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Occurrence data of nickel in feed and animal exposure assessment

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Abstract

Nickel (Ni) is a silvery-white, hard, ductile metal existing in oxidation states; in biological systems, Ni²⁺ is the prevalent form. All analytical results used to estimate animal dietary exposure were reported as Niⁱ, without providing information on specific chemical species. Considering the data provided by Member states, among FoodEx level 1 feed categories, the highest mean Ni levels were measured in 'Minerals and products derived thereof' (n = 72). High mean Ni concentrations were also observed in 'Compound feed' (n = 516), in particular in complementary feeds for fattening cattles, unspecified complementary feed and complementary feeds for fattening pigs. Within grains used as feed (n = 597), the highest mean Ni concentrations were measured in oats. In addition, Ni concentrations in hydrogenated vegetable oils/fats were reported by industry. Exposure to Ni in livestock and companion animals varied according to the animal species. When considering the diets with hydrogenated vegetable oils/fats based on the reported Ni concentrations, the mean exposures varied between 6.0 µg Ni/kg body weight (bw) per day in cats and 79 µg Ni/kg bw per day in laying hens and the high exposure levels varied between 11 µg Ni/kg bw per day in cats and 127 µg Ni/kg bw per day in rabbits. The mean exposure estimates considering the maximum concentration of Ni assumed from good manufacturing practice in hydrogenated vegetable oils/fats (50 mg Ni/kg) varied between 27 µg Ni/kg bw per day in cats and 255 µg Ni/kg bw per day in rabbits; for the high concentration scenarios, exposures varied between 30 µg Ni/kg bw per day and 307 µg Ni/kg bw per day in the same species. The estimated exposures to Ni are in line with the one reported in the 2015 EFSA opinion, using a worst-case scenario. When estimating exposure with a realistic scenario, using the reported Ni concentration in hydrogenated vegetable oils/fats, the exposure of livestock and companion animals is lower (approximately from 1.5 to 6 times, depending on the species) than the 2015 assessment.

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Summary

In 2015, the European Food Safety Authority (EFSA) published a scientific opinion on the risks to animal and public health and the environment related to the presence of nickel (Ni) in feed. The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that adverse effects from Ni in feed are unlikely to occur in cattle, pigs, rabbits, ducks, fish, chicken, turkeys, dogs, goats, sheep, horses and cats. The CONTAM Panel also concluded that chronic exposure to Ni in via animal derived food might be of potential concern in the young population (in particular in 'Toddlers') in average consumers and in high consumers also in 'Other children'. Acute exposures to Ni via animal derived food can pose a risk for Ni sensitised individuals. Ni release to the environment from manure, resulting from its presence in animal feed, is not a major contributor of Ni deposited onto agricultural soils or to the environment.

Following an official request by the European Commission in October 2018, the EFSA Evidence Management Unit (DATA Unit) has estimated chronic dietary exposure to Ni from feed in animals. A total of 2,094 analytical results on Ni in feed were reported by Member States and were available in the EFSA database. In addition, a group of 118 analytical results originally classified as 'grains as crops' for which their final end-use was undefined, were considered as feed as well. Therefore, the data set available for the present assessment contained a total of 2,212 analytical results on Ni in feed. All analytical results were reported as 'nickel', without providing information on specific chemical species. In total, 14 analytical results collected within the suspect sampling strategy were excluded. Finally, 2,198 analytical results were included in the final data set and considered for the animal dietary exposure of the present scientific report.

In addition, 663 Ni analytical results on hydrogenated vegetable oils/fats were provided by industry. These data were used only for the exposure scenario including hydrogenated vegetable oils/fats with the analysed Ni concentration.

The feed samples were collected between 2007 and 2018 in nine different European countries, most of them in Slovakia. The data were mostly reported for forages and roughage feed commodities ($n = 712$) and within that, the highest Ni mean concentrations were observed for unspecified forages and roughage ($n = 18$; lower-bound (LB) and upper-bound (UB) mean = 1,606 $\mu\text{g}/\text{kg}$) and in lucerne ($n = 119$); LB and UB mean = 1,167 $\mu\text{g}/\text{kg}$). Among FoodEx level 1 feed categories, the highest mean Ni levels were measured in 'Minerals and products derived thereof' ($n = 72$) reported at the mean level of 3,896 $\mu\text{g}/\text{kg}$ for LB and 3,905 $\mu\text{g}/\text{kg}$ for UB. High mean Ni concentrations were observed in 'Compound feed' ($n = 516$), in particular in complementary feeds for fattening cattles ($n = 26$; LB and UB mean = 6,813 $\mu\text{g}/\text{kg}$), unspecified complementary feed ($n = 9$; LB and UB mean = 5,270 $\mu\text{g}/\text{kg}$) and complementary feeds for fattening pigs ($n = 6$; LB and UB mean = 4,344 $\mu\text{g}/\text{kg}$). Within grains ($n = 597$), the highest mean Ni concentrations were measured in oats ($n = 26$; LB mean = 1,690 $\mu\text{g}/\text{kg}$; UB mean = 1,702 $\mu\text{g}/\text{kg}$). Within the feed category 'Oil seeds, oil fruits, and products derived thereof' ($n = 204$), the highest Ni concentration were reported for toasted soya ($n = 13$; LB and UB mean = 4,462 $\mu\text{g}/\text{kg}$) and sunflower seeds ($n = 39$; LB and UB mean = 1,566 $\mu\text{g}/\text{kg}$). For the feed category 'Miscellaneous' ($n = 68$), a substantial number of data was available only for glycerine ($n = 36$; LB mean = 350 $\mu\text{g}/\text{kg}$ and UB mean = 358 $\mu\text{g}/\text{kg}$) and unspecified miscellaneous feed commodities ($n = 29$; LB and UB mean = 836 $\mu\text{g}/\text{kg}$). For other feed categories, only a limited number of analytical results were available.

For the samples of hydrogenated vegetable oils/fats ($n = 663$) falling in the feed category 'Oil seeds, oil fruits, and products derived thereof' reported by industry, the LB and UB mean Ni level was 527 and 530 $\mu\text{g}/\text{kg}$, respectively.

Compared to the 2015 EFSA opinion, Ni occurrence in feed is within the same order of magnitude for all feed categories with exception of 'Oats', 'Toasted soya' and 'Complementary feed' for which the current mean Ni concentrations are higher.

Information on the analytical methods used to analyse Ni in feed samples was provided for all data included in the data set. The majority of samples were analysed by atomic absorption spectrometry (AAS), either reported without information or with information on the atomising unit used (electrothermal AAS (ET AAS)/graphite furnace AAS (GF AAS)).

Although in animal nutrition compound feeds (complementary or complete feeds) represent a very large proportion of the feed consumed by farm animals, the available data on the Ni occurrence in these feeds are difficult to use for exposure calculations due to the low number of samples available for each target species or category or feeds not sufficiently characterised to allow a proper utilisation in diet formulations. Two diet scenarios were considered: with or without the inclusion of

hydrogenated vegetable oils/fats as a feed material. The scenarios considering the presence of hydrogenated vegetable oils/fats were performed as follows: (i) a worst-case scenario based on the maximum concentration of Ni assumed from good manufacturing practice in these feed materials (50 mg Ni/kg) and (ii) a second, more realistic scenario in which the Ni concentration reported in hydrogenated vegetable oils/fats was used.

Exposure to Ni in livestock and companion animals varied according to the animal species. When considering the diets with hydrogenated vegetable oils/fats based on the reported Ni concentrations, the mean exposures varied between 6.0 µg/kg body weight (bw) per day in cats and 79 µg/kg bw per day in laying hens and the high exposure levels varied between 11 µg/kg bw per day in cats and 127 µg/kg bw per day in rabbits. The mean exposure estimates considering the maximum Ni concentration assumed from good manufacturing practice (50 mg Ni/kg) varied between 27 µg/kg bw per day in cats and 255 µg/kg bw per day in rabbits. For the high concentration scenarios, exposures varied between 30 µg/kg bw per day and 307 µg/kg bw per day in the same species.

The estimated exposures are in line with the one reported in the 2015 EFSA opinion, using the same worst-case scenario. When estimating exposure with a realistic scenario, using the reported Ni concentration in hydrogenated vegetable oils/fats, the exposure of livestock and companion animals is lower (approximately from 1.5 to 6 times, depending on the species) than in the 2015 assessment.

