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Safety and efficacy of a feed additive consisting of chromium propionate (KemTRACE™ Chromium) for all growing poultry species (Kemin Europa NV)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of chromium propionate (KemTRACE™ Chromium; KemTRACE-Cr) as zootechnical feed additive for all growing poultry species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) Panel was assigned to this mandate. Based on two tolerance studies submitted, the Panel concluded that the additive is safe for chickens for fattening at the maximum recommended supplementation level of 0.4 mg Cr/kg feed from KemTRACE-Cr, but a margin of safety cannot be established; this conclusion can be extended to chickens reared for laying/breeding, but cannot be extrapolated to other growing poultry species. The FEEDAP Panel considered that the use of KemTRACE-Cr in animal nutrition at the proposed conditions of use is safe for the consumer. No concerns for users following any inhalation exposure during the handling of the additive are expected; the additive was shown to be corrosive to the eyes but not irritant to skin or a skin sensitiser. The use of KemTRACE-Cr in animal nutrition according to the proposed conditions of use will not significantly alter the concentration in the receiving environmental compartments of concern; therefore, no safety concern is expected for the environment. Based on three efficacy studies, the FEEDAP Panel concluded that KemTRACE-Cr has the potential to be efficacious as a zootechnical additive in chickens for fattening at the supplementation level of 0.4 mg Cr/kg feed; this conclusion could be extended to chickens reared for laying and chickens reared for breeding, and extrapolated to other poultry species for fattening and reared for laying/breeding.

Keywords: zootechnical additives, other zootechnical additives, chromium propionate, KemTRACE™ Chromium, Safety, Efficacy, poultry

Requestor: European Commission

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Table of contents

1. Introduction

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

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Kemin Europa NV[2] for authorisation of chromium propionate (KemTRACE™ Chromium), when used as a feed additive for all growing poultry species (category: zootechnical additives; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 16 March 2020.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product chromium propionate (KemTRACE™ Chromium), when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

The additive, a preparation containing chromium propionate (brand name: KemTRACE™ Chromium), is intended for use as a zootechnical feed additive (functional group: other zootechnical additives) for all growing poultry species. This feed additive is not authorised in the EU.

The FEEDAP Panel has delivered two scientific opinions on the safety and efficacy of chromium methionine, one as a nutritional feed additive for all animal species (EFSA, 2009a) and another as a zootechnical additive (EFSA FEEDAP Panel, 2020) for dairy cows. In the former opinion, the FEEDAP Panel could not conclude on the safety for target animals and consumers; concerning efficacy, the opinion reported availability of chromium from the additive, but no conclusions could be drawn regarding performance parameters. In the latter opinion, the Panel could not conclude on the efficacy of the additive.

Regarding other outputs, EFSA commissioned the University of Gent (Belgium) to carry out a literature review on selected trace and ultratrace elements, including chromium; this activity resulted in a report (Van Paemel et al., 2010).

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) delivered a scientific opinion on dietary reference values for chromium (EFSA NDA Panel, 2014a); the same Panel delivered an opinion on the substantiation of several health claims related to chromium (EFSA NDA Panel, 2010), and another opinion on a specific health claim (reduction of post-prandial glycaemic responses) related to a combination of various amino acids and chromium picolinate (EFSA NDA Panel, 2014b).

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) delivered a scientific opinion on the risks to public health related to the presence of chromium in food and drinking water (EFSA CONTAM Panel, 2014).

The EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel) has delivered several opinions on the safety of various chromium sources added for nutritional purposes to foodstuffs: trivalent chromium (EFSA ANS Panel, 2010a), a mixture of chromium di- and tri-nicotinate (EFSA, 2008), chromium(III) (EFSA, 2009b), chromium picolinate (EFSA, 2009c; EFSA ANS Panel, 2010b), ChromoPrecise® cellular bound chromium yeast (EFSA ANS Panel, 2012a) and on chromium (III) lactate tri-hydrate (EFSA, 2009d; EFSA ANS Panel, 2012b).

Four chromium compounds (chromium(III) chloride and its hexahydrate, chromium(III) sulfate and its hexahydrate, chromium picolinate and chromium(III) lactate tri-hydrate) are listed as mineral substances which may be added to foods.[3] Five chromium compounds (chromium(III) chloride,

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Kemin Europa NV. Toekomstlaan 42. 2200 Herentals, Belgium.
[3] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26.

chromium(III) lactate trihydrate, chromium nitrate, chromium picolinate and chromium(III) sulfate) are listed as minerals which may be used in the manufacture of food supplements, and four chromium compounds (chromium(III) chloride and its hexahydrate and chromium(III) sulfate and its hexahydrate) as mineral substances which may be added to foods.[4]

Three sources of chromium (chromium(III) chloride and its hexahydrate, chromium(III) sulfate and its hexahydrate and chromium picolinate) are authorised as food for special medical purposes and as total diet replacement for weight control.[5]

Chromium picolinate is authorised as a novel food in the EU.[6]

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[7] in support of the authorisation request for the use of chromium propionate (KemTRACE™ Chromium), as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' elicitation knowledge, to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the additive (KemTRACE chromium, chromium propionate) in animal feed. The Executive Summary of the EURL report can be found in Annex A;[8] from this report the FEEDAP Panel notes that the following is signalled: 'based on the available data, the EURL is not able to recommend for official control the proposed methods based on ICP-AES or ICP-MS, neither any other method for the quantification of the organic chromium content in premixtures and feedingstuffs'.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of chromium propionate (KemTRACE™ Chromium) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

The additive KemTRACE™ Chromium contains 'triaqua-(μ3-oxo)hexa(μ2-propionato-O,O')trichromium(III) propionate' as the active compound referred from here onwards as 'chromium propionate'. The product is intended to be used as a zootechnical feed additive (functional group: other zootechnical additives; claim: improvement of growth parameters and carcass traits) for all growing poultry species. The additive will be referred to in this scientific opinion as KemTRACE-Cr. Unless otherwise indicated, *chromium* in the opinion refers to chromium(III).

