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## Safety of ammonium formate (E 295) for all animal species

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### Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety of ammonium formate for all animal species. In 2015, the FEEDAP Panel delivered an opinion on the safety and efficacy of ammonium formate, calcium formate and sodium formate. In that opinion, the Panel considered the unavoidable presence of formamide, as a contaminant of ammonium formate, of concern for developmental toxicity for reproduction animals and for carcinogenicity for non-food-producing animals. Regarding the safety for the consumer, the Panel concluded that: the use of the additive in dairy animals and laying poultry may raise concerns due to the potential exposure of consumers to formamide. In the current submission, the applicant proposed to reduce the maximum content of ammonium formate in feed to 2,000 mg formic acid equivalent/kg feed from the previously proposed 12,000 mg/kg for pigs and 10,000 mg/kg for all other animal species. Based on the calculation of the maximum safe concentration of formamide in feed, the FEEDAP Panel cannot conclude on the safety of ammonium formate in complete feed for laying hens and sows, since the calculate maximum concentration of formamide in feed (11.5 mg formamide/kg) exceed the maximum safe concentration in feed for these species (5.6 mg formamide/kg for laying hens and 9.9 mg formamide/kg for sows). Based on the results of a residue study in eggs, the use of ammonium formate in animal nutrition at a maximum content of 2,000 mg formic acid equivalent/kg complete feed would not result in concerns on the safety for the consumer.

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**Requestor:** European Commission

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## 1. Introduction

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

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition and in particular, Article 9 defines the terms of such authorisation by the Commission.

The applicant, Nutreco Nederland B.V. Trade,<sup>2</sup> is seeking a Community authorization for Ammonium formate (E295) as a feed additive for all animal species. (Table 1)

**Table 1:** Description of the substances

<b>Category of additive</b>	Technological additive
<b>Functional group of additive</b>	preservatives
<b>Description</b>	Ammonium formate (E295)
<b>Target animal category</b>	All animal species
<b>Applicant</b>	Nutreco Nederland B.V. Trade
<b>Type of request</b>	New opinion

On 05 May 2015, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion<sup>3</sup> on the safety and efficacy of the product when used as a technological additive for all animal species, could not conclude on the safety of ammonium formate for target species and consumers.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of the Authority's opinion. The new data have been received on 09 April 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on ammonium formate as a preservative for all animal species based on the additional data submitted by the applicant.

### 1.2. Additional information

Ammonium formate (E 295) is presently listed in the EU Register of Feed Additives as technological additives (functional group: preservatives) for use in feed for all animal species without time limit, and it is subject to re-evaluation.<sup>4</sup> Ammonium formate is authorised in food legislation as food packaging additive (E 295, Directive 2007/42/EC<sup>5</sup>) for use in 'ingredients for manufacturing' intended to come in contact with food.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) issued two opinions on ammonium formate (JECFA, 1974, 1998) allocating an acceptable daily intake (ADI) of 0–3 mg/kg/body weight (bw) per day.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted in 2015 two opinions<sup>3,6</sup> on ammonium formate as technological additives for all animal species (EFSA FEEDAP Panel, 2015a,b). In those opinions, the FEEDAP Panel could not conclude on the safety of the additive for reproducing and non-food producing animals, and for the consumer.

The applicant has submitted new information to support the safety of ammonium formate as a preservative in feedingstuffs for all animal species.

<sup>1</sup> 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.

<sup>2</sup> Nutreco Nederland B.V. Trade, Stationsstraat 77 3811 MH Amersfoort, Netherlands.

<sup>3</sup> The opinion linked to the previous dossier (related to EFSA-Q-2011-00424) is available on the EFSA website: <https://efsa.online.library.wiley.com/doi/pdf/10.2903/j.efsa.2015.4056>

<sup>4</sup> FEED dossier reference: FAD-2018-0016.

