SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Iodine compounds (E2) as feed additives for all species: calcium iodate anhydrous (coated granulated preparation), based on a dossier submitted by Doxal Italia S.p.A.¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)²,³

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The use of calcium iodate anhydrous as an iodine source is considered safe for all animal species/categories when used up to the currently authorised maximum content of total iodine in feed, with the exception of horses, cats and dogs, for which maximum tolerated levels are 3, 6 and 4 mg I/kg complete feed, respectively. Consumers exposure was calculated in two scenarios applying the currently authorised maximum iodine contents in feed and reduced contents. The iodine content of food of animal origin, if produced taking account of the currently authorised maximum iodine content in feed, would represent a substantial risk to high consumers. The risk would originate primarily from the milk consumption and to a minor extent from eggs consumption. The UL for adults (600 μg/day) would be exceeded by a factor of 2, and that for toddlers (200 μg/day) by a factor of 4. If the authorised maximum iodine concentrations for dairy cows and laying hens were reduced to 2 and 3 mg I/kg feed, respectively, the exposure of adult consumers would be below the UL. However, iodine intake in high-consuming toddlers would remain above the UL (1.6-fold). The formulated additive could pose a risk by inhalation to users. Notwithstanding the potential hazards identified for calcium iodate anhydrous, the preparation is non irritant to skin and eyes but may be a dermal sensitiser; coating may prevent the contact of the active substance to skin and eyes. The use of calcium iodate in animal nutrition is not expected to pose a risk to the environment. Calcium iodate is efficacious to meet iodine requirements. The FEEDAP Panel recommends the maximum iodine contents in complete feed be reduced: dairy cows/minor dairy ruminants, 2 mg I/kg; laying hens, 3 mg I/kg; horses, 3 mg I/kg; cats, 6 mg I/kg; dogs, 4 mg I/kg.

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KEY WORDS

Nutritional additive, compounds of trace elements, iodine, calcium iodate anhydrous, coated granulated preparation, safety, efficacy

¹ On request from the European Commission, Question No EFSA-Q-2011-00747, adopted on 14 March 2013.
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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Trace Elements, including Noël Albert Dierick, Jürgen Gropp, Alberto Mantovani, Joop de Knecht and the late Reinhard Kroker, for the preparatory work on this scientific opinion.

SUMMARY

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 safety and efficacy of calcium iodate, anhydrous (coated granulated preparation) as feed additive for all animal species.

The only known role of iodine in the metabolism is its incorporation into the thyroid hormones, thyroxine and triiodothyronine as well as the precursor iodothyrosines. Both hormones have multiple functions as regulators of cell activity (energy metabolism) and growth and as transmitters of nervous stimuli and play an important role in brain development.

The use of calcium iodate anhydrous as a source of iodine is considered safe for all animal species/categories when used up to the currently authorised maximum content of total iodine in complete feed, with the exception of horses, cats and dogs, for which maximum tolerated levels are 3, 6 and 4 mg I/kg complete feed, respectively.

The exposure of consumers was calculated in two scenarios applying the currently authorised maximum iodine contents in feed and reduced contents. The iodine content of food of animal origin, if produced taking account of the currently authorised maximum content of iodine in feed, would represent a substantial risk to high consumers. The risk would originate primarily from the consumption of milk and to a minor extent from consumption of eggs. The upper tolerable level (UL) for adults (600 µg/day) would be exceeded by a factor of 2, and that for toddlers (200 µg/day) by a factor of 4. If the maximum iodine concentrations in feed for dairy cows and laying hens were reduced to 2 and 3 mg I/kg feed, respectively, the exposure of adult consumers to iodine from food of animal origin would be below the UL. However, iodine intake in high-consuming toddlers would remain above the UL (1.6-fold).

The formulated additive could pose a risk by inhalation to users. Notwithstanding the potential hazards identified for calcium iodate anhydrous, the preparation is non irritant to skin and eyes but may be a dermal sensitisier. Coating may prevent the contact of the active substance to skin and eyes.

The use of calcium iodate in animal nutrition is not expected to pose a risk to the environment.

Calcium iodate is an efficacious source of iodine to meet animal requirements.

The FEEDAP Panel made some recommendations concerning the “Description of the additive”. The Panel also recommended that some of the currently authorised maximum iodine contents in complete feed be modified as follows: dairy cows and minor dairy ruminants, 2 mg I/kg; laying hens, 3 mg I/kg; horses, 3 mg I/kg; cats, 6 mg I/kg and dogs, 4 mg I/kg.
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BACKGROUND

Regulation (EC) No 1831/2003\(^4\) establishes the rules governing the Community authorisation of additives for use in animal nutrition. Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company Doxal Italia S.p.A.\(^5\) for re-evaluation of authorisation of the iodine-containing additive, calcium iodate anhydrous (film granulated preparation) when used as feed additive for all animal species (category: Nutritional additives; functional group: compounds of trace elements).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application.\(^6\) According to Article 8 of that Regulation, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. The particulars and documents in support of the application were considered valid by EFSA as of 8 December 2011.

The additive “Calcium iodate, anhydrous” had been authorised in the EU under the element Iodine-I for all animal species “Without a time limit” (Commission Regulation (EC) No 1459/2005).\(^7\) Following the provisions of Article 10(1) of Regulation (EC) No 1831/2003 the compounds were included in the EU Register of Feed Additives under the category “Nutritional additives” and the functional group “Compounds of trace elements”.\(^8\)

The FEEDAP Panel adopted an opinion on the use of iodine in feedingstuffs (EFSA, 2005). EFSA has issued opinions concerning the re-evaluation of calcium iodate anhydrous and potassium iodate (EFSA 2013a, 2013b, 2013c) and a new use of potassium iodate (EFSA, 2013c).

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and the efficacy of calcium iodate, anhydrous (coated granulated preparation), when used under the conditions described in Table 1.

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\(^5\) Doxal Italia S.p.A. Via Mascagni 6, 20050-Sulpia (MI) – Italy.

\(^6\) EFSA Dossier reference: FAD-2010-0370.


**Table 1:** Description and conditions of use of the additive as proposed by the applicant Doxal Italia S.p.A.

<table>
<thead>
<tr>
<th>Additive</th>
<th>Film granulated preparation of calcium iodate anhydrous</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration number/EC No/No (if appropriate)</strong></td>
<td>E 2</td>
</tr>
<tr>
<td><strong>Category(-ies) of additive</strong></td>
<td>Nutritional additives</td>
</tr>
<tr>
<td><strong>Functional group(s) of additive</strong></td>
<td>Compounds of trace elements</td>
</tr>
</tbody>
</table>

**Description**

<table>
<thead>
<tr>
<th>Composition, description</th>
<th>Chemical formula</th>
<th>Purity criteria (if appropriate)</th>
<th>Method of analysis (if appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodine (calcium iodate anhydrous - E2)</td>
<td>Ca(IO₃)₂</td>
<td>-</td>
<td>Iodometric titration against 0.1 N sodium thiosulphate in the presence of iodide</td>
</tr>
</tbody>
</table>

**Trade name (if appropriate)** | Not applicable |
| **Name of the holder of authorisation (if appropriate)** | Not applicable |

**Conditions of use**

<table>
<thead>
<tr>
<th>Species or category of animal</th>
<th>Maximum Age</th>
<th>Minimum content mg/kg of complete feedingstuffs</th>
<th>Maximum content</th>
<th>Withdrawal period (if appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Equine</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>4 mg/kg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>- Dairy cows</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>5 mg/kg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>- Fish</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>20 mg/kg</td>
<td>Not applicable</td>
</tr>
<tr>
<td>- Other species or categories</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>10 mg/kg</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Other provisions and additional requirements for the labelling**

- For use in animal nutrition only.
- For use in premixtures and in feedingstuffs.
- The additive shall contain minimum iodine in the form of calcium iodate (E2) prepared in order to limit dust emissions to a maximum of 2 mg (total dust) per filter (Stauber-Heubach test).

**Specific conditions or restrictions for handling (if appropriate)** | None |
| **Post-market monitoring (if appropriate)** | Not applicable |
| **Specific conditions for use in complementary feedingstuffs (if appropriate)** | None |

**Maximum Residue Limit (MRL) (if appropriate)**

<table>
<thead>
<tr>
<th>Marker residue</th>
<th>Species or category of animal</th>
<th>Target tissue(s) or food products</th>
<th>Maximum content in tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
**ASSESSMENT**

The FEEDAP Panel considers in the current opinion the highest dietary iodine levels tolerated by target animals in order to derive a safe maximum content of iodine in feed. It considers further the consequences of feeding iodine, at safe levels to the target animals, on consumer exposure to iodine resulting from the consumption of food of animal origin. The Panel examines if, and in which cases, the maximum content of iodine in feed should be further reduced to minimise the risk to consumers.

The Panel does not consider the use of iodine in animal nutrition as a tool to potentially increase the supply of iodine to that part of the population which might have a deficient or marginal intake.

This opinion is based in part on data provided by an applicant involved in the production/distribution of iodine-containing compounds. It should be recognised that these data cover only a fraction of the existing calcium iodate anhydrous.

