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SCIENTIFIC OPINION

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Consumer safety of feed additives containing selenium

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety for the consumer of products from animals fed diets with feed additives containing selenium as an active substance. Based on the limited data set available and the several uncertainties, the FEEDAP Panel concluded that the use of organic selenium at the currently maximum authorised use level of 0.2 mg supplemented selenium from organic sources/kg complete feed (within a maximum of 0.5 mg total selenium/kg complete feed) leads to an exceedance of the UL for all the population categories (except elderly and very elderly), suggesting a concern for consumer safety. It was not possible to conclude on the safety of the currently maximum use level of 0.5 mg total selenium/kg complete feed for all consumer categories. Additional data from studies specifically designed to measure deposition of selenium in tissues and products from animal origin resulting from the use of the different sources of selenium would be required to perform a proper risk assessment.

KEYWORDS

consumer, exposure, nutritional additives, safety, selenium

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 and, in particular, Article 9 thereof defines the terms of the authorisation by the Commission. According to Article 13(1) of Regulation (EC) No 1831/2003, the Commission may request the European Food Safety Authority (EFSA) to issue an opinion on whether an authorisation still meets the conditions set out by that Regulation.

On 24 November 2022, the Panel on Nutrition, Novel Foods and Food Allergens (NDA) of EFSA, in its opinion on the tolerable upper intake level for selenium, concluded that the tolerable upper intake level (UL) of 255 µg Se/day is safe for adult men and women (including pregnant and lactating women). This level is lower than the UL of 300 µg Se/day for adults, set by the Scientific Committee on Food (SCF) in 2000, which was used by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of EFSA to assess the safety for the consumers of feed additives containing selenium.

The different forms of selenium present in the authorised feed additives may result in different deposition levels of selenium in tissues and products of animals receiving that selenium. In order to assess the safety of additives containing selenium as active substance for the consumers, the above-mentioned new UL and the fact that deposition of Se in food products may differ between selenium sources should be considered. For that purpose, available data should be assessed in view of the quantification of the deposition levels in the most relevant poultry, ruminants, pig and fish species for all feed additives containing selenium as active substance that are currently authorised.

As regards feed additives containing selenium as active substance that are currently in the process of being evaluated (ongoing authorisation procedure), the provisions of Regulation (EC) No 1831/2003, in particular Article 8 thereof, apply (Table 1).

TABLE 1 Description of the substances.

Category of additive	Nutritional additives
Functional group of additive	Compounds of trace elements
Description	All additives containing selenium as active substance
Target animal category	All animal species and in particular: poultry, pigs, ruminants and fish
Type of request	New opinion

In view of the above, the Commission requests EFSA to deliver a new opinion on the safety for the consumers of selenium (Se) when used in feed additives, in accordance with Article 13 (1) of Regulation (EC) No 1831/2003. The purpose of the requested opinion is to determine whether the conditions for authorisation set out in that Regulation, with regard to the safety for the consumers of relevant animal products, is still met for the existing authorisations of additives containing selenium as active substance, on the basis of available information and data.

Should it prove necessary to request supplementary information or data to the applicants of the existing authorisations, the nature and details of those information and data should be specified by EFSA in its opinion.

2 | ASSESSMENT

2.1 | Introduction

The FEEDAP Panel adopted several opinions on the safety of selenium, in its inorganic forms (EFSA FEEDAP Panel, 2015, 2016a, 2016b, 2019a), and its organic forms, either from different *Saccharomyces cerevisiae* strains (EFSA FEEDAP Panel, 2006, 2007, 2009a, 2011, 2012, 2017a, 2018a, 2019b, 2020, 2021, 2023, 2024) or from other organic selenium sources[2] (EFSA FEEDAP Panel, 2009b, 2013, 2014, 2018b).

In the evaluations cited above the exposure of the consumers to feed additives containing inorganic or organic forms of selenium was estimated using the 'Theoretical daily human consumption figures' indicated in Regulation (EC) n. 429/2008, refined from 2011 to use the consumption data derived from the Comprehensive European Food Consumption Database (EFSA, 2011). In these opinions, consumer safety was evaluated considering the tolerable upper level (UL) for selenium of 300 µg selenium/day (for adults) as established by the European Commission Scientific Committee on Food (EC, 2000), based on the data from the study by Yang, Yin, et al. (1989), Yang, Zhou, et al. (1989).

[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.
[2]L-Selenomethionine, DL-selenomethionine, zinc-L-selenomethionine, hydroxyanalogue of selenomethionine.

Regarding the inorganic forms of selenium, the Panel concluded that the use of feed additives containing selenium from inorganic sources (sodium selenite and sodium selenate) was of no concern for the consumer, provided that the maximum authorised content of 0.5 mg total selenium/kg feed was respected (EFSA FEEDAP Panel, 2015, 2016a, 2016b, 2019a).

Regarding the organic forms of selenium, the Panel concluded that a maximum supplementation level of 0.2 mg organic selenium/kg feed would be unlikely to result in a health risk for consumers including children of 1–3 years of age (EFSA FEEDAP Panel, 2011). In the subsequent assessments of feed additives containing selenium in its organic forms (selenomethionine from *Saccharomyces cerevisiae*, L-selenomethionine, DL-selenomethionine, hydroxyanalogue of selenomethionine), the FEEDAP Panel considered that no substantial differences in deposition of selenium in tissues/products were to be expected when different sources of selenomethionine were used. Therefore, no further estimate of the consumer exposure and assessment of the consumer safety was done (EFSA FEEDAP Panel, 2006, 2007, 2009a, 2009b, 2012, 2013, 2014, 2017a, 2018a, 2018b, 2019b, 2020, 2021, 2023, 2024).

The methodology used by the FEEDAP Panel to estimate consumer exposure changed following the adoption of the FEEDAP Panel Guidance on the assessment of the safety of feed additives for the consumer in 2017 (EFSA FEEDAP Panel, 2017b). Chronic and acute dietary exposure to residues of feed additives and their metabolites present in food of animal origin for different population groups (e.g. infants, toddlers, adults) in several European countries are estimated using the food consumption data collected from Member States (stored in the EFSA Comprehensive European Food Consumption Database), subsequently disaggregated into raw primary commodities of animal origin.

In 2023, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) issued a Scientific opinion on the tolerable upper intake level for selenium (EFSA NDA Panel, 2023). In this recent opinion, the NDA Panel revised all the available information related to the absorption, distribution, metabolism and excretion (ADME) and toxicological properties of selenium and proposed to lower the UL to 255 µg selenium/day for adults (including pregnant and lactating women) and extrapolated the UL from adults to infants, children and adolescents using the allometric scaling (body weight$^{0.75}$).[3] The ULs apply to total selenium intake from all dietary sources. In its opinion, the NDA Panel used the lowest observed adverse effect level (LOAEL) of 330 µg/day identified from a randomised, placebo-controlled trial in humans (Selenium and Vitamin E Cancer Prevention Trial [SELECT]) (Lippman et al., 2009), as a reference point for the derivation of the UL for selenium, to which an uncertainty factor of 1.3 was applied. The LOAEL identified was associated with an increased risk of developing alopecia, an early sign of selenium toxicity. The NDA Panel noted that additional research is needed regarding potential differences in the toxicity profile of the various dietary forms of selenium (e.g. organic vs. inorganic selenium).

Currently, selenium is authorised for use in all animal species with maximum contents of:

- 0.5 mg total selenium/kg complete feed from all inorganic sources,
- 0.2 mg supplemented selenium from organic sources/kg complete feed (within a maximum of 0.5 mg total selenium/kg complete feed).