<sup>5</sup> Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

<sup>6</sup> The opinion linked to the previous dossier (related to EFSA-Q-2013-00755) is available on the EFSA website: <https://efsa.online.library.wiley.com/doi/epdf/10.2903/j.efsa.2015.4113>

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information<sup>4</sup> to previous applications on the same product.<sup>7</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of ammonium formate is in line with the principles laid down in Regulation (EC) No 429/2008<sup>8</sup> and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017a) and Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017b).

## 3. Assessment

The additive under assessment is ammonium formate, intended to be used as a technological additive (functional group: preservatives) in feed for all animal species. The additive was fully characterised in the previous opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as technological additive for all animal species (EFSA FEEDAP Panel, 2015a).

In its previous opinion (EFSA FEEDAP Panel, 2015a), the Panel concluded that 'the presence of formamide (a developmental toxicant) in ammonium formate additives is a concern. Even if the concentration of formamide in the additive is restricted to a maximum of 0.3%, as proposed, this is considered insufficient to guarantee the protection of reproduction animals. There is also evidence from animal studies of a carcinogenic potential of formamide which is an argument for avoiding the use of ammonium formate-containing additives in non-food-producing animals'.

Regarding the safety for the consumer, the Panel concluded that: 'although the use of ammonium formate in growing/fattening animals would not raise any safety concern for the consumer, its use in dairy animals and laying poultry may raise concerns due to the potential exposure of consumers to formamide'.

The applicant has provided new arguments to support the safety of the additive for the target species and new data on the presence of residues of formamide in eggs. In addition, they proposed a modification in the conditions of use, reducing the maximum ammonium formate content in complete feedingstuffs to 2,000 mg (formic acid equivalent)/kg for all animal species, from the original 12,000 mg/kg for pigs and 10,000 mg/kg for all the other species.

### 3.1. Conditions of use

The applicant is proposing to modify the original conditions of use of the additive as follow:

- a) The additive is intended to be used as a preservative in feedingstuffs for all animal species except for dairy ruminants and non-food-producing animals.
- b) The maximum proposed content in complete feedingstuff is 2,000 mg (formic acid equivalent)/kg.

### 3.2. Safety

#### 3.2.1. Toxicological profile of formamide

In its former opinion (EFSA FEEDAP Panel, 2015a), the FEEDAP Panel identified a concern for the presence of the unavoidable contaminant formamide, because of its reproductive and potential carcinogenic properties. In particular, three studies (Leuscher, 1974; NTP, 2001; George et al., 2000a) were already evaluated in the previous assessment (EFSA FEEDAP Panel, 2015a).

<sup>7</sup> FEED dossier reference: FAD-2018-0016 and FAD-2013-0036.

<sup>8</sup> 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.

In the current dossier, the applicant did not provide any new toxicological data on formamide but proposed a new interpretation of the data already provided and evaluated in the EFSA opinion (EFSA FEEDAP Panel, 2015a).

In the previous EFSA assessment (EFSA FEEDAP Panel, 2015a), a no observed adverse effect level (NOAEL) was identified for reproductive effects (maternal and embryo/fetotoxicity) in a study (Leuscher, 1974) in pregnant New Zealand White rabbits (N = 10/group) given formamide via gavage at 0, 34, 113 or 340 mg formamide/kg bw per day on gestation day 6 to 18. Mortality was increased (7/10) at the top exposure level, with clinical signs of toxicity in some animals at the lower dosage (113 mg formamide/kg bw per day), including inappetence and vaginal bleeding. Post-implantation losses were significantly increased at 113 mg/kg bw per day. Fetal weights were decreased and increased numbers of fetal variations were seen at 113 and 340 mg/kg bw per day. No teratogenic effects were observed. A NOAEL of 34 mg/kg bw per day was identified, based on maternal toxicity and embryotoxicity seen at doses equal or greater than 113 mg formamide/kg bw per day.

