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Assessment of a feed additive consisting of all-rac-alpha tocopheryl acetate (vitamin E) for all animal species for the renewal of its authorisation (DSM)

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of all-rac-alpha tocopheryl acetate (vitamin E) as a feed additive for all animal species. The applicant provided data demonstrating that the additive currently in the market complies with the conditions of authorisation. The FEEDAP Panel confirms that the use of all-rac-alpha-tocopheryl acetate under the current authorised conditions of use is safe for the target species, the consumers and the environment. No concern for user safety is expected from the use of the active substance however, due to the lack of information, the FEEDAP Panel is not able to conclude on its skin sensitisation potential. To draw conclusions on the safety for the user of the final formulated additives, specific studies would be required. There is no need to assess the efficacy of all-rac-alpha-tocopheryl acetate in the context of the renewal of the authorisation.

Keywords: all-rac-alpha tocopheryl acetate, vitamin E, renewal, nutritional additive, vitamins and pro-vitamins, feed, safety

Requestor: European Commission

Question number: EFSA-Q-2020-00136

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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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from DSM Nutritional Products Ltd represented in the EU by DSM Nutritional Products Sp. z o.o[2] for renewal of the authorisation of the product all-rac-alpha-tocopheryl acetate (vitamin E), when used as a feed additive for all animal species (category: nutritional additives; functional group: vitamins, pro-vitamins and chemically well-defined substances having a similar effect).

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 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 20 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 all-rac-alpha-tocopheryl acetate (vitamin E), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of vitamin E, in the form of all-rac-alpha-tocopheryl acetate, RRR-alpha-tocopheryl acetate and RRR-alpha-tocopherol, when used as a feed additive for all animal species (EFSA FEEDAP Panel, 2010). In 2012, the FEEDAP Panel issued another opinion on the safety and efficacy of synthetic alpha-tocopherol when used as a technological additive (antioxidant) for all animal species (EFSA FEEDAP Panel, 2012a) and another opinion on the safety and efficacy of tocopherol-rich extracts of natural origin, tocopherol-rich extracts of natural origin/delta-rich, and synthetic tocopherol for all animal species (EFSA FEEDAP Panel, 2012b).

Vitamin E (3a700) in the form of all-rac-alpha-tocopheryl acetate, RRR-alpha-tocopheryl acetate and RRR-alpha tocopherol is currently authorised as a nutritional additive for all animal species.[3] Alpha-tocopherol is also authorised for use as a technological additive (functional group: antioxidants) in feed for all animal species (1b307).[4]

All-rac-alpha-tocopheryl acetate is described in the European Pharmacopoeia 10.0 (PhEur), monograph 0439 (PhEur, 2020).

The Scientific Committee for Food (SCF) established a tolerable upper intake level (UL) for vitamin E as 270 mg/day for adults and rounded to 300 mg/day (SCF, 2003). The EFSA Panel on Dietetic Products, Nutrition and Allergy issued an opinion on dietary reference values for vitamin E as alpha-tocopherol (EFSA NDA Panel, 2015). The EFSA Panel on Food Additives and Nutrient Sources Added to Food (EFSA ANS Panel) issued an opinion on the evaluation of tocopherol-rich extract (E 306), alpha-tocopherol (E 307), γ-tocopherol (E 308) and δ-tocopherol (E 309) as food additives (EFSA ANS Panel, 2015).

[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] DSM Nutritional Products Ltd represented in the EU by DSM Nutritional Products Sp. z o.o, Wurmisweg 576, Kaiseraugst 4303 (Switzwerland).
[3] Commission Regulation (EU) No 26/2011 of 14 January 2011 concerning the authorisation of vitamin E as a feed additive for all animal species, OJ L 11, 15.1.2011, p. 18–21.
[4] Commission Regulation (EU) No 2015/1152 of 14 July 2015 concerning the authorisation of tocopherol extracts from vegetable oils, tocopherol-rich extracts from vegetable oils (delta rich) and alpha-tocopherol as feed additives for all animal species. OJ L 187, 15.7.2015, p. 5.

