

Procedure for Development of the GMP+ FC scheme

1 Introduction

A standard (or requirements and conditions of a standard) of the GMP+ FC scheme is developed during a number of stages in close cooperation and consultation with experts, partners and participants. At the end of this process, after a positive decision in the International Expert Committee, a new standard is established and published as a part of the GMP+ FC scheme.

This document gives the procedure for the development and decision process of a standard of the GMP+ FC scheme¹. See the annex 1 for a visualization of this process.

2 Preliminary stage

One of the first steps is to collect ideas and requests for improvement. There are a number of sources to collect ideas

- a Partners are invited to propose ideas for improvement. They can, for instance, consult their members for this.
- b The International Expert Committee or one of its subcommittees may request to improve or change a standard.
- c Ideas may be collected from periodic review of existing standards and requirements.
- d Participants (companies and certification bodies) may come up with ideas, for instance during meetings, telephone or Email contacts
- e Also changes in feed law or rules for accreditation may be a trigger for improvement

All the ideas and requests are laid down in an annual working plan, which must be approved by the IEC. Thus, commitment is gained from partners to propose changes.

IEC also decides how to work out the ideas in proposals. In principle, all the stages of the next procedure will be followed. The IEC may decide, however, to follow a different procedure, for instance a consultation by e-mail.

Next to this, IEC authorizes to follow a different procedure for changes regarding:

- a. GMP+ BA1 *Product Standards*. Product standards in the (European) feed law may change at any time, and it might be necessary to implement them quickly. In this event GMP+ International follows a quick procedure (consultation of IEC by e-mail) and skip some steps of the procedure (public consultation) in order to get a quick decision for changes.

¹ GMP+ International may in specific situations bypass (parts of) this procedure. See for more information GMP+ A1 General Regulations, article 11.1.

- b. IDTF – database (International Database Transport Loads). This database with products to be transported and their cleaning regime is managed by an International Technical Working Group wherein all owners of the IDTF (Ovocom, QS, GMP+ International and Qualimat) participate. This International Working Group is authorized to decide on changes and additions without further consultation or approval of the IEC.
- c. FSP - Database. This database with generic risk assessments is managed by a Technical Working Group, who is authorized to decide on proposals regarding changes and additions without further consultation or approval of the IEC.

3 Proposal stage

A first draft (Draft 1) is made by GMP+ International, which needs the positive advice of the concerned subcommittee(s). It might be necessary to draw up successive working drafts until the concerned subcommittee(s) is (are) satisfied that the best technical result has been achieved. Final approval results in Draft 2

4 Public consultation stage

This Draft 2 is published on the website of GMP+ International. All GMP+ certified companies, GMP+ International's partners and possible national GMP+ committees are invited to give remarks and comments. These comments will be discussed during a meeting with the concerned subcommittee(s). The discussion must result in a Final draft to be presented to the IEC.

Note: It might be necessary to draw up successive working drafts after this meeting and consult the subcommittee(s), until agreement on the best technical result has been achieved.

5 Validation of the scheme

For the design and development of new schemes and in the case of major changes in the GMP+ FC scheme, GMP+ International has to carry out a proper validation of the scheme. Validation at least means that a new scheme or in the case of major changes in the GMP+ FC scheme have been tested and it has been demonstrated that the scheme is feasible in practice and meets the expectations of GMP+ International.

Therefore, GMP+ International as scheme owner of the GMP+ FSA module has to determine whether the conformity of the implemented feed safety management system of participants assures feed safety through the feed chain, if it is feasible in practice and if the results are reproducible and reliable.

6 IEC advising stage and establishing

IEC will meet on and advise regarding the Final draft. Based on the IEC's advice, GMP+ International will establish the standard taking into account the rules laid down in the company's statutes.

7 Publication stage

The established version of the standard will be made public.

8 Review stage

The intention is to review the relevant documents after every 3 years.

Annex 1: Schematic overview of development process



