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SCIENTIFIC OPINION

Safety of maximum authorised levels of cobalt and molybdenum for the environment

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety for the environment of feed additives containing trace elements, namely cobalt, copper, iodine, manganese, molybdenum, selenium and zinc. In agreement with the European Commission, the present scientific opinion assesses only cobalt and molybdenum, as these are currently authorised exclusively for use in terrestrial food-producing animals. The safety for the environment of the remaining trace elements will be assessed in a subsequent scientific opinion. Based on the available evidence, the use of cobalt and molybdenum as nutritional additives in terrestrial food-producing animals at the respective current maximum authorised levels in complete feed is considered safe for the environment.

KEYWORDS

environment, maximum authorised levels, nutritional additives, safety, trace elements

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1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] and its implementing rules (Regulation (EC) No 429/2008) describe that an environmental risk assessment (ERA) should be conducted for the terrestrial, the aquatic, and the groundwater compartments.

Taking into account that:

1. Cobalt, copper, iodine, iron, manganese, molybdenum, selenium and zinc are essential nutrients for animals.
2. The authorisation of 42 feed additives containing cobalt, copper, iodine, manganese, molybdenum, selenium and zinc will expire within March 2029 and 5 applications of new feed additives (Article 4(1) of Regulation (EC) No 1831/2003) containing these trace elements have been submitted to date.
3. Recent EFSA opinions on feed additives containing trace elements were inconclusive on the safety of the additive for the environment, in particular, the FEEDAP Panel could not conclude on the safety of the additive for marine sediment compartment for some of these additives.
4. The Guidance document on the safety of feed additives for the environment was updated in 2019 and included, among others, new approaches and changes in default values to calculate predicted environmental concentrations with respect to the previous Guidance document of 2008.
5. The conditions of use for a given trace element are the same across applications because all applicants want to have it authorised at the maximum authorised level.
6. The requests for new authorisations or for renewal of authorisations may be based on data obtained through extensive literature reviews. Applicants may submit different data sets to assess the safety of a given trace element for the environment, which may make difficult to compare the outcome of different assessments.
7. For applications for renewal of the authorisation, there may be inconclusive opinions on the safety of a given trace element for the environment (or for some compartments). If this happens, the EC may need to withdraw the authorisation, and that will lead to health/welfare problems of animals for which the trace elements are essential.

In view of the above, the Commission is seeking a scientific opinion on ERA for feed additives described in Table 1. The purpose of this request is to have standardised ERA for feed additives containing selected trace elements to ensure a high level of protection of the environment and at the same time to allow essential feed additives to be on the market.

Natural background concentration of iron in soil is very high, as iron is a major element in soil and naturally occurs at concentrations in the percent range (Salminen et al., 2005). It is therefore very unlikely that use of iron as trace element in animal nutrition will pose any environmental safety concern. Consequently, iron is not included in this mandate.

TABLE 1 Description of the additives and target animal species.

Category of additives	Nutritional additives
Functional group of additives	Compounds of trace elements
Description	All additives containing cobalt (Co)/copper (Cu)/iodine (I)/manganese (Mn)/molybdenum (Mo)/ selenium (Se)/zinc (Zn)
Target animal category	All animal species for copper, iodine, manganese, selenium, zinc
	Terrestrial animal species for cobalt and molybdenum
Type of request	New opinion

In view of the above and, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission requests EFSA to deliver a new scientific opinion on the safety for the environment of the current maximum authorised levels of the following trace elements: cobalt, copper, iodine, manganese, molybdenum, selenium and zinc, on the basis of the available and/or new data. The opinion should take in consideration the target species for which the trace elements are currently authorised.

During the assessment, and in agreement with the European Commission, the mandate was split into two parts. The present opinion addresses the safety for the environment of Co and Mo, as these are currently authorised exclusively for use in terrestrial food-producing animals; whereas the second part will assess the remaining trace elements, allowing stakeholders additional time to submit data from ongoing studies.

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

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1.2 | Additional information

The mandate from the European Commission was received on 8 July 2024. General information on the mandate and supporting documentation are publicly available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00482.