Animal exposure estimates to Ni have uncertainties relating to the representativeness of the feed samples across Europe. The data set was characterised by a limited number of occurrence data, in particular for compound feed where for certain feed categories just very few analytical results were available. In addition, for mineral feeds—likely to be the most important contributor to Ni content in compound feed—relatively limited and dispersed data were available. The limited representative feed consumption data for livestock and fish (salmonids) across Europe added a considerable uncertainty regarding the total animal exposure to Ni. It was assumed that all animal species can be exposed to Ni from the hydrogenated vegetable oils/fats (with exception of fish (salmonids)) which may have led to overestimation of the real exposure to Ni for the animal species not consuming or consuming rarely the hydrogenated vegetable oils/fats. Samples with left-censored data introduced uncertainties to the overall exposure estimate since the use of the LB in this assessment tends to underestimate, while UB tends to overestimate the dietary exposure. However, the impact resulted to be minor since the data set comprised only a low proportion of left-censored data. The use of a worst-case scenario based on the maximum concentration of Ni assumed from good manufacturing practice in hydrogenated vegetable oils/fats (50 mg Ni/kg) has led to a considerable overestimation of the real animal exposure to Ni. Due to lack of data, it was not possible to quantify exposure from routes other than feed.

Overall, the chronic dietary exposure to Ni presented in this report is likely to overestimate the exposure levels of the European population, in particular for a worst-case scenario.

Efforts should continue to collect occurrence data on Ni in feed in order to improve the representativeness of data. It would be desirable to encourage further research for determination of Ni ingestion from sources other than feed in order to evaluate additional exposure sources. More data on mineral feeds and mineral premixtures should be collected since these materials are those contributing mostly to the Ni content in feed. Where applicable, the analytical data on compound/complete feed should be accurately classified according to the corresponding target animal/category.

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1. Introduction

Nickel (Ni) is a silvery-white, hard, ductile metal existing in oxidation forms -1 , 0 , $+1$, $+2$, $+3$ and $+4$. In biological systems, Ni^{2+} is the prevalent form. The natural occurrence of metallic Ni (Ni^0) is extremely rare but feed might contain metallic Ni, since it is used as a catalyst in the production of certain feed materials. In most experimental studies investigating toxic effects of Ni animals, divalent Ni salts, $NiCl_2$ (CAS: 7718-54-9) and $NiSO_4$ (CAS: 7786-81-4) and their hydrated forms, have been used. Ni is generally considered not to be an essential nutrient in animals. It occurs naturally in soils as a result of the weathering of the parent rock. Further sources of Ni in the environment are atmospheric deposition of Ni as a result of the burning of oil and coal, the use of agricultural fertilisers, particularly phosphates, the application of waste materials including sewage sludge and animal manure. Ni is taken up from the soil in plants both via passive and active transport. Although Ni is an essential nutrient for higher plants their low tolerance towards elevated Ni concentrations acts as a protective barrier to the uptake of high amounts of Ni by livestock (Chaney, 1990).

Animals absorb only a small fraction of the Ni ingested and oral absorption differs between animal species and depends on the chemical form of Ni and the vehicle of administration. Once absorbed, Ni is rapidly distributed. Highest organ/tissue residues are usually found in kidney, lung, liver and muscles. Ni is also excreted in ruminant milk. However, it was not possible to derive carry-over rates from feed to food of animal origin.

Following a request from the European Commission, the EFSA CONTAM Panel has assessed the risks to animal and human health and the environment related to the presence of Ni in feed (EFSA CONTAM Panel, 2015a). In this opinion the main adverse effects observed in toxicity studies with livestock and fish were (i) reduced feed consumption and body weight (growth); (ii) reduced relative organ weights; and (iii) histopathological alterations in liver and kidney and/or altered blood parameters. For cattle, a no observed adverse effect level (NOAEL) of 1.34 mg/kg body weight (bw) per day was identified based on reduced feed intake and growth. For pigs, NOAEL of 12.8 mg/kg bw per day was identified based on reduced feed intake and body weight gain. For rabbits, a NOAEL of 3.75 mg/kg bw per day was identified based on reduced relative weights of liver, kidneys, ovaries, reduced ovary function and altered blood parameters in female animals. For ducks, a NOAEL of 9.4 mg/kg bw per day was identified based on decreased bone density. For fish, a NOAEL of 0.2 mg Ni/kg bw per day was identified based on histopathological alterations in the kidney. For dogs, a NOAEL of 18 mg/kg bw per day was identified based on findings of vomiting, polyuria, lung lesions and bone marrow hyperplasia. For chickens, a lowest observed adverse effect level (LOAEL) of 3 mg/kg bw per day was derived based on slightly reduced growth, slightly reduced relative weights of livers and testicles and mild pathological liver focal fatty infiltration together with a decrease of specific blood parameters. Because of a lack of adequate data no NOAELs/LOAELs were identified for sheep, goats, horses, turkeys and cats.

For the above-mentioned CONTAM opinion (EFSA CONTAM Panel, 2015a), a total of 1,813 analytical results on total Ni in feed were available and exposures were estimated (i) based on Ni concentrations in compound feed and forages and (ii) based from Ni in feed materials including hydrogenated vegetable oils. Based on the reported concentrations in compound feed and forage, the estimated mean upper-bound (UB) exposures ranged from 5.1 (fattening beef cattle) to 61.7 $\mu\text{g}/\text{kg}$ bw per day (laying hens and chickens for fattening). In an alternative worst-case scenario, a 5% inclusion of hydrogenated vegetable oil in the non-forage feeds, containing the maximum acceptable concentration of 50 mg Ni/kg was assumed and applied to rations for different livestock species, resulting in mean UB exposures of 60 $\mu\text{g}/\text{kg}$ bw per day for cattle, 180 $\mu\text{g}/\text{kg}$ bw per day for pigs and ducks, 10 $\mu\text{g}/\text{kg}$ bw per day for fish, 40 $\mu\text{g}/\text{kg}$ bw per day for dogs, 200 $\mu\text{g}/\text{kg}$ bw per day for chickens, 80 $\mu\text{g}/\text{kg}$ bw per day for sheep, 160 $\mu\text{g}/\text{kg}$ bw per day for goats, 40 $\mu\text{g}/\text{kg}$ bw per day for horses, 110 $\mu\text{g}/\text{kg}$ bw per day for turkeys and 40 $\mu\text{g}/\text{kg}$ bw per day for cats.

Overall, the NOAELs/LOAELs identified for the different species were much higher than the estimated chronic exposures. Taking into account the conservatism of the exposure assessments, the CONTAM Panel concluded that adverse effects from Ni in feed in cattle, pigs, rabbits, ducks, fish, chicken and dogs are unlikely to occur. Although for turkeys no NOAEL/LOAEL is available the CONTAM Panel concluded that, based on the margin between worst-case exposure levels and the NOAELs/LOAELs derived in other poultry species adverse effects are unlikely to occur. No NOAELs/LOAELs could be derived for goats, sheep and horses, but since exposures calculated for these species are much lower than the NOAEL in cattle, adverse effects in these species are likewise unlikely to occur. Similarly, no NOAEL/LOAEL could be identified for cats but since the exposure level derived for this species is

much lower than the NOAEL derived for dogs, the CONTAM Panel concluded that adverse effects are unlikely to occur.

In the EFSA opinion on Ni in food, for calculating human exposures to Ni from food of animal origin, occurrence data on Ni in food (EFSA CONTAM Panel, 2015b) were used. The highest chronic dietary exposure to Ni in food of animal origin was estimated for 'Toddlers', ranging between 0.9 and 3.8 lg/kg bw per day lower-bound (LB)–UB for mean dietary exposure and between 1.6 and 5.5 lg/kg bw per day (LB–UB) for high consumers (95th percentile). When not considering infants, for which only two dietary surveys were available, the average contribution of the foods of animal origin to the mean chronic dietary exposure to Ni (LB) ranged between 9.4% (lowest LB in 'Other children') and 29.1% (highest LB in 'Toddlers'). 'Milk and dairy products' was one of the main contributors to the chronic dietary exposure to Ni in the young population, particularly in 'Toddlers'. In 'Adults', high consumption of three representative foods (milk, livestock meat and fish) led to acute dietary exposure estimate of 0.4 µg/kg bw per day, 0.9 µg/kg bw per day and 0.6 µg/kg bw per day, respectively. In 'Toddlers', high consumption of liquid milk led to acute dietary exposure estimates of 1.9 µg/kg bw per day.

The CONTAM Panel concluded that for the average consumers, chronic exposure to Ni from foods of animal origin might be of potential concern in the young population, in particular in 'Toddlers'. In high consumers (95th percentile) exposure might also be of potential concern in 'Other children' as it exceeds the tolerable daily intake (TDI) of 2.8 µg/kg bw per day set in the EFSA opinion Ni in food (EFSA CONTAM Panel, 2015b). Upon comparing acute exposures with the benchmark dose (BMDL)₁₀ for acute oral exposure of 1.1 µg/kg bw per day for Ni sensitised individuals (as set in the EFSA opinion on Ni in food, EFSA CONTAM Panel, 2015b), the CONTAM Panel concluded that Ni-sensitised individuals are at risk of developing eczematous flare up skin reactions through the consumption of food of animal origin as the margin of exposure was below 10.