[4] Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. OJ L 314, 1.12.2009, p. 36.

[5] Regulation (EU) No 609/2013 of the European Parliament and of the council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35.

[6] Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. OJ L 187, 24.7.2018, p. 1.

[7] FEED dossier reference: FAD-2019-0076.

[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2019-0076-cr-propionate.pdf

[9] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

3.1. Characterisation

3.1.1. Characterisation of the additive

[redacted]

[15]

[redacted]

[10] Technical Dossier/Section II/Annex II_02.
[redacted] Technical Dossier/Section II/Annex II_03. [redacted]
[redacted] Technical Dossier/Section II/Annex II_04. [redacted]
[13] Technical Dossier/Section II/Annex II_03.
[14] Technical Dossier/Section II/Annex II_05.
[15] Technical Dossier/Supplementary Information_July 2020/Annex_SIn_5.
[16] Technical Dossier/Supplementary Information_July 2020/Annex_SIn_1.
[17] Technical Dossier/Section II/Annex II_06 and Annex II_07.
[18] [redacted] Technical Dossier/Section II/Annex II_10.
[19] Technical Dossier/Supplementary Information_July 2020/Annex_SIn_8.
[20] Technical Dossier/Supplementary Information_July 2020. [redacted]
[21] [redacted]
[22] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10.
[23] Technical Dossier/Supplementary Information_July 2020/Annex_SIn_9.
[24] Technical Dossier/Section II/Annex II_11 and Annex II_12.

3.1.2. Characterisation of the compound

[redacted]

[redacted]

3.1.3. Manufacturing process

[redacted]

3.1.4. Stability and homogeneity

[redacted]

[25] Technical Dossier/Supplementary Information_August 2020; Technical Dossier/Supplementary Information_September 2020 Annex_SIn1.pdf.
[26] Technical Dossier/Supplementary Information_July 2020.
[27] Technical Dossier/Supplementary Information_August 2020.
[28] Technical Dossier/Section II/Annex II_13.
[29] Technical Dossier/Section II/Annex II_14.

[redacted] Additionally, the Panel notes that the low recovery of the chromium propionate complex in mash and pelleted feed casts doubts regarding the stability of the complex, its potential degradation and the adequacy of the applied quantification analytical method (see Section 2.1 and Annex A).

[redacted]

3.1.5. Conditions of use

The product is intended to be used in compound feed for all growing poultry species to provide a minimum of 0.2 and a maximum of 0.4 mg organic Cr/kg complete feed. The additive should be incorporated in feed via premixtures. The additive can be used during the complete life cycle of all growing poultry species without any withdrawal period.

The FEEDAP Panel notes that the proposed chromium supplementation rate from KemTRACE-Cr falls within the background content of chromium in poultry feed (0.82–1.27 mg Cr/kg; data from Nicholson et al. (1999); Króliczewska et al. (2004) and Yildiz et al. (2004), reported in EFSA (2009a); Dai et al. (2016)).

3.2. Safety

The additive contains chromium propionate (29–32%), propionic acid (37%), sodium propionate (14–17%) and propylene glycol (2%). The FEEDAP Panel has assessed propionic acid and its salts, including sodium propionate (EFSA FEEDAP Panel, 2011). In the light of the outcome of that assessment, and considering that the total propionic acid added from the additive to the complete feed would be ca. 1.0 mg/kg, no safety concerns are expected for the propionic acid or the sodium propionate from the additive.

Propylene glycol is listed under *Miscellaneous* in the EU Catalogue of feed materials.[35]

3.2.1. Safety for the target species

The applicant provided two studies in chickens for fattening to support the safety for the target animals.

[30] Technical Dossier/Section II/Annex II_22.

[31] [redacted]

[32] [redacted]

[33] Technical Dossier/Section II/Annex II_23.

[redacted]

[35] Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials. OJ L 029, 30.1.2013, p. 1.

3.2.1.1. Study 1

[redacted]

[redacted]

[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[36] Technical Dossier/Section III/Annex III_1.

[redacted]

[42] Technical Dossier/Supplementary Information/October 2020/Annex_SIn1.

[43] Technical Dossier/Section III/Annex III_3, Annex III_3.1 and Annex III_3.2.