1. **Introduction**

Iodine occurs in nature as iodide and iodate. Its mineral forms occur ubiquitously in igneous rocks and soils, most commonly as impurities in saltpetre and natural brines. Iodine is an essential trace element for animals and humans. The only known role of iodine in metabolism is its incorporation into the thyroid hormones, thyroxine (T\textsubscript{4}; 3,5,3',5'-tetraiodothyronine) and triiodothyronine (T\textsubscript{3}; 3,5,3'-triiodothyronine) as well as the precursor iodothyrosines. Both hormones have multiple functions as regulators of cell activity (energy metabolism) and growth and as transmitters of nervous stimuli and play an important role in brain development.

The application under assessment is for the use of the coated granulated calcium iodate anhydrous in feed for all animal species. The iodine compound, which is the subject of the assessment, has been submitted for re-evaluation.

A compilation of risk assessments carried out on iodine, including opinions from EFSA’s Panels other than the FEEDAP Panel, can be found in Appendix B. A list of authorisations of iodine in the EU, other than as feed additive, is reported in Appendix C.

EFSA commissioned the University of Gent (Belgium) to carry out a study of selected trace and ultratrace elements, and a technical report was subsequently submitted to EFSA (Van Paemel et al., 2010); iodine was included in this study. Information from this report has been used in the development of this opinion.

2. **Characterisation**

For compounds of trace elements, the element itself is considered the active substance.

The final formulation contains a precisely defined carrier granule to which the active agent, calcium iodate anhydrous, is fixed using filming agents (dispersants and non-ionic surfactants). The additive can be produced with different iodate contents. Products containing 1, 2, 5 and 10 % iodine are exemplarily introduced in the dossier; however, the product is typically produced to contain 10 % iodine.

2.1. **Identity of the additive**

The coated granulated preparation of the additive is based on calcium iodate (IUPAC name calcium diiodate; other name: lautarite), which is identified by the CAS number: 7789-80-2 and the EINECS number 232-191-3. It has a molecular weight of 389.88 Da and its chemical formula is Ca(IO\textsubscript{3})\textsubscript{2}. The final additive contains up to about 10 % iodine. The product consists further of coating agents and dispersants (polyoxyethylene (20) sorbitan monolaurate (E432), glycerol polyethylene glycol ricinoleate (E484), polyethylene glycol 300, sorbitol (E420ii), and maltodextrin) up to 5 % w/w, and feed materials (calcium magnesium carbonate, calcium carbonate, corn cobs) as granulating agents.
made up to 100 % w/w of the final preparation. The coat-granulating agents comply with the EU requirements for food additives and/or the European Pharmacopeia and/or JECFA specifications (see Appendix D).

Batch to batch consistency was demonstrated for two production series of a 10 % iodine-containing preparation. Nine and eleven batches showed mean iodine content of 10.3±0.3 % and 10.7±0.3 %, respectively.\textsuperscript{9}

2.2. Impurities

Analytical data of lead, cadmium, arsenic, and fluorine in three batches of formulated additive raised no concerns (Pb< 10, Cd< 2, As< 10, and F≤ 100 mg/kg).\textsuperscript{10} Mercury content (≤ 9 mg/kg)\textsuperscript{11} appears high; however, a second analysis of the same three batches resulted in <0.005 mg Hg/kg of the coated granulated preparation.\textsuperscript{12} Levels of dioxins (0.40 WHO-TEQ PCDD/F ng/kg) and the sum of dioxins and dioxin-like PCBs (0.42 WHO-TEQ PCDD/F PCB ng/kg) in one product batch were compliant with EU legislation.\textsuperscript{13} Control methods are in place.

2.3. Physical state of the final formulation

The product appears as gritty, free-flowing granulates of white-grey colour. Its bulk density is 1.43 g/cm\textsuperscript{3}.

Particle size distribution, analysed by laser diffraction in three batches, showed a median of 700 µm, with no particles of < 10 µm, up to 1.5% < 50 µm and up to 3.5% < 100 µm.\textsuperscript{14} The dusting potential, measured by the Stauber-Heubach method in 20 batches (the same used for demonstration of batch to batch consistency), was 0.013 g/m\textsuperscript{3}. The mechanical stability of the granules under compression (5 t/cm\textsuperscript{2}) was principally demonstrated, however dusting potential increased from 0.013 to about 0.042 g/m\textsuperscript{3}.

2.4. Characterisation of calcium iodate anhydrous

The calcium iodate anhydrous used for production of the formulated additive is a white/cream crystalline powder containing by specification a minimum of 63 % iodine. Analysis of 6 batches (produced in year 2010) showed iodine contents in the range of 63.6 to 64.7 %.\textsuperscript{15}

Analysis of the same batches showed that heavy metals, arsenic and the sum of dioxins and dioxin-like PCBs complied with the threshold set by Directive 2002/32.\textsuperscript{16}

Up to 99 % of particles (w/w) are of < 150 µm diameter.\textsuperscript{17} The dusting potential for calcium iodate anhydrous was measured as 3.5 g/m\textsuperscript{3}.\textsuperscript{18}

2.4.1. Manufacturing process

The additive is prepared by binding calcium iodate anhydrous onto the surface of the carrier granules coated with several formering agents and dispersants applied as liquids in a low shear granulation process. The coating agents create a “net” across the granule surface and thus capture the iodine
Calcium iodate anhydrous (film granulated preparation) for all species

compound. Material safety data sheets for the process ingredients and the final product were submitted.

2.5. Stability and homogeneity

Stability studies are generally not required for inorganic compounds of trace elements.

To test the homogenous distribution of the additive in premixtures and complete feed, one batch of the final product was incorporated via a premixture into two different formulations of a complete feed for pigs based on barley and cereals. The intended iodine content was 5 mg/kg complete feed. The analysis of ten subsamples each showed coefficients of variation between 4 and 8%.

2.6. Physico-chemical incompatibilities in feed

Based on current knowledge, no incompatibilities resulting from the use of calcium iodate anhydrous in compound feed are expected.

2.7. Conditions of use

The coated granulated calcium iodate anhydrous is intended to be used as a source of the trace element iodine for all animal species and categories up to a maximum total content of 10 mg I/kg complete feed, except for the following: dairy cows and laying hens, 5 mg I/kg complete feed; equines, 4 mg I/kg complete feed; and fish, 20 mg I/kg complete feed. The preparation could be added to compound feedingstuffs either directly or via premixtures.

2.8. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

EFSA has verified the EURL report as it relates to the methods used for the control of iodine (including calcium iodate anhydrous) in animal feed. The Executive Summary of the EURL report can be found in Appendix A.

3. Safety

3.1. Safety for the target species

3.1.1. Tolerance studies

Scientific committees (e.g. the National Research Council (NRC) in the USA and the Society of Nutrition Physiology (GfE) in Germany) have established iodine requirements for food-producing animals of between 0.16 (pigs) and 0.60 mg/kg DM (breeding sows) (see also Flachowsky, 2007). From a study of Wedekind et al. (2010) the requirement of cats can be derived as 0.46 mg I/kg diet. For growing and adult dogs, the NRC (2006) considered data from 1970 and 1975 and concluded that the requirement would be 0.175 mg I/1000 kcal ME; taking into account variation in energy intake and goitrogenic substances, an allowance of 125% of the requirement is recommended.

The upper tolerated levels of dietary iodine as previously published by the FEEDAP Panel (EFSA, 2005) are 5 mg/kg feed for laying hens, 3 mg/kg feed for horses, 4 mg/kg feed for dogs and 6 mg/kg feed for cats. No upper tolerance limits have been established for farmed fish; however, no effects have been observed at levels as high as 60 mg/kg feed. The iodine tolerance of pigs and fish is far above the EU regulations. The upper safe level for dairy cows, calves, chickens for fattening, turkeys, sheep, goat and rabbits could not be determined at that time by the FEEDAP Panel.

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19 Technical Dossier/Section II/Annex II_20_2.4.2.a.
20 It is noted that the entry for Laying hens in Table 1 is missing.
Since the first EFSA opinion on iodine (EFSA, 2005) only a few papers dealing with effects of iodine feed levels close to or at maximum authorised EU levels on animals have been published. Schöne et al. (2009) did not observe any adverse effect of a diet containing 10.1 mg I/kg DM as calcium iodate-hexahydrate when fed to lactating Holstein cows (11 months after calving, mean body weight 674 kg and average milk yield 22.1 kg/day) for only two weeks.

In a study carried out in cattle for fattening, in which iodine from calcium iodate at a level of 8.3 mg/kg feed DM and given until slaughter, zootechnical performance was not significantly different in supplemented animals (11 or 12 animals per treatment) and animals given unsupplemented feed (weight gain 1453, 1419 and 1343 g per day for 0.8, 3.5 and 8.3 mg I/kg DM, respectively). The weight of the thyroid gland increased significantly with the highest iodine dosage (32, 26 and 42 g per animal for 0.8, 3.5 and 8.3 mg I/kg DM, respectively) (Meyer et al., 2008). This increased thyroid weight, together with the lower weight gain, albeit non significant, supports the conclusion that the upper iodine level for cattle for fattening is near to the highest dose tested.

In a study in chickens for fattening comparing various levels of iodine supplementation (0, 1.0, 2.5 and 5 mg/kg feed) from two iodine sources (potassium iodide or potassium iodate) with a control feed (0.15 mg I/kg), Thyroid, offal and muscle showed a dose-dependent increase in iodine content, with levels in the group receiving the highest dietary iodine dose being significantly different to those of the control group. In another study, supplementation of a grower finisher diet for pigs with 8 mg I/kg feed resulted in a similar increase in the weight of the thyroid gland (Berk et al., 2008).