Considering the above, the current assessment aims at determining whether the supplementation of selenium in the animal feeds can be still considered safe for the consumers at the current conditions for authorisations (i.e. 0.5 mg total selenium/kg complete feed and maximum 0.2 mg selenium from organic sources/kg complete feed).

2.2 | Data

For the current assessment, in accordance with the request from the European Commission, the FEEDAP Panel considered only the data on selenium deposition in tissues or products of food-producing animals submitted in the application dossiers for which an assessment has been concluded or is ongoing at the time of adoption of the present opinion. The sources of data, that were considered, included the original reports of tolerance studies, residue studies and efficacy studies and the studies published in the scientific literature submitted in the application dossiers. No additional literature search was performed, and any additional source of information not included in the application dossiers considered. In the following assessment, all the sources of information (original reports of tolerance/residues/efficacy studies and published studies) will be referred to as "studies".

2.3 | Selection of data

A total of 133 studies reporting data on selenium deposition in tissues/products of animal origin were identified in the application dossiers submitted from 2005 to 2023. These studies were individually assessed to identify those reporting relevant data for the scope of the current assessment.

Only the studies that fulfilled all the following criteria were considered in the assessment: (i) oral administration of the selenium source, (ii) presence of a control diet without supplementation of selenium, (iii) analytical results of the levels of

[3]The UL values established for the different age categories are 45 µg Se/day for infants (4–6 months); 55 µg Se/day for infants (7–11 months); 70 µg Se/day for children 1–3 years; 95 µg Se/day for children 4–6 years; 130 µg Se/day for children 7–10 years, 180 µg Se/day for children 11–14years and 230 µg Se/day for adolescents from 15 to 17 years (EFSA NDA Panel, 2023).

selenium in the diets (including the control diet) reported, (iv) intended selenium inclusion level (independently from the source)/analysed selenium level in the control diet within or slightly above the maximum authorised total selenium level (0.5 mg total selenium/kg feed), (v) duration of the studies in line with the requirements of the FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), (vi) full reporting of the results.

After the removal of duplicates, a total of 39 studies were considered. Many of these studies included more than one source of selenium. Results of deposition of selenium were reported from different inclusion levels of selenium (varying from 0.1 to 0.5 mg selenium/kg complete feed) from inorganic sources (11 studies) or from organic sources, either with *Saccharomyces cerevisae* (30 studies) or other organic sources of selenomethionine (11 studies).

Deposition of selenium was reported in tissues (fat, liver, kidney, muscle) from mammals (lambs, cattle for fattening, and pigs (gilts and pigs for fattening)), in tissues (fat or skin/fat, liver, kidney and muscle) from poultry (chickens for fattening, turkeys for fattening and laying hens), in fish, in eggs from laying hens and in milk from dairy cows.

2.4 | Use of the data

2.4.1 | Selection of inclusion levels/analysed concentrations

The assessment, whether the use of additives containing selenium as active substance is still safe for the consumer, was restricted to two main scenarios: results from studies with complete feed containing the maximum authorised levels (i) of about 0.5 mg total selenium/kg feed (without supplementation with organic selenium) and (ii) of about 0.2 mg supplemented organic selenium/kg (without supplementation with inorganic Se). The FEEDAP Panel noted that the exact maximum contents for total selenium as well as the maximum inclusion levels for organic selenium could hardly be identified in the relevant studies. The reasons may be that (i) a slightly different inclusion level from the authorised content was chosen in the experimental design, (ii) the intended selenium levels were not fully confirmed by analysis due to several reasons (heterogeneity of samples, different analytical methods). Consequently, the FEEDAP Panel considered acceptable to use results from studies in which the selenium content was in a certain range around the two figures for the maximum authorised levels. In particular, (i) data from diets with a total selenium analysed between 0.4 and 0.6 mg/kg were taken as representative for the maximum authorised 0.5 mg total selenium/kg feed, (ii) data from diets with an analysed inclusion level of organic selenium between 0.15 and 0.25 mg/kg were taken as representative for 0.2 mg supplemented organic selenium/kg feed.

2.4.2 | Conversion of reported concentrations of selenium in tissues and products

The methodology used to estimate consumer exposure (see Section 3.3) requires that the residues are expressed on fresh matter (FM) basis. In some studies, the results of the analysis of selenium deposition were reported in dry matter (DM). When the DM content of the correspondent tissue/product was reported, the conversion was calculated using the relevant values. When the DM content of the tissues/products was not reported, the conversion from DM to FM was calculated using default values as described in Souci et al. (2008); this approach has been already described and used by the FEEDAP Panel (EFSA FEEDAP Panel, 2011). The default values for DM content in the different tissues were: liver, 30%; kidney, 30%; cattle muscle, 35%; poultry muscle, 26%; lambs muscle, 26%; pig muscle, 24%. For eggs, data on selenium in whole eggs and FM are needed; in many studies, results were reported separately for albumen and yolk, and expressed in DM. For the conversion of results in albumen and yolk, DM contents of 13% and 50%, respectively, were considered. For the conversion from albumen and yolk to whole eggs, albumen was considered to contribute to 73% of the whole egg weight, yolk to 27%.

2.4.3 | Studies considered and selenium deposition

Following the selection strategy described above (see Section 2.4.1), a total of 34 studies were further considered for the assessment. In particular, 14 studies reporting selenium deposition data in tissues/products deriving from the use of inorganic form of selenium (sodium selenite) were used. One of these studies included two supplementation levels of sodium selenite resulting in an analysed selenium concentration in the diets in the range selected. Therefore, a total of 15 sets of deposition data were available. These studies reported selenium deposition in tissues/products from chickens for fattening, turkeys for fattening, laying hens, lambs, pigs for fattening and dairy cows.

Regarding the studies with supplementation of the different forms of organic selenium, three studies were available for hydroxyanalogue of selenomethionine, reporting selenium deposition in tissues/products from chickens for fattening, fish (*Sparus aurata*) and piglets. Regarding the supplementation with selenium from *Saccharomyces cerevisiae*, 17 studies were available, reporting data from chickens for fattening, turkeys for fattening, laying hens, cattle for fattening, lambs, pigs for fattening and dairy cows.

The details of these thirty-four studies, as well as the corresponding selenium concentrations in tissues/products (converted according to the methodology described in Section 2.4.2, when necessary), are reported in Appendix 1. In particular, Table A.1 reports the details of the 14 studies available for inorganic selenium and Table A.2 reports the details of the 20 studies available for all forms of organic selenium.

2.5 | Exposure assessment methodology

To estimate the chronic exposure of consumers to selenium from foods of animal origin, the FEEDAP Panel followed the methodology described in the Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017b) using the residue data as indicated in Section 2.5.1. Exposure to selenium was calculated based on the highest reliable percentile (HRP) of food consumption (raw agricultural food commodities), expressed in mg/kg bw per day for the different population categories and compared to the UL of 255 μg selenium/day as established by the NDA Panel (EFSA NDA Panel, 2023).

This exposure estimate is limited to the consumer exposure via food from animal origin and does not address other sources of consumer exposure (e.g. other food sources, supplements).

2.5.1 | Exposure scenarios

To estimate consumer exposure to selenium from food of animal origin, several scenarios were considered.

According to the Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017a), when more than six samples are analysed, the residue data to be considered for the exposure assessment should be calculated as the arithmetic mean plus 2 standard deviations (SD). When instead less than six samples are available, the highest single value should be used.

