1 Purpose

A complaint is regarded as any query by a customer or other party that questions or expresses doubt about any aspect of the analyses carried out by FBA. This procedure describes how complaints are recorded and investigated.

2 Scope

This procedure applies to all complaints, either verbal or written, received from FBA customers' or other parties.

3 References

3.1 Form QF016 (Complaints Log).

3.2 Form QF017 (Complaint Investigation Report).

3.3 Procedure QP007 (Dealing with non-conformances).

3.4 Form QF006 (Non-conformance (Corrective Action) Report.

3.5 Procedure QP008 (Opportunity and Improvement)

3.6 Form QF007 (Opportunity and Improvement Form)

3.7 Form QF011 (Opportunity / Improvement Log)

3.8 Procedure QP013 (Risk Assessment)

3.9 Form QF030 (Risk Assessment Form)

3.10 Form QF033 (Risk Assessment Log)

3.11 Form LF013 (Telephone Call Log Sheet)

4 Procedure

4.1 Complaints can be received either verbally (by phone or in person) or in written format (by letter, email, or fax). If received by phone, the initial point of record of a complaint may be on form LF013 (Telephone Call Log Sheet). Where a complaint has been communicated verbally the complainant will be asked to submit the complaint in writing.

4.2 All complaints received at FBA are immediately communicated to the Laboratory Manager. The Quality Manager must also be informed immediately when a complaint is received. The Lab Manager will liaise with the customer. The Quality Manager will liaise with the technical team where relevant. The Quality Manager can also liaise with the customer in place of the Lab Manager.

4.3 The Quality Manager is responsible for overseeing the complaints process. The Quality Manager ensures that all complaints are acknowledged to the complainant in writing (for traceability purposes).

4.4 The Quality Manager ensures that all complaints are recorded and fully investigated in a timely manner, that appropriate corrective actions are put in place and that the outcome is communicated to the complainant.

4.5 Initially a complaint will be validated. The complaint is assessed to determine if the complaint relates to laboratory activities that FBA is responsible for, and if deemed to be the case the complaint will be addressed. FBA is responsible for all decisions at all levels of the handling process for complaints.

4.6 Once the complaint has been validated and FBA is satisfied that a complaint investigation is warranted, the complaint is entered on the Complaints Log (Form QF016).

4.7 The Complaints Log contains the following information:

- Customer Complaint (CC) reference number (See format below).

  Example: CC01 ← Number Sequence starting at 01

- Date of complaint.
- Complainant.
- Nature of the complaint.
- Confirmation that the complaint has been validated (Y/N).
- Complaint Investigator.
- Date closed.

4.8 The Quality Manager will allocate the complaint to an investigator, i.e. a staff member who will be responsible for the complaint investigation. If appropriate the Quality Manager can be the complaint investigator, but only where impartiality can be demonstrated.

4.9 Review of a complaint and final decisions on outcomes of the complaint investigation will be carried out by personnel who were not involved in the original laboratory activities in question.

4.10 Any communications with the complainant regarding the complaint investigation will be carried out by the Lab Manager or management personnel who were not involved in the original laboratory activities in question.

4.11 It may be the case that an investigator was involved in the original lab activities under examination. This may arise where the person's expertise or technical input is required to feed into a complaint investigation. In such an instance an

independent impartial member of management must review and have input into the course of the investigation. Where this happens the impartial management personnel will sign the relevant section of form QF017 to verify that impartiality has been exercised during the investigation.

4.12 This procedure, QP006, describing FBA policy on handling of complaints can be communicated to any interested parties on request. QP006 is also available for view on FBA's website.

4.13 The person responsible for the complaint investigation will complete the relevant sections of the Complaint Investigation Report (QF017), which will provide details of both the complaint and any immediate action(s) taken.

4.14 During a complaint investigation, FBA gathers and verifies all the information necessary to confirm the details of the complaint.

4.15 Based on the findings from the investigations the form will also indicate what, if any, further action is required to resolve the complaint.

4.16 If it is deemed that a non-conformance in the system has occurred, procedure QP007 (Dealing with non-conformances) will be implemented and a non-conformance (corrective action) report produced (QF006).

4.17 If, however, investigations suggest that an improvement to the Quality Management System is more appropriate, then procedure QP008 (Opportunity and Improvement) will be implemented and an Opportunity and Improvement Form produced (QF007).

4.18 The customer may receive feedback from FBA or be required to submit additional information by the Quality Manager or another appropriate member of management, as relevant, during the course of an investigation. Any such communication with the customer cannot be made by a person originally involved in the activities in question.

4.19 Once the Complaint Investigation Report is complete and any corrective/ preventive actions or improvements have been implemented the report is signed and dated by the Complaint Investigator.

4.20 The customer / complainant will be informed of the outcome of the complaint investigation and be made aware when the handling of their complaint is formally closed.

4.21 Once the customer has been informed of the outcome of the investigation and the Complaint Investigation report has been deemed closed it is signed and dated by the Quality Manager. Refer to section 4.11 for independent signatory which will demonstrate impartiality if it has been the case that a complaint has been made about activities that the Quality Manager was originally involved in.

4.22 It may arise during the course of the complaint investigation that completion of a risk assessment is deemed necessary. This is dependent on the observations made and/or the nature of the original issue. Procedure QP013 (Risk Assessment) is applied for this action as well as completion of form QF030 (Risk Assessment Form).

4.23 The write-up of any non-conformances, improvements and/or Risk Assessments which have been identified during the course of the complaint investigation are the responsibility of the assigned investigator, unless otherwise instructed by the Quality Manager.

4.24 The Complaint Investigation Report is filed in the Customer Complaints File along with copies of all relevant documentation, or at least references to relevant document report numbers, including non-conformance (corrective action) and improvement reports. These files are stored for a minimum of 5 years as described in QP009 (Control of Records) which satisfies INAB specification for retention of records.