Tocopherol-rich extract (E 306), alpha-tocopherol (E 307), γ-tocopherol (E 308) and δ-tocopherol (E 309) are authorised as food additives.[5] Vitamin E is authorised for use in food for nutritional purposes,[6] for use in cosmetics as antioxidant[7] and as a veterinary medicinal product.,[8,9]

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[10] in support of the authorisation request for the use of all-rac-alpha-tocopheryl acetate (vitamin E) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[11]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of all-rac-alpha-tocopheryl acetate (vitamin E) is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance document: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017).

3. Assessment

Vitamin E (tocopherol) is currently authorised as a feed additive in the form of three active substances: all-rac-alpha-tocopheryl acetate, RRR-alpha-tocopheryl acetate and RRR-alpha-tocopherol. This assessment regards the renewal of the authorisation of vitamin E in the form of all-rac-alpha-tocopheryl acetate (> 93%), when used as a nutritional additive (functional group: vitamins, provitamins and chemically well-defined substances having a similar effect) in feed and water for drinking for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the active substance

All-rac-alpha-Tocopheryl acetate is identified with the Chemical Abstracts service (CAS) number 7695-91-2 and it has a molecular formula $C_{31}H_{52}O_3$.

All-rac-alpha-Tocopheryl acetate is a slightly greenish-yellow, clear and odourless viscous oil that is practically insoluble in water, but freely soluble in ethanol, chloroform, acetone, ether and vegetable oils.[13,14]

[5] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Text with EEA relevance. OJ L 83, 22.3.2012.

[6] 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.

[7] Commission Decision of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (2006/257/EC). OJ L 97, 5.4.2006, p. 1.

[8] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1.

[9] Commission Regulation (EC) No 997/1999 of 11 May 1999 amending Annexes I, II and III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 122, 12.5.1999, p. 24.

[10] FEED dossier reference: FAD-2020-0011.

[11] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0047.pdf

[12] 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.

[13] Technical dossier/Section II/Annex_II_02.

[14] Technical dossier/Section II/Annex_II_03.

The applicant stated that the manufacturing process and the composition of the additive have not been modified since the previous authorisation and data have been provided from recent batches on the composition of the additive to support this statement.

The applicant provided results on batch-to-batch variation on five recent batches of the active substance. The analysis showed that the content of all-rac-alpha-tocopheryl acetate ranged from 94.6% to 95.7% (mean: 95.08%)[15] and demonstrated compliance with the existing specifications (purity criteria: > 93%).

Possible impurities listed in the European Pharmacopoeia were also measured in five batches, namely all-rac-*trans*-2,3,4,6,7-pentamethyl-2-(4,8,12-trimethyltridecyl)-2,3-dihydrobenzofuran-5-yl acetate (impurity A, 0.49-0.51%), all-rac-*cis*-2,3,4,6,7-pentamethyl-2(4,8,12-trimethyltridecyl)-2,3-dihydrobenzofuran-5-yl acetate (impurity B, 0.85–0.87%); all-rac-alpha-tocopherol (impurity C, 0.07–0.26%); 4-methoxy-2,3,6-trimethyl-5-[(all-*RS*,*E*)-3,7,11,15-tetramethylhexadec-2 enyl] phenylacetate (impurity D), and (all-*RS*, all-*E*)-2,6,10,14,19,23,27,31-octamethyldotriaconta-12,14,18-triene (impurity E, 0.35–0.36% for the sum of impurities D and E).[16] The detected amounts of impurities were below the limits specified in the European Pharmacopoeia monograph (PhEur, 2020).

The levels of pyridine (< 20 mg/kg) and toluene (< 20 mg/kg) that can be present as residual solvents were measured in the same five batches.[16] The results complied with VICH specifications (for pyridine: 200 mg/kg and for toluene: 890 mg/kg). Five batches of the active substance were also analysed for the presence of arsenic (< 3 mg/kg), lead (< 2 mg/kg), cadmium (< 1 mg/kg), mercury (< 0.1 mg/kg) and iron (≤ 1 mg/kg).[17] Based on the results obtained, no concerns are identified.

3.1.2. Characterisation of the formulated additive

According to the information provided by the applicant, all-rac-alpha-tocopheryl acetate is placed on the market in the form of two formulated additives containing ≥ 50% all-rac-alpha-tocopheryl acetate: an adsorbate powder and a spray-dried powder. The applicant submitted the typical formulation composition, specification and analyses of five batches showing compliance with specifications.[18,19]

Dioxins (polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F)) were determined in three batches of the additive produced as adsorbate powder and amounted to 0.108 ng WHO-PCDD/F-TEQ/kg, and the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) was 0.221 ng WHO-PCDD/F-DL-PCB-TEQ/kg.[20] Based on the results obtained, no concerns are identified.