In the current dossier, the applicant provided a different interpretation of the results of the available studies (Leuscher, 1974; NTP, 2001; George et al., 2000), expressing criticism towards the study in rabbits (Leuscher, 1974) selected by EFSA to derive the NOAEL for reproductive toxicity. This study was done before the issue of the Organisation for Economic Co-operation and Development (OECD) guidelines for reproductive and developmental studies. The applicant proposed instead to re-consider two more recent National Toxicology Program (NTP) studies, one performed in rabbits and another one in rats, already submitted in the original application and assessed by the FEEDAP Panel in the previous opinion.

In the first study (NTP, 2001),<sup>9</sup> female New Zealand White rabbits were dosed by gavage with formamide (35, 70 or 140 mg/kg bw per day) or its vehicle (deionised/distilled water) on GD 6 through 29. The study was conducted in a two-replicates design. Twenty-four naturally mated female rabbits (12 per replicate) were assigned to each group; mortality and other signs of toxicity (e.g. reduction body weight, feed intake, gravid uterine weight) were noted in does only at the highest dose, resulting in a maternal NOAEL of 70 mg/kg bw per day. In addition, formamide caused significant treatment-related developmental toxicity at 140 mg/kg per day, consisting of reduced mean live litter size and fetal body weight per litter. Consequently, the developmental toxicity NOAEL was also 70 mg/kg per day.

In the second study (George et al., 2000), mated female rats were administered formamide via gavage at doses of 0, 50, 100 and 200 mg/kg bw per day on GD 6 through 19. No maternal mortality was observed throughout the experiment. The administration of the highest formamide dosage (200 mg/kg bw per day) resulted in the decrease of maternal body weight, weight gain and gravid uterine weight. Formamide did not affect prenatal viability or the incidence of fetal malformations or variations but decreased the average fetal body weight/litter at both 200 and 100 mg/kg/bw per day. The NOAEL for maternal toxicity in rats was 100 mg formamide/kg bw per day and the NOAEL for developmental toxicity was 50 mg formamide/kg bw/day. Taking into account the results of the above described studies, the applicant proposes to retain the value of 50 mg formamide/kg bw per day as the NOAEL for the developmental toxicity.

The FEEDAP Panel considers that the three studies (Leuscher, 1974; NTP, 2001; George et al., 2000) were already evaluated in the previous assessment (EFSA FEEDAP Panel, 2015a) and that no new evidence on the toxicological profile of formamide has been provided by the applicant in the current application. The FEEDAP Panel further considers that the three studies remain valid and there is no ground for a modification of the conclusions previously reached. Consequently, the FEEDAP Panel concludes that the lowest NOAEL of 34 mg/kg bw per day, identified in the three studies, is still valid for formamide.

### 3.2.2. Safety for the target species

In the previous opinion (EFSA FEEDAP Panel 2015a), the FEEDAP Panel estimated the exposure of reproductive animals (sows, laying hens and dairy cows) to formamide considering the maximum content of ammonium formate of 12,000 mg/kg complete feed for pigs and 10,000 mg/kg complete feed for the other species, and the maximum concentration of 0.3% formamide in the additive. The resulting exposure corresponded to 2.1, 3.4 and 1.8 mg formamide/kg bw per day for sows, laying hens and dairy cows, respectively. The Panel concluded that 'the difference between the potential

<sup>9</sup> Technical dossier/Section III/Ref\_III\_15\_NTP\_2001.

exposure and the NOAEL identified in the rabbit study is considered insufficient to guarantee the protection of reproduction animals' (EFSA FEEDAP Panel, 2015a).

The applicant does not support the application for the authorisation of the additive for lactating ruminants and non food-producing animals and asks to reduce the maximum inclusion level of ammonium formate in complete feed to 2,000 mg/kg (as formic acid equivalent), with a maximum content of formamide of 0.3% additive, will reduce the maximum formamide content in complete feed to 11.5 mg/kg.

