ANNEX

PART A

CHEMICAL ACTIVE SUBSTANCES

SECTION 6

Residues in or on treated products, food and feed

6.4. Feeding studies

The objective of feeding studies shall be to determine residues in products of animal origin which result from residues in feed.

The results from a feeding study conducted with laying hens shall be extrapolated to all food producing poultry. The results from a feeding study with lactating cows and, where necessary, with pigs shall be extrapolated to all food producing mammals.
Circumstances in which required

Feeding studies shall be provided where metabolism studies indicate that residues at levels of above 0,01 mg/kg may occur in edible animal tissue, milk, eggs or fish, taking into account the residue levels in potential feeding stuffs, obtained at the 1 × dose rate, calculated on the dry weight basis.

Feeding studies shall not be required where intake is below 0,004 mg/kg bw/day, except in cases where the residue, that is to say the active substance, its metabolites or breakdown products, as defined in the residue definition for risk assessment, tends to accumulate.

6.4.1. *Poultry*

Poultry feeding studies shall be carried out in laying hens. For each treatment regime chosen a minimum of nine chickens should be treated.

In general, the feed shall be administered in three dosages (first dose = expected residue level). The animals shall be dosed for a minimum of 28 days or until plateau level is reached in eggs.

6.4.2. *Ruminants*

Ruminant feeding studies shall be carried out in lactating cows. For each treatment regime chosen, a minimum of three dairy cows shall be treated.

In general, the feed shall be administered in three dosages (first dose = expected residue level). The animals shall be dosed for a minimum of 28 days or until plateau level is reached in milk.

6.4.3. *Pigs*

Where it appears from the metabolism studies that metabolic pathways differ significantly in pigs as compared to ruminants, a pig feeding study may be conducted. For each treatment regime chosen a minimum of three pigs shall be treated.

In general, the feed shall be administered in three dosages (first dose = expected residue level). The animals shall be dosed for at least the same time as ruminants.

6.4.4. *Fish*

A fish feeding study may be required where residues at levels above 0,01 mg/kg may be reasonably expected in edible tissues, based on the findings of the fish metabolism study and the estimated maximum residues which might occur in fish feed. Particular attention should be laid on lipophilic substances with an intrinsic tendency for accumulation.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/556 reg. 21(4)
- Annex Pt. A s. 8 word omitted by S.I. 2019/556 reg. 21(5)(b)(xiv)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. B s. 9 words omitted by S.I. 2019/556 reg. 21(5)(c)(vi)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by S.I. 2019/556 reg. 21(2)(a)
- Art. 1(2) inserted by S.I. 2019/556 reg. 21(2)(b)