Three batches of each formulation of the formulated additive were tested for dusting potential according to Stauber–Heubach method.[21] The average value of dust was 2 g/m^3 (range: 1.91–2.1 g/m^3) and 5.5 g/m^3 (range: 4.65–6.8 g/m^3) for the adsorbate powder and for the spray-dried powder formulation, respectively.

The particle size distribution of five batches of the additive produced as adsorbate powder was measured by laser diffraction[22]; the analysis showed that 10% of the particles measured less than 33 μm, 50% less than 101 μm and 90% less than 236 μm.

Stability and the capacity for homogeneous distribution of the additive were evaluated by EFSA in a previous assessment (EFSA FEEDAP Panel, 2010). No new data have been provided in the current application.

3.1.3. Conditions of use

All-rac-alpha-tocopheryl acetate (vitamin E, purity > 93%) is currently authorised for use in feed and in water for drinking for all animal species without a maximum content.

The authorisation, under other provisions, foresees:

1) If vitamin E content is mentioned in the labelling, the following equivalencies for the units of measurement of the contents shall be used:

[15] Technical dossier/Section II/Annex_II_04.
[16] Technical dossier/Section II/Annex_II_10.
[17] Technical dossier/Section II/Annex_II_12.
[18] Technical dossier/Section II/Annex_II_05.
[19] Technical dossier/Section II/Annex_II_06.
[20] Technical dossier/Section II/Supplementary Information (July 2020)/Appendix 2.
[21] Technical dossier/Section II/Supplementary Information (July 2020)/Appendix 1.
[22] Technical dossier/Section II/Annex_II_13.

- 1 mg all-rac-alpha-tocopheryl acetate = 1 IU
- 1 mg RRR-alpha-tocopherol = 1.49 IU
- 1 mg RRR-alpha-tocopheryl acetate = 1.36 IU

2) Vitamin E may be used also via water for drinking

The applicant proposes to keep the same conditions of use as authorised.

3.2. Safety

The safety of the vitamin E in the form of all-rac-alpha-tocopheryl acetate for the target species, consumer, user and the environment was evaluated in a previous opinion (EFSA FEEDAP Panel, 2010). The FEEDAP Panel concluded that 'vitamin E at the current use levels is safe for all animal species. Information on hypervitaminosis E is not sufficiently consistent to derive a maximum content for vitamin E in feedingstuffs, based on safety for target species'. The Panel also concluded that the use of the product as a feed additive raises no concern for consumer safety or for the environment. Concerning the safety for the user, no irritating effects were observed when all-rac-alpha-tocopheryl acetate was tested for dermal and ocular irritation. Sensitisation studies were not provided. The Panel concluded that 'no concern for user safety is expected from the use of the active substances vitamin E in feed additives. However, to draw conclusions on the final formulated additives, specific studies would be required'.

The applicant carried out a structured database search,[23,24,25] using three different database platforms: PubMed, ScienceDirect and CAB Abstracts. The search was limited to information available since the last authorisation in 2010 until September 2019. The main keywords used were: 'vitamin E OR tocopherol OR tocopheryl OR all-rac-alpha-tocopheryl acetate OR 7695-91-2'. Specific subject areas were added in order to restrict the search (such as safety for the different target species [e.g. 'safety for pigs', 'safety for poultry' etc.], safety for user/workers, safety for consumers and safety for the environment). A detailed description of the iterations used and the inclusion/exclusion criteria applied for the selection were provided.[26] The applicant identified 122 papers which were considered relevant for the assessment of the safety of vitamin E. None of the papers identified a safety concern for the target species, the consumer and the environment. No papers were retrieved concerning the safety for the user.

3.2.1. Reassessment of the consumer exposure

In the previous FEEDAP Panel opinion (EFSA FEEDAP Panel, 2010), a 'worst-case scenario' exposure assessment for the consumer, based on the consumption model described in Regulation (EC) No 429/2008 and on data from literature on vitamin E content in edible tissues and products from animals treated with vitamin E at levels far higher than the practical use (1,000 mg/kg feed), indicated that the theoretical exposure of consumers amounted to about 45% of the UL (300 mg alpha-tocopherol equivalents/day).