In order to calculate the maximum feed concentration of formamide which can be considered safe for the target species, the Panel used the approach described in the Guidance on safety for the target species (EFSA FEEDAP Panel, 2017a). The NOAEL of 34 mg/kg bw per day for formamide was used (see Section 3.2.1). Applying an uncertainty factor (UF) of 100 to the NOAEL, the maximum calculated safe concentration in feed for laying hens and sows would correspond to 5.6 and 9.9 mg/kg complete feed, respectively. Both values are below the calculated concentration of formamide in complete feed (11.5 mg/kg).

Therefore, the FEEDAP Panel is not in the position to conclude on the safety of ammonium formate at a maximum concentration of 2,000 mg formic acid equivalent/kg complete feed for laying hens and sows.

### 3.2.3. Safety for the consumer

In its previous opinion, the Panel raised concerns for the safety of consumers regarding the use of the additive in dairy animals and laying poultry due to the potential exposure of consumers to formamide. In the present submission, the applicant has provided a residue study in laying hens.

#### 3.2.3.1. Residue study

A study on the transfer of formamide from feed to eggs of laying hens was submitted. A total of 87 laying hens (Dekalb White, 77 weeks old) were distributed into five groups according to the experimental protocol described on Table 2. A standard laying hen feed was supplemented with ammonium formate at 0.5 times the maximum dose proposed for use (group 1: equivalent to 1,000 mg formic acid/kg) and at that dose (groups 2, 3, 4 and 5: 10,000 mg/kg). In these groups, ammonium formate was spiked with increasing doses of formamide and the analytically measured average values in feed were retained for transfer calculations of formamide.

**Table 2:** Experimental protocol of the residue studies in eggs

Group number	Laying hens/pens (animals/pen)	Ammonium formate inclusion level (as formic acid equivalent, mg/kg feed)	Formamide content in the additive %	Formamide spiked level	Analysed formamide concentration in feed (mg/kg) <sup>2</sup>
1	30, 10 (3)	1,000	0.3	0.5 × <sup>1</sup>	7.3
2	30, 10 (3)	10,000	0.3	5 ×	66.3
3	9, 3 (3)	10,000	1.2	20 ×	208
4	9, 3 (3)	10,000	2.1	35 ×	340
5	9, 3 (3)	10,000	3.0	50 ×	542

<sup>1</sup>Level corresponding to the level deriving from the use of the additive at the maximum recommended concentration of 2000 mg formic acid equivalent/kg complete feed.

<sup>2</sup>Analytically determined average values.

All animals were accustomed for 7 days to the control feed then were administered the formamide spiked feed from day 7 until day 40. Eggs were collected per pen per day at day 6 (pre-experimental period), day 37, day 38 and day 39, homogenised and kept at –20°C; the samples were analysed in duplicate.

The analysis of the eggs indicated similar formamide concentrations after 31, 32 and 33 days of exposure, indicating that the metabolic steady-state was reached. A linear relationship was shown to

occur between the formamide level in the feed and that measured in the eggs, with: formamide in eggs (mg/kg) =  $0.0494 \times [\text{formamide in feed (mg/kg)}] + 0.4493$  ( $R^2 = 0.9606$ ).

On the basis of the linear regression equation between formamide in layer feed and formamide in eggs, it can be calculated that the expected amount of formamide in eggs will be 1.02 mg/kg at the maximum recommended level of 2,000 mg formic acid equivalents/kg of complete feed with maximum 0.3% formamide. Using the upper 95% confidence level of the regression, the expected concentration of formamide in eggs would be 1.32 mg/kg.

The FEEDAP Panel notes that formamide concentrations in feed used to calculate the linear regression for formamide in feed and in eggs were not centred at the expected maximum inclusion level of formamide in feed. This value is 11.5 mg formamide/kg complete feed, the values used in the experiment and consequently in the regression analysis are between 7.3 and 542 mg/kg (see Table 2). However, the high  $R^2$  is considered to partially compensate this weakness.

