Protocol for designation of laboratories providing BVD testing for the National Programme

1. A formal application is made by the laboratory to the Chairman of the BVD Implementation Group (BVDIG) on the standard application form, in which the applicant confirms that s/he has read the Laboratory Designation Criteria and the General Terms and Conditions of Participation/Designation in the National BVD Eradication Programme and agrees to be bound by and observe these.

2. The application is checked by the BVDIG for compliance with those non-technical criteria specified in Appendix 1 of this protocol which are relevant at the point of application for designation.

3. The completed application is referred to the National Reference Laboratory (NRL) for evaluation of technical criteria, as specified in Appendix 1.

4. The NRL reports to BVDIG within one month of the date of application with a recommendation based on whether or not the technical criteria are satisfied.

5. If the application is successful, the Chairman of the BVDIG will recommend to the Department of Agriculture, Food and the Marine (DAFM) that, where necessary, the Schedule of Designated Laboratories in the relevant legislation be amended accordingly. The Chairman will simultaneously inform the applicant in writing of the nature of the recommendation being made to DAFM, but advising the applicant that formal designation cannot be considered to be in place until such time as the Schedule has been amended. On foot of receipt of confirmation from DAFM of the required amendment to the Schedule, the Chairman will communicate this information to the applicant in writing.

6. If the application is unsuccessful, the Chairman of the BVDIG will communicate the decision to the applicant, furnishing details as to why the application was unsuccessful, and including the report from the NRL in the event that the refusal to designate was based wholly or partially on failure to fulfil the technical criteria. The communication will draw the attention of the applicant to the appeals procedure, set out in the Terms and Conditions of Designation (Paragraph 20).

Protocol for delisting a designated laboratory providing BVD testing for the National Programme

Voluntary withdrawal

7. Following receipt of a written application from a designated laboratory to have itself withdrawn from the AHI listing of designated laboratories, the Chairman of the BVDIG will request DAFM to amend the Schedule of Designated Laboratories in the relevant legislation be accordingly. On foot of such amendment to the Schedule, the Chairman of the BVDIG will communicate this information to the applicant.

Review of performance

8. In the event that a failure to comply with any of the designation criteria is detected or reported, the Chairman of the BVDIG writes to the laboratory, indicating that the matter is under review, notifying it that further information may be sought, of its obligation to cooperate with such requests for information, and alerting it to the fact that suspension or loss of its designated status is one possible outcome of the review.

9. Non-compliance with technical criteria

   (a) The NRL will investigate any suspected non-compliance in respect of the technical criteria, as specified in Appendix 1.

   (b) In exceptional circumstances, where the nature of the suspected non-compliance is such as to potentially compromise the integrity of the national BVD eradication programme, the NRL may recommend to the BVDIG the suspension of the laboratory's designated status, pending the outcome of the review.

   (c) In the first instance the NRL will write to the laboratory, requesting that the laboratory furnish a written report, together with whatever documentary material may be relevant, within [10] working days, outlining the reasons for the non-compliance and proposing remedial action, where appropriate.

   (d) In carrying out its review, the NRL may request *inter alia* a meeting with laboratory staff and/or a site visit.

   (e) The NRL will report to the BVDIG any failure on the part of the laboratory to co-operate with the review.

   (f) On completion of its review, the NRL will issue a report to the Chairman of the BVDIG with a recommendation, based on its examination of the technical criteria, to: (1) retain the designated status; or (2) retain the designated status, but with the

attachment of special conditions; or (3) revoke the designated status,. This report will be forwarded by the Chairman of the BVDIG to the Minister for Agriculture, Food and the Marine, together with such recommendations, if any, relating to non-technical criteria as the BVDIG may make.

(g) The Chairman of the BVDIG will simultaneously communicate the recommendations as per (f) above to the designated laboratory.

10. Non-compliance with non-technical criteria

(a) A sub-group of the BVDIG will investigate suspected, material non-compliance in respect of non-technical criteria, as specified in Appendix 1. The Programme Manager will in all instances participate in sub-groups carrying out such reviews; however the Chairman of the BVDIG is precluded from participation.

(b) In exceptional circumstances, where the nature of the suspected non-compliance is such as to potentially compromise the integrity of the national BVD eradication programme, the sub-group of the BVDIG may recommend to the BVDIG the suspension of the laboratory's designated status, pending the outcome of the review.

(c) In the first instance the sub-group of the BVDIG will write to the laboratory, bringing the non-compliance to its attention and requesting that the laboratory furnish a written report, together with whatever documentary material may be relevant, within [10] working days, outlining the reasons for the non-compliance and proposing remedial action.

(d) In carrying out its review, the sub-group of the BVDIG may request *inter alia* a meeting with laboratory staff and/or a site visit.

(e) The sub-group of the BVDIG will report to the BVDIG any failure on the part of the laboratory to co-operate with the review.

(f) On completion of its review, the subgroup of the BVDIG will report the results to the Chairman of the BVDIG with a recommendation, based on its examination of the non-technical criteria, to: (1) retain the designated status; or (2) retain the designated status, but with the attachment of special conditions; or (3) to revoke its designated status, based on its examination of the non-technical criteria.

(g) The Chairman of the BVDIG will simultaneously communicate the recommendations as per (f) above to the designated laboratory.

11. Decision to retain designated laboratory status

(a) The BVDIG will consider, as appropriate, the reports of the NRL in relation to the technical criteria and/or of the sub-group in relation to the non-technical criteria. Following such consideration, and in the event that the BVDIG is satisfied that the suspected non-compliance was not substantiated, or, if substantiated, has been satisfactorily resolved, the Chairman of the BVDIG will issue a letter to the laboratory to this effect, appending, as appropriate, a copy of the NRL report and/or that of the sub-group of the BVDIG, together with such special conditions as may have been attached to the laboratory's designated status.

12. Decision to revoke designated laboratory status

(a) The BVDIG will consider, as appropriate, the reports of the NRL in relation to the technical criteria and/or that of the sub-group of the BVDIG in relation to the non-technical criteria. Following such consideration, and in the event that the BVDIG is satisfied that the suspected non-compliance was substantiated and remains unresolved, the Chairman of the BVDIG will recommend to DAFM that the Schedule of Designated Laboratories in the relevant legislation be amended accordingly. Simultaneously, the Chairman of the BVDIG will issue a letter to the laboratory to this effect, setting out the reasons for the recommendation and appending, as appropriate, a copy of the NRL report and/or that of the sub-group of the BVDIG. This communication will draw the attention of the laboratory to the appeals procedure, set out in the Terms and Conditions of Designation (Paragraph 20).

Appendix 1

Technical criteria

Verification of appropriate accreditation for all combinations of tests and matrices used within the programme

Viability of contingency plan

Proficiency testing and technical reviews

Use of test kits and reagents approved by the NRL

Evaluation of BVD tests, examinations and analyses carried out at designated laboratories

Non-technical criteria

Completeness of applications

Compliance with file structural error rate specified in designation criteria document

Compliance with file reporting timeframes specified in designation criteria document

Compliance with requirement to retain samples in accordance with the protocol specified in designation criteria document

Confirmed ability to transfer test results according to specified formats to the programme database

Fitness for purpose of the systems of financial and administrative control and reporting