In the current assessment, the FEEDAP Panel performed an updated exposure assessment following the methodology described in the Guidance on consumer safety (EFSA FEEDAP Panel, 2017) (Appendix A). Based on the literature search provided by the applicant, the Panel identified three relevant papers (Ouraji et al., 2011; Song et al., 2014; Kidane et al., 2015) with new residue data not available at the time of the previous assessment. In addition, the Panel opted to use more realistic feed supplementation figures (i.e. 100 mg/kg feed instead of 1,000 mg/kg) also from the studies already assessed in the previous opinion. When data were available for the same species and food items at the same supplementation concentration, the highest value was considered. The input data used are reported in Table 1.

[23] Technical dossier/Section III/Annex_III_2.
[24] Technical dossier/Supplementary_Information (July 2020)/Section III/Appendix I.
[25] Technical dossier/Supplementary_Information (February 2021)/Section III/Appendix III.
[26] Technical dossier/Section III/Annex III.2 Appendix I and Appendix II.

Table 1: Input data on vitamin E content in food of animal origin used for the consumer exposure assessment

Animal products	mg/kg wet tissue/products	Reference
Birds fat (skin/fat)	12* (24)	Sunder and Flachowsky (2001)†
Birds liver	17	Sunder and Flachowsky (2001)†
Birds meat	8	Sunder and Flachowsky (2001)†
Fish	135	Tocher et al. (2002)†
Mammals fat tissue	2.3* (4.6)	Yang et al. (2009)†
Mammals liver	4.6	Yang et al. (2009)†
Mammals meat	9	Song et al. (2014)
Mammals offals and slaughtering products (other than liver)	2.7	Yang et al. (2009)†
Milk	1.5	Kidane et al. (2015)
Seafood	8	Ouraji et al. (2011)
Eggs	68	Sunder and Flachowsky (2001)†

No data were retrieved for the following food categories: 'Birds offals and slaughtering products (other than liver)' and 'honey'. However, it is expected that the contribution of these food categories to the overall exposure would be limited.
*: The original value (in parenthesis) was divided by 2 to take into consideration the ratio skin/fat.
†: Paper used in EFSA FEEDAP Panel (2010).

The results of the dietary exposure to vitamin E for the different population categories are reported in Table 2.

Table 2: Chronic human dietary exposure to vitamin E

Population category	Maximum HRP* (mg/kg/bw per day)	Default body weight (EFSA Scientific Committee, 2012)	Exposure (mg/day)	UL† (mg/day) (European Commission, 2003)	% UL
Infants	0.43	5	2.15		
Toddlers	0.95	12	11.4	100	11.4
Other children	0.8	23	18.4	120	15.3
Adolescents	0.49	52.4**	25.6	260	9.8
Adults	0.41	70	28.7	300	9.5
Elderly	0.37	70	25.9		
Very elderly	0.33	70	23.1		

bw: body weight.
*: HRP: maximum highest reliable percentile.
†: UL: Tolerable upper level.
**: (Average of 43.4 and 61.3 kg).

In 2003, the SCF established an UL for vitamin E for adults as 300 mg/day (SCF, 2003), based on the body weight (bw), the UL for children (1–3 years) and adolescents was set at 100 and 260 mg/day, respectively. To compare the vitamin E dietary exposure calculation to the UL, the FEEDAP Panel used the highest reliable percentile (HRP) for the different population categories and converted it from mg/kg bw per day into mg/person per day using the default bw values (EFSA Scientific Committee, 2012). The contribution to the consumer exposure to vitamin E from products of animals fed with the additive ranged from 9.5% to 15.3% of the ULs (Table 2).

For the population groups infants and elderly as well as very elderly, no UL was established by the SCF. However, the FEEDAP Panel assumes that the exposure would still be in the same relation to the UL as for the other population categories.

The FEEDAP Panel concludes that there is no safety concern for the consumer resulting from the intake of food from all animal species fed with vitamin E in the form of all-rac-alpha-tocopheryl acetate under the conditions of the existing authorisation.