[redacted]

3.2.1.2. Study 2

[redacted]

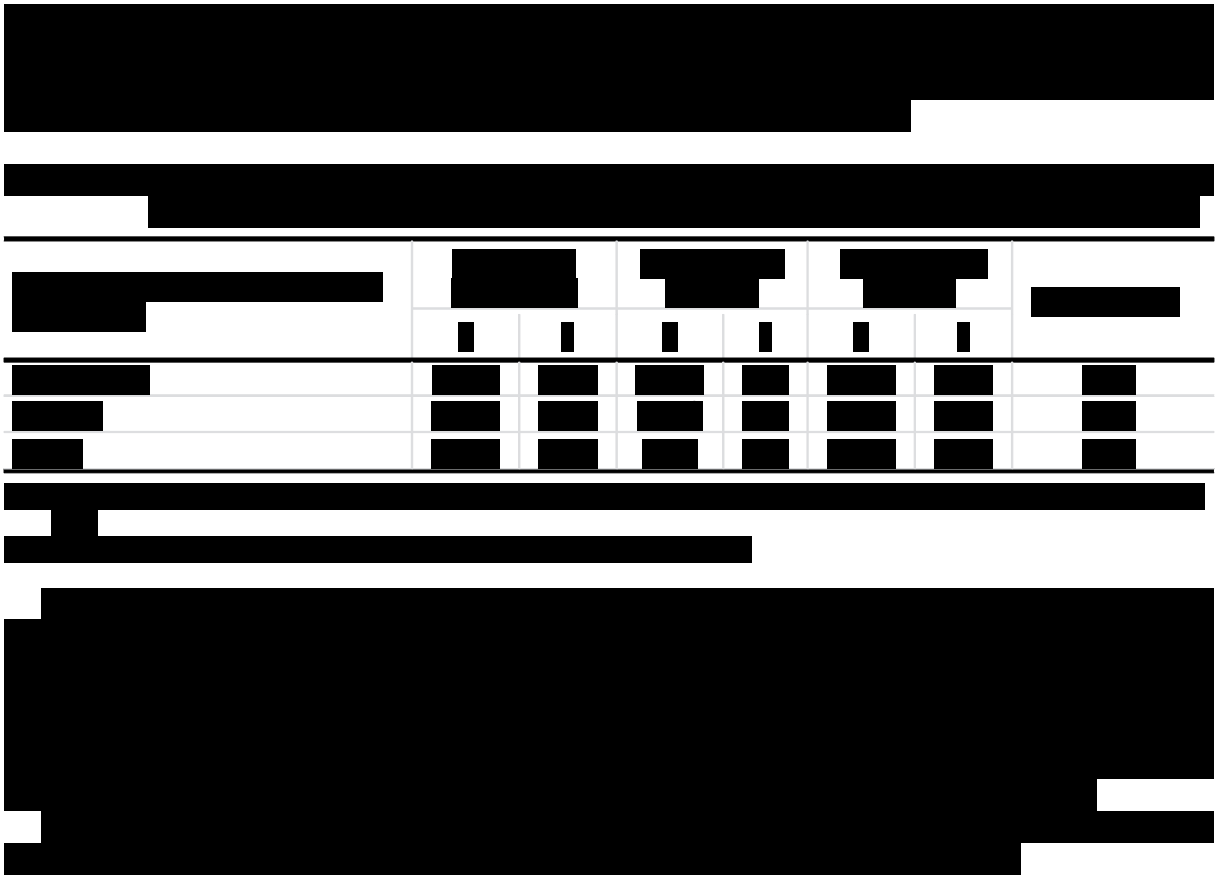
[redacted]

[45] Technical Dossier/Section III/Annex III_6.

[redacted]

[47] Technical Dossier/Supplementary Information_July 2020/Annex_SIn_10.

[redacted]



3.2.1.3. Conclusions on safety for the target species

The results from a tolerance trial in chickens for fattening showed no adverse effects of the addition of the additive up to the intended level of 4 mg chromium from KemTrace-Cr/kg feed, which corresponded to an analysed value of 2.71 mg chromium/kg feed, indicated that the additive would be tolerated up to 6.8-fold the maximum inclusion level. However, the data from another study in chickens for fattening showed an adverse effect on the performance of male chickens; this effect was seen with the addition of 2 mg Cr from KemTrace-Cr/kg feed, which corresponded to an analysed value of 2.15 mg Cr/kg feed. These findings would cast some doubts on the safety of this supplemental level of chromium from KemTrace-Cr in chickens for fattening.

Therefore, with the data available, the FEEDAP Panel concludes that the additive is safe for chickens for fattening at the highest inclusion level of 0.4 mg Cr/kg feed from KemTRACE-Cr, but a margin of safety cannot be established. This conclusion can be extended to chickens reared for laying and reared for breeding, but cannot be extrapolated to other growing poultry species.

3.2.2. Safety for the consumer

3.2.2.1. Absorption, distribution, metabolism and excretion (ADME)

[redacted]

The additive under assessment contains an appreciable portion of propionic acid and sodium propionate. Propionic acid and its salts were already evaluated by EFSA FEEDAP Panel (2011). In that opinion, the fate of the compounds in the organism was considered: 'Propionic acid and its salts are efficiently metabolised in the organism by entering different metabolic pathways, mainly the fatty acid and tricarboxylic acid pathways. When propionic acid (or its salts) is ingested by livestock and poultry, residues in meat, milk, or eggs are considered negligible, given that propionic acid is used by most organs and tissues and can be metabolised to carbohydrates, amino acids, and lipids'. Thus, in the organism, the complete degradation of propionic acid and sodium propionate present in the additive is expected.

3.2.2.2. Residue studies

3.2.2.2.1. Residue study 1

[redacted]

[50] Technical Dossier/Section III/Annex III_7.

[51] Technical Dossier/Section III/Annex III_11.1 and Annex III_11.2. Technical Dossier/Supplementary Information_July 2020_Annex_SIn_11.

[redacted]

[53] Technical Dossier/Supplementary information October 2020/AnnexSIn5.

[redacted]

Owing to the large variation between the intended and analysed chromium levels in feed, and considering that neither the minimum nor the maximum recommended levels of chromium from the additive were reached, these data are not supportive of residue studies, and therefore cannot be considered for the risk assessment.