The Ni release to the environment from manure, resulting from its presence in animal feed, is not a major contributor of Ni deposited onto agricultural soils or to the environment.

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

The European Food Safety Authority Panel on Contaminants in the Food Chain (CONTAM Panel) has provided a scientific opinion on the risks to animal and public health and the environment to the presence of nickel in feed.¹

The CONTAM Panel concluded that any adverse impact of nickel via feed to cattle, pigs, rabbits, ducks, fish, dogs, chickens, horses, sheep, goats and cats is unlikely. Concerning the assessment of human health risks from the presence of nickel in food of animal origin, the CONTAM Panel concluded that in the average population the current levels of chronic exposure to nickel, considering only foods of animal origin, might be of potential concern in the young population. Regarding acute dietary exposure, the CONTAM Panel concluded that nickel-sensitized individuals are also at risk of developing eczematous flare-up skin reactions through the consumption of food of animal origin. The contribution of food of animal origin to human dietary exposure to nickel should therefore not be underestimated, particularly in age classes with high dietary exposure to nickel. However from the available data it was not possible to determine carry-over rates from feed to food of animal origin.

It is therefore appropriate to regulate the level of nickel in feed in order to ensure a high level of human health protection. It was however observed that the occurrence data on nickel in feed used in the EFSA scientific opinion were mainly originating from one Member State and are therefore not necessarily representative for the presence of nickel in feed in the EU.

It was therefore found appropriate to monitor the presence of nickel in feed across the EU before considering the setting of regulatory levels of nickel in feed or any other risk management measures needed to ensure a high level of animal and human health protection.

Commission Recommendation (EU) 2016/1110² recommends to Member States and feed business operators to monitor the presence of nickel in feed and to provide these data to EFSA on a regular basis and by the latest by October 2017.

It is appropriate to provide a report on the available occurrence data on nickel in feed and to provide estimates of animal exposure.

¹ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks to animal and public health and the environment related to the presence of nickel in feed. EFSA Journal 2015;13(4):4074,76 pp. <https://doi.org/10.2903/j.efsa.2015.4074> Available on: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4074>

² Commission Recommendation (EU) 2016/1110 of 28 June 2016 on the monitoring of the presence of nickel in feed (OJ L183, 8.7.2016, p. 68).

TERMS OF REFERENCE

In accordance with Art. 31 (1) of Regulation (EC) No 178/2002 the Commission asks EFSA for a report on the available occurrence data of nickel in feed and to provide estimates of animal exposure.

2. Data and methodologies

2.1. Data

2.1.1. Occurrence data in feed

2.1.1.1. Data collection and validation

Following an European Commission mandate to EFSA, a call for an annual collection of chemical contaminant occurrence data in feed, including Ni, was issued in December 2010 with a closing date of 1 October of each year.³ European national authorities and similar bodies, research institutions, academia, food business operators and other stakeholders are invited to submit analytical data on Ni in feed.

At the time of the data extraction (December 2018), a total of 2,212 analytical results on Ni in feed were reported by Member States and were available in the EFSA database. In addition, 663 Ni analytical results on hydrogenated vegetable oils/fats were reported by industry. All analytical results were reported as Ni, without providing information on specific chemical species.

The data submission to EFSA followed the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010a); occurrence data were managed following the EFSA standard operational procedures (SOPs)⁴ on 'Data collection and validation' and on 'Data analysis of food consumption and occurrence data'.

2.1.1.2. Data analysis

In line with the EFSA SOP on 'Data analysis of food consumption and occurrence data' to ensure an appropriate quality of the data used in the exposure assessment, the initial data set was evaluated by applying several data cleaning and validation steps. Special attention was paid to different parameters such as 'Sampling strategy', 'Sampling year', 'Sampling country', 'Analytical methods', 'Reporting unit', 'Limit of detection', and the codification of samples feed samples according to the catalogue of feed materials described in Commission Regulation 68/2013⁵. The outcome of the data analysis is presented in Section 3.

The left-censored (LC) data (results below the limit of detection (LOD) or below limit of quantification (LOQ)) were treated by the substitution method as recommended in the 'Principles and Methods for the Risk Assessment of Chemicals in Food' (WHO/IPCS, 2009). The same method is indicated in the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010b). The guidance suggests that the LB and UB approach should be used for chemicals likely to be present in the food (e.g. naturally occurring contaminants, nutrients and mycotoxins). The LB is obtained by assigning a value of zero (minimum possible value) to all samples reported as lower than the LOD (< LOD) or LOQ (< LOQ). The UB is obtained by assigning the numerical value of LOD to values reported as < LOD and LOQ to values reported as < LOQ (maximum possible value), depending on whether LOD or LOQ is reported by the laboratory.

2.1.2. Animal consumption data

The feeds consumed (and the feed intake) by the most relevant farm livestock and companion animals can only be based on estimates, since no comprehensive feed consumption database exists covering the EU. The animal species and categories considered were: (i) ruminants (dairy cows (producing approximately 40 kg milk/day) for which non-forage feeds accounted for 40% of the diet (on a dry matter (DM) basis), beef cattle (reared on forage based diets or cereal based diets), lactating sheep, milking and fattening goats; (ii) pigs (starter, finisher and lactating sows); (iii) poultry

³ <http://www.efsa.europa.eu/en/data/call/datex101217>

⁴ <https://www.efsa.europa.eu/en/corporate/pub/sops>

⁵ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials Text with EEA relevance (OJ L 29, 16.1.2013, p. 1).

(broiler, laying hens, turkeys for fattening and ducks for fattening); (iv) rabbits; (v) farmed fish (salmonids); (vi) companion animals (dogs, cats) and (vii) horses.

The default values for the animals' body weight and for the feed intake (as DM/day) considered for the exposure calculation are reported in Appendix A, Tables A.1.1, A.1.2 and A.1.3. These values are those already considered in the previous opinion of the CONTAM Panel (EFSA CONTAM Panel, 2015a) such allowing a direct comparison of the results from the current exposure with that obtained in 2015.

2.1.3. Feed classification

Feed samples were classified according to the Catalogue of feed materials as described in Commission Regulation No 68/2013⁶ and recorded according to the FoodEx classification system.

2.2. Methodologies

2.2.1. Animal diets

Estimated example diets for each animal species and category were used to calculate the exposure to Ni. The diets, already presented and extensively described by the EFSA CONTAM Panel (2015a), are presented in Appendix A, Table A.2. For ruminants, the contribution of non-forage feed to the total diet was estimated to be: 40% for dairy cows, 85% and 50% for beef cattle reared on forage-based and cereal-based diets, respectively, 50% for sheep lactating, 75% and 40% for dairy and fattening goats, respectively. For cats and dogs, the cereal based compound feed was estimated to contribute to 55% and 65% of the diets, respectively. It is to be noted that these diets used to calculate exposure are generally in line with those proposed also by other institutions (e.g. Dutch Centraal Veevoeder Bureau, Institut national de la recherche agronomique; see Van Paemel et al., 2010).

2.2.2. Animal dietary exposure assessment

In 2015, due to the lack of information on the species for which the compound feeds were destined, the CONTAM Panel could not use the Ni concentration reported in compound feed for exposure assessment for any livestock category (EFSA CONTAM Panel, 2015a). Therefore, the exposure was estimated using the example diets, as described in Section 2.2.1 and Appendix A, Section A.2. In the present report, the same approach based on the example diets was also followed, since the currently available data on Ni concentration in compound feed does not either allow to estimate exposure for specific livestock categories.

The exposure estimates were calculated using two models with or without the inclusion of hydrogenated vegetable oils/fats as a feed material; the maximum inclusion level assumed by the EFSA CONTAM Panel (2015a) of 5% hydrogenated vegetable oil in the compound feed was retained. Finally, three scenarios were considered in the calculation of animal exposure:

- i) a worst-case scenario with inclusion of hydrogenated vegetable oils/fats based on the maximum concentration assumed from good manufacturing practice of Ni in these feed materials (50 mg Ni/kg) as considered in the previous CONTAM Panel opinion (EFSA CONTAM Panel, 2015a);
- ii) more realistic scenario with inclusion of hydrogenated vegetable oils/fats based on the Ni concentration reported in hydrogenated vegetable oils;
- iii) a scenario without inclusion of hydrogenated vegetable oils/fats.

