

## Accreditation of the GMP+ FSA scheme

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## 1 Introduction

In 2008, the former 'Centraal College van Deskundigen Diervoeder' made the decision to use the GMP+ FSA scheme to make the transition from a product certificate (GMP+ C3) to a process certificate (GMP+ C6). The change has had no substantive consequences for the standards. Mainly because in a previous stage the choice was made to not only look at the end product in the product certificate but also at the process that precedes it. The difference between both certificates is that, in product certification an end product sample has to be taken at all times, and in process certification only when there is any doubt about the proprietary monitoring system.

In 2009, GMP+ International (then PDV) agreed with the Accreditation Council that an administrative procedure with limited document research would be performed at the Dutch CIs. Meanwhile, based on the transition to process certification, various interviews have been conducted with the Accreditation Council. These showed that the Accreditation Council mainly has difficulties establishing when an auditor has doubts about the proprietary monitoring system.

During the meetings with the Accreditation Council, it was proposed that the Dutch CIS would be allowed to use the Accreditation Council logo for process certification until January 1<sup>st</sup> 2012, provided that a number of conditions were met, including the definition of doubt as included in the GMP+ C6 §2.5.

Over the past couple of months, a work group from the Dutch CIs and GMP+ International have tried to define doubt the right way, but the Accreditation Council has labeled this as inadequate.

## 2 Current situation

As a consequence of the Accreditation Council not approving the proposal of the work group, the GMP+ FSA scheme is not accepted as process certification scheme (GMP+ C6). The GMP+ C3 expires July 1<sup>st</sup> 2012.

In the countries surrounding us, the discussion of GMP+ International with the Accreditation Council is viewed with indignation. The Deutsche Akkreditierungsstelle (DAkkS) sees no problems accepting the GMP+ FSA scheme as process certification scheme.

A number of (re)newed standards exists, such as the GMP+ B2(2010) and the GMP+ B3 (2007) that have not been accepted through the GMP+ C3 meaning that the certificates cannot be issued with an accreditation logo. This mainly causes problems for companies outside of Europe, since they attach great value to the accreditation logo.

### **3 And now....**

Since GMP+ C6 is not accepted by the Accreditation Council and the GMP+ C3 expires July 2012, a decision has to be made on how to handle accreditation in the future. A number of possible scenarios have been worked out below.

#### **3.1 Reverting to GMP+ C3 and dropping GMP+ C6**

IT is possible to revert to product certification under the GMP+ C3. The downside of this is that, often, one reverts to taking a sample per audit per product. In addition, a number of (re)new(ed) standards, including the GMP+ B3(2007) have not yet been governed by the GMP+ C3. This would have to be realized, with the question whether these standards can be accredited under the GMP+ C3.

#### **3.2 Maintaining GMP+ C3 accepted and maintaining GMP+ C6 not accepted**

In this situation, the GMP+ C6 would be revoked voluntarily by GMP+ International for acceptance at the Accreditation Council. This means that certificates could be issued that are certified according to the GMP+ C6 but they cannot carry an accreditation logo. Mainly companies who trade with companies outside of Europe will be hindered by this. Outside of Europe, people attach great value to accreditation. By maintaining the GMP+ C3 the problem is partly solved. Since the GMP+ C3 is accepted by the Accreditation Council, companies who trade with other companies outside of Europe, could receive a GMP+ certificate according to the GMP+ C3. However, with the exception of the standards that have not yet been accepted through the GMP+ C3. This would have to be realized, with the question whether these standards can be accredited under the GMP+ C3.

#### **3.3 GMP+ FSA scheme accepted under the ISO17021**

The Accreditation Council has indicated that they believe that the GMP+ FSA scheme should be accepted according to ISO17021 because it supposedly is a quality management system. There are a number of downsides to having the GMP+ FSA scheme accepted according to the ISO17021.

For the CIs this means that they have to convert their internal system from the EN45011 to the ISO17021. This involves rewriting procedures and education of auditors. A number of CIs currently don't work with ISO17021 and will have to start from the beginning.

For companies, this means that no logo may be used on the GMP+ products (such as bagged goods). Accompanying documents can also not have a GMP+ logo.

In addition, a number of adjustments will have to be made to the GMP+ FSA scheme. To what extent this will affect the work method of the CIs or the companies, will have to be further investigated.

#### **3.4 Accepting GMP+ FSA scheme through EA**

Another option is to offer the scheme to the European Accreditation (EA). This can be done under the GMP+ C6 or under the ISO17021.

The Accreditation Council indicates that they believe that the best thing for us to do would be to offer the GMP+ FSA scheme under the ISO17021 to the EA.

Following the issues above, a meeting was held with DAkkS. The DAkkS didn't see any problems offering the GMP+ FSA scheme under the current GMP+ C6 to the EA.

If the decision is made to have the acceptance of the GMP+ FSA scheme occur through the EA, a decision will also have to be made about how the accreditation is handled in the meantime.

### **3.5 No acceptance / accreditation**

Another decision that can be made is to drop the requirement of accreditation in the GMP+ FSA scheme.

## **4 Decision**

The IEC is asked to make a decision based on the above-mentioned situations.

If it is decided that the EA is the best route, a decision has to be made on how GMP+ International should handle the acceptance of the scheme in the meantime (until acceptance EA).