In another study in pigs (initial body weight 27 kg, final 115 kg) fed diets supplemented with iodine from calcium iodate anhydrous at 0, 0.5, 1.0, 2.0 and 5.0 mg/kg, no effects of iodine dose on zootechnical endpoints were observed (Franke et al., 2008). Supplementation with 5 mg I/kg significantly increased the weight of the thyroid gland (by 57%) compared with the unsupplemented control group (background 0.17 mg I/kg). Thyroid, offal and muscle showed a dose-dependent increase in iodine content, with levels in the group receiving the highest dietary iodine dose being significantly different to those of the control group. In another study, supplementation of a grower finisher diet for pigs with 8 mg I/kg feed resulted in a similar increase in the weight of the thyroid gland (Berk et al., 2008).

A study in chickens for fattening comparing various levels of iodine supplementation (0, 1.0, 2.5 and 5.0 mg I/kg feed) from two sources (potassium iodide and calcium iodate), did not show any adverse effect of iodine supplementation on performance and thyroid weight (Röttger et al., 2011). The data revealed a dose-dependent increase in iodine concentration in muscle, liver and thyroid gland.

In two dose-effect experiments conducted in laying hens, KI or Ca(IO₃)₂ was added in different quantities to feed (0, 0.25, 0.5, 2.5 and 5 mg/kg complete feed; measured data: 0.44, 0.75, 1.98, 2.44 and 4.01 mg I/kg). After four weeks of experimental feeding no effects on laying performance or the composition of the eggs (other than iodine concentration) were registered in the first study with 60 hens (Röttger et al., 2012). The second study was carried out as a long term experiment (164 days). Hens of two breeds (Lohmann Selected Light (white feathers) and Lohmann Brown (brown feathers); 432 hens each) were fed with or without 10% rapeseed cake as source of an iodine antagonist (glucosinolate content: 13.8 μmol/g) in the feed. The laying performance of hens was not significantly influenced by iodine supplementation. Rapeseed cake significantly reduced feed intake and daily egg mass production, but did not influence feed to egg mass ratio. Only in diets containing 10% rapeseed cake, which by itself increased thyroid weight, did iodine supplementation of 2.5 and 5 mg/kg feed result in a significant increase in thyroid gland weight (Röttger, 2012).

Forty-two healthy euthyroid castrated cats (14 males and 28 females; 1.6–13.6 years old) were fed a dry basal diet (0.23 mg/kg I) for a minimum of one month (pre-test) then switched to a different basal
diet supplemented with seven levels of potassium iodide for one year (experimental period) (Wedekind et al., 2010). The analysed iodine concentrations were 0.17, 0.23, 0.47, 1.1, 3.1, 6.9 and 8.8 mg I/kg DM diet. Response variables included iodine concentrations in serum, urine and faeces, urinary iodine:creatinine ratio, iodine balance, technetium-99m ($^{99}$Tc$^{m}$) pertechnetate thyroid:salivary ratio, complete blood count and serum chemistry parameters as well as serum thyroid hormone profiles. No significant changes in food intake, body weight or clinical signs were noted. Serum iodine, daily urinary iodine, daily faecal iodine and urinary iodine:creatinine ratio were linear functions of iodine intake.

3.1.2. Conclusions on the safety for target species

In the absence of new data, the FEEDAP Panel reiterates the maximum iodine levels in complete feed considered safe for target animals in 2005: higher than 60 mg/kg feed for farmed fish, 3 mg/kg feed for horses and 4 mg/kg feed for dogs. The newly published data on the iodine tolerance in cats do not invalidate the previous conclusion of the FEEDAP Panel that cats tolerate up to 6 mg I/kg complete feed.

Newer findings in chickens for fattening identified the highest dietary concentration tested (5 mg/kg) as safe for these target animals. The FEEDAP Panel does not expect that the currently authorised maximum level for chickens for fattening (10 mg/kg complete feed) poses concerns for the safety of these target animals. The upper safe level concluded in 2005 for laying hens (5 mg I/kg feed) was based on egg quality criteria. More recent findings applying increased thyroid weight as an endpoint do not essentially modify the former conclusion. This upper safe limit complies with current EU legislation.

In two studies in pigs for fattening no significant effects on the weight of the thyroid gland were observed at levels up to 8 mg I/kg feed. This observation is considered consistent with the currently established EU regulation for the maximum content of iodine in feed (10 mg I/kg) which is likely coincident with the upper tolerated level.

The available studies with dairy cows did not raise any concern over the safety of the currently established maximum content in feed (5 mg/kg). However, recent experimental data obtained in cattle for fattening also indicate that the currently established maximum iodine content in feed (10 mg/kg) coincides with the upper tolerated level.

The iodine tolerance of fish is above the current EU regulation (maximum content 20 mg I/kg complete feed for fish).

The FEEDAP Panel emphasises that the above estimates on the upper safe level, with the exception of fish, do not contain a margin of safety.

Finally, the FEEDAP Panel concludes that the use of calcium iodate anhydrous and potassium iodide as sources of iodine in animal nutrition is safe for all animal species/categories provided the above estimates of the upper tolerated levels of iodine in complete feed are respected.

3.2. Safety for the consumer

Iodine metabolism in food-producing animals is well-known and has been summarised by EFSA (2005). Owing to its physiological function the thyroid gland is the tissue with the highest iodine concentration, containing 60–90% of the body pool of the element.

3.2.1. Iodine deposition studies in food-producing animals

No specific studies were provided by the applicant. The FEEDAP Panel published a comprehensive review on tissue deposition of iodine (EFSA, 2005). In the current opinion only studies published after that opinion are reviewed. The FEEDAP Panel considers that, based on the available data, no
meaningful differences in bioavailability are expected among calcium iodate, potassium iodide or other inorganic iodine compounds. For consumer safety assessment, the available studies on iodine deposition in edible tissues and products after supplementation of feed with inorganic iodine compounds were considered together.
3.2.1.1. Ruminants

Dairy ruminants

Average values from bulk sample analysis of various European studies were between 100 and 200 µg I/L milk (EFSA, 2005). These values are generally confirmed by recent studies; for details see Tables E1 and E2 in Appendix E.

Values between 100 and 240 µg I/L milk (Haug et al. 2012) are also given in various Food Tables of North European countries (Norway: 190; Denmark: 243; Sweden: 140; Finland: 170; Iceland: 112 µg I/L). Much lower values (20 to 60 µg I/L cow milk) are given in the “Food Composition and Nutrition Tables” of Souci et al. (2008).

Only data from the Czech Republic (Kursa et al., 2004; Travnicek et al., 2006a) are higher (mean values 324 and 489 µg I/L milk, respectively), likely due to a specific feed supplementation program.

The data in Appendix E indicate that (i) milk produced by organic farming shows consistently lower iodine concentrations than milk from conventional farms and (ii) milk collected during the summer (outdoor feeding) shows lower iodine concentrations than winter samples (indoor feeding). Differences in feeding practices in summer and winter may contribute to the differences in iodine concentration in milk in summer and winter. Previous findings indicate that ambient temperatures also influence the iodine concentration in milk (which increases with increasing environmental temperature: Lengemann, 1979; Lengemann and Wentworth, 1979). The use of iodine as a disinfectant (udder hygiene, teat dipping, disinfection of the milking machine and other equipment) may also influence iodine content in milk (reviewed in EFSA, 2005; Flachowsky et al., 2007; Borucki Castro et al., 2012; see also Table E3 in Appendix E).

In its previous opinion (EFSA, 2005), the FEEDAP Panel also calculated the expected iodine concentrations in milk from feed intake using regression formulas taken from publications by Binnerts (1958) and Alderman and Stranks (1967). These results are not in accordance with more recent findings, likely because of the development of new analytical techniques (e.g. ICP-MS). In a study with 32 dairy cows, Franke et al. (2009) taking into consideration various influencing factors (e.g. two iodine sources, six iodine dosages, rape seed meal as source of glucosinolates) derived the following linear regression equations (x= mg I/kg feed dry matter, y= µg I/kg milk):

\[ y = 342.2x - 73.1 \quad (R^2 = 0.98): \text{ Low glucosinolate diet (without rapeseed meal, calcium iodate)} \]
\[ y = 298.3x - 64.0 \quad (R^2 = 0.97): \text{ Low glucosinolate diet (without rapeseed meal, potassium iodide)} \]
\[ y = 112.0x - 24.3 \quad (R^2 = 0.96): \text{ High glucosinolate diet (with rapeseed meal, calcium iodate)} \]
\[ y = 136.5x - 67.1 \quad (R^2 = 0.94): \text{ High glucosinolate diet (with rapeseed meal, potassium iodide)} \]

Table 2 summarises the expected iodine concentrations in milk based on the above equations.

**Table 2:** Milk iodine concentrations (µg/kg) at various feed concentrations of iodine considering different glucosinolate contents in complete feed of dairy cows (calculations based on regression equations by Franke, 2009 and Franke et al., 2009)

<table>
<thead>
<tr>
<th>Diet type</th>
<th>0.5</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>No glucosinolates</td>
<td>90</td>
<td>250</td>
<td>560</td>
<td>880</td>
<td>1200</td>
<td>1500</td>
</tr>
<tr>
<td>High glucosinolates(^1)</td>
<td>20</td>
<td>80</td>
<td>200</td>
<td>330</td>
<td>450</td>
<td>580</td>
</tr>
</tbody>
</table>

\(^1\)0.58 mmol glucosinolates/kg DM or 11.0-13.7 mmol glucosinolates/cow and day from rape seed.

