra to inform them of that without delay. Defra will, in turn, notify the Commission and other Member States without delay. |

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| **General principles** | (i) It is the prerogative of each TCA to decide whether to pursue the 'exclusion' option (Articles 26b(1)) or the 'restrict/ban' option (Article 26b(3)), where it wants to avoid or limit the commercial planting of GM crops in its territory. However, recognising that the exclusion option is administratively more straightforward and expected to offer a more legally secure outcome, it is anticipated that in general this option will be favoured unless there are compelling reasons to pursue a restriction/ban.<br><br>(ii) If there is a domestic legal challenge against a decision to exercise either of the two options, the TCA concerned and not Defra as the UK CA will be responsible for defending its decisions and actions, dealing with the outcome of the case, and for bearing any financial costs (for example, legal costs and any compensation) that arise in that context.<br><br>(iii) The mechanism for handling infraction proceedings involving the devolved administrations is set out in the Memorandum of Understanding and Supplementary Agreements between the United Kingdom Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive Committee. |

The FSA has its own Memorandum of Understanding upholding the Memorandum of Understanding and Supplementary Agreements between the United Kingdom Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive Committee.

**Annex F – contact points**

Please advise Defra when these change. Defra will circulate any changes to all the DAs, including any changes to the Defra contact point

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28 October 2015