Changes B and BA documents

GMP+ International

Information meeting, 19 November 2014




Feed for Food

Outline

- GMP+ BA2 Control of Residues
- Purchasing and labelling
- EWS
- Gatekeeper purchase of (former) foodstuff
- GMP+ BA10 Minimum Requirements for Purchasing
- Transport

Feed for Food

GMP+ BA2

General

- Regrouping of requirements to control residue limits (carry-over) in feed mills.
- New: validation and verification of the effectiveness (monitoring).
- Additional requirements related to carry-over in production and transportation equipment.

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GMP+ BA2

Regrouping

Regrouping and transferring of requirements to GMP+ BA2, which were already laid down in:

- GMP+ BA1, Part B. Residue limits for coccidiostats and feed medicines in compound feed, feed materials and premixtures.
- GMP+ BA4, Part B. Methods of measuring carry-over.

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New requirement: Validation and verification about controlling residues.

To control the residue limits in feed for milk, meat, eggs producing animals. Information is needed about:

- Residue limits for coccidiostats / feed medicines.
- Carry-over in the production line(s).
- Product/trade name for specific Wall adhesion factor (safety factor)

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New requirement: Validation and verification about controlling residues.

The table of calculations (or other documentation) has to be validated

and

verified by analysis in feed (monitoring) to check the continuous effectiveness of controlling residues.

- 2 times per year *or*
- 4 times per year

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Monitoring

The minimum frequency of monitoring depends on the use of the Wall adhesion factor in calculated (forbidden) production sequences.

- 2 times per year: when using the safety factor per product (from 1 to 3)
- 4 times per year: when not using the safety factor

When the safety factor is not tested in products = factor 3 has to be used.

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Monitoring / analysing

Verification must be carried out by means of analysing the residue levels of the feed additive or specific veterinary medical product.

When more veterinary medical products / feed additives are used in the production, the one with the highest safety factor should be analysed as part of the verification.

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Residue limits

Coccidiostats:

The GMP+ residue limits are based on Regulation (EU) 574/2011.

(Compound feed, feed materials and premixtures)

Feed medicines:

GMP+ product standards.

Directive 90/167/EEC

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New residue limits

For other substances, for which a withdrawal time has been established in feed for milk, egg and meat (last period) producing animals a residue limit is established: 1 mg/kg.

For example: Flubendazol. This feed medicine is not an antibiotic but has a withdrawal time for broilers of 7 days before the broilers go to the slaughter house.

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Limits for carry-over coccidiostats

The residue limits in egg, milk and meat (last period) producing animals for coccidiostats are based on EU-legislation with a maximum carry-over of 1%.

In feed for young broiler is added 125 mg/kg Monensin-sodium cf. Directive(EU) 1831/2003. The residue limit for feed for laying hens is 1,25 mg/kg.

This refers to a maximum carry-over of 1%.

GMP+ BA2

Limit for carry-over of antibiotics

New in GMP+ BA2 is the addition when there is no residue limit for the specific antibiotic laid down: the '2,5% rule' is applicable.

This means not more then 2,5% of the dosed amount quantity antibiotics may contaminate the next critical feed in the production sequence.

Competent authorities in different countries can have stricter regulation for production of medicated feed. (Due interpretation of Directive 90/167/EEC).