3.2.2.2.2. Residue study 2

[redacted]

3.2.2.3. Toxicological studies

3.2.2.3.1. Genotoxicity studies, including mutagenicity

[redacted]

3.2.2.3.1.1. Bacterial reverse mutation test

[redacted]

[54] Technical Dossier/Section III/Annex III_12.

[redacted] The FEEDAP Panel concludes that the test item did not induce gene mutations in bacteria under the experimental conditions employed in this study.

3.2.2.3.1.2. In vitro mammalian cell micronucleus test

[redacted] The FEEDAP Panel concludes that the test item did not induce chromosome damage *in vitro* in mammalian cells under the experimental conditions employed in this study.

3.2.2.3.1.3. In vitro mammalian gene mutation test

[redacted] The FEEDAP Panel concludes that the test item did not induce significant increase of mutation frequency *in vitro* in mammalian cells under the experimental conditions applied in the present study.

3.2.2.3.1.4. In vivo mammalian erythrocyte micronucleus test

[redacted] The FEEDAP

[55] Technical Dossier/Section III/Annex III_13.
[56] Technical Dossier/Section III/Annex_III_14.
[57] Technical Dossier/Section III/Annex_III_15.

Panel concludes that the test item did not induce chromosome damage *in vivo* under the experimental conditions applied in the present study.

3.2.2.3.2. Repeated dose toxicity studies

[redacted]

3.2.2.3.2.1. 28-day Study

[redacted]

In view of the results observed, it can be stated that the No Observed Adverse Effect Level (NOAEL) for KemTRACE-Cr administered by oral gavage was found to be 1,000 mg/kg bw per day in Sprague Dawley rats under the experimental conditions of the present study, corresponding to 96 mg Cr/kg bw per day.

[58] Technical Dossier/Section III/ Annex_III_19.
[59] Technical Dossier/Section III/Annex_III_18.
[60] Technical Dossier/Section III/Annex_III_16.

[redacted]

3.2.2.3.2.2. 90-day Study

Therefore, under the conditions of the study, the NOAEL for KemTRACE-Cr could be determined as 500 mg/kg bw per day, corresponding to 48 mg Cr/kg bw per day.

[65] Technical Dossier/Section III/Annex_III_17.

3.2.2.3.3. Chronic oral toxicity study

[redacted] the FEEDAP Panel considers the dose of 400 mg KemTRACE-Cr/kg bw per day as the NOAEL, corresponding to 36 mg Cr/kg bw per day.

3.2.2.3.4. Carcinogenicity study

The applicant did not submit carcinogenicity studies performed with the additive under assessment.

3.2.2.3.5. Reproduction toxicity study

[redacted] Therefore, 600 mg/kg bw per day, the highest dose tested, was considered the no observed adverse effect level (NOAEL) in the present two-generation reproductive toxicity study, corresponding to 49 mg Cr/kg bw per day.

3.2.2.3.6. Conclusions on Toxicology

The FEEDAP Panel concludes that, based on the studies provided, KemTRACE-Cr is not genotoxic or mutagenic. The Panel identified an NOAEL of 400 mg KemTRACE-Cr/kg bw per day from the chronic toxicity study (up to 12 months) with Sprague Dawley rats as a reference point for the safety assessment of consumer exposure; this NOAEL corresponds to 36 mg Cr(III)/kg bw per day.

3.2.2.4. Assessment of consumer exposure and consumer safety assessment

The FEEDAP Panel performed an exposure assessment following the methodology described in the Guidance on consumer safety (EFSA FEEDAP Panel, 2017a–c) (Appendix A). [redacted]

[66] Technical Dossier/Section III/Annex_III_20.
[67] Technical Dossier/Section III/Annex_III_21.

The residue values from the Residue study 2 (converted from ng/g to mg/g) were used as input data for the exposure calculation and are reported in Table 5. The results of the chronic exposure to chromium are reported in Table 6.

[redacted]

The FEEDAP Panel considers that the exposure in all the population groups is negligible.

An NOAEL of 400 mg KemTRACE-Cr/kg bw per day (corresponding to 36 mg Cr(III)/kg bw per day) was identified based on a chronic toxicity study performed in rats. Based on the NOAEL and the highest estimated exposure (0.0003 mg Cr(III)/kg bw per day in infants and toddlers), the FEEDAP Panel calculated a margin of exposure (MOE) greater than 10^5 which was considered of no concern. Therefore, the FEEDAP Panel does not consider necessary to set an ADI.

3.2.2.5. Conclusions on safety for the consumer

The FEEDAP Panel considers that the use of KemTRACE-Cr in animal nutrition under the proposed conditions of use is safe for the consumer.

3.2.3. Safety for user

3.2.3.1. Effect on respiratory system

[redacted]

The results of the study indicate that there would be no concern for users following any inhalation exposure during the handling of the additive. Furthermore, considering that the product is presented as liquid, exposure to users by the respiratory route is unlikely.

[68] Technical Dossier/Section III/Annex_III_23.

3.2.3.2. Effects on eyes and skin

3.2.3.2.1. Acute dermal irritation/corrosion study

[redacted] Therefore, the FEEDAP Panel concludes that the additive is non-irritant to skin.[71]

3.2.3.2.2. Skin sensitisation

[redacted] The results indicated that the additive can be considered a non-sensitiser under the conditions of the test.