It should be noted, that the hydrogenated vegetable oils/fats are not widely used in diets for pigs, poultry and horses, however their consumption cannot be excluded. Therefore, it was assumed that all animal species, with exception of fish (salmonids), can be exposed to Ni from the hydrogenated vegetable oils/fats. This may have led to overestimation of the real exposure to Ni for the animal species not consuming or consuming rarely the hydrogenated vegetable oils/fats.

For all three scenarios, the mean LB and UB values for each feedingstuff were used to estimate the mean Ni dietary exposure levels. To estimate the high Ni dietary exposure levels the high percentiles LB and UB values (P75, P90 or P95, depending on the number of data available) were used.

The animal exposure based on total Ni intake per day and per kg body weight was finally calculated.

⁶ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials. OJ L 29, 30.1.2013, p. 1–64.

3. Assessment

3.1. Current occurrence data on Ni in feed

3.1.1. Current occurrence data on Ni in feed provided by Member States

3.1.1.1. Data collection summary

By the end of December 2018, an initial data set of 2,094 analytical results on Ni in feed was available in the EFSA database. In addition, a group of 118 analytical results were originally classified as 'grains as crops' and their final end-use was undefined. An analysis of their Ni concentrations showed consistency to the analytical results reported as feed, and therefore were finally considered as feed. Therefore, the final data set contained a total of 2,212 analytical results on Ni in feed.

The data considered in the present assessment were provided by ten European countries. The major contributor of data was Slovakia which reported 81% of data, followed by the Czech Republic and France. Results were reported on samples collected between the years 2007 and 2018.

In order to guarantee an appropriate quality, the occurrence data were carefully evaluated and a list of validation steps was applied before being used to estimate dietary exposure. In particular, duplicates (analytical results transmitted twice or repeated analysis of the same sample), an incomplete or incorrect description of the relevant variables (e.g. parameter type, feed classification, result value, LOD or LOQ) were carefully evaluated.

Particular attention was paid to data reported as suspect samples. Suspect samples are the samples taken repeatedly from the same site as a consequence of evidence or suspicion of contamination, and are often taken as a follow-up of demonstrated non-compliance with legislation. As they may lead to an overestimation of the contamination levels, results reported as 'Suspect sampling' (n = 14) were excluded from further analysis.

The LODs/LOQs of Ni data reported to EFSA varied between laboratories, analytical methods and feed commodities, with lower LODs/LOQs for atomic absorption spectrometry (AAS) as compared to other analytical methods and in 'Cereal grains, their products and by-products' and 'Forages and roughage, and products derived thereof' as compared to other feed categories (for further details see Section 3.1.1.3). An evaluation of appropriateness of LODs/LOQs was performed by comparing of the average LB/UB concentrations of the relevant feed commodities based on the typical expanded uncertainty associated to the analytical results, which in an ideal case is reported by the laboratory (CODEX, 2004). Although in most of the cases measurement uncertainty is not reported by the data providers, all the analytical results possess an associated uncertainty that is highly influenced by the measured nominal concentration. As an example, typical expanded uncertainties when reporting nominal concentration between 100 µg/kg and 1,000 µg/kg would be 11%. When the differences between average LB/UB estimations expressed in percentage of the LB ($[(UB - LB) \times 100/LB]$) are lower than this specified percentage, no LOQ cut-offs shall be applied on the data set (EFSA, 2018). Since this was the case of all relevant feed commodities, no LOQ cut-offs were applied to the Ni analytical results considered in the present assessment.

The majority of the Ni data (98%) were obtained for samples collected within official EU or national monitoring programmes, while the remaining samples were collected within other programmes types (e.g. surveys).

Results were reported on whole weight (97% of analytical results) or on 88% DM (3% of analytical results). For consistency, the latter ones were converted to values expressed on a whole-weight basis. The conversion was based on the moisture content reported.

Recoveries of the analytical methods were reported only for 1% of the data. Nevertheless, the analytical results were submitted to EFSA as corrected for recovery in approximately 83% of cases. 10% of results were not corrected for recovery and for 7% of the results this information was not given. Due to lack of information on recovery rates for results which were reported as not corrected for recovery, no corrections could have been applied.

The analytical results reported by Member States and included in the final data set (n = 2,198) were collected in nine different European countries, most of them in Slovakia (n = 1,795), the Czech Republic (n = 253) and France (n = 49) (Figure 1). It should be noted that the origin of the data was not always the European country reporting the data, i.e. the data set also contained samples originating from South America and Asia. The samples were collected between 2007 and 2018 (Figure 2).

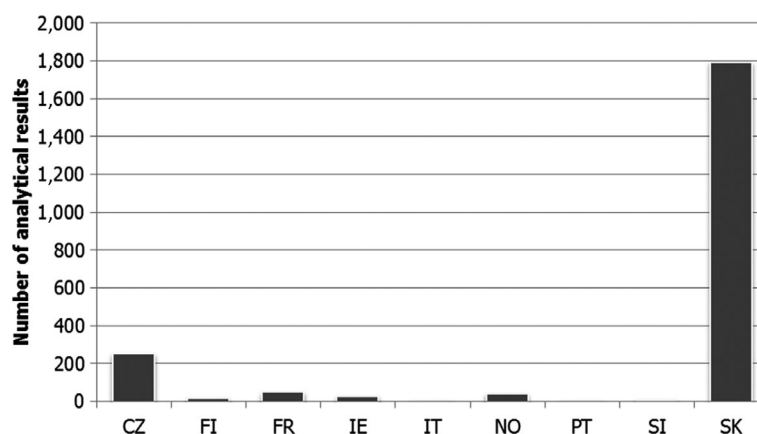


Figure 1: Distribution of the analytical results of Ni across the European countries (after excluding non-qualifying data). CZ, Czech Republic; FI, Finland; FR, France; IE, Ireland; IT, Italy; NO, Norway; PT, Portugal; SI, Slovenia; SK, Slovakia

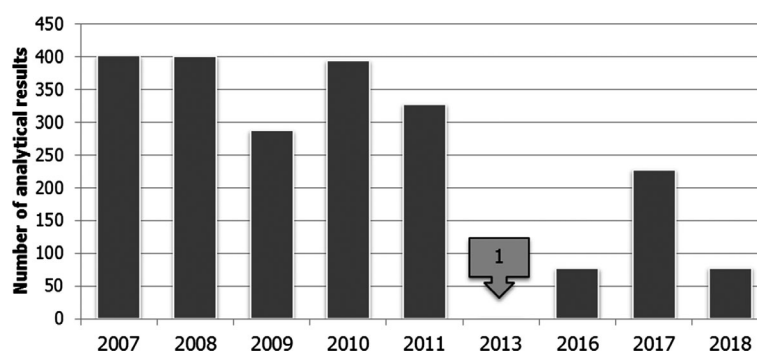


Figure 2: Distribution of the analytical results of Ni over the sampling years (after excluding non-qualifying data). Only one analytical result was sampled in 2013

3.1.1.2. Distribution of analytical results across feed categories

According to Commission Regulation No 68/2013 classification, as referenced in the FoodEx classification system, the available feed analytical results belonged to 12 different groups (see Figure 3).

The most frequently analysed feed category at FoodEx level 1 was 'Forages and roughage, and products derived thereof', 'Cereal grains, their products and by-products' and 'Compound feed' with 712, 597 and 516 analytical results of Ni reported, respectively (Figure 3). Other feed categories were less covered and some of them (e.g. 'Tubers, roots, and products derived thereof', 'Land animal products and products derived thereof', etc.) comprised only limited number of data.

The feed category 'Forages and roughage, and products derived thereof' mainly comprised analytical data on forage meal ($n = 524$) and lucerne ($n = 119$). Among the feed category 'Cereal grains, their products and by-products' the most represented analytical results were barley ($n = 198$), wheat ($n = 179$) and maize ($n = 176$). The feed category 'Compound feed' was represented by 434 analytical results reported as complete feed and 82 analytical results as complementary feed; among these, apart from unspecified feed compound commodities, the majority of them were on complete/complementary feed intended for livestock animals (for more details see Appendix B, Table B.1).