In the current assessment, most of the results of the residue analysis (i.e. in all the published studies and in many of the reports available) were reported as mean value. Therefore, the residue data selected and reported for all the studies (see Appendix 1, Tables A.1 and A.2) was the mean value and considered as a single sample analysis. To follow the requirements of the guidance, and to have a worst-case scenario exposure, two main scenarios were initially considered: one with selenium residues for all the tissue/products at the highest single value, and one with the arithmetical mean plus 2 SD for the tissue/product for which more than six values were available and the highest single values for the remaining foods of animal origin. However, the FEEDAP Panel recognised that calculating the arithmetical mean plus 2 SD from values that were already mean values is a very conservative approach and of low precision. Therefore, only the results of the scenarios with selenium residues at the highest single value are further reported in the text of the opinion. The scenarios with the arithmetical mean plus 2 SD (including the input data, the estimated chronic dietary exposure and its contribution to the UL and the details of the exposure estimate) are reported in Appendix B (for inorganic selenium) and in Appendix C (for organic selenium.

According to the above Guidance, the data for residue in meat should be calculated using the residue data in muscle and fat at different proportions (80:20 for mammals' meat, 90:10 (skin plus fat) for poultry meat). However, considering the limited data available for selenium deposition in fat, the consumer exposure was estimated in two different scenarios, one with muscle data only, and one with meat (calculated as muscle plus fat) data, when sufficient data were available.

Regarding the exposure to selenium from inorganic sources, deposition data, using analysed total concentration from 0.4 to 0.6 mg/feed, have been considered to assess the exposure at the authorised level of 0.5 mg total selenium/kg complete feed from all inorganic sources. Considering that the selenium concentration for poultry fat (skin plus fat) and muscle are very similar and data for mammals' fat are absent, the calculations of the content of selenium in meat with or without fat resulted in practically identical values. Therefore, the value for muscle was used to calculate the residues in meat.

Regarding the exposure to organic selenium, due to the limited amount of data available for the different sources which would have prevented a complete exposure assessment from all the animal products, the deposition data have been combined from those available for selenium from *Saccharomyces cerevisiae* and hydroxyanalogue of selenomethionine, using selenium supplementation levels from 0.15 to 0.25 mg/feed. In the absence of any data on selenium deposition in fat, the value for muscle was used to calculate the residues in meat.

2.5.2 | Default values for consumer population body weight

An UL of 255 μg selenium/day has been established by the NDA Panel for adult men and women (including pregnant and lactating women) and the ULs for the other age groups were derived from the UL for adults using the allometric scaling (body weight$^{0.75}$), as follows: 45 μg selenium/day for infants (4–6 months); 55 μg selenium/day for infants (7–11 months); 70 μg selenium/day for children 1–3 years; 95 μg selenium/day for children 4–6 years; 130 μg selenium/day for children 7–10 years, 180 μg selenium/day for children 11–14 years and 230 μg selenium/day for adolescents from 15 to 17 years (EFSA NDA Panel, 2023) (Table 2).

The FEEDAP Panel noted that the population categories used in the methodology described in the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), used for the exposure assessment, includes only one group for 'infants', 'other children' and 'adolescents'.

Since the conversion of the HRP results from μg/bw per day to μg/day is needed to allow the comparison of the exposure of the different population categories to the respective ULs, the FEEDAP Panel applied the default body weight values, as used in the NDA Panel opinion (NDA Panel, 2023) as described in Table 2, to cover all the above categories.

For the population groups 'elderly' and 'very elderly', the UL derived for the age group 'Adults' (255 μg/day) applies.

TABLE 2 Correspondence between the ULs for all the age groups as defined by the EFSA NDA Panel (EFSA NDA Panel, 2023) and the population categories as defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b).

FEEDAP population categories	NDA population categories	Default body weight (kg)	ULs (μg/day)	ULs expressed as μg/kg bw per day
(FEEDAP Panel, 2017b)	EFSA NDA Panel (2023)			
Infants (< 12 months old)	Infants (4–6 months)	7.2	45	6.25
	Infants (7–11 months)	8.6	55	6.39
Toddlers (≥ 12 months to <36 months old)	Toddlers (1–3 years)	11.9	70	5.88
Other children (≥ 36 months to <10 years old)	Other children (4–6 years)	19	95	5
	Other children (7–10 years)	28.7	130	4.52
Adolescents (≥ 10 years to < 18 years old)	Adolescents (11–14 years)	44.6	180	4.03
	Adolescents (15 to 17 years)	60.3	230	3.81
Adults (≥ 18 years to <65 years old)	Adults	70	255	3.64
Elderly (≥ 65 years to <75 years old)				
Very elderly (≥ 75 years old)				

Abbreviations: bw, body weight; UL, upper level.

2.6 | Consumer safety

2.6.1 | Inorganic selenium

The input values used for the exposure calculation are reported in Table 3.

TABLE 3 Input data on inorganic selenium content in food of animal origin for the consumer exposure assessment.

Commodities	Selenium concentration (mg/kg FM)
Birds' fat tissue	0.310
Birds' liver	0.810
Birds' meat	0.250
Birds' offals and slaughtering products (other than liver)	0.989
Fish (meat)	–
Honey	–
Mammals' fat tissue	–
Mammals' liver	0.618
Mammals' meat	0.130
Mammals' offals and slaughtering products (other than liver)	1.518
Milk	0.026
Seafood	–
Whole eggs	0.327

Abbreviation: FM, fresh matter.

The results of the consumer exposure assessment are reported, together with the comparison of the estimated exposure for the different consumer categories with the corresponding UL, in Table 4. For detailed results per age class, country and surveys, see Appendix D, Table D.1.

TABLE 4 Chronic human dietary exposure to inorganic selenium.

Population category	HRP* (mg selenium/kg bw per day)	%UL**
Infants (4–6 months)	0.00508	81
Infants (7–11 months)	0.00508	79
Toddlers (1–3 years)	0.00518	88
Other children (4–6 years)	0.00564	113
Other children (7–10 years)	0.00564	125
Adolescents (11–14 years)	0.00296	73
Adolescents (15–17 years)	0.00296	78
Adults	0.00233	64
Elderly	0.00173	48
Very elderly	0.00173	48

Abbreviations: bw, body weight; HRP, highest reliable percentile.

*The HRP calculated for the population categories defined by the defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b) are used for the corresponding categories defined by the NDA Panel (e.g. the HRP for infants < 12 months is used for the categories of infants 4–6 months and infants 7–11 months as defined by the NDA Panel).

**Contribution as percentage to the UL for the different population categories, as defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), was calculated applying the following formula: (maximum HRP × bw/UL) × 100.

The UL is exceeded for the population classes 'other children'. This exceedance is driven only by the survey in one country (Austria, see Appendix D) of a total of 18 surveys (with one other country with exposure at 101% of the UL). Exposure is close to the UL for infants (79%–81%), toddlers (88%) and adolescents (73%–77.5%) and markedly below the respective UL values for adults, elderly and very elderly. However, the Panel notes that selenium deposition data are missing in fish and seafood, honey and mammal fat. In addition, only two sets of data were available for mammals' tissues and only one for milk.

2.6.2 | Organic selenium

The input values used for the exposure calculation are reported in Table 5.

TABLE 5 Input data on organic selenium content in food of animal origin for the consumer exposure assessment.

Commodities	Selenium concentration (mg/kg FM)
Birds' fat tissue	–
Birds' liver	0.885
Birds' meat	0.550
Birds' offals and slaughtering products (other than liver)	0.680
Fish (meat)	0.450
Honey	–
Mammals' fat tissue	–
Mammals' liver	0.680
Mammals' meat	0.260
Mammals' offals and slaughtering products (other than liver)	1.660
Milk	0.051
Seafood	–
Whole eggs	0.366

Abbreviation: FM, fresh matter.

In Table 6, the results of the consumer exposure assessment are reported, together with the comparison of the estimated exposure for the different consumer categories with the corresponding UL. For detailed results per age class, country and surveys, see Appendix E, Table E.1.