3.2.2. Conclusions on safety

Based on the above and the fact that the manufacturing process, the composition of the additive and the conditions of use for the species/categories for which the additive is authorised have not been modified, the Panel considers that there is no evidence to reconsider the conclusions reached in previous assessment. The FEEDAP Panel concludes that vitamin E in the form of all-rac-alpha-tocopheryl acetate remains safe for the target species, the consumer and the environment under the conditions of use currently authorised. No concern for user safety is expected from the use of the active substance however, due to the lack of information, the FEEDAP Panel is not able to conclude on its skin sensitisation potential. To draw conclusions on the safety for the user of the final formulated additives, specific studies would be required.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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[27] and Good Manufacturing Practice.

4. Conclusions

The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation.

The FEEDAP Panel concludes that all-rac-alpha-tocopheryl acetate (vitamin E) remains safe for all the animal species, for the consumers and the environment under the conditions of use currently authorised. No concern for user safety is expected from the use of the active substance; however, due to the lack of information, the FEEDAP Panel is not able to conclude on its skin sensitisation potential. To draw conclusions on the safety for the user of the final formulated additives, specific studies would be required.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5. Documentation as provided to EFSA/Chronology

Date	Event
04/02/2020	Dossier received by EFSA. Vitamin E/all-rac-alpha tocopheryl acetate for all animal species. Submitted by DSM Nutritional Products Sp. z o.o. on behalf of DSM Nutritional Products Ltd.
04/03/2020	Reception mandate from the European Commission
20/03/2020	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 and safety*
17/07/2020	Comments received from Member States
28/07/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
08/12/2020	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*
04/02/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
17/03/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

[27] 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.

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Abbreviations

EFSA ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CFU	colony forming unit
CV	coefficient of variation
DL-PCB	dioxin-like polychlorinated biphenyl
EURL	European Union Reference Laboratory

FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
HRP	highest reliable percentile
IU	International Unit
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans
RAC	raw agricultural commodity
SCF	Scientific Committee for Food
UL	upper level

Appendix A – Calculation of consumer exposure with FACE model

Methodology

As described in the Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017), 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 35 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 inclu des con sumption 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 coccidiostats from their use in (non-reproductive) poultry, the following list of commodities is considered: meat, fat, liver, other offals (including kidney).

Depending on the nature of the health-based guidance derived, either a chronic or acute exposure assessment may be required.

For chronic exposure assessments, the total relevant residues will be combi ned 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.

As opposed to the chronic exposure assessments, acute exposure calculation will be carried out for each RAC value separately. The higher percentile (usually the 95th percentile) exposures based on the consuming days only will be calculated for each food commodity, dietary survey and age class separately

As described in the Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017), 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[28] 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 vitamin E from their use in (non-reproductive) poultry, the following list of commodities is considered: meat, fat, liver, other offals (including kidney).

Depending on the nature of the health-based guidance derived, either a chronic or acute exposure assessment may be required.

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.

As opposed to the chronic exposure assessments, acute exposure calculation will be carried out for each RAC value separately. The higher percentile (usually the 95th percentile) exposures based on the consuming days only will be calculated for each food commodity, dietary survey and age class separately.

[28] 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.

Appendix B – Detailed results on chronic exposure calculation

Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to ATX base d on residue data in salmonids and crustaceans.

Table B.1: Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to vitamin E based on residue data