3.2.3.2.3. Acute eye irritation/corrosion study

[redacted] indicating that KemTRACE-Cr will induce irreversible effects upon ocular exposure.

3.2.3.3. Conclusions on safety for the user

On the basis of the studies submitted, no concerns for users following any inhalation exposure during the handling of the additive are expected; the additive was shown to be corrosive to the eyes but not irritant to skin or a skin sensitiser.

3.2.4. Safety for the environment

[redacted]

[redacted]

[redacted] the use of KemTRACE-Cr will not significantly alter the

[69] Technical Dossier/Section III/Annex_III_25.
[70] Available online: https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf.
[71] Technical Dossier/Spontaneous submission of Information_July 2020/Annex_SIn_15.
[72] Technical Dossier/Section III/Annex_III_24.
[73] Technical Dossier/Section III/Annex_III_26.
[74] FOREGS database. Available online: http://weppi.gtk.fi/publ/foregsatlas/article.php?id=15.

concentration of chromium in the receiving environmental compartments of concern and will not pose an additional risk for the environment.

3.2.4.1. Conclusions on safety for the environment

The use of KemTRACE-Cr in animal nutrition according to the proposed conditions of use will not significantly alter the concentration of chromium in the receiving environmental compartments of concern. No concern for the environment is expected.

3.3. Efficacy

Three efficacy studies were provided by the applicant to examine the effects of the additive on the zootechnical parameters and carcass yield in chickens for fattening.

3.3.1. Efficacy studies in chickens for fattening

[redacted]

[redacted]

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[75] Technical dossier/Section IV/Annex_IV_3.
[76] Technical Dossier/Supplementary Information October 2020/Annex6.
[77] Technical Dossier/Supplementary Information October 2020/Annex7.
[78] Technical Dossier/Supplementary Information October 2020/Annex8.
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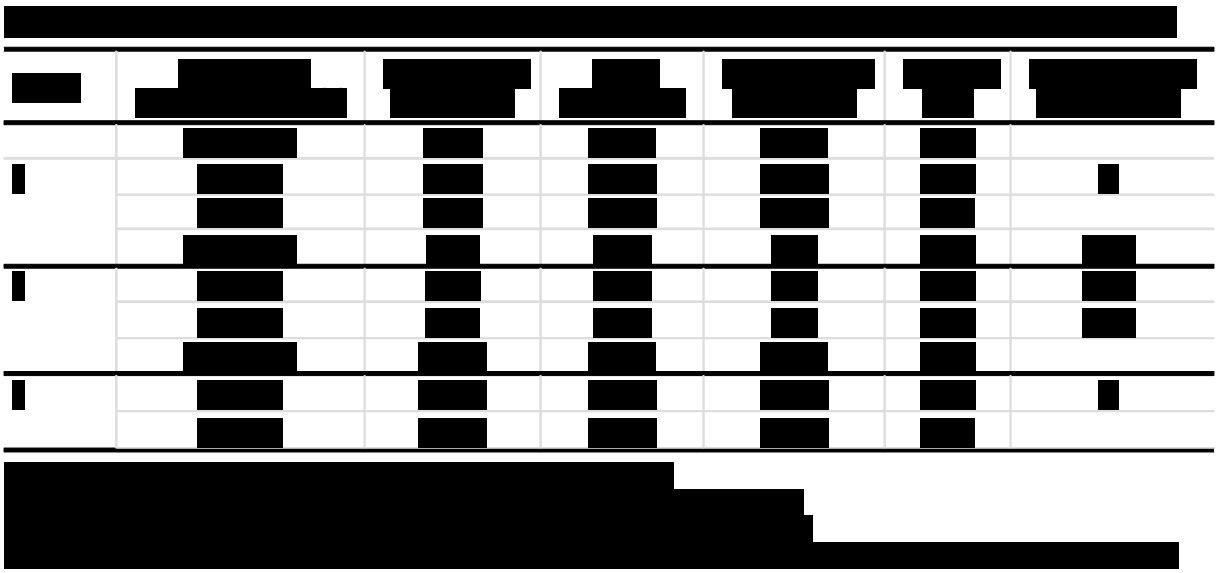