TABLE 6 Chronic human dietary exposure to organic selenium.

Population category	HRP* (mg selenium/bw per day)	%UL**
Infants (4–6 months)	0.00938	150
Infants (7–11 months)	0.00938	146
Toddlers (1–3 years)	0.00959	163
Other children (4–6 years)	0.01026	205
Other children (7–10 years)	0.01026	227
Adolescents (11–14 years)	0.00557	138
Adolescents (15–17 years)	0.00557	146
Adults	0.00369	101
Elderly	0.00306	84
Very elderly	0.00324	89

Abbreviations: bw, body weight; HRP, highest reliable percentile; UL, upper level.

*The HRP calculated for the population categories defined by the defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b) are used for the corresponding categories defined by the NDA Panel (e.g. the HRP for infants < 12 months is used for the categories of infants 4–6 months and infants 7–11 months as defined by the NDA Panel). **Contribution as percentage to the UL for the different population categories, as defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), was calculated applying the following formula: (maximum HRP × bw/UL) × 100.

The UL is exceeded in all consumer categories, except elderly and very elderly. The Panel notes that only one data was available for fish and no data for poultry and mammals' fat, honey and seafood.

2.6.3 | Discussion of the results

The results of the two scenarios (for inorganic and organic selenium, respectively) in which the arithmetical mean plus 2 SD was considered (see Appendicies B and C) did not substantially differ from the results presented above, therefore they are not further discussed.

Based on the available data, when considering the total selenium content in complete feed of 0.5 mg/kg, deriving from the use of inorganic sources of selenium, the exposure assessment showed that there is no exceedance of the UL except for the population group 'other children'.

When the supplementation of complete feeds with organic forms of selenium at about 0.2 mg/kg feed (with total selenium ≤ 0.5 mg/kg feed) is considered, the UL was not exceeded in the population categories ‘elderly’ and ‘very elderly’ only. Adults' exposure is at the UL level, while the UL is exceeded in all other consumer categories.

The FEEDAP Panel noted that the main limitation influencing the present assessment is the lack of adequate and sufficient data to perform a complete and proper exposure assessment.

In particular, the following main uncertainties/limitations were identified:

- The use of the studies submitted in the application dossiers only, allowed the Panel to perform a rough assessment, based on two scenarios, with a maximum total selenium and organic selenium.
- Most of the studies available were not designed as deposition studies, but as efficacy or target animal safety studies.
- Published studies reported only limited information on the methodologies applied and did not provide a full set of raw data for the relevant tissues/products.
- A complete dataset (and a sufficient amount of data) for the relevant tissue/product at the authorised maximum levels for both inorganic and organic selenium was not available.
- In many studies, only one or few tissues are analysed for each species and not the set of tissues/products required in the guidance on the safety of the additives for the consumer.
- Deposition data were often expressed in tissues DM, whereas fresh matter is required. For conversion the Panel had to use default values, which might not be accurate enough to be fully representative.
- When the number of available data does not allow calculation of mean + 2 SD, as usually required, single values (extremely low or high) affected the exposure calculation.
- Different methods of analysis of selenium in biological samples are available with differences in terms of sensitivity and specificity. More than the final determination step, the pre-analytical steps for samples handling (mineralisation, possible volatilisation, partial reduction) may directly affect the results. In most of the published studies, the analytical methods of selenium in tissues made only reference to literature, without full details on the methods used and the validation, limiting the reliability of these data.

- The limited data available did not allow to apply a mathematical estimation of selenium tissue deposition at certain dietary levels that could allow for the estimation of residues at exactly the maximum authorised levels, without using a range of dietary levels (e.g. using regression analysis).

In addition, the FEEDAP Panel notes that the exposure assessment does not take into considerations sources of selenium other than foods of animal origin.

The FEEDAP Panel, owing the limited database and the above-mentioned limitations and uncertainties, considered that: (i) a differentiation between the organic sources of selenium (i.e., selenium from different *Saccharomyces cerevisiae*, different forms of selenomethionine) is not possible and (ii) the estimated exposure in the two scenarios and the corresponding contribution to the ULs is not to be considered as complete; and concluded, based on the data set, that:

- The use of organic selenium at the currently maximum authorised use level of 0.2 mg supplemented selenium from organic sources/kg complete feed (within a maximum of 0.5 mg total selenium/kg complete feed) leads to an exceedance of the UL in all population categories (except elderly and very elderly), suggesting a concern for consumer safety.
- It is not possible to conclude on the safety of the currently maximum use level of 0.5 mg total selenium/kg complete feed for all consumer categories.

The FEEDAP Panel notes that these conclusions have a high degree of uncertainty due to the limitations of the dataset already described above.

2.6.4 | Need for additional data

For a more reliable estimate of the consumer exposure, the FEEDAP Panel considered that additional data on selenium deposition in tissues and products of animal origin would be required.

These data should be generated in dedicated selenium deposition studies (or derived from existing studies, provided that the following requirements are respected).

Regarding the maximum content of total selenium in complete feed, studies should be done with sodium selenite at graded inclusion levels (preferred minimum three), up to the currently maximum authorised total selenium of 0.5 mg/kg complete feed. Control diets should contain low background selenium levels (< 0.1 mg/kg complete feed).

Regarding the organic forms of selenium, studies should be done with at least one source of selenium from *Saccharomyces cerevisiae* (preferably all) and one from selenomethionine (L or DL isomers, zinc-L-, or hydroxyanalogue) (preferably all forms). The studies should be done in a two-factorial design, with the above organic sources of selenium at graded inclusion levels, up to the currently maximum authorised level of 0.2 mg organic selenium and with at least two maximum total selenium contents in complete feed. Control diets should contain low background selenium levels (< 0.1 mg/kg complete feed).

The above studies should be designed to have deposition data in tissues from chickens for fattening, cattle for fattening, pigs for fattening and salmonids. In addition, deposition data should be provided in milk from dairy cows and eggs from laying hens. The minimum number of animals/samples are detailed in Section 2.1.2.2 of the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b).

Analytical data on selenium concentration in the additives and in all experimental diets should be generated using official control methods as included in the relevant authorising regulations. Analytical data on total selenium concentration in tissues/products (on FM basis) should be provided using fully described and validated methods.

3 | CONCLUSIONS

Based on the limited data set available and the several uncertainties linked to it, the FEEDAP Panel concludes that:

- The use of organic selenium at the currently maximum authorised use level of 0.2 mg supplemented selenium from organic sources/kg complete feed (within a maximum of 0.5 mg total selenium/kg complete feed) leads to an exceedance of the UL for all the population categories (except elderly and very elderly), suggesting a concern for consumer safety.
- It is not possible to conclude on the safety of the currently maximum authorised use level of 0.5 mg total selenium/kg complete feed for all consumer categories.

Additional data from studies specifically designed to measure deposition of selenium in tissues and products from animal origin resulting from the use of the different sources of selenium would be required to perform a proper risk assessment.

ABBREVIATIONS

ADME	absorption, distribution, metabolism, excretion
BW	body weight
DM	dry matter
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

FM	fresh matter
HRP	highest reliable percentile
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
LOAEL	lowest observed adverse effect level
SCF	Scientific Committee on Food
SD	standard deviation
SELECT	Selenium and Vitamin E Cancer Prevention Trial
UL	upper level

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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APPENDIX A

Details of the studies available for inorganic selenium and for all forms of organic selenium

TABLE A.1 Details of the 14 studies available for inorganic selenium and analysed selenium concentration in tissues and products from food producing animals.