The data in Table 2 also indicate that feed manufacturers do not make use of the high iodine feed supplementation as permitted by EU legislation, as already concluded by the FEEDAP Panel in the previous iodine opinion (EFSA, 2005). Considering the values observed in bulk milk, the mean
supplementation is not likely to exceed 2 mg iodine per kg DM. This conclusion is confirmed by a similar consideration based on German feed samples (Grünewald et al., 2006).

**Cattle for fattening**

The iodine content of beef muscles in the “Food Composition and Nutrition Tables” (Souci et al., 2008) was reported to be 20–70 μg/kg fresh weight, the value in liver being 140 μg/kg.

The effect of iodine supplementation on the iodine content of beef was investigated in a dose-response experiment with 34 growing/fattening German Holstein bulls with body weight ranging between 223 and 550 kg (Meyer et al., 2008). The animals were fed a maize silage/concentrate (free of glucosinolate) ration containing one of three iodine doses (0.79, 3.52 or 8.31 mg iodine per kg DM). After slaughtering, the iodine content of liver, kidney, meat (*M. longissimus dorsi*, *M. glutaeus medius*) and thyroid gland was determined by ICP-MS. Iodine concentration in muscle, liver and kidney (Table 3) showed a statistically significant dose-related increase. However, when considering absolute values for meat, the data confirmed the previous assessment by the FEEDAP Panel (EFSA, 2005) that meat is not a major source of dietary iodine for the consumer.

**Table 3:** Iodine concentration (μg/kg fresh weight) of meat (beef) and liver at various feed concentrations of iodine in complete feed of growing/fattening bulls (calculations based on data of Meyer et al., 2008)

<table>
<thead>
<tr>
<th>Food of animal origin</th>
<th>Iodine (mg/kg feed DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Meat (Beef)</td>
<td>25</td>
</tr>
<tr>
<td>Liver</td>
<td>75</td>
</tr>
<tr>
<td>Kidney</td>
<td>95</td>
</tr>
</tbody>
</table>

3.2.1.2. Pigs

The iodine content of pork meat in the “Food Composition and Nutrition Tables” (Souci et al., 2008) was reported to be 30–50 μg I/kg fresh matter, and of liver 140 μg I/kg fresh matter. Pork muscle from iodine-unsupplemented pigs is reported to contain about 28 μg I/kg fresh matter (Kaufmann and Rambeck, 1998; He et al., 2002).

Herzig et al. (2005) investigated the iodine concentration in pork meat collected from 18 herds in 10 districts of the Czech Republic during 2004, and found it to range from 5 to 66 μg I/kg, with an average of 26 μg I/kg.

Schöne et al. (2006), Berk et al. (2008) and Franke et al. (2008) found a close correlation between iodine supplementation and thyroid iodine stores, iodine concentration in blood serum, liver and meat (see also Table 4). It should be noted that the absolute values for iodine concentrations in meat are lower by one dimension than those in liver, independent of the level of dietary iodine.

**Table 4:** Iodine concentration (μg/kg fresh weight) of meat and liver at various feed concentrations of iodine in complete feed of growing/fattening pigs (calculations based on data of Berk et al., 2008 and Franke et al., 2008)

<table>
<thead>
<tr>
<th>Food of animal origin</th>
<th>Iodine (mg/kg feed DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Meat</td>
<td>5</td>
</tr>
<tr>
<td>Liver</td>
<td>60</td>
</tr>
</tbody>
</table>
3.2.1.3. Poultry

Chickens for fattening

The “Food Composition and Nutrition Tables” of Souci et al. (2008) do not contain data on the iodine concentration in meat and liver of poultry.

Two experiments were performed in chickens for fattening, using calcium iodate or potassium iodide (Röttger et al., 2011). In each experiment, 288 one-day-old broiler chickens were divided into four groups (72 birds/group) and fed diets supplemented with 0–5 mg I/kg feed. Six birds per group were slaughtered at 35 days: samples of blood, thyroid gland, liver, pectoral and thigh meat were taken. Results are summarised in Table 5.

Table 5: Iodine concentration (µg/kg fresh weight) of meat and liver at various feed concentrations of iodine in complete feed of growing/fattening broilers (calculations based on data of Röttger et al., 2011)

<table>
<thead>
<tr>
<th>Food of animal origin</th>
<th>Iodine (mg/kg feed DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>Meat</td>
<td>5</td>
</tr>
<tr>
<td>Liver</td>
<td>20</td>
</tr>
</tbody>
</table>

Since the highest iodine concentration was 5 mg/kg, the study does not allow extrapolations to iodine concentrations in edible tissues at the maximum EU authorised iodine concentrations in feed of 10 mg/kg.

Laying hens

The iodine content of eggs in the “Food Composition and Nutrition Tables” (Souci et al. 2008) was reported to be 85–100 µg/kg fresh weight.

Travnicek et al. (2006b) found a higher iodine content in eggs from large flocks (31.2 µg/egg; corresponding to 500 µg/kg fresh weight) than in eggs from small flocks (10 µg/egg; corresponding to 160 µg/kg fresh weight). The authors suggest that the differences may be caused by higher iodine supplementation in commercial compound feed used in large farms.

Röttger et al. (2012) fed diets (for details see Section 3.1.1) with iodine contents of between 0.44 and 4.01 mg/kg from potassium iodide or calcium iodate to hens (six per group) for four weeks. At the end of the experiment, the hens were slaughtered and samples were taken from various organs and tissues. Eggs were collected during the fourth week. The iodine concentration increased in all tissue samples, but the highest increase was found in eggs (from 144 to 1304 µg I/kg fresh weight). Comparative regression analyses showed that, at a similar iodine intake, iodine supplementation in the form of KI resulted in significantly higher iodine deposition in eggs than supplementation from Ca(IO₃)₂.

Röttger (2012) performed a long-term experiment (164 days) in laying hens (for details see Section 3.1.1) with four variables: two iodine sources (KI and Ca(IO₃)₂), five iodine concentrations in feed (unsupplemented, 0.25, 0.5, 2.5 and 5 mg/kg mixed feed), with and without glucosinolate-containing feed (10% rape seed cake in mixed feed), and two breeds. All the analysed factors had a certain influence on the iodine content of the eggs, which cannot be described in detail here. Table 6 summarises the influence of the iodine concentration of feed and rape seed cake as glucosinolate source on the iodine content of eggs. Insignificant differences were measured between iodine sources; Lohmann Brown hens laid eggs with significantly higher iodine content than eggs from Lohmann Selected Light.
**Table 6:** Iodine concentration (µg/kg fresh weight)\(^1\) of eggs produced by laying hens receiving various feed concentrations of iodine and considering different glucosinolate contents in complete feed (calculations based on data of Röttger, 2012 and Röttger et al., 2012)

<table>
<thead>
<tr>
<th>Diet type</th>
<th>Iodine (mg/kg feed DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td>No glucosinolates</td>
<td>300</td>
</tr>
<tr>
<td>With glucosinolates(^2)</td>
<td>200</td>
</tr>
</tbody>
</table>

\(^1\)Average from KI and Ca(IO\(_3\))\(_2\) supplementation and two hen breeds (see Röttger, 2012).

\(^2\)1.4 mmol/kg complete feed.

3.2.1.4. Fish

No data were available on the relation between dietary iodine and iodine deposition in flesh in farmed salmonids and other fish. Data from “Food Composition and Nutrition Tables” (Souci et al. 2008) are listed in Table E4 of Appendix E.

3.2.1.5. Conclusion on iodine deposition studies in food-producing animals

The content of iodine in animal tissues and products is related to the iodine intake and, thus, to the iodine concentration in the feed. In response to feed supplementation with iodine sources, the iodine level in edible tissues/products is generally found to be highest in milk and eggs, followed by kidney and liver, whereas in muscle tissue it is rather low. Dietary factors (e.g. glucosinolates), animal management practices (e.g. teat disinfection) and environmental conditions (temperature) may also influence the iodine deposition.

3.2.2. Toxicological studies

Excess iodine primarily causes hyperthyroidism and may trigger autoimmune thyroiditis especially in previously iodine-deficient populations and may eventually lead to goitre and hypothyroidism, especially in fetuses and people already suffering from thyroid problems (EC, 2002). Secondary effects include changes in the levels and metabolism of steroid hormones and amenorrhea.

Iodine compounds have generally produced negative results in mutagenicity assays. Results of epidemiological studies, in which the relationship between iodine intake and the incidence of thyroid cancer was investigated, suggest that high iodine intake may be a risk factor particularly in populations with previous iodine deficiency; this effect is related to tumour promotion resulting from chronic hormone imbalance in the gland tissue, whereas the available evidence does not indicate a direct carcinogenic effect of iodine.

The Scientific Committee on Food (SCF) established an upper intake level (UL) of 600 µg I/day for adults on the basis of the biochemical changes in thyroid-stimulating hormone (TSH) levels and the TSH response to thyrotropin-releasing hormone (TRH) administration, and applying an uncertainty factor of 3 (EC, 2002). This UL was also considered to be acceptable for pregnant and lactating women based on evidence of a lack of adverse effects at exposures significantly in excess of this level. Since there is no evidence of increased susceptibility in children, the ULs for children were derived by the SCF (EC, 2002) by adjustment of the adult UL on the basis of body surface area (body weight\(^{0.75}\), i.e. 200 µg I/day for toddlers.