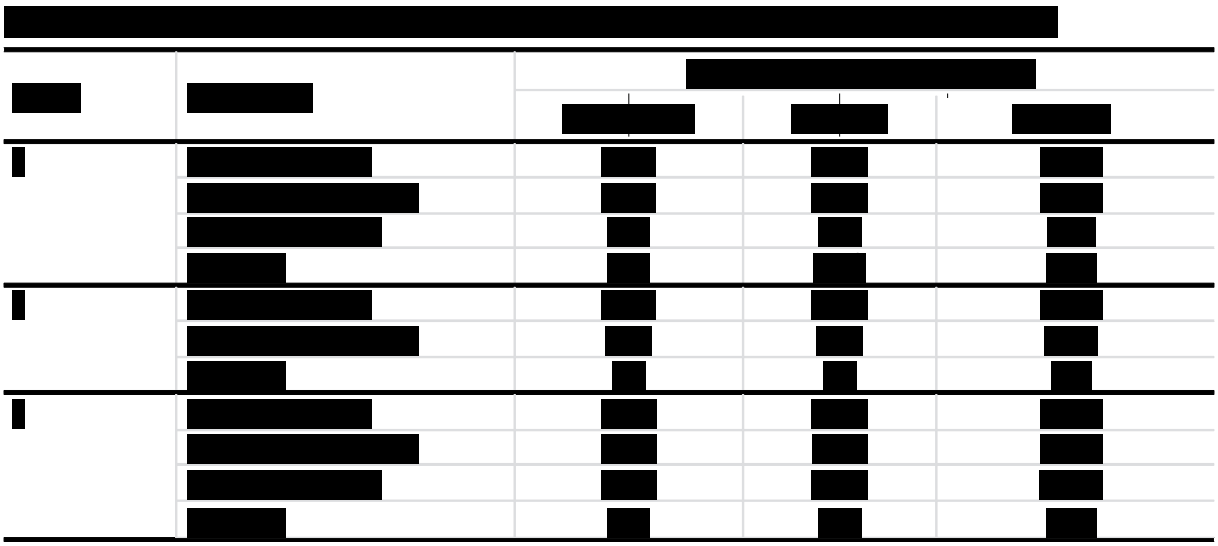

[redacted]

3.3.2. Conclusions on efficacy

Based on the results of three studies in chickens for fattening from which positive effects in the performance and carcass traits were identified, the FEEDAP Panel concludes that KemTRACE-Cr has the potential to be efficacious as a zootechnical additive in chickens for fattening at the supplementation level of 0.4 mg Cr/kg feed. This conclusion can be extended to chickens reared for laying and chickens reared for breeding, and extrapolated to other poultry species for fattening and reared for laying/breeding.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[80] and Good Manufacturing Practice.

4. Conclusions

The FEEDAP Panel concludes that the additive is safe for chickens for fattening at the maximum recommended supplementation level of 0.4 mg Cr/kg feed from KemTRACE-Cr, but a margin of safety cannot be established. This conclusion can be extended to chickens reared for laying/breeding, but cannot be extrapolated to other growing poultry species.

The FEEDAP Panel considers that the use of KemTRACE-Cr in animal nutrition under the proposed conditions of use is safe for the consumer.

No concerns for users following any inhalation exposure during the handling of the additive are expected; the additive was shown to be corrosive to the eyes but not irritant to skin or a skin sensitiser.

The use of KemTRACE-Cr in animal nutrition according to the proposed conditions of use will not significantly alter the concentration in the receiving environmental compartments of concern. No safety concern for the environment is expected.

The FEEDAP Panel concludes that KemTRACE-Cr has the potential to be efficacious as a zootechnical additive in chickens for fattening at the supplementation level of 0.4 mg Cr/kg feed. This conclusion can be extended to chickens reared for laying and chickens reared for breeding, and extrapolated to other poultry species for fattening and reared for laying/breeding.

5. Documentation as provided to EFSA/Chronology

Date	Event
27/11/2019	Dossier received by EFSA. Chromium Propionate: All growing poultry species. Submitted by Kemin Europa N.V.
12/12/2019	Reception mandate from the European Commission
16/03/2020	Application validated by EFSA – Start of the scientific assessment
28/05/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety for the target species, safety for the consumer, efficacy.*
16/06/2020	Comments received from Member States
01/07/2020	Reception of supplementary information from the applicant - Scientific assessment re-started

[80] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

Date	Event
01/07/2020	Reception of spontaneous information from the applicant – Safety for the users
14/07/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
17/07/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation.*
27/07/2020	Clarification teleconference during risk assessment with the applicant according to the "EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products"
18/08/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
07/09/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation.*
14/09/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
16/09/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for target animals, efficacy.*
08/10/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
18/03/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Glossary

In the context of the Dossier KemTRACE-Cr, the following definitions are used:

Chromium (III) or Cr(III)	In the additive and premixture (KemTRACE-Cr) described in the current dossier, the trivalent chromium Cr(III), is exclusively bound to propionate.
Organic Chromium	In feed samples, Cr(III) is bound to organic carriers (including under the form chromium propionate) or chelating ligands naturally found in this matrix. Referring to the latter, the applicant uses the term organic chromium.
Elemental Chromium	In the dossier, the term 'elemental chromium' refers to chromium (either bound or unbound)

Abbreviations

ADI	average daily intake
AME	apparent metabolisable energy
ANOVA	analysis of variance
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
bw	body weight
CONTAM	The EFSA Panel on Contaminants in the Food Chain
CP	crude protein
CV	coefficient of variation
EURL	European Union Reference Laboratory
FEEDAP	The EFSA Panel on Additives and Products or Substances used in Animal Feed
FOB	neurological observations
GEF	global evaluation factor
GHS	globally harmonised system (of classification & labelling chemicals)
GIT	upper gastrointestinal tract
GLP	good laboratory practice
ICP-AES	inductively coupled plasma atomic emission spectroscopy
ICP-MS	inductively coupled plasma-mass spectrometry
LC-HRMS	liquid chromatography high resolution mass spectrometry
LD	lethal dose
LOD	limit of detection
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MF	mutant frequency
MNC	mononuclear cells
MOE	margin of exposure
NCE	normochromatic erythrocytes
NDA	The EFSA Panel on Dietetic Products, Nutrition and Allergies
NOAEL	no observed adverse effect level
OECD	organization for economic co-operation and development
PCE	polychromatic erythrocytes
PCV	packed cell volume
PMN	polymorphonuclear cells
RBC	red blood cells count

SEM	pooled standard errors
UHPLC-HRMS	ultra-high-performance liquid chromatography-high-resolution mass spectrometry
UHPLC-MS	ultra-high-performance liquid chromatography mass spectroscopy
WBC	white blood cell
WHO	World Health Organization

Appendix A – Calculation of consumer exposure

Methodology

As described in the Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017a–c), consumption data of edible tissues and products as derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) will be used to assess exposure to residues from the use of feed additives in different EU countries, age classes[81] and special population groups. For each EU country and age class, only the latest survey available in the Comprehensive Database will be used.