					Selenium concentrations										
					Birds				Fish	Mammals					
Study	Source of selenium	Selenium supplementation (mg/kg)	Total selenium in complete feed (mg/kg)	Animal species/ category	Fat skin (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Meat (mg/kg)	Fat (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Milk (mg/kg)	Whole eggs (mg/kg)
1	Sodium selenite	0.5	0.55	Chickens for fattening	0.130	0.690	0.160	0.740							
2	Sodium selenite	0.5	0.56	Chickens for fattening	0.150	0.640	0.140								
3	Sodium selenite	0.5	0.59	Turkeys for fattening	0.160	0.710	0.250	0.840							
4	Sodium selenite	0.1	0.416	Laying hens											0.244
4	Sodium selenite	0.3	0.536	Laying hens											0.288
5	Sodium selenite	0.3	0.5	Laying hens											0.290
6	Sodium selenite	0.4	0.452	Laying hens											0.220
7	Sodium selenite	0.4	0.46	Laying hens		0.510	0.110	0.440							0.210
8	Sodium selenite	0.4	0.46	Laying hens	0.130	0.510	0.110	0.130							0.208
9	Sodium selenite	0.4	0.46	Laying hens	0.310	0.507	0.101	0.334							0.216
10	Sodium selenite	0.4	0.5	Laying hens		0.810	0.130	0.989							0.248
11	Sodium selenite	0.6	0.57	Laying hens											0.327
12	Sodium selenite	0.3	0.47	Pigs for fattening							0.120	0.048			
13	Sodium selenite	0.25	0.4136	Lambs for fattening							0.618	0.130	1.518		
14	Sodium selenite	0.35	0.45848	Dairy cows										0.026	
Average + 2 Standard Deviation						0.806	0.348	1.013							0.335

TABLE A.2 Details of the 20 studies available for organic selenium and analysed selenium concentration in tissues and products from food producing animals.

					Selenium concentrations										
					Birds				Fish	Mammals					
Study	Source of selenium	Selenium supplementation (mg/kg)	Total selenium in complete feed (mg/kg)	Animal species/ category	Fat skin (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Meat (mg/kg)	Fat (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Milk (mg/kg)	Whole eggs (mg/kg)
1	Selenium from Saccharomyces cerevisiae	0.2	0.24	Chickens for fattening		0.660	0.250	0.680							
2	Selenium from Saccharomyces cerevisiae	0.2	0.25	Chickens for fattening		0.580	0.210	0.610							
3	Selenium from Saccharomyces cerevisiae	0.2	0.27	Chickens for fattening			0.047								
4	Hydroxyanalogue of selenomethionine	0.2	0.3	Chickens for fattening			0.380								
5	Selenium from Saccharomyces cerevisiae	0.2	0.31	Chickens for fattening			0.250								
6	Selenium from Saccharomyces cerevisiae	0.15	0.29	Laying hens											0.366
7	Selenium from Saccharomyces cerevisiae	0.2	0.227	Laying hens											0.220
8	Selenium from Saccharomyces cerevisiae	0.2	0.227	Laying hens											0.220
9	Selenium from Saccharomyces cerevisiae	0.23	0.39	Laying hens		0.885	0.550	1.150							
10	Hydroxyanalogue of selenomethionine	0.25	0.52	Fish					0.450						
11	Hydroxyanalogue of selenomethionine	0.2	0.33	Piglets							0.570	0.260	1.420		
12	Selenium from Saccharomyces cerevisiae	0.2	0.42	Pigs for fattening							0.390	0.210			

TABLE A.2 (Continued)

Study	Source of selenium	Selenium supplementation (mg/kg)	Total selenium in complete feed (mg/kg)	Animal species/ category	Selenium concentrations									
					Birds				Fish	Mammals				
					Fat skin (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Meat (mg/kg)	Fat (mg/kg)	Liver (mg/kg)	Muscle (mg/kg)	Offals (mg/kg)	Milk (mg/kg)	Whole eggs (mg/kg)
13	Selenium from Saccharomyces cerevisiae	0.2	0.42	Pigs for fattening							0.390	0.210			
14	Selenium from Saccharomyces cerevisiae	0.15	0.11	Cattle for fattening							0.590	0.140	1.380		
15	Selenium from Saccharomyces cerevisiae	0.15	0.264	Cattle for fattening							0.590	0.160			
16	Selenium from Saccharomyces cerevisiae	0.21	0.2816	Lambs for fattening							0.540	0.180	1.290		
17	Selenium from Saccharomyces cerevisiae	0.25	0.352	Lambs for fattening							0.680	0.220	1.660		
18	Selenium from Saccharomyces cerevisiae	0.2	0.2464	Dairy cows										0.026	
19	Selenium from Saccharomyces cerevisiae	0.2	0.27368	Dairy cows										0.041	
20	Selenium from Saccharomyces cerevisiae	0.25	0.352	Dairy cows										0.051	
Average + 2 Standard Deviation							0.620				0.698	0.288			

APPENDIX B

Input values and exposure assessment for inorganic selenium, using the arithmetical mean plus 2 standard deviations for the tissue/product for which more than six residue values were available and the highest single values for the remaining foods of animal origin

TABLE B.1 Input data on inorganic selenium content in food of animal origin for the consumer exposure assessment.

Commodities	Selenium concentration (mg/kg FM)
Birds' fat tissue	0.310
Birds' liver	0.865
Birds' meat	0.306
Birds' offals and slaughtering products (other than liver)	1.197
Fish (meat)	–
Honey	–
Mammals' fat tissue	–
Mammals' liver	0.618
Mammals' meat	0.130
Mammals' offals and slaughtering products (other than liver)	1.518
Milk	0.026
Seafood	–
Whole eggs	0.335

Abbreviation: FM, fresh matter.

TABLE B.2 Chronic human dietary exposure to inorganic selenium and its contribution to the UL.

Population category	HRP* (mg Se/kg bw per day)	%UL**
Infants (4–6 months)	0.00520	83
Infants (7–11 months)	0.00520	81
Toddlers (1–3 years)	0.00550	93
Other children (4–6 years)	0.00580	116.0
Other children (7–10 years)	0.00580	128.0
Adolescents (11–14 years)	0.00310	76.8
Adolescents (15–17 years)	0.00310	81.3
Adults	0.00240	65.9
Elderly	0.00180	49.4
Very Elderly	0.00180	49.4

Abbreviations: bw, body weight; HRP, highest reliable percentile; UL, upper level.

*The HRP calculated for the population categories defined by the defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b) are used for the corresponding categories defined by the NDA Panel (e.g. the HRP for infants < 12 months is used for the categories of infants 4–6 months and infants 7–11 months as defined by the NDA Panel).

**Contribution as percentage to the UL for the different population categories, as defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), was calculated applying the following formula: (maximum HRP × bw/UL) × 100.

TABLE B.3 Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to selenium based on residue data.