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Feed for Food

Purchasing and labelling

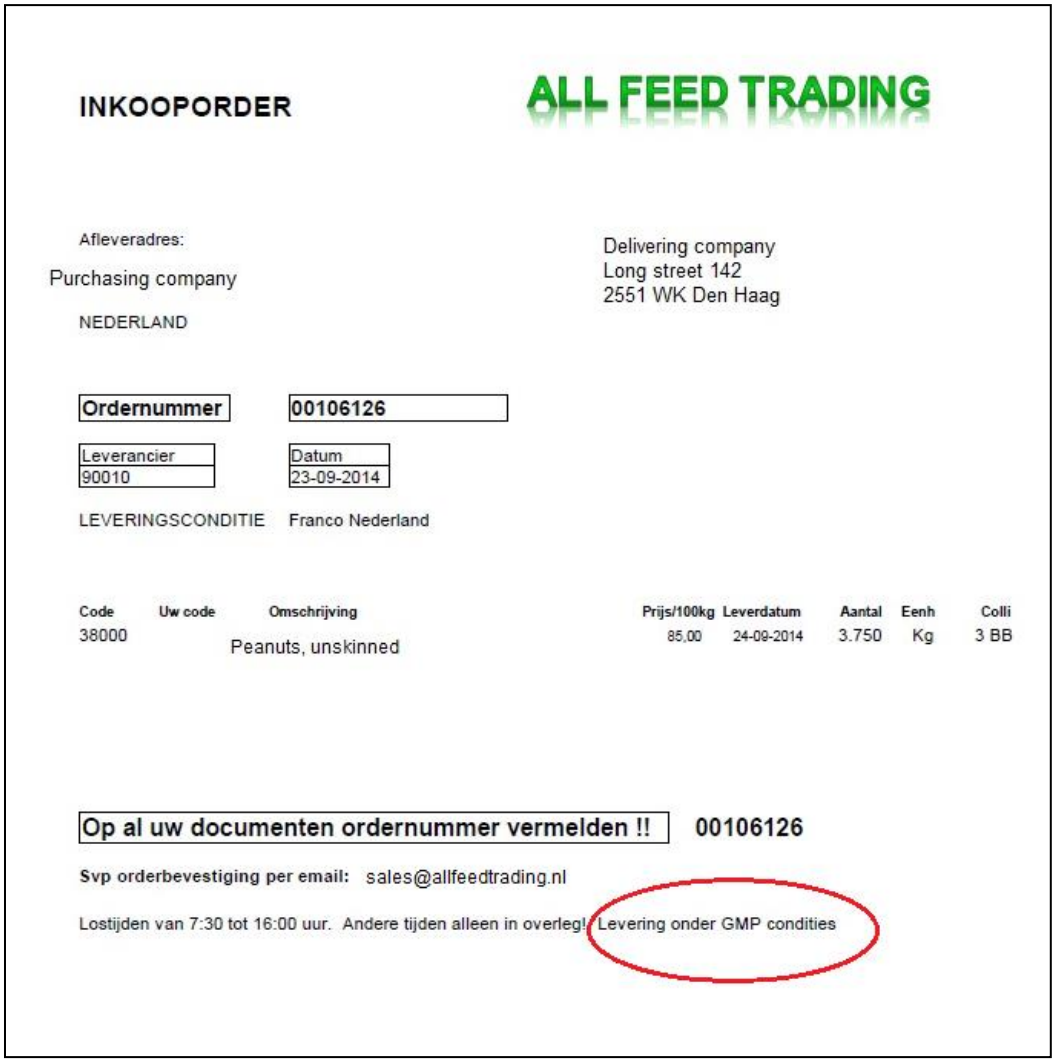
There must be a clear communication (both ways: buyer to supplier and supplier to buyer) concerning the status of the product.

Requirement	Standard	Effective date
Purchasing: The participant must state in writing clearly and unambiguously the status of product or service he wants to purchase: GMP+ assured or equivalent.	B1, B2, B3	1-10-2015

Feed for Food

Purchasing and labelling

There must be a clear communication (both ways: buyer to supplier and supplier to buyer) concerning the status of the product.



INKOOPORDER

ALL FEED TRADING

Afleveradres:

Purchasing company

NEDERLAND

Delivering company
Long street 142
2551 WK Den Haag

Ordernummer	00106126

Leverancier	Datum
90010	23-09-2014

LEVERINGSCONDITIE Franco Nederland

Code	Uw code	Omschrijving	Prijs/100kg	Leverdatum	Aantal	Eenh	Colli
38000		Peanuts, unskinned	85,00	24-09-2014	3.750	Kg	3 BB

Op al uw documenten ordernummer vermelden !! **00106126**

Svp orderbevestiging per email: sales@allfeedtrading.nl

Lostijden van 7:30 tot 16:00 uur. Andere tijden alleen in overleg! Levering onder GMP condities

Feed for Food

Purchasing and labelling

There must be a clear communication (both ways: buyer to supplier and supplier to buyer) concerning the status of the product.