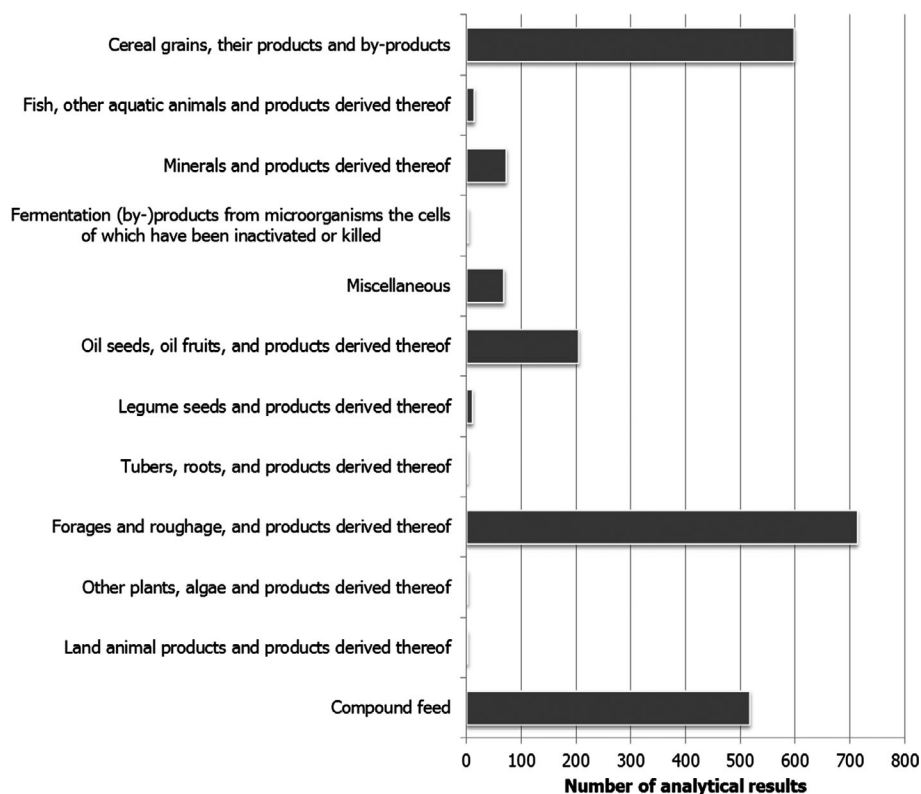


Figure 3: Distribution of analytical results of Ni across the feed categories according to Commission Regulation No 68/2013 (after excluding non-qualifying data)

Table 1 and Figure 4 summarise the number of analytical results and the percentage of LC data per feed category at FoodEx level 1. Considering only the feed categories with a substantial number of data ($n \geq 6$), the highest proportion of LC data was observed for feed categories 'Miscellaneous' (47%) and 'Fish, other aquatic animals and products derived thereof' (38%), while for other feed categories very low proportion of LC data was reported and for several of them all analytical results were quantified (e.g. 'Legume seeds and products derived thereof') (see Table 1).

Table 1: Distribution of analytical results of Ni per feed category according to Commission Regulation No 68/2013

Feed category level 1	Analytical data of Ni	
	N	LC
Cereal grains, their products and by-products	597	10%
Fish, other aquatic animals and products derived thereof	13	38%
Minerals and products derived thereof	72	25%
Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed	3	0%
Miscellaneous	68	47%
Oil seeds, oil fruits, and products derived thereof	204	3%
Legume seeds and products derived thereof	10	0%
Tubers, roots, and products derived thereof	1	0%
Forages and roughage, and products derived thereof	712	6%
Other plants, algae and products derived thereof	1	100%
Land animal products and products derived thereof	1	0%
Compound feed	516	5%
Total	2,198	9%

N: number of analytical results; LC: left-censored data.

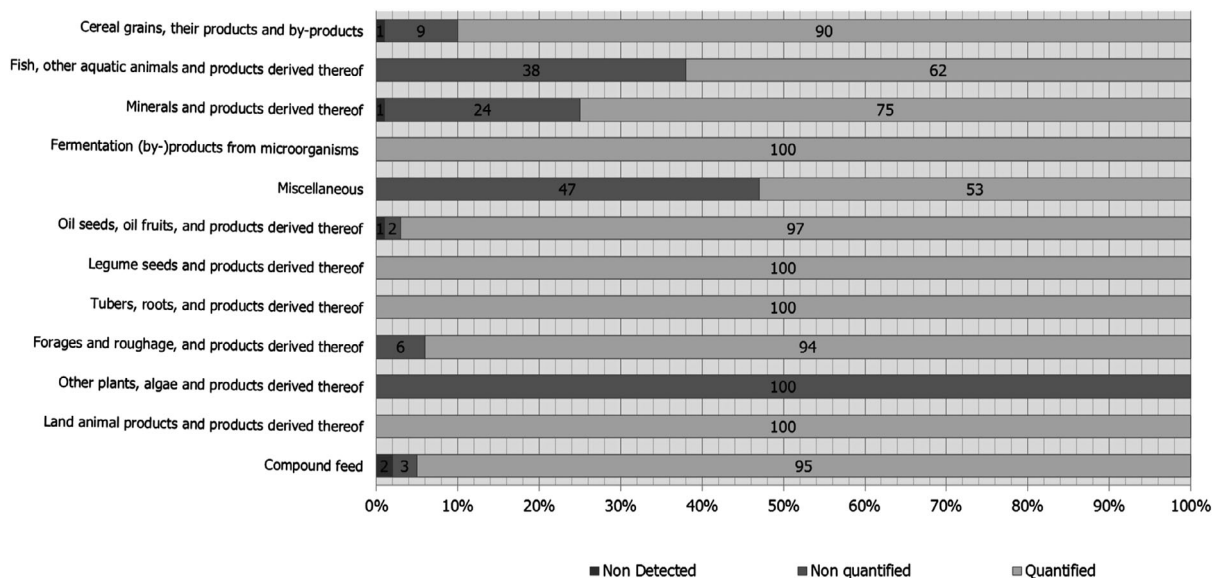


Figure 4: Distribution (%) of analytical results of Ni per feed category according to Commission Regulation No 68/2013. Not detected: results below LOD. Not quantified: results below LOQ

3.1.1.3. Analytical methods

Information on the analytical methods used to analyse Ni in feed samples was provided for all data included in the data set. The majority of Ni analytical results were analysed by AAS, either reported without information (n = 1,680) or with information on the atomising unit used (electrothermal AAS (ET AAS)/graphite furnace AAS (GF AAS)) (n = 26). Other data were reported as obtained using the inductively coupled plasma-based analytical methods using two different analytical techniques: inductively coupled plasma mass spectrometry (ICP-MS) (n = 283) and inductively coupled plasma optic emission spectroscopy (ICP-OES) (n = 209).

The distribution of analytical results across the analytical methods used for the analysis of Ni in feed samples is illustrated in Figure 5.

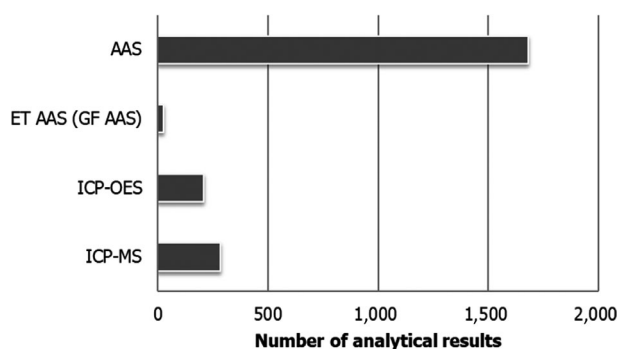


Figure 5: Distribution of analytical results across the analytical methods used for the analysis of Ni in feed samples (after excluding non-qualifying data)

The distribution of the LOQs across the feed categories with a sufficient number of data is displayed in Figure 6. The highest median LOQ of 300 µg/kg was reported for 'Fish, other aquatic animals and products derived thereof', 'Minerals and products derived thereof' and 'Miscellaneous' and the lowest median LOQ was reported for 'Cereal grains, their products and by-products' and 'Forages and roughage, and products derived thereof' (10 µg/kg).