3.2.3. Assessment of consumer safety

The FEEDAP Panel considers that the new studies on iodine in edible tissues and products do not modify substantially the deposition values used by EFSA (2005). However, the FEEDAP Panel considers that the consumers exposure assessment should be performed using the EFSA comprehensive food consumption database as well as the approach laid down in the FEEDAP guidance on consumer safety (EFSA, 2012).
Based on the assumptions of the FEEDAP Panel’s opinion on iodine in feed, up to 180 µg iodine/day may be provided by a consumption of 9 g iodised salt in adults (EFSA, 2005); the balance is given by food of animal origin, which represent the major iodine source for the general population. However, the contribution of supplements or special functional foods (seaweed) can be important in some groups, but it is currently difficult to assess.

The EFSA comprehensive food consumption database provides conservative figures for the intake of the main relevant food items (95th percentile, consumers only); in adults: meat 290 g/day, egg 70 g/day, milk 1.5 L/day, and in toddlers: meat 90 g/day, egg 35 g/day, milk 1.05 L/day.

According to the FEEDAP Panel’s guidance on consumer safety, the two food sources resulting in the highest iodine consumption figures should be used for estimating consumer exposure based on 95th percentile/consumers only figures. Food processing should be considered before estimating consumer exposure. Several publications indicate that milk pasteurization results in an approximate reduction in the iodine concentration of at least 27% (Wheeler et al., 1983; Aumont et al., 1987; Pedriali et al., 1997; Norouzian, 2011).

A further assumption is made regarding iodine concentration in milk, considering that about 50% of dairy cows receive diets containing rapeseed derived feed materials and taking into account the larger collection areas of dairy industries (Johner et al., 2012a). The FEEDAP Panel uses as iodine concentration in milk the average of the values calculated for low and high glucosinolate diets (Table 2). This assumption is further supported by the values observed in bulk milk throughout Europe (except in the Czech Republic) which are in the 60–250 µg/L range (see Tables D1 and D2), depending on feed, season and type of farming. According to Table 2, the outcome of the calculation at 2 mg total iodine in DM for dairy cows would be 380 µg I/L milk, indicating that the FEEDAP model is conservative. With a similar reasoning the values obtained in eggs from hens fed diets with or without glucosinolates can be averaged.

The following values are used for exposure scenarios: at 2 and 5 mg I/kg DM feed for dairy cow: 280 and 760 µg I/L milk (also considering a loss by pasteurisation), respectively; at 10 mg I/kg DM feed for cattle for fattening: 100 µg I/kg beef meat (pork meat is lower); at 3 and 5 mg I/kg feed for laying hens: 825 and 1300 µg I/kg egg.

The calculations identified that in both population groups, adults and toddlers, milk is by far the main source of iodine exposure, this being in agreement with consumption surveys (Gireli et al., 2004; Bader et al., 2005; Hampel et al., 2009; Johner et al., 2011, 2012a,b; Soriguer et al., 2011). In both groups of consumers, egg is the second largest iodine source of animal origin.

Based on the currently authorised maximum contents of total iodine in complete feed, the exposure of 95th percentile adult consumers from milk and eggs would be 1230 µg/day, which exceeds by more than twice the UL; reducing the maximum iodine concentrations for dairy cows from 5 to 2 mg/kg feed and for laying hens from 5 to 3 mg/kg feed would reduce the exposure of 95th percentile consumers to 480 µg/day. If adding 180 µg I/day from 9 g iodised salt per person and day, the maximum iodine intake would amount to 660 µg I/day.

In the case of toddlers, the analogous exposure of 95th percentile consumers from milk and eggs would result in an intake of 840 µg/day at the currently authorised maximum contents of total iodine in complete feed for cows and laying hens. This amount exceeds by more than four times the UL. Reducing the maximum iodine concentrations for dairy cows from 5 to 2 mg/kg feed and for laying hens from 5 to 3 mg/kg feed would reduce the exposure of 95th percentile consumers to 320 µg/day. For details on consumer exposure calculations, see Appendix F.

The FEEDAP Panel reiterates its above statement that the exposure data are based on a conservative consumption model that includes high consumers only and which assume that all feed compounders use the maximum authorised iodine content in complete feed. Except in areas adopting specific...
programmes of feed supplementation, such as the Czech Republic (reported iodine concentrations in milk of about 500 µg I/L milk: Travnicek et al., 2011), practical supplementation levels in dairy ruminants would probably not exceed 2 mg iodine per kg DM, depending also on the goitrogen content of feed materials. This conclusion is confirmed by similar considerations based on German feed samples (Grünewald et al., 2006). A consideration of the values observed in bulk milk throughout Europe (60–250 µg/L milk; see Tables E1 and E2) and the model developed by Franke et al. (2009) indicates (see also Table 2) that maximum supplementation levels in practice would be 1 mg/kg (low-glucosinolate feed) and somewhat higher than 2 mg/kg (high-glucosinolate feed).

The FEEDAP Panel also notes that iodine-deficient populations are recognised as more susceptible to iodine excess (EC, 2002) and that there are indications of persisting subclinical iodine deficiency in Europe, particularly among some sub-groups such as pregnant women, children and consumers of organic products (Bath et al., 2011; Vanderpump et al., 2011; Zimmermann and Andersson, 2011; Andersson et al., 2012; Raverot et al., 2012).

Recent biomonitoring studies in humans, based on urinary iodine as an established biomarker, do not indicate that the EU population is generally exposed to excess levels of iodine (Gireli et al., 2004; Remer et al., 2006; Remer, 2007; Thamm et al., 2007; Mazzarella et al., 2009; Anderson et al., 2010; Hampel et al., 2010; Hilty and Zimmermann, 2011; Raverot et al., 2012).

3.2.4. Conclusions on consumer safety

The iodine content of food of animal origin, if produced from animals receiving the currently authorised maximum contents of total iodine in complete feed for dairy cows and laying hens (5 mg/kg), would represent a substantial risk to consumers, mainly for high-consuming (95th percentile) adults and toddlers. The risk would originate primarily from the consumption of milk and, to some extent, from consumption of eggs. The ULs would for adults be exceeded by a factor of 2 (1230 vs. 600 µg I/day), and for toddlers by a factor of 4 (840 vs. 200 µg I/day).

Exposure of adult consumers to iodine from foods of animal origin would be below the UL (480 vs 600 µg I/day) if the maximum iodine concentrations in feed for dairy cows and laying hens are reduced to 2 and 3 mg I/kg feed, respectively. However, iodine intake would remain above the UL (1.6-fold) for high-consuming toddlers (320 vs. 200 µg I/day). 21

3.3. Safety for the users/workers

3.3.1. Inhalation

Data on inhalation toxicity were not available. The potential for inhalation exposure is very low (about 0.013 g final preparation/m³ ~ 0.001 g iodine/m³ under the conditions of the Stauber Heubach test). Based on the scenario for inhalation exposure in a premixture factory (EFSA, 2012), assuming that all premixture batches were prepared with the additive, the iodine inhaled during a 8 hour working day could amount to 1.25 mg/person. The Agency for Toxic Substances and Disease Registry (ATSDR) could not derive a minimum risk level for iodine inhalation exposure because of a lack of information on dose response relationships for the inhalation pathway (ATSDR, 2004). The conservatively calculated daily amount of inhaled iodine (0.8 mg) exceeds the UL for oral daily intake (0.6 mg/adult person). Despite its low dusting potential, the formulated additive could pose a risk by inhalation to users.

3.3.2. Irritation

The potential of the additive (10% iodine) to cause dermal and eye irritation was studied initially in vitro followed by an in vivo assay. A three dimensional human epidermis model and the application of

21 An iodine exposure of toddlers at the level of the UL would be achieved only if iodine for dairy cows fed glucosinolates-free diets were reduced further to 1 mg I/kg DM.
500 mg of the additive to the skin of three rabbits (OECD 404) identified the additive as non-irritant to skin. The Bovine Corneal Opacity and Permeability assay and the ocular instillation of 100 mg of the additive to one eye of each of three rabbits (OECD 405) identified the additive as non-irritant to eyes.

Calcium iodate anhydrous is coated by film granulation, which gives further assurance of users/workers safety by reducing the contact of the active substance to skin and eyes.

3.3.3. Sensitisation

No data on skin sensitisation by the additive were provided. In the absence of data, calcium iodate should be considered as dermal sensitiser.

3.3.4. Conclusion on the safety for the users/workers

The formulated additive could pose a risk by inhalation to users. Notwithstanding the potential hazards identified for calcium iodate anhydrous, the preparation is non irritating to skin and eyes but may be a dermal sensitiser. Coating may prevent the contact of the active substance to skin and eyes.

3.4. Safety for the environment

Iodine is a naturally occurring element. Its content in soil depends on geological origin. The lowest iodine concentrations are found in granites, and the highest in boulder clay (Anke et al., 1993). The iodine content ranges from 6 to 10 mg/kg in soils derived from igneous rocks, from 2.2 to 4.5 mg/kg in soils derived from sedimentary rocks and is approximately 5 mg/kg in soils from all types of metamorphic rocks. In soils from Germany, the iodine content was 2.4 mg/kg in a loam soil, 3.2 mg/kg in a sandy loam soil, 3.6 mg/kg in a loamy sand soil and 1.8 mg/kg in sand. In Ireland, peaty soil contained 32 mg iodine/kg, whereas soil derived from limestone and red sandstone contained 3.5 and 2.4 mg iodine/kg, respectively (Anonymous, 1956). The iodine concentration in 42 soils in County Wexford (Ireland) ranged from 3 to 30 mg/kg. Loam and clay loam soils had consistently higher values than loamy sand and sandy loam soils. The average iodine concentration in soil increased in the order: loamy sand (3.73 mg/kg) < sandy loam (4.74 mg/kg) < sandy clay loam (6.26 mg/kg) < loam (12.17 mg/kg) < clay loam (19.01 mg/kg). The iodine concentration was not related to the distance from the sea (McGrath and Fleming, 1988). In rainwater the iodine concentration is around 1 μg/L.