Requirement	Standard	Effective date
Delivery by GMP+ certified company: Negative labelling changes to positive labelling **on 1-10-2015.** When feed assured under GMP+ FSMS is delivered, the status of this feed must be clearly reported to the customer in writing by the time of delivery at latest.	BA6	1-10-2015 **No transition period!!!**
Proposal to be discussed in SC Transport (Jan. 2015): Status of transport (GMP+ assured) must be reported on freight documents.		

Feed for Food

Purchasing and labelling

There must be a clear communication (both ways: buyer to supplier and supplier to buyer) concerning the status of the product.

Requirement	Standard	Effective date
Positive labelling starts **on 1-10-2015.** When feed is produced under two certification schemes which both require positive labelling (e.g. GMP+ and QS) the feed must be labelled accordingly (e.g. both GMP+ and QS assured status must be declared).	BA6	1-10-2015 **No transition period!!!**

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EWS: informing the customers

Requirement	Standard	Effective date
- In case of exceeding the maximum permitted levels of undesirable substances in feed (see legislation or GMP+ BA1) the customers must be informed within 12 hours after confirmation of the contamination. - In case of all other perceived non-conformities and irregularities the customers must be informed as soon a possible.	B1, B2, B3	1-1-2015

Feed for Food

EWS: informing the customers (2)

Examples of other perceived non-conformities and irregularities:

- Matters directly observable in the product (color, smell).
- Analytical results falling outside standards or specifications (exceeding action limit, high levels in the absence of standards).
- Signals or suspicions of increasing levels in certain regions.
- Abnormal illness/death of animals.
- Unusual or inexplicable occurrences.

EWS: informing the competent authority

Requirement	Standard	Effective date
If it is a legal obligation, the participant must notify the non-conformity to the competent authority in the country of region of residence	B1, B2, B3	1-1-2015

Feed for Food

EWS: informing the principal

Requirement	Standard
Already existing requirement In the event of non-conformities or irregularities in the feed at a participant which provides service to third parties (storage and transshipment companies, freight brokers and transport companies), this will be immediately reported to the owner of the feed (principal).	B3, B4

Feed for Food

EWS: informing GMP+ Int. and CB
GMP+ BA5

Requirement	Effective date
The participant (producer, trader) is obliged to notify GMP+ International and the CB in case of exceeding the maximum permitted level(s) of undesirable substances in feed as mentioned in legislation or/and GMP+ BA1.	1-8-2014
Whenever non-conforming feed is purchased as GMP+ assured, an EWS notification is obliged, even when the participant decides to sell the non-conforming feed as non-GMP+ assured. There may be more of this batch on the GMP+ market and GMP+ participants must be warned.	
The notification must be carried out within 12 hours after confirmation of the contamination	
Informing the competent authority if this is a legal obligation.	

Feed for Food

EWS: informing GMP+ Int. and CB
GMP+ BA5 (2)

Requirement	Effective date
The participant may notify GMP+ International and the CB in case of other non-conformities or irregularities related to feed safety aspects (others than complaints), not controlled by the participant, which could have consequences for other companies.	1-8-2014
Above mentioned perceived non-conformities and irregularities shall be notified as soon as possible.	

Feed for Food

EWS: informing GMP+ Int. and CB
GMP+ BA5 (3)

Requirement	Effective date
GMP+ International informs CB when its client is involved in an EWS notification.	1-8-2014
Involvement of the certification body in the EWS procedure will be described in a guideline / rules.	