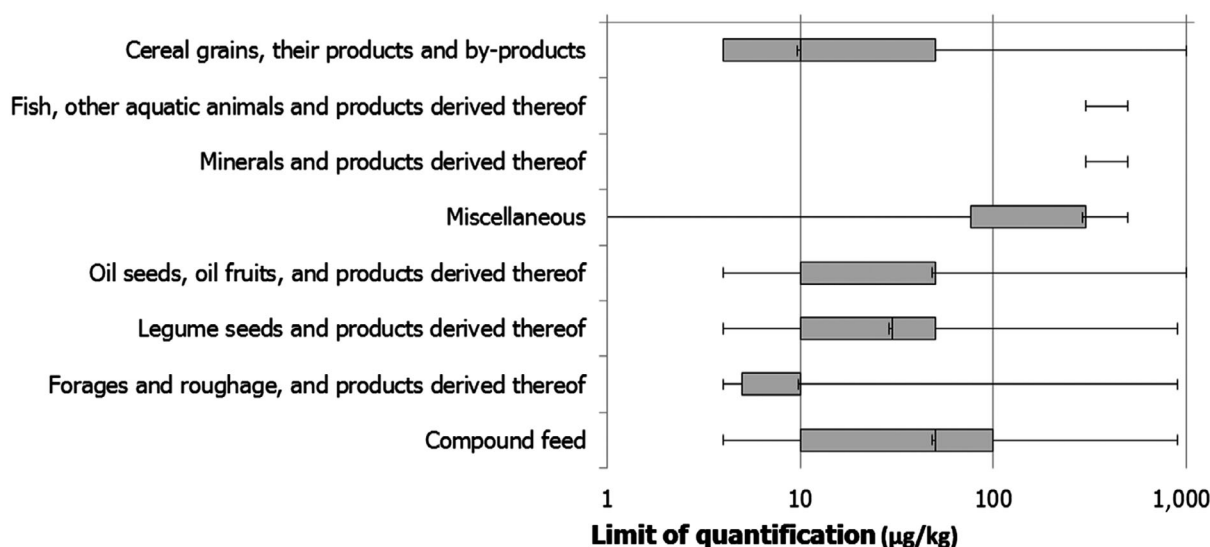


Figure 6: Distribution of the LOQs of analytical results of Ni across the feed categories (Box-plot on logarithmic scale: whiskers at minimum and maximum, box at P25 and P75 with line at P50). For 21 analytical results only the LOD, but no LOQ value was reported, and therefore those data are not included in the figure. Feed categories with limited number of results were not included in the figure

Regarding the analytical methods, the laboratories using AAS reported the lowest LOQs with a median of 10 µg/kg. On the other hand, higher LOQs were shown in the samples analysed by ICP-OES (median of 300 µg/kg).

Published information on LOQ values of occurrence data of Ni in animal feed and feed materials is very limited. Although the majority of the reported LOQs are in line with those described in recent literature (King and Sheridan, 2019), many analytical methods still reported relatively high LOQs (up to maximum of 5,000 µg/kg). This may have a significant impact on the UB estimations when dealing with LC data. Nevertheless, it is worth to note that in the present assessment an impact of high LOQ values on the UB estimations was minor since the data set comprised only low proportion of LC data.

3.1.2. Current occurrence data on Ni in feed provided by industry

The European Vegetable Oil and Protein Meal Industry Federation (FEDIOL) provided EFSA with data on Ni concentrations in 663 samples of hydrogenated vegetable oil/fat products ('Oil seeds, oil fruits, and products derived thereof' FoodEx level 1 feed category) intended to be added into feed. The samples were obtained between 2012 and 2015. The majority of the Ni analytical results were from samples analysed by the AAS, while ICP or ICP-MS analytical method was used only for a small part of the data set. Overall, the data set was characterised by low proportion of LC data (6%) with the LOQ of 10 µg/kg reported for all data. The Ni analytical results were reported for hydrogenated palm fat (n = 612), hydrogenated coconut oil (n = 3), hydrogenated palm oil (n = 43) and hydrogenated rapeseed oil (n = 5).

These data were used only for the exposure scenario including hydrogenated vegetable oils/fats with the analysed Ni concentration.

3.1.3. Occurrence data by feed category

An overview of the number of data points, the proportion of LC data as a percentage, the mean, median, 75th percentile (P75) and 95th percentile (P95) concentration values of the feed categories relevant for the present assessment is presented in Table 2. A detailed statistical description (up to FoodEx level 3) for all Ni data reported is presented in Appendix B, Table B.1.

The occurrence data on Ni were available for 12 FoodEx level 1 feed categories with a majority of analytical results available for 'Forages and roughage, and products derived thereof' (n = 712), 'Cereal grains, their products and by-products' (n = 597) and 'Compound feed' (n = 516). The data set was characterised by a low percentage of LC data. Among the FoodEx level 1 feed categories with a substantial number of data, Ni was most frequently found in 'Oil seeds, oil fruits, and products derived

thereof' (97% of quantified results), Compound feed (95% of quantified results) and 'Forages and roughage, and products derived thereof' (94% of quantified results).

Among all the FoodEx level 1 feed categories, 'Minerals and products derived thereof' was the one with the highest mean Ni concentration reported being at the level of 3,896 $\mu\text{g}/\text{kg}$ for LB and 3,905 $\mu\text{g}/\text{kg}$ for UB. This feed category contained mostly data on dicalcium phosphate, magnesium oxide and calcium carbonate. Similarly, the studies reported in the literature observed the highest concentration levels of Ni in minerals as compared to other types of feed materials (Nicholson et al., 1999; Dai et al., 2016).

The data reported for the feed category 'Forages and roughage, and products derived thereof' covered, at the FoodEx level 2, five feed categories referring to unspecified forages and roughage, lucerne, cereal straw, clover meal and forage meal. The highest mean Ni concentrations were observed in unspecified forages and roughage ($n = 18$; LB and UB mean = 1,606 $\mu\text{g}/\text{kg}$) and in lucerne ($n = 119$; LB and UB mean = 1,167 $\mu\text{g}/\text{kg}$).

Within grains, the highest mean concentrations were measured in oats ($n = 26$; LB mean = 1,690 $\mu\text{g}/\text{kg}$; UB mean = 1,702 $\mu\text{g}/\text{kg}$). Maize, wheat, barley and rye were less contaminated (LB mean concentrations in the range of 139–403 $\mu\text{g}/\text{kg}$), while for rice and triticale only a limited number of data was available. Previously published information on occurrence levels of Ni in cereals used as feed commodity is very limited. Higher Ni levels in cereal grain feeds than those considered in the present assessment were reported for wheat, maize and barley (Alexieva et al., 2007).

For 'Compound feed' (considering only feed categories with a substantial number of data), complementary feeds for fattening cattles was the feed category with the highest Ni mean concentration levels reported ($n = 26$; LB and UB mean = 6,813 $\mu\text{g}/\text{kg}$). High mean Ni concentrations were found also in unspecified complementary feed (LB and UB mean = 5,270 $\mu\text{g}/\text{kg}$) and complementary feeds for fattening pigs (LB and UB mean = 4,344 $\mu\text{g}/\text{kg}$); however, these observations were based on very limited data ($n = 9$ and $n = 6$, respectively). Generally, Ni levels reported to EFSA were lower than those reported in the literature for compound feed for pigs, poultry, horses and fish (Nicholson et al., 1999; Alexieva et al., 2007; Maule et al., 2007; Dai et al., 2016). On the other hand, Dai et al. (2016) reported lower Ni concentrations for feed for beef cattle.

Considering the data provided by Member States, the feed category 'Oil seeds, oil fruits, and products derived thereof' contained predominantly rape seeds ($n = 149$ data points) and the Ni concentration levels were for both LB and UB mean at a level of 762 $\mu\text{g}/\text{kg}$. High concentration levels were reported for toasted soya ($n = 13$; LB and UB mean = 4,462 $\mu\text{g}/\text{kg}$) and sunflower seeds ($n = 39$; LB and UB mean = 1,566 $\mu\text{g}/\text{kg}$). For the samples of hydrogenated vegetable oil/fat products reported by FEDIOL ($n = 663$) the LB and UB mean Ni level was 527 and 530 $\mu\text{g}/\text{kg}$, respectively.

Within the feed category 'Miscellaneous', a substantial number of data was available only for glycerine ($n = 36$; LB = 350 $\mu\text{g}/\text{kg}$ and UB mean = 358 $\mu\text{g}/\text{kg}$) and unspecified miscellaneous feed commodities ($n = 29$; LB and UB mean = 836 $\mu\text{g}/\text{kg}$).

In the following feed categories, a limited number of quantified results was available: 'Land animal products and products derived thereof' (one result at a level of 1,740 $\mu\text{g}/\text{kg}$ measured in processed animal protein), 'Legume seeds and products derived thereof' (up to 2,945 $\mu\text{g}/\text{kg}$ measured in peas), 'Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed' (up to 1,090 $\mu\text{g}/\text{kg}$ measured in yeasts and related products), 'Fish, other aquatic animals and products derived thereof' (up to 1,100 $\mu\text{g}/\text{kg}$ measured in fish meal) and 'Tubers, roots, and products derived thereof' (one result at level of 207 $\mu\text{g}/\text{kg}$ measured in potatoes).

For the feed category 'Other plants, algae and products derived thereof', no quantified results of Ni were reported.