2 | DATA AND METHODOLOGIES

2.1 | Methodology

The methodology used by the FEEDAP Panel to assess the safety of feed additives containing trace elements for the environment is described in the FEEDAP Panel Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

Trace elements may accumulate in the different environmental compartments. Following oral administration in terrestrial species, a fraction of the ingested trace element is excreted and subsequently introduced into agricultural soils through manure application. Although a certain fraction can be retained by soil's biota, trace elements are not subject to degradation. The environmental risk assessment (ERA) for the different target species is addressed by calculating the predicted environmental concentration (PEC) of a specific trace element in the relevant environmental compartment using the Feed Additives Environmental Risk Assessment (FERA) calculation tool.[2] The worst-case PEC is then compared with the natural background concentration of the respective trace element in that environmental compartment. For soil, the 90th percentile (P90) of concentrations measured in pristine or minimally impacted areas (depending on data availability) is used as a representation of the natural background concentration.[3] A similar approach is followed for freshwater and freshwater/marine sediment.

Potential removal of trace elements from soil through uptake by biota is not considered when calculating PEC_{soil} values and estimating soil enrichment.

When the PEC_{soil} is below 10% of the natural background concentration of the trace element in soil, the contribution from the feed additive is not expected to raise safety concerns for groundwater or freshwater.

For freshwater sediment, no safety concerns are expected when the PEC in freshwater is below the natural background concentration of the respective trace element.

2.2 | Data

For the current assessment, in accordance with the request from the European Commission, the FEEDAP Panel considered existing data publicly available (e.g. Forum of European Geological Surveys (FOREGS) Geochemical atlas of Europe; Geochemical mapping of agricultural and grazing land soil (GEMAS) database, Land Use/Cover Area (LUCAS) frame statistical Survey, European groundwater geochemistry (EGG) project, scientific literature) and unpublished data. EFSA also launched a call for all potentially relevant available data (published, unpublished or newly generated data) from interested parties. For the trace elements under assessment, the data obtained and the derived P90 values are described in the corresponding sections.

2.2.1 | Data from Forum of European Geological Surveys (FOREGS)

For soil, freshwater and freshwater sediment, the data from the FOREGS[4] Geochemical Atlas of Europe (Salminen et al., 2005) were considered a reliable reference source for the purpose of the current assessment, since all samples were collected from pristine areas (not affected by point or diffuse pollution). Sampling was carried out in each country by national teams, between 1997 and 2001. All samples were analysed by the same analytical methodology, which is described in additional publications available on the website.[5]

[2]FERA calculation tool available online at EFSA web site: https://www.efsa.europa.eu/en/applications/feedadditives/tools.

[3]Additional indications on how to derive a natural background concentration are given in the minutes of the 38th meeting of the FEEDAP Panel working group on Environment. available online: Minutes of the FEEDAP WG on Environment.

[4]Available online: http://weppi.gtk.fi/publ/foregsatlas/, accessed on 5 June 2026.

[5]More details are provided in the related publications available online: http://weppi.gtk.fi/publ/foregsatlas/.

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2.2.2 | Data from Geochemical Mapping of Agricultural and Grazing Land Soil in Europe (GEMAS) project

The GEMAS[6] project was conducted within the framework of REACH Regulation 1907/2006,[7] with the objective of measuring the concentrations of trace elements in agricultural soils that were not surveyed in the FOREGS Geochemical Atlas (2005). The GEMAS database contains information on trace element concentrations in European arable land and grassland soils. Soil samples were collected between spring 2008 and spring 2009, with arable land samples collected at a depth of 0–20 cm and grassland at a depth of 0–10 cm topsoil (Reimann et al., 2014). Sampling and analytical methodologies were harmonised and in line with REACH requirements and followed a stringent quality control system. However, unlike data from the FOREGS, the GEMAS database does not allow to discriminate between data originating from pristine areas and data from areas potentially affected by anthropogenic activities. The statistics related to the trace elements under assessment in soil, including the corresponding P90 values, were made available by representatives of the GEMAS project.

2.2.3 | Data from Land Use/Cover Area (LUCAS) frame statistical Survey

Samples of the LUCAS database[8] were collected in 2009 across 24 European Union (EU) member states,[9] covering approximately 91% of the total EU territory. In a first phase, a systematic sample (master sample) of 1,078,764 points were selected, with points spaced 2 km in the four cardinal directions covering the EU territory.[10] These points were assigned to 7 land-cover categories (arable land, permanent crops, grassland, wooded areas and shrubland, bare land, artificial land, water). About ¼ of these points was selected for sampling, and about 75% of the selected points (61%–97.4% depending on the country) were analysed. A standardised sampling procedure was used to collect around 0.5 kg of topsoil (0–20 cm). The samples were shipped to a central laboratory for physical and chemical analyses. More information on the analytical methods is available in Cristache et al. (2014). The statistics related to some trace elements under assessment, including the corresponding P90 in soil, were made available by LUCAS representatives.