Population class	Survey's country	Number of subjects	HRP value	HRP description
Infants	Bulgaria	523	0.4307512765	95th
Infants	Germany	142	0.2187406332	95th
Infants	Denmark	799	0.3643741241	95th
Infants	Finland	427	0.1893018911	95th
Infants	United Kingdom	1,251	0.4385794945	95th
Infants	Italy	9	0.0636808234	50th
Toddlers	Belgium	36	0.3630401581	90th
Toddlers	Bulgaria	428	0.7009082960	95th
Toddlers	Germany	348	0.4116913805	95th
Toddlers	Denmark	917	0.4067212385	95th
Toddlers	Spain	17	0.5399953486	75th
Toddlers	Finland	500	0.5026258459	95th
Toddlers	United Kingdom	1,314	0.5576633660	95th
Toddlers	United Kingdom	185	0.5139483784	95th
Toddlers	Italy	36	0.9509516529	90th
Toddlers	Netherlands	322	0.4029951191	95th
Other children	Austria	128	0.5204588196	95th
Other children	Belgium	625	0.4858161922	95th
Other children	Bulgaria	433	0.6389241335	95th
Other children	Czech Republic	389	0.5663914191	95th
Other children	Germany	293	0.3991452721	95th
Other children	Germany	835	0.4018474802	95th
Other children	Denmark	298	0.4190325702	95th
Other children	Spain	399	0.7639502309	95th
Other children	Spain	156	0.8033340849	95th
Other children	Finland	750	0.4873081000	95th
Other children	France	482	0.4983838298	95th
Other children	United Kingdom	651	0.4063760054	95th
Other children	Greece	838	0.5747174989	95th
Other children	Italy	193	0.7088970815	95th
Other children	Latvia	187	0.3495764652	95th
Other children	Netherlands	957	0.3691574625	95th
Other children	Netherlands	447	0.3102352691	95th
Other children	Sweden	1,473	0.4331044897	95th
Adolescents	Austria	237	0.2967982330	95th
Adolescents	Belgium	576	0.2148765628	95th
Adolescents	Cyprus	303	0.2428191588	95th
Adolescents	Czech Republic	298	0.3945966400	95th
Adolescents	Germany	393	0.2973475130	95th
Adolescents	Germany	1,011	0.1789520701	95th
Adolescents	Denmark	377	0.1906919355	95th
Adolescents	Spain	651	0.4507975970	95th
Adolescents	Spain	209	0.4999138582	95th
Adolescents	Spain	86	0.3403338670	95th
Adolescents	Finland	306	0.2437208440	95th

Population class	Survey's country	Number of subjects	HRP value	HRP description
Adolescents	France	973	0.2847918189	95th
Adolescents	United Kingdom	666	0.2257091976	95th
Adolescents	Italy	247	0.3393086625	95th
Adolescents	Latvia	453	0.2567828328	95th
Adolescents	Netherlands	1,142	0.2200749334	95th
Adolescents	Sweden	1,018	0.2788554025	95th
Adults	Austria	308	0.2577812148	95th
Adults	Belgium	1,292	0.2357205935	95th
Adults	Czech Republic	1,666	0.2642757492	95th
Adults	Germany	10,419	0.2312981689	95th
Adults	Denmark	1,739	0.1588249466	95th
Adults	Spain	981	0.4108790208	95th
Adults	Spain	410	0.3801787696	95th
Adults	Finland	1,295	0.2884024962	95th
Adults	France	2,276	0.2223089799	95th
Adults	United Kingdom	1,265	0.2145990136	95th
Adults	Hungary	1,074	0.1946949122	95th
Adults	Ireland	1,274	0.2254313550	95th
Adults	Italy	2,313	0.2726351382	95th
Adults	Latvia	1,271	0.2675406839	95th
Adults	Netherlands	2,055	0.2136426705	95th
Adults	Romania	1,254	0.2412836201	95th
Adults	Sweden	1,430	0.3297923301	95th
Elderly	Austria	67	0.2556848549	95th
Elderly	Belgium	511	0.2491690524	95th
Elderly	Germany	2,006	0.2469505979	95th
Elderly	Denmark	274	0.1814049292	95th
Elderly	Finland	413	0.2955716066	95th
Elderly	France	264	0.2307550410	95th
Elderly	United Kingdom	166	0.2317731638	95th
Elderly	Hungary	206	0.1518530414	95th
Elderly	Ireland	149	0.2538258532	95th
Elderly	Italy	289	0.2699101855	95th
Elderly	Netherlands	173	0.2728336915	95th
Elderly	Netherlands	289	0.2448166029	95th
Elderly	Romania	83	0.2526038943	95th
Elderly	Sweden	295	0.3708740714	95th
Very elderly	Austria	25	0.0960991456	75th
Very elderly	Belgium	704	0.2537964585	95th
Very elderly	Germany	490	0.2460313267	95th
Very elderly	Denmark	12	0.1553462252	75th
Very elderly	France	84	0.2051944623	95th
Very elderly	United Kingdom	139	0.2370715240	95th
Very elderly	Hungary	80	0.1394129042	95th
Very elderly	Ireland	77	0.2231317175	95th
Very elderly	Italy	228	0.2257162465	95th
Very elderly	Netherlands	450	0.2449734615	95th
Very elderly	Romania	45	0.1976181874	90th
Very elderly	Sweden	72	0.3373048154	95th

bw: body weight.