Table 2: Summary statistics of the levels of Ni in feed

Feed category (level 1)	Feed category (level 2)	N	% LC	Concentration range (LB–UB) ($\mu\text{g}/\text{kg}$) ^(a)			
				Mean	Median	P75	P95
Cereal grains, their products and by-products	Cereal grains, unspecified	7	0	684–684	290–290	–	–
	Barley	198	14	202–203	130–130	259–259	520–520
	Triticale	1	0	525–525	–	–	–
	Wheat	179	12	399–405	214–233	450–450	1,716–1,716
	Maize	176	3	403–410	220–220	475–495	1,520–1,520
	Oats	26	4	1,690–1,702	1,090–1,090	1,809–1,809	–
	Rice, broken	3	0	1,561–1,561	–	–	–
	Rye	7	29	139–141	170–170	–	–
Minerals and products derived thereof	Minerals and products derived thereof, unspecified	3	33	9,767–9,867	–	–	–
	Calcium carbonate	23	26	1,618–1,618	655–655	1,700–1,700	–
	Magnesium oxide	18	11	3,127–3,127	3,420–3,420	3,680–3,680	–
	Dicalcium phosphate	18	0	8,585–8,585	5,450–5,450	7,660–7,660	–
	Sodium chloride	9	89	358–358	300–300	–	–
	Potassium chloride	1	100	0–300	–	–	–
Oil seeds, oil fruits, and products derived thereof	Rape seed	149	3	762–762	540–540	960–960	2,270–2,270
	Toasted soya (beans)	13	0	4,462–4,462	3,240–3,240	4,350–4,350	–
	Sunflower seed	39	0	1,566–1,566	1,370–1,370	1,850–1,850	–
	Vegetable oil and fat	2	100	0–600	–	–	–
	Linseed	1	100	0–300	–	–	–
Oil seeds, oil fruits, and products derived thereof ^(b)	Vegetable oil and fat	663	6	527–530	120–120	500–500	2,200–2,200
Forages and roughage, and products derived thereof	Forages and roughage, and products derived thereof, unspecified	18	0	1,606–1,606	1,125–1,125	2,020–2,020	–
	Lucerne	119	3	1,167–1,167	630–630	1,877–1,877	3,720–3,720
	Cereals straw	1	0	1,111–1,111	–	–	–
	Clover meal	50	10	483–484	210–210	570–570	–
	Forage meal	524	6	651–652	352–352	752–752	2,363–2,363
Compound feed	Complete feed	434	5	953–961	660–660	1,320–1,320	2,760–2,760
	Complementary feed (incomplete diet)	82	4	4,254–4,266	2,190–2,190	5,490–5,490	17,100–17,100

N: number of analytical results; LC: left-censored data; P75: 75th percentile; P95: 95th percentile; LB: lower-bound; UB: upper-bound.

(a): The different percentiles were only described when a minimum number of analytical results were available; 60 results for the 95th percentile, 11 results for the 75th percentile and 6 results for the median. Results obtained on occurrence data with fewer analytical results may not be statistically robust (EFSA, 2011).

(b): Analytical results on hydrogenated vegetable oil/fat products reported by FEDIOL.

Before the occurrence data were used to estimate animal dietary exposure, the data were grouped at different FoodEx levels according to their Ni levels and the number of analytical results available (Appendix B, Table B.2). The FoodEx level 3 were used when the number of samples were sufficient. However, in some cases the data were grouped at the upper FoodEx level in order to have a proper representation of a given feed category; additionally, when grouping, the nutritional similarity of the feed materials was taken into account.

3.2. Previously reported occurrence data on Ni in feed

Occurrence data previously published on the Ni concentrations in animal feed and feed materials are very limited, in particular as for the European region.

Ni concentration levels were in Europe studied in different feed commodities in England and Wales (Nicholson et al., 1999) and in Bulgaria (Alexieva et al., 2007). The levels ranged from 0.1 to 11.2 mg/kg DM for dairy cattle feed and from 0.2 to 8.3 mg/kg DM for beef cattle feed. In particular, the highest Ni concentrations were measured in minerals and rolled oats and barley (Nicholson et al., 1999). Alexieva et al. (2007) observed Ni levels up to 16 mg/kg (expressed on fresh weight) in 'other ingredients' and within the grain feed commodities, the highest levels were found in wheat (up to 14 mg/kg). Compound feeds for pigs contained Ni between 0.4–4.3 mg/kg DM and 1.3–6.8 mg/kg fresh weight. Ni concentrations in compound feeds for poultry ranged from 0.7 mg/kg DM (for turkey) to 7.0 mg/kg fresh weight (for poultry layers). Imran et al. (2014) found Ni Levels within the same order of magnitude in poultry feeds in Pakistan (mean Ni concentration of 4.1 mg/kg). Ni levels in poultry feed, rabbit feed and brand samples from Saudi Arabia ranged from 0.5 to 3.3 mg/kg (Alkhalaf et al., 2010).

Heavy metal contamination of animal feed including Ni was studied in Texas (Dai et al., 2016). The highest mean Ni concentrations of 56.9 and 26.5 mg/kg were observed in minerals and premixes, respectively. For other feed commodities different mean Ni levels were measured to be between 1.0 mg/kg and 5.6 mg/kg. Few data for Ni levels are available for commercial complete fish feed samples collected from 11 fish hatcheries in the US (Maule et al., 2007). The mean Ni concentrations ranged from 2.6 to 3.6 mg/kg DM. Lower Ni content was reported in different brands of fish feed sampled in Nigeria with the mean Ni concentrations ranging from 0.2 to 1.1 mg/kg (Salawu et al., 2016).

Only very limited information on Ni contamination in forages has been published. Data collected in different countries reported mean levels of 0.1–1.1 mg/kg for pasture grasses and 1.2–2.7 mg/kg for legumes (Kabata-Pendias and Pendias, 1992). The potential for forage analysis as indicators of mineral deficiencies or excesses of livestock during different sewage water treatments was examined in Pakistan by Ahmad et al. (2013). Ni concentration in forages during the water treatments ranged from 7.4 mg/kg to 10.2 mg/kg of dry weight.

In 2010, EFSA commissioned a study on trace and ultratrace elements in feed; Ni was considered (Van Paemel et al., 2010). In this report, the authors reported a few data on Ni concentrations in feed materials and complete feedingstuffs. These concentrations appear to be in the range of those collected by the Member States and feed business operators monitoring activities subject of this report (e.g. maize: 0.36 to 0.90 mg/kg; oat: 1.0 mg/kg; barley: 0.04 mg/kg; wheat 0.56 mg/kg; soybean meal: 3.91; alfalfa pellets 3.69 mg/kg).

3.3. Feed processing

Ni catalysts are used to hydrogenate vegetable oils/fats used as important feed ingredients for livestock (in particular for ruminants) and companion animals from which trace amounts may remain in the vegetable oils/fats. Virtually, once the desired degree of hydrogenation has been achieved, the hydrogen flow is stopped and the catalyst is filtered from hydrogenated oil/fat and all the spent Ni catalyst is recovered and reused, although trace amounts may remain in the oil (Venne, 1993). The maximum content of Ni in hydrogenated vegetable oils/fats in EU is regulated by the feed legislation (Commission Regulation (EU) No 68/2013) indicating that the Ni contents exceeding 20 mg/kg are required to be declared.

Ni migration as a result of food/feed processing may be a source of dietary exposure to Ni. Stainless steel materials are widely used for feed processing equipment and containers. Small amounts of metallic elements in the stainless steel may migrate into the processed feed although the quality of stainless steel used is usually selected to adequately meet the varying requirements of corrosion resistance. Therefore, it is believed that the contribution to the exposure from this source is rather negligible compared to the contribution from Ni naturally present in feed.

3.4. Animal exposure

The mean and high percentile dietary exposure levels were calculated as described in Section 2.2.2. The detailed results are summarised below in Tables 3–10.

In all the scenarios, the results indicate that, for each of the target species examined, the values obtained with the LB or the UB dietary concentrations gave similar or identical exposure. Therefore, the description of the exposure estimates in the present report refers to UB only. In all the livestock and companion animals, the highest exposure was obtained in the scenario considering the maximum concentration assumed from good manufacturing practice of Ni (EFSA CONTAM Panel, 2015a), i.e. the so-called 'worst-case scenario'. The exposures obtained in the other two scenarios (reported analysed Ni content in hydrogenated vegetable oils/fats or no hydrogenated vegetable oils/fats in the diets) were similar or even identical within each of the animal species/categories considered.

The results of the realistic scenario based on Ni levels in hydrogenated vegetable oils/fats as reported are described below in detail in the following paragraphs.

