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Food Standards Agency

FSA opinion on an application for four feed additives for use in animal feed

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Document subject and purpose

In this document we publish the Food Standards Agency (FSA) opinions on an application for four feed additives for use in animal feed. These opinions take into account the previous European Food Safety Authority's (EFSA) safety assessments, as well as potential impacts that would result from the provisional authorisation of these feed additives, and other legitimate factors that Ministers may want to consider before making a decision regarding their authorisation.

There are five cobalt(II) compounds, currently authorised for use in GB under Retained Regulation (EC) 601/2013. In accordance with Article 14 of Retained Regulation (EC) 1831/2003 (REUL) the FSA received an application for renewal of coated granulated cobalt(II) carbonate in July 2022. Accordingly, this feed additive will remain on the GB market under its existing authorisation until a decision is made on the renewal application.

A feed additive can only remain on the market after its initial authorisation expired if a renewal request is submitted at least 12 months prior to its expiry date. The

applicant for cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate heptahydrate submitted an application for new authorisations in November 2022 in accordance with Article 4 of REUL 1831/2003. This was less than 12 months before their initial authorisation expired and consequently authorisation of these four feed additives will expire on 15 July 2023.

Once the authorisation has expired, products containing the additive cannot lawfully be placed on the market, processed, or used.

The FSA has informally engaged with stakeholders to understand the impact of these feed additives being unavailable to the market. We have considered the EFSA opinions on safety and efficacy based on their full risk assessments as provided in the annexes.

Our key findings are:

- these feed additives have a long history of safe use, over many decades,
- an urgent authorisation is needed to maintain market supply of cobalt additives, satisfy the nutritional needs of animals and ensure the protection of animal welfare,
- the coated granulated cobalt(II) carbonate feed additive that is authorised for the GB market cannot meet market demand, in part due to its characterisation (solubility).
- there are no alternatives to these compounds that could meet nutritional requirements.
- there is a serious risk that animal health will be negatively and severely impacted (almost immediately) if cobalt was to become unavailable in animal feed. This impact would increase over time.

The FSA opinions on the additives will be presented to Ministers allow them to decide on whether to authorise the individual feed additives for use in England and Wales.

The FSA opinion for each feed additive is published within a separate annex, with the assigned FSA/FSS regulated product ID number. These feed additives belong to the ‘nutritional’ additive category and to the functional group ‘compounds of trace

elements' for ruminants (for example: cattle, sheep goats) with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.

(Ctrl+Click to follow link):

Annex A: RP1798a - Cobalt(II) acetate tetrahydrate as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals (Jervois Finland Oy)

Background

Name of applicant:
Jervois Finland Oy

Address of applicant:
PO Box 286
FL-67101 Kokkola
Finland

The FSA opinion is that cobalt(II) acetate tetrahydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety or human health at the intended concentrations of use. The information on which this opinion is based can be found in the EFSA opinion. The proposed terms of authorisation are set out below.

EFSA Risk Assessment:

The FSA has considered the published EFSA risk assessment and opinion and the European Reference Laboratory (EURL) analytical method evaluation report:

- EFSA Journal No.2791 (2012): Scientific opinion on safety and efficacy of cobalt compounds (E3) as feed additives for all animal species.
- EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402).

Conclusions from EFSA Risk Assessment:

EFSA No.2791 (2012) concluded on cobalt(II) acetate tetrahydrate that:

- whilst EFSA acknowledges that cobalt can pose a hazard, feeding supplemental cobalt in the form of the additive up to the maximum total content allowed in feed is safe for all animal species.
- no safety concern for the consumer is expected for threshold effects of oral cobalt and it does not pose risks to the environment.
- cobalt is available for cobalamin synthesis in the rumen and therefore effective in ruminants and this conclusion is extrapolated to horses and rabbits.
- on worker safety, the additive is a skin and eye irritant and a skin and respiratory sensitiser. Its dust is a hazard to persons handling these substances and exposure by inhalation must be avoided.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Legislation (REUL) 1831/2003 for feed additives:

1. Article 15: Urgent authorisation provisions apply.
2. Article 16 and point (d) of Annex III: Labelling and packaging requirements apply, if authorised.
3. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of cobalt compounds in animal feed as detailed in the EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402). Valid analytical methods exist for:
    - the identification of acetate in the additive
    - the crystallographic characterisation of the additive
    - the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials

- for determination of particle size distribution.

4. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

1: Additive details

Additive category	(3) Nutritional additives
Functional group	(b) Compounds of trace elements
Feed additive	Cobalt(II) acetate tetrahydrate
ID No	3b301
Target species	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.
Authorisation period	5 years from the date of authorisation

2: Additive composition

Cobalt(II) acetate tetrahydrate as crystals or granules, with a minimum content of 23% cobalt. Particles < 50 µm: below 1 %

3: Characterisation / identification of the active substance(s)

- Chemical formula: $Co(CH_3COO)_2 \times 4H_2O$
- CAS no: 6147-53-1

4: Conditions of use

Species or category of animal	**Maximum age**	**Element (cobalt): mg/kg of complete feed with a moisture content of 12%**

Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.	n/a	Minimum level: No minimum Maximum level: 1 (total)

5: Other Provisions

1. The additive must be incorporated into compound feed in the form of a premixture.
2. The following statements must be made on the labelling of the additive and premixture:
   - The element (cobalt) content must be declared.
   - "It is recommended to limit the supplementation with Cobalt to 0.3 mg/kg in complete feed. In this context, the risk for Cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account."
3. The following declaration must be made on the instructions of use on the compound feed:
   - "Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken."

6: Analytical methods

For the identification of acetate in the additive:

European Pharmacopoeia monograph 01/2008:20301.

For the crystallographic characterisation of the additive:

X-Ray diffraction.

For the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials:

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017.

For determination of particle size distribution:

Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020.

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin and eye irritant
    - Skin and respiratory sensitiser.
- Major animal species and their subgroups are defined in Annex IV of REUL 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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Annex B: RP1798b - Cobalt(II) carbonate as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals (Jervois Finland Oy)

Background

Name of applicant:
Jervois Finland Oy

Address of applicant:
PO Box 286
FL-67101 Kokkola
Finland

The FSA opinion is that cobalt(II) carbonate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety or human health at the intended concentrations of use. The information on which this opinion is based can be found in the EFSA opinion. The proposed terms of authorisation are set out below.

EFSA Risk Assessment:

The FSA has considered the published EFSA risk assessment and opinion and the European Reference Laboratory (EURL) analytical method evaluation report:

EFSA Journal No.2727 (2012): Scientific opinion on safety and efficacy of cobalt carbonate as feed additive for ruminants, horses and rabbits.

- EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402).

Conclusions from EFSA Risk Assessment:

EFSA No.2727 (2012) concluded on cobalt(II) carbonate that:

- whilst EFSA acknowledges that cobalt can pose a hazard, feeding supplemental cobalt in the form of the additive up to the maximum total content in feed is safe for the target species.
- no safety concern for the consumer is expected for threshold effects of oral cobalt and it does not pose risks to the environment.
- cobalt is available for cobalamin synthesis in the rumen and therefore effective in ruminants and this conclusion is extrapolated to horses and rabbits.
- on worker safety, the additive is a skin and eye irritant and a skin and respiratory sensitiser. Its dust is a hazard to persons handling these substances and exposure by inhalation must be avoided.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Legislation (REUL) 1831/2003 for feed additives:

1. Article 15: Urgent authorisation provisions apply.
2. Article 16 and point (d) of Annex III: Labelling and packaging requirements apply, if authorised.
3. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of cobalt compounds in animal feed as detailed in the EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402). Valid analytical methods exist for:
    - the identification of carbonate in the additive
    - the crystallographic characterisation of the additive
    - the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials

- for determination of particle size distribution.

4. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

2: Additive details

Additive category	(3) Nutritional additives
Functional group	(b) Compounds of trace elements
Feed additive	Cobalt(II) carbonate
ID No	3b302
Target species	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.
Authorisation period	5 years from the date of authorisation

2: Additive composition

Cobalt(II) carbonate as a powder containing a minimum content of 46% cobalt.
Cobalt carbonate: minimum 75%
Cobalt hydroxide: 3% - 15%
Water: maximum 6%
Particles < 11 µm: below 90 %

3: Characterisation / identification of the active substance(s)

- Chemical formula: $CoCO_3$
- CAS no: 513-79-1

4: Conditions of use

Species or category of animal	Maximum age	Element (cobalt): mg/kg of complete feed with a moisture content of 12%
Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.	n/a	Minimum level: No minimum Maximum level: 1 (total)

5: Other Provisions

1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
2. The following statements must be made on the labelling of the additive and premixture:
   - The element (cobalt) content must be declared.
   - "It is recommended to limit the supplementation with Cobalt to 0.3 mg/kg in complete feed. In this context, the risk for Cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account."
3. The following declaration must be made on the instructions of use on the compound feed:
   - "Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken."

6: Analytical methods

For the identification of carbonate in the additive:

European Pharmacopoeia monograph 01/2008:20301.

For the crystallographic characterisation of the additive:

X-Ray diffraction.

For the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials:

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017.

For determination of particle size distribution:

Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020.

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin and eye irritant
    - Skin and respiratory sensitiser.
- Major animal species and their subgroups are defined in Annex IV of REUL 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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Annex C: RP1798c - Cobalt(II) carbonate hydroxide (2:3) monohydrate as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals (Jervois Finland Oy)

Background

Name of applicant:
Jervois Finland Oy

Address of applicant:
PO Box 286
FL-67101 Kokkola
Finland

The FSA opinion is that cobalt(II) carbonate hydroxide (2:3) monohydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety or human health at the intended concentrations of use. The information on which this opinion is based can be found in the EFSA opinion. The proposed terms of authorisation are set out below.

EFSA Risk Assessment:

The FSA has considered the published EFSA risk assessment and opinion and the European Reference Laboratory (EURL) analytical method evaluation report:

EFSA Journal No.2791 (2012): Scientific opinion on safety and efficacy of cobalt compounds (E3) as feed additives for all animal species.

- EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402).

Conclusions from EFSA Risk Assessment:

EFSA No.2791 (2012) concluded on cobalt(II) carbonate hydroxide (2:3) monohydrate that:

- whilst EFSA acknowledges that cobalt can pose a hazard, feeding supplemental cobalt in the form of the additive up to the maximum total content in feed is safe for all animal species.
- no safety concern for the consumer is expected for threshold effects of oral cobalt and it does not pose risks to the environment.
- cobalt is available for cobalamin synthesis in the rumen and therefore effective in ruminants and this conclusion is extrapolated to horses and rabbits.
- on worker safety, the additive is a skin and eye irritant and a skin and respiratory sensitiser. Its dust is a hazard to persons handling these substances and exposure by inhalation must be avoided.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Legislation (REUL) 1831/2003 for feed additives:

1. Article 15: Urgent authorisation provisions apply.
2. Article 16 and point (d) of Annex III: Labelling and packaging requirements apply, if authorised.
3. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of cobalt compounds in animal feed as detailed in the EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402). Valid analytical methods exist for:
    - the identification of carbonate in the additive
    - the crystallographic characterisation of the additive

- the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials
- for determination of particle size distribution.

4. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

3: Additive details

Additive category	(3) Nutritional additives
Functional group	(b) Compounds of trace elements
Feed additive	Cobalt(II) carbonate hydroxide (2:3) monohydrate
ID No	3b303
Target species	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.
Authorisation period	5 years from the date of authorisation

2: Additive composition

Cobalt(II) carbonate hydroxide (2:3) monohydrate as a powder with a minimum content of 50% cobalt. Particles < 50 µm: below 98 %

3: Characterisation / identification of the active substance(s)

- Chemical formula: $2CoCO_3 \times 3Co(OH)_2 \times H_2O$
- CAS no: 51839-24-8

4: Conditions of use

Species or category of animal	Maximum age	Element (cobalt): mg/kg of complete feed with a moisture content of 12%
Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.	n/a	Minimum level: No minimum Maximum level: 1 (total)

5: Other Provisions

1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
2. The following statements must be made on the labelling of the additive and premixture:
   - The element (cobalt) content must be declared.
   - "It is recommended to limit the supplementation with Cobalt to 0.3 mg/kg in complete feed. In this context, the risk for Cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account."
3. The following declaration must be made on the instructions of use on the compound feed:
   - "Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken."