2.2.4 | Data from the European Groundwater Geochemistry (EGG) project

Data from the EGG project, provided by GEMAS representatives, were used as a proxy for groundwater concentrations of the trace elements under assessment. The data were originally published in the Geochemistry of European Bottled Water Atlas (Reimann & Birke, 2010), comprising the results of 1785 bottled mineral water samples from 38 European countries, representing 1247 different sources at 884 locations. Samples were analysed in a single laboratory using inductively coupled plasma optical emission spectroscopy (ICP–OES), and statistics are publicly available (Demetriades et al., 2015). While the concentrations measured are largely determined by the geology of the source aquifers, they may also be influenced by bottling-related factors and potential leaching from packaging materials. Nevertheless, the dataset provides a useful representation of the natural variability of trace element concentrations in groundwater across Europe.

2.2.5 | Data submitted through the call for data

EFSA launched a call for data,[11] which was open from 23 October 2024 to 23 January 2025. Data on trace element concentrations in different environmental compartments were submitted by the Czech Republic (Central Institute of Supervising and Testing in Agriculture), Norway (Institute of Marine Research) and Poland (Chief Inspectorate of Environmental Protection (GIOŚ) and Krakow University).

From the data submitted, only a limited number of datasets pertained to pristine or minimally impacted areas. In addition, the submitted data had been analysed using different analytical methods. In some cases, the numerical values of the limit of detection (LOD) or the limit of quantification (LOQ) of the analytical method were provided, whereas in others the results were simply reported as being below the analytical limit ('<') with no further information. Freshwater data often contained repeated measurements of the same sample site during the year. Due to these limitations, the datasets received through the call for data were mainly used as supporting evidence. When possible, P90 values were calculated from the data submitted and presented, together with P90 values obtained from other sources, in the relevant sections of this opinion.

[6]GEMAS Project Home available online: https://gemas.eurogeosurveys.org/, accessed on 5 June 2026.

[7]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ 30.12.2006, L 396/849.

[8]Eurostat, LUCAS project home page online: LUCAS - Land use and land cover survey - Statistics Explained - Eurostat.

[9]Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

[10]LUCAS 2009 (Land Use/Cover Area frame Survey) quality report. Available online: lan_esms_an_2.pdf.

[11]Call for data for determination of natural background concentrations of trace elements (Co, Cu, I, Mn, Mo, Se or Zn) in the environment.

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When the results were reported as below the LOD or LOQ of the analytical method, only the datasets in which the fraction of these values represented less than 40% of the observations were used to derive a P90. In such cases, half the value of the LOD or the LOQ were inputted and all measurements were included in the calculation of the P90.[12] Where the same sampling site was sampled at different times in a year (e.g. a site sampled four times/year), all analytical values were used to derive the P90.

3 | ASSESSMENT

Several feed additives containing the trace elements cobalt (Co), copper (Cu), iodine (I), manganese (Mn), molybdenum (Mo), selenium (Se) or zinc (Zn), either in inorganic (e.g. copper(II) oxide, zinc oxide) or organic forms (e.g. copper bislysinate, zinc chelate of glycine) are currently authorised in the EU with specific total maximum use levels in feed for different animal species and categories.[13]

The present opinion assesses the safety for the environment of the currently authorised maximum use levels of Co and Mo in the EU. The assessment of Cu, Mn, I, Se and Zn will be addressed in a separate opinion.

3.1 | Cobalt

Co is currently authorised for ruminants with functional rumen, Equidae and lagomorphs at a maximum total content of 1 mg Co/kg complete feed.[14]

3.1.1 | Available data to establish natural background concentrations of Co

All the relevant data available to establish natural background concentrations of Co are reported in Table 2. Only samples from pristine areas are considered for the calculation of a natural background concentration (P90).

TABLE 2 Available data on concentrations of Co in the different environmental compartments.

Compartment	Source	Year	Number of samples (% < LOD or LOQ)	Exclusively pristine areas	P90	Unit
Soil	FOREGS	1997–2001	837	Yes	17	mg/kg soil dw
	LUCAS	2009	21,537	No	15.9	
	GEMAS grassland	2009	~2050	No	17	
	GEMAS cropland	2009	~2050	No	17	
	Central Institute (Czech Republic)	2019	176	Yes	17.7	
	Dane GIOŚ (Poland)	2010, 2015 and 2020	216 per year[1] (3%)	No	8	
	University of Krakow	2016	13[2]	No	–	
Groundwater	EGG project	2009	884[3]	No	0.125	µg/L
Freshwater	FOREGS	1997–2001	807	Yes	0.58	µg/L
	Dane GIOŚ (Poland)	2016–2021 and 2026	3050–3974 (93%–100%)[4]	No	–	
	University of Krakow	2016, 2017, 2019, 2021	2–10[2]	No	–	
Freshwater sediment	FOREGS	1997–2001	845	Yes	20	mg/kg sed dw
	Dane GIOŚ (Poland)	2016–2023	151–419 depending on the year (0.2–4.5%)	No	10	
	University of Krakow	2019, 2021	8, 11[2]	No	–	