The forms of aqueous iodine found in natural environments depend on pH and electrochemical potential ($E_h$). The dominant forms are the inorganic species iodate ($\text{IO}_3^-$), iodide ($\text{I}^-$), and molecular iodine ($\text{I}_2$). Thermodynamically, under typical pH and $E_h$ ranges found in natural soil environments, $\text{I}^-$ ion should be the most prevalent phase. While $\text{IO}_3^-$ exists under more oxidising conditions. Soil solution measurements support thermodynamic predictions in that $\text{I}^-$ ion is the prevalent form in soil solutions under most conditions and $\text{IO}_3^-$ is usually present only in soil solutions associated with oxidised conditions found in alkaline desert soils. Aqueous dissolved $\text{I}^-$ ion in soil sorbs to clays, hydrous oxides, and soil organic matter, with sorption generally increasing with decreasing pH. In alkaline soils, $\text{I}^-$ ion is mobile and has even been evaluated as an inert tracer in soil water studies (as reviewed by Mackowiak et al., 2005).

In culture studies on rice (Oryza sativa), a nutrient solution containing 1.7 mg $\text{IO}_3^-$ per litre had no effect on rice biomass but 17 mg $\text{IO}_3^-$ per litre had a small negative effect (Mackowiak and Grossl, 1999). There are few data available on the toxicity of any of the iodine species to soil and aquatic organisms. In general, iodate appears to be less toxic than iodide.

Fish appear not be very sensitive to $\text{I}^-$ ion and $\text{IO}_3^-$, with species average LC$_{50}$ values in rainbow trout of 4190 and 336 mg/L, respectively (US EPA Ecotox Database; Laverock et al., 1995). Daphnia magna is more sensitive to $\text{I}^-$ ion (species average 48h LC$_{50}$ of 0.84 mg/L) than to $\text{IO}_3^-$ (species average 48h LC$_{50}$ of 72 mg/L) (US EPA Ecotox Database; Laverock et al., 1995). Several other

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22 Available from http://cfpub.epa.gov/ecotox/ecotox_home.cfm
species are similarly tolerant to $\Gamma^-$ ion, the 24h LC$_{50}$ value in zebra mussel being 226 mg/L and the no observed effect concentration (NOEC) for bluegreen algae (Scenedesmus quadricauda) being 66 mg/L (Bringmann and Kuhn, 1978). In contrast to elemental iodine, iodide and iodate have very low antibacterial activity.

Iodine from iodide or iodate in feed can enter the environment via direct excretion of manure or urine on pasture or spreading of sludge and slurry collected from intensively reared animals. Based on the calculation method provided in the technical guidance on environmental risk assessment (EFSA, 2008), the highest increase of iodine in soil is around 180 μg/kg after a one-year application of manure from pigs from fattening assuming that 100% of the intake via feed will be excreted. This concentration is well below the background concentration and is therefore not expected to pose an environmental risk.

3.4.1. Conclusions on safety for the environment

The use of calcium iodate and potassium iodide in animal nutrition will not increase the iodine concentration in the environment considering the background concentration of iodine in the different compartments. It is not expected to pose a risk to the environment.

4. Efficacy

Iodine is an established essential trace element (Mc Dowell, 2003; Suttle, 2010). Efficacy trials are not required for compounds of trace elements already authorised as feed additives.

The applicant provided an in vitro study to demonstrate the availability of iodine from the coated granulated additive. The dissolution of the active compound from the coated granulated form was compared with that from calcium iodate anhydrous after 1, 2, 5 and 10 minutes in buffer solutions at pH values of 3.0, 6.0 and 7.4. No differences in water iodine concentrations were observed between the formulated additive and calcium iodate anhydrous. It can therefore be concluded that the coated granulated additive effectively releases the iodine salt under the various pH conditions occurring in gastrointestinal tract.

4.1. Conclusions on efficacy

Iodine is an established essential trace element. The use of calcium iodate anhydrous as iodine source in animal nutrition is extensively documented in scientific literature. Iodate is released in the gastrointestinal tract. The coated granulated calcium iodate anhydrous is efficacious to meet the animal needs of iodine. The additive under application does not require further confirmation of efficacy.

5. Post-market monitoring

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

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The use of calcium iodate anhydrous as source of iodine is considered safe for all animal species/categories when used up to the currently authorised maximum content of total iodine in

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23 Technical Dossier/Section IV/Annex IV_1_4.1.2.a.
complete feed, with the exception of horses, cats and dogs, for which maximum tolerated levels are 3, 6 and 4 mg I/kg complete feed, respectively.

The iodine content of food of animal origin, if produced taking account the use of the currently authorised maximum content of total iodine in complete feed, would represent a substantial risk to consumers, mainly high-consuming adults and toddlers. The risk would originate primarily from the consumption of milk and, to some extent, from consumption of eggs. The UL for adults would be exceeded by a factor of 2 and for toddlers by a factor of 4. If the authorised maximum iodine concentrations in feed for dairy cows and laying hens were reduced to 2 and 3 mg I/kg feed, respectively, the exposure of adult consumers to iodine from food of animal origin would be below the UL. However, iodine intake in high-consuming toddlers would remain above the UL (1.6-fold).

The formulated additive could pose a risk by inhalation to users. Notwithstanding the potential hazards identified for calcium iodate anhydrous, the preparation is non irritant to skin and eyes but may be a dermal sensitiser. Coating may prevent the contact of the active substance to skin and eyes.

The use of calcium iodate in animal nutrition is not expected to pose a risk to the environment.

Calcium iodate is an efficacious source of iodine to meet animal requirements.

**RECOMMENDATIONS**

The FEEDAP Panel recommends the following improvement in the description of the additive under application: The denomination of the additive should be changed to “Coated granulated calcium iodate anhydrous” to describe a distinctive identity.

The authorisation should reflect the real iodine content of the additive (1, 2, 5 or 10 %).

Based on considerations of animal and consumer safety, the FEEDAP Panel recommends to modify some of the currently authorised maximum iodine contents in complete feed as follows:

- dairy cows and minor dairy ruminants: 2 mg I/kg complete feed
- laying hens: 3 mg I/kg complete feed
- horses: 3 mg I/kg complete feed
- cats: 6 mg I/kg complete feed
- dogs: 4 mg I/kg complete feed

To prevent the release of elemental iodine under the acidic conditions of the stomach by the comproportionation reaction, the simultaneous use of different iodine sources should be avoided.

Regarding the outcome of the risk assessment in toddlers, the FEEDAP Panel recommends that the consequences of a potential reduction in the iodine content of feed should be accompanied by biomonitoring the iodine status of toddlers.

**DOCUMENTATION PROVIDED TO EFSA**

3. Evaluation report of the European Union Reference Laboratory for Feed Additives on the methods(s) of analysis for Iodine.
4. Comments from Member States received through the ScienceNet.
REFERENCES


Bringmann G and Kuhn R, 1978. Limiting values for the noxious effects of water pollutant material to blue algae (Microcystis aeruginosa) and green algae (Scenedesmus quadricauda) in cell propagation inhibition tests (Grenzwerte der Schadwirkung). Wasser, 50, 45–60


EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2013a. Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species: calcium iodate anhydrous and potassium iodide, based on a dossier submitted by Ajay Europe SARL. EFSA Journal 2013;11(2):3099

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2013b. Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species: calcium iodate anhydrous, based on a dossier submitted by Calibre Europe SPRL/BVBA. EFSA Journal 2013,11(2):3100.

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2013c. Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all species: calcium iodate anhydrous and potassium iodide, based on a dossier submitted by HELM AG. EFSA Journal 2013,11(2):3101.


Franke K, 2009. Effect of various iodine supplementations and species on the iodine transfer into milk and on serum, urinal and faecal iodine of dairy cows fed rations varying in the glucosinolate content. Thesis (PhD), Martin-Luther-University Halle-Wittenberg, Germany. 120 pp.


Calcium iodate anhydrous (film granulated preparation) for all species


APPENDICES

APPENDIX A

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Iodine

In the current application authorisation is sought under articles 4(1) and 10(2) for Potassium iodide and Calcium iodate anhydrous under the category/functional group (3b) "nutritional additives"/"compounds of trace elements", according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additives for all categories and species.

According to the Applicants Potassium iodide is a white to yellow crystalline powder with a minimum content of 67 % total iodine and 21 % potassium, while Calcium iodate anhydrous is a white crystalline powder with a minimum content of 63 % total iodine and 10 % calcium.

The feed additives are intended to be incorporated into premixtures, feedingstuffs and water (only for KI). All Applicants proposed the maximum total iodine levels in feedingstuffs set in the previous legislation: 4 mg/kg for equine; 5mg/kg for dairy cows and laying hens; 20 mg/kg for fish and 10 mg/kg for other species and categories.