6: Analytical methods

For the identification of carbonate in the additive:

European Pharmacopoeia monograph 01/2008:20301.

For the crystallographic characterisation of the additive:

X-Ray diffraction.

For the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials:

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017.

For determination of particle size distribution:

Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020.

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin and eye irritant
    - Skin and respiratory sensitiser.
- Major animal species and their subgroups are defined in Annex IV of REUL 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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Annex D: RP1798d - Cobalt(II) sulphate heptahydrate as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals (Jervois Finland Oy)

Background

Name of applicant:
Jervois Finland Oy

Address of applicant:
PO Box 286
FL-67101 Kokkola
Finland

The FSA opinion is that cobalt(II) sulphate heptahydrate, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety or human health at the intended concentrations of use. The information on which this opinion is based can be found in the EFSA opinion. The proposed terms of authorisation are set out below.

EFSA Risk Assessment:

The FSA has considered the published EFSA risk assessment and opinion and the European Reference Laboratory (EURL) analytical method evaluation report:

EFSA Journal No.2791 (2012): Scientific opinion on safety and efficacy of cobalt compounds (E3) as feed additives for all animal species.

- EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402).

Conclusions from EFSA Risk Assessment:

EFSA No.2791 (2012) concluded on cobalt(II) sulphate heptahydrate that:

- whilst EFSA acknowledges that cobalt can pose a hazard, feeding supplemental cobalt in the form of the additive up to the maximum total content in feed is safe for all animal species.
- no safety concern for the consumer is expected for threshold effects of oral cobalt and it does not pose risks to the environment.
- cobalt is available for cobalamin synthesis in the rumen and therefore effective in ruminants and this conclusion is extrapolated to horses and rabbits.
- on worker safety, the additive is a skin and eye irritant and a skin and respiratory sensitiser. Its dust is a hazard to persons handling these substances and exposure by inhalation must be avoided.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Legislation (REUL) 1831/2003 for feed additives:

1. Article 15: Urgent authorisation provisions apply.
2. Article 16 and point (d) of Annex III: Labelling and packaging requirements apply, if authorised.
3. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of cobalt compounds in animal feed as detailed in the EURL analytical method evaluation report (Cobalt Group: FAD-2010-0337-0371-0402). Valid analytical methods exist for:
    - the identification of sulphate in the additive
    - the crystallographic characterisation of the additive
    - the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials

- for determination of particle size distribution.

4. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

4: Additive details

Additive category	(3) Nutritional additives
Functional group	(b) Compounds of trace elements
Feed additive	Cobalt(II) sulphate heptahydrate
ID No	3b305
Target species	Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.
Authorisation period	5 years from the date of authorisation

2: Additive composition

Cobalt(II) sulphate heptahydrate as a powder with a minimum content of 20% cobalt.
Particles < 50 µm: below 95 %

3: Characterisation / identification of the active substance(s)

- Chemical formula: $CoSO_4 \times 7H_2O$
- CAS no: 10026-24-1

4: Conditions of use

Species or category of animal	**Maximum age**	**Element (cobalt): mg/kg of complete feed with a moisture content of 12%**

Ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals.	n/a	Minimum level: No minimum Maximum level: 1 (total)

5: Other Provisions

1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
2. The following statements must be made on the labelling of the additive and premixture:
   - The element (cobalt) content must be declared.
   - "It is recommended to limit the supplementation with Cobalt to 0.3 mg/kg in complete feed. In this context, the risk for Cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account."

   The following declaration must be made on the instructions of use on the compound feed:

   - "Protective measures to avoid exposure with Cobalt by inhalation or by dermal route should be taken."

6: Analytical methods

For the identification of sulphate in the additive:

European Pharmacopoeia monograph 01/2008:20301.

For the crystallographic characterisation of the additive:

X-Ray diffraction.

For the determination of total cobalt in the feed additive, premixtures, compound feed and feed materials:

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) in accordance with BS EN 15510:2017

- Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion in accordance with BS EN 15621:2017.

For determination of particle size distribution:

Particle size analysis, laser diffraction methods in accordance with BS ISO 13320:2020.

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin and eye irritant
    - Skin and respiratory sensitiser.
- Major animal species and their subgroups are defined in Annex IV of REUL 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in REUL 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

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