While the residue data reported for feed additives refer to organs and tissues (raw agricultural commodities. RAC), the Comprehensive Database includes consumption data for foods as consumed. In order to match those consumption data with the available residue data for feed additives, the consumption data reported in the Comprehensive Database have been converted into RAC equivalents. For assessing the exposure to chromium from their use in poultry, the following list of commodities is considered: meat, liver and other offals (kidney). In the case of the additive under assessment, the FEEDAP Panel considered that only the chronic exposure assessment would be appropriate.

For chronic exposure assessments, the total relevant residues will be combined for each individual with the average daily consumptions of the corresponding food commodities, and the resulting exposures per food will be summed in order to obtain total chronic exposure at individual level (standardised by using the individual body weight). The mean and the higher percentile (usually the 95th percentile) of the individual exposures will be subsequently calculated for each dietary survey (country) and each age class separately.

Detailed results on chronic exposure calculation

Table A.1: Chronic dietary exposure per population class, country and survey (mg/kg body weight per day) to chromium residues based on residue data in chickens for fattening

Population class	Survey's country	Number of subjects	HRP(1)	HRP description
Infants	Bulgaria	523	0.0002610422	95th
Infants	Germany	142	0.0000462322	95th
Infants	Denmark	799	0.0000569355	95th
Infants	Finland	427	0.0000851225	95th
Infants	United Kingdom	1,251	0.0001122799	95th
Infants	Italy	9	0.0000000000	50th
Toddlers	Belgium	36	0.0001255564	90th
Toddlers	Bulgaria	428	0.0002994947	95th
Toddlers	Germany	348	0.0000816632	95th
Toddlers	Denmark	917	0.0000631728	95th
Toddlers	Spain	17	0.0001230769	75th
Toddlers	Finland	500	0.0001359756	95th
Toddlers	United Kingdom	1,314	0.0001294743	95th
Toddlers	United Kingdom	185	0.0001323967	95th
Toddlers	Italy	36	0.0001121455	90th
Toddlers	Netherlands	322	0.0001377606	95th
Other children	Austria	128	0.0001087622	95th
Other children	Belgium	625	0.0001501970	95th
Other children	Bulgaria	433	0.0002498790	95th
Other children	Czech Republic	389	0.0002318841	95th
Other children	Germany	293	0.0000847909	95th
Other children	Germany	835	0.0000855948	95th
Other children	Denmark	298	0.0000706172	95th

[81] Infants: < 12 months old, toddlers: ≥ 12 months to < 36 months old, other children: ≥ 36 months to < 10 years old, adolescents: ≥ 10 years to < 18 years old, adults: ≥ 18 years to < 65 years old, elderly: ≥ 65 years to < 75 years old, and very elderly: ≥ 75 years old.

Population class	Survey's country	Number of subjects	HRP(1)	HRP description
Other children	Spain	399	0.0001599067	95th
Other children	Spain	156	0.0002237978	95th
Other children	Finland	750	0.0001159343	95th
Other children	France	482	0.0000971715	95th
Other children	United Kingdom	651	0.0001168900	95th
Other children	Greece	838	0.0001143963	95th
Other children	Italy	193	0.0001205390	95th
Other children	Latvia	187	0.0001298914	95th
Other children	Netherlands	957	0.0001004959	95th
Other children	Netherlands	447	0.0001265456	95th
Other children	Sweden	1,473	0.0000948131	95th
Adolescents	Austria	237	0.0000751522	95th
Adolescents	Belgium	576	0.0000687412	95th
Adolescents	Cyprus	303	0.0000726739	95th
Adolescents	Czech Republic	298	0.0001707490	95th
Adolescents	Germany	393	0.0000657262	95th
Adolescents	Germany	1,011	0.0000538202	95th
Adolescents	Denmark	377	0.0000552265	95th
Adolescents	Spain	651	0.0000928711	95th
Adolescents	Spain	209	0.0001246327	95th
Adolescents	Spain	86	0.0001018043	95th
Adolescents	Finland	306	0.0000696663	95th
Adolescents	France	973	0.0000645070	95th
Adolescents	United Kingdom	666	0.0000856706	95th
Adolescents	Italy	247	0.0000535676	95th
Adolescents	Latvia	453	0.0000791579	95th
Adolescents	Netherlands	1,142	0.0000948657	95th
Adolescents	Sweden	1,018	0.0000713887	95th
Adults	Austria	308	0.0000860621	95th
Adults	Belgium	1,292	0.0000650923	95th
Adults	Czech Republic	1,666	0.0000860126	95th
Adults	Germany	10,419	0.0000530948	95th
Adults	Denmark	1,739	0.0000360015	95th
Adults	Spain	981	0.0000865352	95th
Adults	Spain	410	0.0000865190	95th
Adults	Finland	1,295	0.0000681722	95th
Adults	France	2,276	0.0000541177	95th
Adults	United Kingdom	1,265	0.0000632333	95th
Adults	Hungary	1,074	0.0000823568	95th
Adults	Ireland	1,274	0.0000847606	95th
Adults	Italy	2,313	0.0000457636	95th
Adults	Latvia	1,271	0.0000707351	95th
Adults	Netherlands	2,055	0.0000777646	95th
Adults	Romania	1,254	0.0000992240	95th
Adults	Sweden	1,430	0.0000728628	95th
Elderly	Austria	67	0.0000758215	95th
Elderly	Belgium	511	0.0000528905	95th
Elderly	Germany	2,006	0.0000416717	95th
Elderly	Denmark	274	0.0000291164	95th
Elderly	Finland	413	0.0000551021	95th