For the characterisation of Potassium iodide in the feed additive, Applicants (FAD-2010-0148 and FAD-2010-0231) suggested the titrimetric method described in the European Pharmacopoeia (Eur.Ph. 6 01/2008:0186) and in the Food Chemicals Codex (FCC) monographs. For the characterisation of Calcium iodate in the feed additive, all Applicants suggested the same titrimetric method, based on the iodate conversion to tri-iodide as described in the European Pharmacopoeia (Eur.Ph. 6 01/2008:20504) and in the FCC monographs. Even though no performance characteristics are available, the EURL recommends for official control the titrimetric methods described in the European Pharmacopoeia and the FCC monographs for the characterisation of Potassium iodide and Calcium iodate in the feed additives.

For the quantification of total calcium and total potassium in the feed additives, the EURL identified two ring-trial validated methods - EN ISO 6869:2000, based on atomic absorption spectrometry (AAS) after dilution in hydrochloric acid; and - EN 15510:2007, based on inductively coupled plasma atomic emission spectrometry (ICP-AES) after dilution in hydrochloric acid, for which relative precisions were reported ranging from 4 to 25 %. Based on these performance characteristics, the EURL recommends for official control the two methods (EN ISO 6869:2000 and EN 15510:2007) for the quantification of total calcium and total potassium in the feed additives.

For the quantification of total iodine in premixtures and feedingstuffs, Applicant (FAD-2010-0148) submitted the ring-trial validated CEN method EN 15111:2007 designed for the quantification of iodine in foodstuffs by inductively coupled plasma mass spectrometry (ICP-MS). The following

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performance characteristics are reported for a total iodine concentration ranging from 0.2 to 40 mg/kg:

- a relative standard deviation for \textit{repeatability} (RSD_r) ranging from 0.7 to 7.8 \%; and
- a relative standard deviation for \textit{reproducibility} (RSD_R) ranging from 6.2 to 19 \%.

The Applicant applied the above mentioned CEN method to analyse \textit{premixtures} and two \textit{feedingstuffs} (including a mineral feed) containing \textit{Potassium iodide} or \textit{Calcium iodate} with iodine concentrations ranging from 4 to 1000 mg/kg. The reported recovery rates range from 95 to 105 \% while the reported relative precisions (ranging from 2 to 15\%) are in good agreement with those of the EN 15111:2007 method. This demonstrates the applicability (cf. extension of scope) of the CEN method to \textit{premixtures} and \textit{feedingstuffs}. Based on the experimental evidence provided, the EURL recommends for official control the EN 15111:2007 method for the quantification of \textit{total iodine} in \textit{premixtures} and \textit{feedingstuffs}.

Applicant FAD-2010-0231 provided no experimental data for the quantification of \textit{total iodine} in \textit{water}. Hence, the EURL could not evaluate nor recommend any method for official control to determine \textit{total iodine} in \textit{water}.

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

List of Risk Assessment Reports on iodine

Besides the reports cited in the Background section, risk assessments from other EU bodies and Institutions have been carried out (see list below).

1. EC Health and Consumers Scientific Committees Opinions

Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine. (http://ec.europa.eu/food/fs/sc/scf/out146_en.pdf)

2. EU Risk Assessment Reports


3. EFSA-NDA Panel Opinions

Scientific Opinion on the substantiation of health claims related to iodine and thyroid function and production of thyroid hormones (ID 274), energy-yielding metabolism (ID 274), maintenance of vision (ID 356), maintenance of hair (ID 370), maintenance of nails (ID 370), and maintenance of skin (ID 370) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 - EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (http://www.efsa.europa.eu/en/efsajournal/pub/1214.htm)


Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) and improved bioavailability of nutrients (ID 384, 1728, 1752, 1755), energy and nutrient supply (ID 403, 413, 457, 487, 667, 1675, 1710, 2901, 4496) and presence of a nutrient in the human body (ID 720) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 - EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (http://www.efsa.europa.eu/en/efsajournal/pub/1743.htm)

Scientific Opinion on the substantiation of health claims related to iodine and contribution to normal cognitive and neurological function (ID 273), contribution to normal energy-yielding metabolism (ID 402), and contribution to normal thyroid function and production of thyroid hormones (ID 1237) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 - EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (http://www.efsa.europa.eu/en/efsajournal/pub/1800.htm)
APPENDIX C

List of authorisations of iodine compounds other than feed additive

The following iodine compounds are authorised for use in food (Regulation (EC) No 1170/2009): sodium iodide, sodium iodate, potassium iodide and potassium iodate which may be used in the manufacture of food supplements and may be added to food.

The following iodine compounds can be used for the manufacturing of dietetic foods (Commission Regulation (EC) No 953/2009): sodium iodide, sodium iodate, potassium iodide and potassium iodate.

The following iodine compounds can be used for the manufacturing of processed cereal-based foods and baby foods for infants and young children (Commission Directive 2006/125/EC): sodium iodide, sodium iodate, potassium iodide and potassium iodate.

The following iodine compounds are listed in Table 1 of the Annex of Regulation 37/2010 as Allowed substances, no MRL required: 3,5-Diiodo-L-thyrosine, iodine and iodine inorganic compounds (sodium iodide, sodium iodate, potassium iodide, potassium iodate and iodophors including polyvinylpyrrolidoneiodine) and iodine organic compounds such as iodoform.

The following iodine compounds are listed in Annex of Commission Implementing Regulation (EU) No 540/2011 as “Active substances approved for use in plant protection products”: 6-iodo-2-propoxy-3-propylquinoxalin-4(3H)-one, 4-iodo-2-[3-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)ureidosulfonyl]benzoate and 4-hydroxy-3,5-di-iodobenzonitrile.

The following iodine compounds are “Active substances identified as existing” listed in Annex I of the Commission Regulation (EC) No 1457/2007: iodoform/triiodomethane, iodine, iodine in the form of iodophor, iodine complex in solution with non-ionic detergents, polyvinylpyrrolidione iodine, alkylaryl polyether alcohol-iodine complex, iodine complex with ethylene-propylene block co-Polymer (pluronic), iodine complex with poly alkylenglycol, iodinated Resin/polyiodide Anion Resin, potassium iodide, iodine monochloride, p-[(diiodomethyl)sulphonyl]toluene, 3-iodo-2-propynyl butylcarbamate and quaternary ammonium iodides. According to Annex II of the same Regulation, the following iodine compounds are “Active substances to be examined under the review programme”: iodine, p-[(diiodomethyl)sulphonyl] toluene, 3-iodo-2-propynyl butylcarbamate, quaternary ammonium iodides and polyvinylpyrrolidone iodine.

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The following iodine compounds will not be added to the Annex I, IA or IB of the Directive 98/8/EC according to the Commission Decision of 14 October 2008: iodine, p-[(diodomethyl)sulphonyl] toluene and quaternary ammonium iodides.

The following iodine compounds can be used for cosmetic purposes (Regulation (EC) No 1223/2009 of the European Parliament and of the Council): Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl) benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigment; and 3-Iodo-2-propynylbutylcarbamate. However, the following iodine compounds are prohibited in cosmetic products use, under the above mentioned Regulation: [4-(4-hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid (Tiratricol (INN)) and its salts, piprocurarium iodide (INN), N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisoproplammonium salts, e. g. isopropamide iodide (INN), furfuryltrimethylammonium salts, e. g. furtrethonium iodide (INN), iodine, gallamine triethiodide (INN), 5,5′-Di-isopropyl-2,2′-dimethylbiphenyl-4,4′-diyl dihypoiodite (thymol iodide), trifluoriodomethane, iodomethane (methyl iodide), 4,4′-thiodianiline and its salts.

According to the Annex of Regulation (EC) No 432/2012 the following health claims can be made only for food which is at least a source of iodine as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006: iodine contributes to normal cognitive function, iodine contributes to normal energy-yielding metabolism, iodine contributes to normal functioning of the nervous system, iodine contributes to the maintenance of normal skin and iodine contributes to the normal production of thyroid hormones and normal thyroid function.

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APPENDIX D

SPECIFIC PURITY CRITERIA FOR THE COAT-GRANULATING AGENTS

Polyoxylethylene (20) sorbitan monolaureate (E432) meets the purity criteria defined in Commission directive 98/86/EC.\textsuperscript{12}

Glycerol polyethyleneglycol ricinoleate (E484) meets the purity criteria specified in the United States Pharmacopoeia entry for Polyoxyxl 35 castor oil and the European Pharmacopoeia entry for macrogolglyceryl ricinoleate (monograph 01/2005:1082).

Polyethylene glycol 300 comprises 100% polyethylene glycol in accordance with Ph Eur monograph 1444 and JECFA Monograph 316.

Sorbitol meets the purity criteria specified for sorbitol liquid in Commission Directive 95/31/EC.\textsuperscript{13}

Maltodextrin (food grade) has the specific purity criteria SO\textsubscript{2} max 10 mg/kg and heavy metals max 0.5 mg/kg.