Population class	Survey's country	Number of subjects	HRP value	HRP description
Infants	Bulgaria	523	0.0052456790	95th
Infants	Germany	142	0.0023268583	95th
Infants	Denmark	799	0.0033255689	95th
Infants	Finland	427	0.0024580887	95th
Infants	Italy	9	0.0012666096	50th
Infants	United Kingdom	1251	0.0027738219	95th
Toddlers	Belgium	36	0.0038306791	90th
Toddlers	Bulgaria	428	0.0054921142	95th
Toddlers	Germany	348	0.0038823641	95th
Toddlers	Denmark	917	0.0038618137	95th
Toddlers	Spain	17	0.0045332827	75th
Toddlers	Finland	500	0.0043316874	95th
Toddlers	Italy	36	0.0035590057	90th
Toddlers	Netherlands	322	0.0036880250	95th
Toddlers	United Kingdom	1314	0.0039844751	95th
Toddlers	United Kingdom	185	0.0040092468	95th
Other children	Austria	128	0.0057571519	95th
Other children	Belgium	625	0.0041822100	95th
Other children	Bulgaria	433	0.0049152152	95th
Other children	Germany	293	0.0034956352	95th
Other children	Germany	835	0.0028376627	95th
Other children	Denmark	298	0.0032540358	95th
Other children	Spain	399	0.0036738281	95th
Other children	Spain	156	0.0043949100	95th
Other children	Finland	750	0.0038782361	95th
Other children	France	482	0.0040076863	95th
Other children	Greece	838	0.0036595269	95th
Other children	Italy	193	0.0034975775	95th
Other children	Latvia	187	0.0027527919	95th
Other children	Netherlands	957	0.0030974019	95th
Other children	Netherlands	447	0.0028421497	95th
Other children	Sweden	1473	0.0033180512	95th
Other children	Czechia	389	0.0042460347	95th

(Continues)

TABLE B.3 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Other children	United Kingdom	651	0.0030124126	95th
Adolescents	Austria	237	0.0024226863	95th
Adolescents	Belgium	576	0.0015889818	95th
Adolescents	Cyprus	303	0.0015101175	95th
Adolescents	Germany	393	0.0021878807	95th
Adolescents	Germany	1011	0.0014403712	95th
Adolescents	Denmark	377	0.0016598157	95th
Adolescents	Spain	651	0.0021024201	95th
Adolescents	Spain	209	0.0027755269	95th
Adolescents	Spain	86	0.0019963958	95th
Adolescents	Finland	306	0.0018132653	95th
Adolescents	France	973	0.0022487071	95th
Adolescents	Italy	247	0.0020261430	95th
Adolescents	Latvia	453	0.0020648331	95th
Adolescents	Netherlands	1142	0.0021211229	95th
Adolescents	Sweden	1018	0.0020191947	95th
Adolescents	Czechia	298	0.0030542006	95th
Adolescents	United Kingdom	666	0.0016185701	95th
Adults	Austria	308	0.0018294463	95th
Adults	Belgium	1292	0.0014358208	95th
Adults	Germany	10,419	0.0014706630	95th
Adults	Denmark	1739	0.0012291038	95th
Adults	Spain	981	0.0017797038	95th
Adults	Spain	410	0.0016942922	95th
Adults	Finland	1295	0.0015885906	95th
Adults	France	2276	0.0016527527	95th
Adults	Hungary	1074	0.0020342811	95th
Adults	Ireland	1274	0.0014549367	95th
Adults	Italy	2313	0.0012905091	95th
Adults	Latvia	1271	0.0016229674	95th
Adults	Netherlands	2055	0.0015491622	95th
Adults	Romania	1254	0.0022668789	95th
Adults	Sweden	1430	0.0016408492	95th
Adults	Czechia	1666	0.0023845657	95th

TABLE B.3 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Adults	United Kingdom	1265	0.0012348912	95th
Elderly	Austria	67	0.0016864249	95th
Elderly	Belgium	511	0.0013889164	95th
Elderly	Germany	2006	0.0013935363	95th
Elderly	Denmark	274	0.0011688457	95th
Elderly	Finland	413	0.0013597825	95th
Elderly	France	264	0.0015340594	95th
Elderly	Hungary	206	0.0017516553	95th
Elderly	Ireland	149	0.0014800563	95th
Elderly	Italy	289	0.0011446463	95th
Elderly	Netherlands	173	0.0012881473	95th
Elderly	Netherlands	289	0.0012201709	95th
Elderly	Romania	83	0.0017295337	95th
Elderly	Sweden	295	0.0015183584	95th
Elderly	United Kingdom	166	0.0011254974	95th
Very elderly	Austria	25	0.0010363122	75th
Very elderly	Belgium	704	0.0014416893	95th
Very elderly	Germany	490	0.0014520315	95th
Very elderly	Denmark	12	0.0008162467	75th
Very elderly	France	84	0.0016296120	95th
Very elderly	Hungary	80	0.0015854963	95th
Very elderly	Ireland	77	0.0013880069	95th
Very elderly	Italy	228	0.0010689073	95th
Very elderly	Netherlands	450	0.0011913149	95th
Very elderly	Romania	45	0.0018060720	90th
Very elderly	Sweden	72	0.0015893483	95th
Very elderly	United Kingdom	139	0.0012700371	95th

Abbreviations: bw, body weight; HRP, highest reliable percentile.

APPENDIX C

Input values and exposure assessment for organic selenium, using the arithmetical mean plus 2 standard deviations for the tissue/product for which more than six residue values were available and the highest single values for the remaining foods of animal origin

TABLE C.1 Input data on organic selenium content in food of animal origin for the consumer exposure assessment.

Commodities	Selenium concentration (mg/kg FM)
Birds' fat tissue	–
Birds' liver	0.885
Birds' meat	0.620
Birds' offals and slaughtering products (other than liver)	0.680
Fish (meat)	0.450
Honey	-
Mammals' fat tissue	-
Mammals' liver	0.752
Mammals' meat	0.278
Mammals' offals and slaughtering products (other than liver)	1.660
Milk	0.051
Seafood	–
Whole eggs	0.366

Abbreviation: FM, fresh matter.

TABLE C.2 Chronic human dietary exposure to organic selenium and its contribution to the UL.

	HRP* (mg Se/bw per day)	%UL**
Population category	**Sub-scenario D**	**Sub-scenario D**
Infants (4–6 months)	0.00990	158
Infants (7–11 months)	0.00990	155
Toddlers (1–3 years)	0.01020	173
Other children (4–6 years)	0.01040	208
Other children (7–10 years)	0.01040	230
Adolescents (11–14 years)	0.00580	144
Adolescents (15–17 years)	0.00580	152
Adults	0.00380	104
Elderly	0.00310	85
Very elderly	0.00330	91

Abbreviations: bw: body weight; HRP: highest reliable percentile; UL: upper level.

*The HRP calculated for the population categories defined by the defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b) are used for the corresponding categories defined by the NDA Panel (e.g. the HRP for infants < 12 months is used for the categories of infants 4–6 months and infants 7–11 months as defined by the NDA Panel). **Contribution as percentage to the UL for the different population categories, as defined by the EFSA FEEDAP Panel Guidance (EFSA FEEDAP Panel, 2017b), was calculated applying the following formula: (maximum HRP × bw/UL) × 100.

TABLE C.3 Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to selenium based on residue data.