Population class	Survey's country	Number of subjects	HRP(1)	HRP description
Elderly	France	264	0.0000453278	95th
Elderly	United Kingdom	166	0.0000526307	95th
Elderly	Hungary	206	0.0000630194	95th
Elderly	Ireland	149	0.0000692899	95th
Elderly	Italy	289	0.0000501282	95th
Elderly	Netherlands	173	0.0000593316	95th
Elderly	Netherlands	289	0.0000504183	95th
Elderly	Romania	83	0.0000899502	95th
Elderly	Sweden	295	0.0000678490	95th
Very elderly	Austria	25	0.0000180887	75th
Very elderly	Belgium	704	0.0000615403	95th
Very elderly	Germany	490	0.0000455771	95th
Very elderly	Denmark	12	0.0000152033	75th
Very elderly	France	84	0.0000504867	95th
Very elderly	United Kingdom	139	0.0000390602	95th
Very elderly	Hungary	80	0.0000602307	95th
Very elderly	Ireland	77	0.0000706108	95th
Very elderly	Italy	228	0.0000457884	95th
Very elderly	Netherlands	450	0.0000484540	95th
Very elderly	Romania	45	0.0000864240	90th
Very elderly	Sweden	72	0.0000518101	95th

(1): HRP: highest reliable percentile, i.e. the highest percentile that is considered statistically robust for combinations of dietary survey, age class and possibly raw primary commodity, considering that a minimum of 5, 12, 30 and 61 observations are, respectively, required to derive 50th, 75th and 90th and 95th percentile estimates. Estimates with less than five observations were not included in this table.

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Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for KemTRACE chromium (chromium propionate)

In the current application, an authorisation is sought under Article 4(1) for *chromium propionate* under the category/functional group (4d) 'zootechnical additives'/'other zootechnical additives', according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the *feed additive* for all growing poultry species.

According to the Applicant, the active substance of the *feed additive* is *chromium propionate*. The *feed additive* is to be marketed as a liquid preparation with a content of *chromium propionate* ranging from 29 to 32% (w/w), which corresponds to a *chromium* content ranging from 7 to 10% (w/w). The *feed additive* is intended to be incorporated into *feedingstuffs* through *premixtures*. The Applicant proposed minimum and maximum levels of the *chromium* content added via the use of chromium propionate, which the Applicant defined as organic *chromium*, ranging from 0.2 to 0.4 mg/kg *feedingstuffs*.

For the quantification of the *chromium propionate* content in the *feed additive,* the Applicant submitted two single-laboratory validated methods, namely a method based on liquid chromatography coupled to high-resolution mass spectrometry (LC-HRMS) and a method based on liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS). The LC-MS/MS method was further verified and the following performance characteristics were obtained for the quantification of the *chromium propionate* content in the *feed additive* in the frame of the validation and verification studies: a relative standard deviation for *repeatability* (RSD_r) ranging from 2.0 to 7.2%, a relative standard deviation for *intermediate precision* ($RSDi_p$) ranging from 5.5 to 7.9% and a *recovery* rate $_{(Rrec)}$ ranging from 91 to 103%.

Based on the acceptable performance characteristics available, the EURL recommends for official control the single-laboratory validated and further verified method based on LC-MS/MS for the quantification of the *chromium propionate* content in the *feed additive*.

For the quantification of the *chromium propionate* content in *premixtures* and *feedingstuffs,* the Applicant submitted the above-mentioned methods based on LC-HRMS and LC-MS/MS after an appropriate sample preparation. However, the Applicant did not provide the EURL with proper validation and/or verification data when applying the LC-HRMS and/or LC-MS/MS methods for the quantification of chromium propionate in premixtures and feedingstuffs.

Based on the available performance information, the EURL is not able to recommend for official control the above-mentioned methods based on LC-HRMS or LC-MS/MS for the quantification of the chromium propionate content in premixtures and feedingstuffs.

For the quantification of the total *chromium* content in the *feed additive,* the Applicant submitted a single-laboratory validated and further verified method based on inductively coupled plasma-atomic emission spectrometry (ICP-AES). The following performance characteristics were obtained for the quantification of the total *chromium* content in the *feed additive* in the frame of the validation and verification studies: an RSD_r ranging from 0.3 to 0.9%, an $_{RSDip}$ ranging from 0.9 to 1.1% and an $_{Rrec}$ of 100%.

Based on the acceptable performance characteristics available, the EURL recommends for official control the single-laboratory validated and further verified method based on ICP-AES for the quantification of the total *chromium* content in the *feed additive* (*chromium propionate*).

For the quantification of the organic *chromium* content in mineral–vitamin *premixtures* and *feedingstuffs,* the Applicant proposed in-house methods based on ICP-AES and/or ICP-MS. Non-acceptable recoveries (lower than 60%) were reported for an average organic *chromium* content in the analysed samples of *premixtures* and *feedingstuffs*.

Based on the available data, the EURL is not able to recommend for official control the proposed methods based on ICP-AES or ICP-MS, neither any other method for the quantification of the organic *chromium* content in *premixtures* and *feedingstuffs*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.