More details about the submission of a risk assessment

1. Submission of a risk assessment

- a) You should draw up a proposal for a risk assessment in accordance with the <<u>format</u>>, established by GMP+.
- b) Additional information can also be sent to assist in the acceptance of the risk assessment.
- c) As a quideline in drawing it up you can use the HACCP manual (GMP+ D2.1)
- d) For examples of a generic risk assessment please consult the <u>demo version of the FSP</u> at www.gmpplus.org
- e) You submit the proposal via: info@gmpplus.org
- f) Because of the method of handling the documents they should be submitted as Word documents (not PDF documents).
- g) The risk assessment will be screened for completeness. You will then receive a confirmation of receipt. This is not yet a screening of the content of the risk assessment.

2. Initial screening by GMP+ International

The following sections will be checked / examined during this initial screening:

- a) Product name and definition: the product name should be generic. Brand names will not be accepted. If possible you should use the product name and definition from the 'Catalogue of Feed Materials'. If the product is also known under another name then you should include this as a synonym in the data sheet.
- b) You should specify all the processing aids used.
- c) Flowcharts: the global and detailed flow charts should be clear. All inputs and outputs (for example raw materials, processing aids used, interim products, waste products, etc.) should be mapped out.
- d) Risk estimation: You should include all (potential) hazards in the hazards analysis table (incl. the rest of the information requested in this table).
- e) Screening by GMP+ (if necessary) of relevant product-specific information such as published company information, GMP+ fact sheets, EFSA reports, publications by, among others, VWA, RIKILT and TNO.
- f) You will receive the findings of this screening (questions, suggestions, corrections) per E-mail.

 Once all the questions from the first screening have been answered then the risk assessment will be included in the Feed Support Products.
- g) Entering of the draft risk assessment will be done by GMP+ . You will receive a copy of the entered risk assessment for approval. If you agree with this draft then the risk assessment can be handled by the external experts.

3. Second screening by external experts

The risk assessment will be handled by external experts (Technical Committee FSP). Any questions or comments will be communicated to you. All questions and comments should be answered. Depending on the answer, the risk assessment should be presented again to the experts. This process will stop when there is a positive advice from the external experts and it is approved for publication in the Feed Support Products. You will be informed of the approval

4. Publication in the Feed Safety Database

The risk assessment will be published in three languages (Dutch, English and German) in the FSP. An electronic newsletter will be sent by GMP+ International about the publication of new products in the FSP.

Summary

Process		By whom?
1.	Submission of a new risk assessment in accordance with the format established by GMP+ International	Submitter / company
2.	Mail confirmation of receipt (incl. findings of the e screening).	GMP+ International
3.	Initial screening of the content and feedback of the findings to the submitter.	GMP+ International
4.	Answer questions arising from the first screening of the content	Submitter / company
5.	Assess responses (per E-mail) arising from the first screening (incl. entering the risk assessment into the FSP) until the draft risk assessment is ready for handling by the external experts.	GMP+ International
6.	Put the first draft version on the agenda for handling during a meeting of the external experts.	GMP+ International
7.	Discuss the first draft version during a meeting of the external experts.	GMP+ International
8.	Feedback of findings or questions to the submitter.	GMP+ International
9.	Send responses arising from the findings of the external experts for handling (approval) of the risk assessment.	Submitter / company
10.	Assess the response of the submitter (possible feedback to the external experts)	GMP+ International
11.	Send confirmation of approval to the submitter. Publication in the FSP (publication of the approved risk assessment in three languages) and make known by way of the newsletter.	GMP+ International