### 3.2.3.2. Consumer exposure

For the current assessment, the exposure of consumers has been calculated following the methodology described in the most recent Guidance on the safety of feed additives for consumers (EFSA FEEDAP Panel, 2017b) (for further details see Appendix A), using the residue data reported in the residue study (see Section 3.2.3.1).

The exposure to formamide at the 95th percentile varied between 0.0017 mg/kg bw per day in the category 'elderly' and 0.0055 mg/kg bw per day in the category 'other children'.

The NOAEL identified for formamide (34 mg/kg bw and day) is by a factor of 20,000 and 6,200, respectively, higher than the estimated exposure of consumers.

### 3.2.3.3. Conclusions on the safety for the consumer

Based on the above, the FEEDAP Panel concludes that use of ammonium formate in feed for laying hens at the maximum use level of 2,000 mg/kg complete feed would not raise concerns on the safety for the consumers.

Considering the outcome of the previous opinion and the new data assessed above, the FEEDAP Panel concludes that use of ammonium formate in animal nutrition at the proposed conditions of use is safe for the consumers.

## 4. Conclusions

The FEEDAP Panel cannot conclude on the safety of ammonium formate in complete feed for laying hens and sows, since the calculated maximum concentration of formamide in feed (11.5 mg formamide/kg) exceeded the maximum safe concentration in feed for these species (5.6 mg formamide/kg for laying hens and 9.9 mg formamide/kg for sows).

The use of ammonium formate in diets of laying hens at the maximum use level of 2000 mg/kg is considered safe for the consumers. Considering also the outcome of the previous opinion, the FEEDAP Panel concludes that use of ammonium formate in animal nutrition at the proposed conditions of use is safe for the consumers.

## 5. Documentation as provided to EFSA/Chronology

Date	Event
09/04/2018	Dossier received by EFSA. Ammonium formate (E 295) submitted by Nutreco
02/05/2018	Reception mandate from the European Commission
22/05/2018	Application validated by EFSA – Start of the scientific assessment
18/03/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

## References

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## Abbreviations

ADI	acceptable daily intake
bw	body weight
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
NOAEL	no observed adverse effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
RAC	raw agricultural commodities
UF	uncertainty factor
WHO	World Health Organization

## 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, 2017b), 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<sup>10</sup> 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 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 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.

### Detailed results on chronic exposure calculation

**Table A.1:** Chronic dietary exposure per population class, country and survey (mg/kg bw per day) of consumers to formamide residues eggs of laying hens fed ammonium formate (containing 0.3% formamide) at the concentration of 2,000 mg formic acid equivalent/kg complete feed

Population class	Survey's country	Number of subjects	HRP <sup>(1)</sup>	HRP description
Infants	Bulgaria	523	0.00453	95th
Infants	Denmark	799	0.00100	95th
Infants	Finland	427	0.00000	95th
Infants	Germany	142	0.00116	95th
Infants	Italy	9	0.00000	50th
Infants	United Kingdom	1,251	0.00292	95th
Toddlers	Belgium	36	0.00258	90th
Toddlers	Bulgaria	428	0.00516	95th
Toddlers	Denmark	917	0.00226	95th
Toddlers	Finland	500	0.00178	95th
Toddlers	Germany	348	0.00318	95th
Toddlers	Italy	36	0.00295	90th
Toddlers	Netherlands	322	0.00372	95th
Toddlers	Spain	17	0.00408	75th
Toddlers	United Kingdom	1,314	0.00401	95th
Toddlers	United Kingdom	185	0.00355	95th