Population class	Survey's country	Number of subjects	HRP value	HRP description
Infants	Bulgaria	523	0.0099068440	95th
Infants	Germany	142	0.0045722957	95th
Infants	Denmark	799	0.0067465823	95th
Infants	Finland	427	0.0049347647	95th
Infants	Italy	9	0.0025516335	50th
Infants	United Kingdom	1251	0.0056144022	95th
Toddlers	Belgium	36	0.0071345636	90th
Toddlers	Bulgaria	428	0.0101503248	95th
Toddlers	Germany	348	0.0074490961	95th
Toddlers	Denmark	917	0.0076544817	95th
Toddlers	Spain	17	0.0078929110	75th
Toddlers	Finland	500	0.0087249028	95th
Toddlers	Italy	36	0.0083336096	90th
Toddlers	Netherlands	322	0.0069515967	95th
Toddlers	United Kingdom	1314	0.0078719859	95th

(Continues)

TABLE C.3 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Toddlers	United Kingdom	185	0.0076587128	95th
Other children	Austria	128	0.0103890546	95th
Other children	Belgium	625	0.0079076094	95th
Other children	Bulgaria	433	0.0090169333	95th
Other children	Germany	293	0.0065132989	95th
Other children	Germany	835	0.0053287024	95th
Other children	Denmark	298	0.0064688469	95th
Other children	Spain	399	0.0070744946	95th
Other children	Spain	156	0.0080209789	95th
Other children	Finland	750	0.0076057309	95th
Other children	France	482	0.0076239417	95th
Other children	Greece	838	0.0069719078	95th
Other children	Italy	193	0.0069177840	95th
Other children	Latvia	187	0.0053887032	95th
Other children	Netherlands	957	0.0057580276	95th
Other children	Netherlands	447	0.0055850801	95th
Other children	Sweden	1473	0.0064687023	95th
Other children	Czechia	389	0.0083781679	95th
Other children	United Kingdom	651	0.0057624930	95th
Adolescents	Austria	237	0.0043668833	95th
Adolescents	Belgium	576	0.0031246461	95th
Adolescents	Cyprus	303	0.0030169287	95th
Adolescents	Germany	393	0.0041236222	95th
Adolescents	Germany	1011	0.0027835676	95th
Adolescents	Denmark	377	0.0033915238	95th
Adolescents	Spain	651	0.0041899075	95th
Adolescents	Spain	209	0.0053274407	95th
Adolescents	Spain	86	0.0041248261	95th
Adolescents	Finland	306	0.0038489689	95th
Adolescents	France	973	0.0043823227	95th
Adolescents	Italy	247	0.0038853165	95th
Adolescents	Latvia	453	0.0039156367	95th
Adolescents	Netherlands	1142	0.0039830981	95th
Adolescents	Sweden	1018	0.0040181399	95th

TABLE C.3 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Adolescents	Czechia	298	0.0057881201	95th
Adolescents	United Kingdom	666	0.0032191866	95th
Adults	Austria	308	0.0036882278	95th
Adults	Belgium	1292	0.0028218584	95th
Adults	Germany	10,419	0.0027727947	95th
Adults	Denmark	1739	0.0024406314	95th
Adults	Spain	981	0.0036864766	95th
Adults	Spain	410	0.0034067838	95th
Adults	Finland	1295	0.0031986845	95th
Adults	France	2276	0.0030733252	95th
Adults	Hungary	1074	0.0033586092	95th
Adults	Ireland	1274	0.0029567167	95th
Adults	Italy	2313	0.0025179410	95th
Adults	Latvia	1271	0.0031911239	95th
Adults	Netherlands	2055	0.0029812125	95th
Adults	Romania	1254	0.0037723519	95th
Adults	Sweden	1430	0.0033429684	95th
Adults	Czechia	1666	0.0038192919	95th
Adults	United Kingdom	1265	0.0024266187	95th
Elderly	Austria	67	0.0027848822	95th
Elderly	Belgium	511	0.0027736175	95th
Elderly	Germany	2006	0.0026266142	95th
Elderly	Denmark	274	0.0023164496	95th
Elderly	Finland	413	0.0027544209	95th
Elderly	France	264	0.0027033738	95th
Elderly	Hungary	206	0.0027495185	95th
Elderly	Ireland	149	0.0030361205	95th
Elderly	Italy	289	0.0022469571	95th
Elderly	Netherlands	173	0.0024073302	95th
Elderly	Netherlands	289	0.0022776552	95th
Elderly	Romania	83	0.0030601977	95th
Elderly	Sweden	295	0.0031395534	95th
Elderly	United Kingdom	166	0.0023433431	95th
Very elderly	Austria	25	0.0020628150	75th

(Continues)

TABLE C.3 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Very elderly	Belgium	704	0.0028943811	95th
Very elderly	Germany	490	0.0026998589	95th
Very elderly	Denmark	12	0.0018024145	75th
Very elderly	France	84	0.0028553663	95th
Very elderly	Hungary	80	0.0028066054	95th
Very elderly	Ireland	77	0.0028891975	95th
Very elderly	Italy	228	0.0021564429	95th
Very elderly	Netherlands	450	0.0023857724	95th
Very elderly	Romania	45	0.0032572650	90th
Very elderly	Sweden	72	0.0032896358	95th
Very elderly	United Kingdom	139	0.0026344272	95th

Abbreviations: bw, body weight; HRP, highest reliable percentile.

APPENDIX D

Detailed results on chronic exposure calculation using the highest deposition values – inorganic selenium

Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to selenium based on residue data.

TABLE D.1 Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to selenium based on residue data.

Population class	Survey's country	Number of subjects	HRP value	HRP description
Infants	Bulgaria	523	0.0050791878	95th
Infants	Germany	142	0.0023246905	95th
Infants	Denmark	799	0.0032871152	95th
Infants	Finland	427	0.0023906983	95th
Infants	Italy	9	0.0011961392	50th
Infants	United Kingdom	1251	0.0025921418	95th
Toddlers	Belgium	36	0.0038092990	90th
Toddlers	Bulgaria	428	0.0051765554	95th
Toddlers	Germany	348	0.0038208108	95th
Toddlers	Denmark	917	0.0038044166	95th
Toddlers	Spain	17	0.0043950165	75th
Toddlers	Finland	500	0.0042500814	95th
Toddlers	Italy	36	0.0034161888	90th
Toddlers	Netherlands	322	0.0035961397	95th
Toddlers	United Kingdom	1314	0.0038651407	95th
Toddlers	United Kingdom	185	0.0038300817	95th
Other children	Austria	128	0.0056392116	95th
Other children	Belgium	625	0.0040801897	95th
Other children	Bulgaria	433	0.0046079863	95th
Other children	Germany	293	0.0034267807	95th
Other children	Germany	835	0.0027755520	95th
Other children	Denmark	298	0.0031626157	95th
Other children	Spain	399	0.0035156743	95th
Other children	Spain	156	0.0040801182	95th
Other children	Finland	750	0.0038145530	95th
Other children	France	482	0.0038520071	95th
Other children	Greece	838	0.0035651260	95th

(Continues)

TABLE D.1 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Other children	Italy	193	0.0034475064	95th
Other children	Latvia	187	0.0026751664	95th
Other children	Netherlands	957	0.0029992222	95th
Other children	Netherlands	447	0.0026827100	95th
Other children	Sweden	1473	0.0032170921	95th
Other children	Czechia	389	0.0039880257	95th
Other children	United Kingdom	651	0.0028710136	95th
Adolescents	Austria	237	0.0023476381	95th
Adolescents	Belgium	576	0.0015041188	95th
Adolescents	Cyprus	303	0.0014555836	95th
Adolescents	Germany	393	0.0021672443	95th
Adolescents	Germany	1011	0.0014160844	95th
Adolescents	Denmark	377	0.0016322049	95th
Adolescents	Spain	651	0.0020244635	95th
Adolescents	Spain	209	0.0026670228	95th
Adolescents	Spain	86	0.0018838339	95th
Adolescents	Finland	306	0.0017762708	95th
Adolescents	France	973	0.0021851695	95th
Adolescents	Italy	247	0.0019760385	95th
Adolescents	Latvia	453	0.0019804208	95th
Adolescents	Netherlands	1142	0.0019867578	95th
Adolescents	Sweden	1018	0.0019495057	95th
Adolescents	Czechia	298	0.0029579584	95th
Adolescents	United Kingdom	666	0.0015377217	95th
Adults	Austria	308	0.0017710261	95th
Adults	Belgium	1292	0.0013918463	95th
Adults	Germany	10,419	0.0014203757	95th
Adults	Denmark	1739	0.0011905680	95th
Adults	Spain	981	0.0016801190	95th
Adults	Spain	410	0.0016407200	95th
Adults	Finland	1295	0.0015152504	95th
Adults	France	2276	0.0016182638	95th
Adults	Hungary	1074	0.0019595761	95th
Adults	Ireland	1274	0.0013459650	95th