Abbreviations: dw, dry weight; FOREGS, Forum of European Geological Surveys Geochemical atlas of Europe; GEMAS, Geochemical mapping of agricultural and grazing land soil database; LOD, limit of detection of the analytical method; LOQ, limit of quantification of the analytical method; LUCAS, Land Use/Cover Area frame statistical Survey and EGG is the European groundwater geochemistry project; P90, the 90th percentile; sed dw: sediment dry weight.

[1]14 samples (3%) were < LOQ and the P90 was calculated including all values.

[2]Insufficient number of analysed samples to calculate a P90.

[3]Using bottled mineral water as a proxy for groundwater.

[4]High percentage of values < LOD or LOQ preventing the calculation of a P90.

[12]Half the value of the LOD or the LOQ were inputted in the dataset to derive the P90.

[13]European Union Register of Feed Additives. Available online: https://ec.europa.eu/food/food-feed-portal/screen/feed-additives/search.

[14]Commission Implementing Regulation (EU) 2023/1455 of 13 July 2023 concerning the urgent provisional authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate, heptahydrate as feed additives for ruminants with a functional rumen, Equidae and lagomorphs. OJ L 179, 14.7.2023, pp. 103–111.

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The P90s in soil range from 8 to 17.7 mg Co/kg soil dry weight (dw). Data from Poland, which also include soils from non-pristine areas, show a comparatively lower P90 value in comparison to the other datasets, probably due to the different geochemical characteristics of land. Among the available data, the P90 of the FOREGS database (17 mg Co/kg soil dw) is considered a relevant value because of the relatively large number of samples analysed and the fact that the samples originated from areas not affected by anthropogenic activities.

Available data on Co concentrations in freshwater are from the FOREGS database, where the P90 of 807 analysed samples is 0.58 µg Co/L.

For freshwater sediment, the FOREGS database provides a P90 for Co of 20 mg/kg sediment dw from a total of 845 samples.

3.1.2 | Predicted environmental concentration of Co in soil and risk characterisation

As regards the use of Co in terrestrial farm animals, cattle for fattening are considered the worst-case scenario. Considering a concentration in feed of 1 mg Co/kg feed, the PEC_{soil} after 1 year of manure application is 17 µg Co/kg soil dw. As the PEC_{soil} is below 10% the natural background concentration of Co in soil (1.7 mg Co/kg soil dw), no further risk assessment is needed. It is noted that continuous use of Co at the maximum authorised level over 10 years of production may lead to an increase of the Co natural background concentration by 1%.

Since the PEC_{soil} is three orders of magnitude below the natural background concentration in soil, the contribution of Co used in animal nutrition is not expected to raise safety concerns for groundwater, surface water or freshwater sediment.

In conclusion, the use of Co as a nutritional additive in terrestrial food-producing animals at the maximum authorised level in complete feed is considered safe for the environment.

3.2 | Molybdenum

Mo is currently authorised as sodium molybdate dihydrate for use in sheep up to a maximum content of 2.5 mg Mo/kg complete feed.[15]

3.2.1 | Available data to establish natural background concentrations of Mo

All the relevant data available to establish natural background concentrations of Mo are reported in Table 3. Only samples from pristine areas are considered for the calculation of a natural background concentration (P90).

TABLE 3 Available data on concentrations of Mo in the different environmental compartments.

Compartment	Source	Year	Number of samples (% < LOD or LOQ)	Exclusively pristine areas	P90	Unit
Soil	FOREGS	1997–2001	840	Yes	1.81	mg/kg soil dw
	GEMAS grassland	2009	~2050	No	1.28	
	GEMAS cropland	2009	~2050	No	1.24	
	Central Institute (Czech Republic)	2019	176	Yes	0.81	
	University of Krakow	2019, 2021	8, 11	No	–	
Groundwater	EGG project	2009	884[1]	No	2.14	µg/L
Freshwater	FOREGS	1997–2001	807	Yes	1.07	µg/L
	Dane GIOŚ (Poland)	2016–2021 and 2026	4–3990 (83–99%)[2]	No	–	
	University of Krakow	2016, 2017, 2019, 2021	2–10[3]	No	–	
Freshwater sediment	FOREGS	1997–2001	848	Yes	1.89	mg/kg sed dw
	Dane GIOŚ (Poland)[4]	2017	421 (21%)	No	5.2	