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

Population class	Survey's country	Number of subjects	HRP <sup>(1)</sup>	HRP description
Other children	Austria	128	0.00324	95th
Other children	Belgium	625	0.00261	95th
Other children	Bulgaria	433	0.00476	95th
Other children	Czech Republic	389	0.00340	95th
Other children	Denmark	298	0.00225	95th
Other children	Finland	750	0.00247	95th
Other children	France	482	0.00315	95th
Other children	Germany	293	0.00331	95th
Other children	Germany	835	0.00337	95th
Other children	Greece	838	0.00482	95th
Other children	Italy	193	0.00395	95th
Other children	Latvia	187	0.00287	95th
Other children	Netherlands	957	0.00326	95th
Other children	Netherlands	447	0.00284	95th
Other children	Spain	399	0.00395	95th
Other children	Spain	156	0.00552	95th
Other children	Sweden	1,473	0.00228	95th
Other children	United Kingdom	651	0.00269	95th
Adolescents	Austria	237	0.00200	95th
Adolescents	Belgium	576	0.00156	95th
Adolescents	Cyprus	303	0.00128	95th
Adolescents	Czech Republic	298	0.00199	95th
Adolescents	Denmark	377	0.00107	95th
Adolescents	Finland	306	0.00087	95th
Adolescents	France	973	0.00168	95th
Adolescents	Germany	393	0.00268	95th
Adolescents	Germany	1,011	0.00141	95th
Adolescents	Italy	247	0.00224	95th
Adolescents	Latvia	453	0.00224	95th
Adolescents	Netherlands	1,142	0.00170	95th
Adolescents	Spain	651	0.00277	95th
Adolescents	Spain	209	0.00355	95th
Adolescents	Spain	86	0.00145	95th
Adolescents	Sweden	1,018	0.00144	95th
Adolescents	United Kingdom	666	0.00154	95th
Adults	Austria	308	0.00114	95th
Adults	Belgium	1,292	0.00124	95th
Adults	Czech Republic	1,666	0.00140	95th
Adults	Denmark	1,739	0.00090	95th
Adults	Finland	1,295	0.00139	95th
Adults	France	2,276	0.00117	95th
Adults	Germany	10,419	0.00132	95th
Adults	Hungary	1,074	0.00153	95th
Adults	Ireland	1,274	0.00116	95th
Adults	Italy	2,313	0.00151	95th
Adults	Latvia	1,271	0.00194	95th
Adults	Netherlands	2,055	0.00134	95th
Adults	Romania	1,254	0.00181	95th
Adults	Spain	981	0.00163	95th
Adults	Spain	410	0.00165	95th

Population class	Survey's country	Number of subjects	HRP <sup>(1)</sup>	HRP description
Adults	Sweden	1,430	0.00183	95th
Adults	United Kingdom	1,265	0.00124	95th
Elderly	Austria	67	0.00123	95th
Elderly	Belgium	511	0.00112	95th
Elderly	Denmark	274	0.00103	95th
Elderly	Finland	413	0.00109	95th
Elderly	France	264	0.00098	95th
Elderly	Germany	2,006	0.00120	95th
Elderly	Hungary	206	0.00129	95th
Elderly	Ireland	149	0.00133	95th
Elderly	Italy	289	0.00118	95th
Elderly	Netherlands	173	0.00110	95th
Elderly	Netherlands	289	0.00117	95th
Elderly	Romania	83	0.00165	95th
Elderly	Sweden	295	0.00170	95th
Elderly	United Kingdom	166	0.00111	95th
Very elderly	Austria	25	0.00075	75th
Very elderly	Belgium	704	0.00121	95th
Very elderly	Denmark	12	0.00069	75th
Very elderly	France	84	0.00102	95th
Very elderly	Germany	490	0.00124	95th
Very elderly	Hungary	80	0.00136	95th
Very elderly	Ireland	77	0.00124	95th
Very elderly	Italy	228	0.00119	95th
Very elderly	Netherlands	450	0.00110	95th
Very elderly	Romania	45	0.00132	90th
Very elderly	Sweden	72	0.00214	95th
Very elderly	United Kingdom	139	0.00103	95th

bw: body weight.

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