TABLE D.1 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Adults	Italy	2313	0.0012436266	95th
Adults	Latvia	1271	0.0015763301	95th
Adults	Netherlands	2055	0.0014802589	95th
Adults	Romania	1254	0.0021507872	95th
Adults	Sweden	1430	0.0015675997	95th
Adults	Czechia	1666	0.0023258155	95th
Adults	United Kingdom	1265	0.0011599213	95th
Elderly	Austria	67	0.0016317215	95th
Elderly	Belgium	511	0.0013330302	95th
Elderly	Germany	2006	0.0013555387	95th
Elderly	Denmark	274	0.0011403573	95th
Elderly	Finland	413	0.0013029000	95th
Elderly	France	264	0.0014772800	95th
Elderly	Hungary	206	0.0017321632	95th
Elderly	Ireland	149	0.0014742661	95th
Elderly	Italy	289	0.0010859288	95th
Elderly	Netherlands	173	0.0012326480	95th
Elderly	Netherlands	289	0.0011690477	95th
Elderly	Romania	83	0.0016330914	95th
Elderly	Sweden	295	0.0014377425	95th
Elderly	United Kingdom	166	0.0010940887	95th
Very elderly	Austria	25	0.0010071298	75th
Very elderly	Belgium	704	0.0014028356	95th
Very elderly	Germany	490	0.0014447137	95th
Very elderly	Denmark	12	0.0007925117	75th
Very elderly	France	84	0.0015333031	95th
Very elderly	Hungary	80	0.0014918812	95th
Very elderly	Ireland	77	0.0012862945	95th
Very elderly	Italy	228	0.0010081095	95th
Very elderly	Netherlands	450	0.0011592891	95th
Very elderly	Romania	45	0.0017307656	90th
Very elderly	Sweden	72	0.0015394167	95th
Very elderly	United Kingdom	139	0.0012550581	95th

Abbreviations: bw, body weight; HRP, highest reliable percentile.

APPENDIX E

Detailed results on chronic exposure calculation using the highest deposition values – All sources of organic selenium

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

Population class	Survey's country	Number of subjects	HRP value	HRP description
Infants	Bulgaria	523	0.0093791500	95th
Infants	Germany	142	0.0045183705	95th
Infants	Denmark	799	0.0066340415	95th
Infants	Finland	427	0.0047669771	95th
Infants	Italy	9	0.0024304784	50th
Infants	United Kingdom	1251	0.0053903560	95th
Toddlers	Belgium	36	0.0067758809	90th
Toddlers	Bulgaria	428	0.0095891322	95th
Toddlers	Germany	348	0.0073057877	95th
Toddlers	Denmark	917	0.0075177507	95th
Toddlers	Spain	17	0.0075836090	75th
Toddlers	Finland	500	0.0085067582	95th
Toddlers	Italy	36	0.0079827893	90th
Toddlers	Netherlands	322	0.0067445207	95th
Toddlers	United Kingdom	1314	0.0076619970	95th
Toddlers	United Kingdom	185	0.0075587660	95th
Other children	Austria	128	0.0102585792	95th
Other children	Belgium	625	0.0076275584	95th
Other children	Bulgaria	433	0.0087479059	95th
Other children	Germany	293	0.0063780760	95th
Other children	Germany	835	0.0051822274	95th
Other children	Denmark	298	0.0062993958	95th
Other children	Spain	399	0.0068325182	95th
Other children	Spain	156	0.0076714218	95th
Other children	Finland	750	0.0073788019	95th
Other children	France	482	0.0073278080	95th
Other children	Greece	838	0.0067846754	95th
Other children	Italy	193	0.0067677785	95th
Other children	Latvia	187	0.0052729504	95th
Other children	Netherlands	957	0.0055480766	95th
Other children	Netherlands	447	0.0052956750	95th

TABLE E.1 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Other children	Sweden	1473	0.0062999128	95th
Other children	Czechia	389	0.0080398035	95th
Other children	United Kingdom	651	0.0055108304	95th
Adolescents	Austria	237	0.0041830616	95th
Adolescents	Belgium	576	0.0029858643	95th
Adolescents	Cyprus	303	0.0028437452	95th
Adolescents	Germany	393	0.0040292962	95th
Adolescents	Germany	1011	0.0026836657	95th
Adolescents	Denmark	377	0.0033051373	95th
Adolescents	Spain	651	0.0040818092	95th
Adolescents	Spain	209	0.0051067491	95th
Adolescents	Spain	86	0.0039022014	95th
Adolescents	Finland	306	0.0037246851	95th
Adolescents	France	973	0.0042655066	95th
Adolescents	Italy	247	0.0038061002	95th
Adolescents	Latvia	453	0.0037414991	95th
Adolescents	Netherlands	1142	0.0038357034	95th
Adolescents	Sweden	1018	0.0039032436	95th
Adolescents	Czechia	298	0.0055728660	95th
Adolescents	United Kingdom	666	0.0030563578	95th
Adults	Austria	308	0.0034820950	95th
Adults	Belgium	1292	0.0027059955	95th
Adults	Germany	10,419	0.0026886463	95th
Adults	Denmark	1739	0.0023507749	95th
Adults	Spain	981	0.0035303829	95th
Adults	Spain	410	0.0032866583	95th
Adults	Finland	1295	0.0031374813	95th
Adults	France	2276	0.0029482794	95th
Adults	Hungary	1074	0.0031501108	95th
Adults	Ireland	1274	0.0027672988	95th
Adults	Italy	2313	0.0024370859	95th
Adults	Latvia	1271	0.0030650350	95th
Adults	Netherlands	2055	0.0028579100	95th
Adults	Romania	1254	0.0035983324	95th

(Continues)

TABLE E.1 (Continued)

Population class	Survey's country	Number of subjects	HRP value	HRP description
Adults	Sweden	1430	0.0031722680	95th
Adults	Czechia	1666	0.0036838705	95th
Adults	United Kingdom	1265	0.0023033999	95th
Elderly	Austria	67	0.0027322289	95th
Elderly	Belgium	511	0.0026960992	95th
Elderly	Germany	2006	0.0025533801	95th
Elderly	Denmark	274	0.0022564369	95th
Elderly	Finland	413	0.0027153416	95th
Elderly	France	264	0.0026442980	95th
Elderly	Hungary	206	0.0026180050	95th
Elderly	Ireland	149	0.0029985244	95th
Elderly	Italy	289	0.0021612512	95th
Elderly	Netherlands	173	0.0023546215	95th
Elderly	Netherlands	289	0.0022155048	95th
Elderly	Romania	83	0.0028823866	95th
Elderly	Sweden	295	0.0030589907	95th
Elderly	United Kingdom	166	0.0022828969	95th
Very elderly	Austria	25	0.0020045827	75th
Very elderly	Belgium	704	0.0028084192	95th
Very elderly	Germany	490	0.0026555174	95th
Very elderly	Denmark	12	0.0017606404	75th
Very elderly	France	84	0.0027107954	95th
Very elderly	Hungary	80	0.0026220492	95th
Very elderly	Ireland	77	0.0026948959	95th
Very elderly	Italy	228	0.0020781214	95th
Very elderly	Netherlands	450	0.0023281764	95th
Very elderly	Romania	45	0.0030987247	90th
Very elderly	Sweden	72	0.0032371646	95th
Very elderly	United Kingdom	139	0.0025744222	95th

Abbreviations: bw, body weight; HRP, highest reliable percentile.