Abbreviations: dw, dry weight; EGG, European groundwater geochemistry project; FOREGS, Forum of European Geological Surveys Geochemical atlas of Europe; GEMAS, Geochemical mapping of agricultural and grazing land soil database; LOD, limit of detection of the analytical method; LOQ, limit of quantification of the analytical method; LUCAS, Land Use/Cover Area frame statistical Survey; P90, 90th percentile; sed dw, sediment dry weight.

[1]Using bottled mineral water as a proxy for groundwater.

[2]The high percentage of values < LOD or LOQ do not allow calculating a P90.

[3]Insufficient number of analysed samples to calculate a P90.

[4]Additional data available for years 2016–2023, but the high percentage of values < LOD or LOQ do not allow calculating a P90.

[15]Commission Implementing Regulation (EU) 2019/1965 of 26 November 2019 concerning the authorisation of sodium molybdate dihydrate as a feed additive for sheep. OJ L 307, 28.11.2019, pp. 12–14.

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Considering the main datasets (pristine and non-pristine samples), the P90 values in soil range from 0.81 to 1.81 mg Mo/kg soil dw. Among the available data, the P90 of the FOREGS database (1.81 mg Mo/kg soil dw) is considered as the reference value because of the number and distribution of samples tested and the origin of the samples from areas not affected by anthropogenic activities.

Available data on Mo concentrations in freshwater are from the FOREGS database, where the P90 of 807 analysed samples is 1.07 µg Mo/L.

The available data on Mo concentrations in freshwater sediment originate also from FOREGS database, which reports a P90 of 1.89 mg Mo/kg freshwater sediment dw from a total of 848 samples analysed.

3.2.2 | Predicted environmental concentration of Mo in soil and risk characterisation

The PEC_{soil} of Mo after 1 year of use of the additive at the maximum authorised level in sheep feed depend on the sheep category considered, ranging from 30.3 µg Mo/kg soil dw in the case of sheep for fattening to 34.4 µg Mo/kg soil dw in adult sheep.

The PEC_{soil} is below 10% of natural background concentration of Mo in soil (0.181 mg Mo/kg soil dw), and therefore, no further risk assessment is needed. It is noted that continuous use at the maximum authorised level over 10 years of production of meat sheep may lead to an increase of the Mo natural background concentration in soil by 19%. Table 4 presents the estimated time to double the natural concentration of Mo in soil for the different species and categories.

TABLE 4 Estimated time (in years) to double the natural background concentration of Mo in soil, for different species and categories.

Species and/or category	PEC soil after 1 year of production (µg Mo/kg soil dry weight)	Years to double the natural background concentration of 1.81 mg Mo/kg soil dry weight
Adult meat sheep	34.4	53
Adult dairy sheep	32.9	55
Lamb for fattening	30.9	59
Sheep for fattening	30.3	60

Abbreviation: PEC, predicted environmental concentration.

Since the PEC_{soil} is at least one order of magnitude below the natural background concentration in soil, Mo administration in feed is not expected to raise safety concerns for groundwater, surface water or freshwater sediment.

In conclusion, the use of Mo as a nutritional additive in terrestrial food-producing animals at the maximum authorised level in complete feed is considered safe for the environment.

4 | CONCLUSIONS

The use of cobalt and molybdenum as nutritional additive in terrestrial food-producing animals at the respective current maximum authorised levels in complete feed is considered safe for the environment.

ABBREVIATIONS

Co	cobalt
Cu	copper
DOI	digital object identifier
dw	dry weight
EGG	European Groundwater Geochemistry project
ERA	environmental risk assessment
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FERA	Feed additives environmental risk assessment tool
FOREGS	Forum of European Geological Surveys
GEMAS	Geochemical Mapping of Agricultural and grazing land Soil in Europe
GIOŚ	Chief Inspectorate of Environmental Protection
I	iodine
ICP–OES	inductively coupled plasma optical emission spectroscopy
JRC	Join Research Centre
LOD	limit of detection
LOQ	limit of quantification
LUCAS	Land Use/Cover Area frame statistical Survey
Mn	Manganese
Mo	molybdenum

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P90	90th percentile
PEC	Predicted environmental concentration in a given environmental compartment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Se	selenium
Sed dw	sediment dry weight
WG	Working group
Zn	zinc

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