APPENDIX E

Iodine in milk and fish. Data from recent literature

Table E1: Influence of type of farming on the iodine content of bulk milk (µg/kg) in some European studies

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Country</th>
<th>Type of farming</th>
<th>Remarks</th>
<th>Organic</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rey Crespo et al. (2012)</td>
<td>Spain</td>
<td></td>
<td></td>
<td>78</td>
<td>157</td>
</tr>
<tr>
<td>Bath et al. (2012)</td>
<td>UK</td>
<td></td>
<td></td>
<td>144</td>
<td>250</td>
</tr>
<tr>
<td>Johner et al. (2012)</td>
<td>Germany</td>
<td></td>
<td></td>
<td>58</td>
<td>112</td>
</tr>
<tr>
<td>Köhler et al. (2012)</td>
<td>Germany</td>
<td></td>
<td></td>
<td>92</td>
<td>143</td>
</tr>
<tr>
<td>Rozenska et al. (2011)</td>
<td>Czech Republic</td>
<td></td>
<td></td>
<td>302</td>
<td>350</td>
</tr>
</tbody>
</table>

Table E2: Influence of summer (outdoor, grazing) and winter (indoor) animal feeding/keeping on the iodine content of bulk milk (µg/kg) in some European studies

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Country</th>
<th>Type of animal feeding/keeping</th>
<th>Remarks</th>
<th>Outdoor</th>
<th>Indoor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travnicek et al. (2006)</td>
<td>Czech Republic</td>
<td>Outdoor</td>
<td></td>
<td>351</td>
<td>494</td>
</tr>
<tr>
<td>Paulikova et al. (2008)</td>
<td>Slovakia</td>
<td>Outdoor</td>
<td>Cow milk</td>
<td>155</td>
<td>127</td>
</tr>
<tr>
<td>Paulikova et al. (2008)</td>
<td>Slovakia</td>
<td>Outdoor</td>
<td>Sheep milk</td>
<td>56</td>
<td>198</td>
</tr>
<tr>
<td>Paulikova et al. (2008)</td>
<td>Slovakia</td>
<td>Outdoor</td>
<td>Goat milk</td>
<td>48</td>
<td>89</td>
</tr>
<tr>
<td>Hampel et al. (2009)</td>
<td>Germany</td>
<td>Outdoor</td>
<td></td>
<td>108</td>
<td>134</td>
</tr>
<tr>
<td>Rozenska et al. (2011)</td>
<td>Czech Republic</td>
<td>Outdoor</td>
<td>Sheep milk</td>
<td>38</td>
<td>72</td>
</tr>
<tr>
<td>Soriguier et al. (2011)</td>
<td>Spain</td>
<td>Outdoor</td>
<td></td>
<td>247</td>
<td>270</td>
</tr>
<tr>
<td>Rey Crespo et al. (2012)</td>
<td>Spain</td>
<td>Outdoor</td>
<td>Organic farming</td>
<td>35</td>
<td>73</td>
</tr>
<tr>
<td>Haug et al. (2012)</td>
<td>Norway</td>
<td>Outdoor</td>
<td></td>
<td>92</td>
<td>122</td>
</tr>
<tr>
<td>Johner et al. (2012)</td>
<td>Germany</td>
<td>Outdoor</td>
<td></td>
<td>87</td>
<td>110</td>
</tr>
</tbody>
</table>

Table E3: Influence of iodine concentration of teat-disinfectant and application form on the increase of iodine concentration of milk by various authors

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Available iodine in disinfectants (g/L)</th>
<th>Application of disinfectants</th>
<th>Increase of iodine in milk (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galton et al. (1986)</td>
<td>1</td>
<td>A</td>
<td>35</td>
</tr>
<tr>
<td>Ryssen et al. (1985)</td>
<td>2</td>
<td>A</td>
<td>11-60</td>
</tr>
<tr>
<td>Berg and Padgitt (1985)</td>
<td>2.5</td>
<td>A</td>
<td>7</td>
</tr>
<tr>
<td>Rasmussen et al. (1991)</td>
<td>2.5</td>
<td>A</td>
<td>54</td>
</tr>
<tr>
<td>Rasmussen et al. (1991)</td>
<td>2.5</td>
<td>B/A</td>
<td>69</td>
</tr>
<tr>
<td>Falkenberg et al. (2002)</td>
<td>2.7</td>
<td>B</td>
<td>30</td>
</tr>
<tr>
<td>Flachowsky et al. (2007)</td>
<td>3</td>
<td>A</td>
<td>54</td>
</tr>
<tr>
<td>Rasmussen et al. (1991)</td>
<td>5</td>
<td>A</td>
<td>20</td>
</tr>
<tr>
<td>Borucki Castro et al. (2012)</td>
<td>5</td>
<td>B (complete cleaning)</td>
<td>25</td>
</tr>
<tr>
<td>Galton et al. (1984)</td>
<td>5</td>
<td>A</td>
<td>36</td>
</tr>
<tr>
<td>Rasmussen et al. (1991)</td>
<td>5</td>
<td>B/A</td>
<td>41</td>
</tr>
<tr>
<td>Borucki Castro et al. (2012)</td>
<td>5</td>
<td>B (incomplete cleaning)</td>
<td>88</td>
</tr>
<tr>
<td>Hamann and Heeschen (1982)</td>
<td>5</td>
<td>A</td>
<td>120</td>
</tr>
</tbody>
</table>
Calcium iodate anhydrous (film granulated preparation) for all species

Berg and Padgitt (1985)  10  A  7
Swanson et al. (1990)  10  A  46
Galtion et al. (1984)  10  A  90
Galtion et al. (1986)  10  A  76
Galtion et al. (1984)  10  B/A  150
Galtion et al. (1986)  10  B/A  110
Conrad and Hemken (1978)  10  A  88
Borucki Castro et al. (2012)  10  A  49
Borucki Castro et al. (2012)  10  A (spraying)  409
Borucki Castro et al. (2012)  10  B (complete cleaning)  54

1: A: after milking; B: before milking

Table E4: Iodine concentration (µg/kg fresh weight) of salt- and fresh water fish, crustaceans and molluscs (“Food Composition and Nutrition Tables”, Souci et al. (2008))

<table>
<thead>
<tr>
<th>Species</th>
<th>Average</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt-water fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flounder</td>
<td>260</td>
<td>44</td>
<td>1 540</td>
</tr>
<tr>
<td>Halibut</td>
<td>370</td>
<td>220</td>
<td>520</td>
</tr>
<tr>
<td>Herring</td>
<td>470</td>
<td>240</td>
<td>670</td>
</tr>
<tr>
<td>Cod</td>
<td>2 290</td>
<td>1 210</td>
<td>5 480</td>
</tr>
<tr>
<td>Mackerel</td>
<td>500</td>
<td>390</td>
<td>820</td>
</tr>
<tr>
<td>Sardine</td>
<td>320</td>
<td>130</td>
<td>540</td>
</tr>
<tr>
<td>Haddock</td>
<td>1 350</td>
<td>600</td>
<td>5 100</td>
</tr>
<tr>
<td>Plaice</td>
<td>530</td>
<td>260</td>
<td>2 400</td>
</tr>
<tr>
<td>Alaska pollack</td>
<td>880</td>
<td>570</td>
<td>1 030</td>
</tr>
<tr>
<td>Tuna</td>
<td>500</td>
<td>400</td>
<td>500</td>
</tr>
<tr>
<td>Fresh-water fish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eel</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perch</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trout</td>
<td>35</td>
<td>30</td>
<td>36</td>
</tr>
<tr>
<td>Carp</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmon</td>
<td>340</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustaceans and molluscs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oyster</td>
<td>580</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown shrimp</td>
<td>910</td>
<td>510</td>
<td>1 300</td>
</tr>
<tr>
<td>Lobster</td>
<td>1 000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mussel</td>
<td>1 500</td>
<td>1 010</td>
<td>4 470</td>
</tr>
<tr>
<td>Soft clam</td>
<td>1 200</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

References


Calcium iodate anhydrous (film granulated preparation) for all species


Calcium iodate anhydrous (film granulated preparation) for all species


APPENDIX F

Exposure to iodine of adults and toddlers resulting from consumption of food produced from animals administered different dietary iodine concentrations

Scenario I: Currently authorised iodine concentration in feed: at total iodine level in feed of 5 (dairy cows, laying hens) or 10 (cattle for fattening) mg/kg complete feed

<table>
<thead>
<tr>
<th></th>
<th>Food</th>
<th>Intake (kg)</th>
<th>Iodine level (µg/kg)</th>
<th>Iodine intake (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADULTS</td>
<td>Meat</td>
<td>0.290</td>
<td>100</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Milk*</td>
<td>1.500</td>
<td>760</td>
<td>1140</td>
</tr>
<tr>
<td></td>
<td>Egg*</td>
<td>0.070</td>
<td>1300</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1231</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Only the two items contributing at the highest amount to the iodine intake are summed.

Scenario II: Reduced iodine concentrations in feed, as proposed by the FEEDAP Panel: at total iodine level in feed of 2 (dairy cows), 3 (laying hens) and 10 (cattle for fattening) mg/kg complete feed

<table>
<thead>
<tr>
<th></th>
<th>Food</th>
<th>Intake (kg)</th>
<th>Iodine level (µg/kg)</th>
<th>Iodine intake (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADULTS</td>
<td>Meat</td>
<td>0.290</td>
<td>100</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Milk*</td>
<td>1.500</td>
<td>280</td>
<td>420</td>
</tr>
<tr>
<td></td>
<td>Egg*</td>
<td>0.070</td>
<td>825</td>
<td>58</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>478</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Only the two items contributing at the highest amount to the iodine intake are summed.

1 Exposure calculated according to the Guidance on Consumer safety (EFSA, 2012) based on the EFSA Comprehensive European Food Consumption Database