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Feed for Food

Gatekeeper purchase of (former) foodstuff

Requirement	Standard	Effective date
The requirements for the purchase of (former) foodstuff from non-GMP+ FSA (or equivalent) certified food companies are laid down more clearly in a new Annex 6 of GMP+ BA10.	GMP+ BA10	1-1-2015

Feed for Food

Gatekeeper purchase of (former) foodstuff

Scope: products

The protocol applies to:

- Foodstuff
- Former foodstuff

But cannot be used for the purchase of:

- Raw material
- By-products
- Feed additives
- Food additives
- Prohibited products

Feed for Food

Gatekeeper purchase of (former) foodstuff

Foodstuff	Former foodstuff
• Finished food product • Original destination: human consumption • Labelled as foodstuff by food company • No longer intended for human consumption due to: - commercial reasons - logistical reasons - practical reasons	•Finished / semi-finished foodstuff and food ingredients • Original destination: human consumption • Not labelled as foodstuff by food company • No longer intended for human consumption due to: - problems of manufacturing - packaging defects - other defects

Gatekeeper purchase of (former) foodstuff

Foodstuff	Former foodstuff
• Surplus sugar • Broken biscuits • Misshapen fruit • Surplus sweets • Mayonnaise • Returned bread from supermarket.	• Remnants of smoked fish • Remnants of biscuits containing packaging residues • Ingredients of biscuits (e.g. wheat flour).

Feed for Food

Gatekeeper purchase of (former) foodstuff

Scope: companies

The protocol applies to

- the GMP+ participant (producer, trader) that purchases (former) foodstuff intended for use as feed directly from a non-GMP+ FSA (or equivalent) certified food company. This also applies to GMP+ FSA certified central purchasing offices.

The protocol is not applicable when

- (former) foodstuff demonstrably originates from a GMP+ FSA (or equivalent) certified food company.

Feed for Food

Gatekeeper purchase of (former) foodstuff

Requirement
The purchase of former foodstuff is only possible with approval from GMP+ International (=exemption).
The participant must ensure that the former foodstuff is included in a (generic) risk assessment (FSP). Not required for foodstuff.
The GMP+ participant purchasing (former) foodstuff that is not yet suitable as feed material cannot sell these products to another participant. These (former) foodstuffs must be processed into feed material first.

Gatekeeper purchase of (former) foodstuff

Requirement
In order to be able to purchase (former) foodstuff a fully FSDS (or equivalent document) must be completed. Not required for (former) foodstuff purchased from wholesale or retail.
Annual audit at non-GMP+ FSA certified supplier must be carried out, by GMP+ participant (2 times in 3 years) and by CB (1 time in 3 years). For this supplier audit no minimum audit time is determined.

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Feed for Food

GMP+ BA10
Minimum Requirements for Purchasing

Redesign, names of annexes are more simple and clear, sequences of annexes reshuffled.

Requirement	Effective date
Growers excluded from the FSA scheme, GMP+ B6 deleted	31-12-2015
Gatekeeper (former) foodstuffs	1-1-2015
Gatekeeper for storage and transhipment	1-1-2016
Mutual recognition with GTP, EFISC and GAFTA	1-10-2014

Feed for Food

GMP+ BA10
Minimum Requirements for Purchasing (2)

Redesign, names of annexes are more simple and clear, sequences of annexes reshuffled.

Requirement	Effective date
Purchase requirements for mineral feed materials are adjusted	1-10-2014
Purchase from grower - All growers under gatekeeper - More clear responsibilities for the purchasing company	1-10-2015
Gatekeeper protocol for road transport adapted = Poland is A country	1-1-2015
Gatekeeper (former) foodstuffs	1-1-2015

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Feed for Food

Transport

Requirement	Standard	Effective date
Each individual transport company must apply HACCP principles and establish an adequate HACCP plan. As support, GMP+ International will provide some examples of already existing HACCP plans. Quality of the water used for cleaning of the loading compartments is a part of the HACCP plan. See for possible risks the risk assessment for water (in the log-in part of FSP)	B4	1-1-2016
Vermin control must also apply to loading compartments loaded with feed products. (As discussed in the harmonisation meeting)	B4	1-1-2016

Feed for Food