- The dietary exposure to Ni in dairy cows varied between about 21 and 62 $\mu\text{g Ni/kg bw}$ per day in the mean and high exposure scenarios. The exposure of beef cattle was calculated considering two models: one in which the diet is based on cereal and another in which it is based on forage; the mean exposure was estimated to be 10 and 11 $\mu\text{g Ni/kg bw}$ per day for the cereal-based and the forage-based diets, respectively; the corresponding high exposures were 25 and 35 $\mu\text{g Ni/kg bw}$ per day. Sheep mean and high exposure were 32 and 84 Ni/kg bw per day, respectively. For milking goats and fattening goats, the mean exposure was 65 and 35 Ni/kg bw per day, respectively; the high exposure was 108 and 80 Ni/kg bw per day.
- For pigs, the highest mean exposure was identified for pigs starter (61 $\mu\text{g Ni/kg bw}$ per day) followed by lactating sows (30 $\mu\text{g Ni/kg bw}$ per day) and pigs finisher (25 $\mu\text{g Ni/kg bw}$ per day). The same trend could be identified for the high exposure, with pigs starter, sows and pigs finisher with exposures of 71, 38 and 33 $\mu\text{g Ni/kg bw}$ per day, respectively.
- In poultry species, values of mean exposure were in the similar range for the *Gallus gallus domesticus* categories, being in the range of 62 $\mu\text{g Ni/kg bw}$ per day (broilers) to 79 (laying hens), while for ducks for fattening the exposure was somewhat lower (64 $\mu\text{g Ni/kg bw}$ per day), and yet much lower for turkeys for fattening (35 $\mu\text{g Ni/kg bw}$ per day). The corresponding values for the high exposure were 91, 110, 80 and 48 Ni/kg bw per day for broilers, laying hens, ducks and turkeys, respectively. Rabbits had the exposures identified as 70 $\mu\text{g Ni/kg bw}$ per day (mean) and 127 (high) $\mu\text{g Ni/kg bw}$ per day.
- Horses also showed a relatively low exposure in both exposure scenarios, with 18 (mean exposure level) and 23 (high exposure level) $\mu\text{g Ni/kg bw}$ per day.
- The lowest exposure levels were estimated for dogs and cats with the mean exposure levels being 6.0 $\mu\text{g Ni/kg bw}$ per day (cats) and 7.0 $\mu\text{g Ni/kg bw}$ per day (dogs) and high exposure levels being 11 $\mu\text{g Ni/kg bw}$ per day (cats) and 12 $\mu\text{g Ni/kg bw}$ per day (dogs).

Mean exposure estimates based on a worst-case scenario considering the maximum Ni concentration assumed from good manufacturing practice (50 mg Ni/kg) varied between 27 $\mu\text{g/kg bw}$ per day in cats and 255 $\mu\text{g/kg bw}$ per day in rabbits. For the high concentration scenarios, exposures varied between 30 $\mu\text{g/kg bw}$ per day and 307 $\mu\text{g/kg bw}$ per day in the same species.

For fish (salmonids), given the no consumption of the hydrogenated vegetable oils/fats, only the exposure scenario without hydrogenated vegetable oils/fats was considered. The exposure was estimated at the level of 15 and 18 $\mu\text{g Ni/kg bw}$ per day for the mean and high exposure, respectively.

Table 3: Estimated mean LB and UB dietary concentrations and chronic exposure of ruminants and horses to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Livestock category	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Dairy cows	LB	21	669	13,848	21	1,658	34,330	53
	UB	21	671	13,890	21	1,660	34,371	53
Beef: cereal-based	LB	9	460	3,860	10	2,562	21,522	54
	UB	9	461	3,875	10	2,564	21,536	54
Beef: forage-based	LB	11	549	4,938	11	1,785	16,069	36
	UB	11	550	4,949	11	1,787	16,080	36
Sheep: lactating	LB	32	691	1,936	32	1,928	5,399	90
	UB	32	693	1,941	32	1,930	5,404	90
Goat: lactating	LB	64	1,148	3,904	65	3,004	10,212	170
	UB	64	1,149	3,907	65	3,004	10,215	170
Goats: fattening	LB	34	926	1,388	35	1,915	2,873	72
	UB	34	926		35	1,916	2,874	72
Horses	LB	17	865	7,789	17	2,102	18,920	42
	UB	17	884	7,958	18	2,121	19,088	42

LB: lower bound; UB upper bound; DM: dry matter; bw: body weight.

Table 4: Estimated mean LB and UB dietary concentrations and chronic exposure of pigs, poultry and rabbits to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Livestock category	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Pig starter	LB	60	1,214	1,214	61	3,688	3,688	184
	UB	60	1,223	1,223	61	3,696	3,696	185
Pig finisher	LB	24	821	2,464	25	3,295	9,885	99
	UB	24	830	2,491	25	3,304	9,911	99
Lactating sow	LB	29	997	5,985	30	3,471	20,827	104
	UB	29	1,007	6,041	30	3,480	20,882	104
Broilers	LB	61	1,028	123	62	3,502	420	210
	UB	61	1,037	124	62	3,510	421	211
Laying hens	LB	77	1,308	157	78	3,782	454	227
	UB	77	1,316	158	79	3,789	455	227
Turkeys for fattening	LB	34	1,036	414	35	3,509	1,404	117
	UB	34	1,042	417	35	3,515	1,406	117
Ducks for fattening	LB	63	1,363	191	64	3,837	537	179
	UB	63	1,371	192	64	3,844	538	179
Rabbits	LB	68	931	140	70	3,404	511	255
	UB	68	931	140	70	3,405	511	255

LB: lower bound; UB upper bound; DM: dry matter; bw: body weight.

Table 5: Estimated mean LB and UB dietary concentrations and chronic exposure of cats and dogs to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Animal species	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Cats	LB	6	414	25	6	1,774	106	27
	UB	6	417	25	6	1,777	107	27
Dogs	LB	7	489	176	7	2,097	755	30
	UB	7	493	177	7	2,101	756	30

LB: lower bound; UB upper bound; DM: dry matter.

Table 6: Estimated mean LB and UB dietary concentrations and chronic exposure of fish (salmonids) to Ni

Animal species	Scenario	Without hydrogenated vegetable oils/fats
		Ni intake $\mu\text{g}/\text{kg bw}$
Fish (salmonids)	LB	15
	UB	15

LB: lower bound; UB upper bound; bw: body weight.

Table 7: Estimated high LB and UB dietary concentrations and chronic exposure of ruminants and horses to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Livestock category	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Dairy cows	LB	61	1,952	40,414	62	2,908	60,203	93
	UB	61	1,953	40,436	62	2,909	60,226	93
Beef: cereal-based	LB	23	1,173	9,852	25	3,204	26,916	67
	UB	23	1,173	9,852	25	3,204	26,917	67
Beef: forage-based	LB	34	1,773	15,953	35	2,968	26,708	59
	UB	34	1,773	15,953	35	2,968	26,708	59
Sheep: lactating	LB	81	1,798	5,035	84	2,993	8,381	140
	UB	81	1,799	5,038	84	2,994	8,384	140
Goat: lactating	LB	104	1,915	6,509	108	3,707	12,604	210
	UB	104	1,915	6,510	108	3,707	12,604	210
Goats: fattening	LB	78	2,130	3,194	80	3,086	4,628	116
	UB	78	2,130	3,194	80	3,086	4,628	116
Horses	LB	21	1,114	10,023	22	2,309	20,778	46
	UB	22	1,132	10,189	23	2,327	20,944	47

LB: lower bound; UB upper bound; DM: dry matter; bw: body weight.

Table 8: Estimated high LB and UB dietary concentrations and chronic exposure of pigs, poultry and rabbits to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Livestock category	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Pig starter	LB	65	1,409	1,409	70	3,799	3,799	190
	UB	65	1,417	1,417	71	3,807	3,807	190
Pig finisher	LB	30	1,108	3,325	33	3,498	10,495	105
	UB	30	1,117	3,350	33	3,507	10,520	105
Lactating sow	LB	35	1,267	7,599	38	3,657	21,939	110
	UB	35	1,275	7,651	38	3,665	21,991	110
Broilers	LB	84	1,505	181	90	3,895	467	243
	UB	84	1,511	181	91	3,901	468	234
Laying hens	LB	103	1,832	220	110	4,222	507	253
	UB	104	1,837	220	110	4,227	507	254
Turkeys for fattening	LB	45	1,445	578	48	3,835	1,534	128
	UB	45	1,451	580	48	3,841	1,536	128
Ducks for fattening	LB	75	1,709	239	80	4,099	574	191
	UB	75	1,716	240	80	4,106	575	192
Rabbits	LB	119	1,699	255	127	4,089	613	307
	UB	119	1,700	255	127	4,090	613	307

LB: lower bound; UB upper bound; DM: dry matter; bw: body weight.

Table 9: Estimated high LB and UB dietary concentrations and chronic exposure of cats and dogs to Ni from diets without or with the addition of hydrogenated vegetable oils/fats

Animal species	Scenario	Without hydrogenated vegetable oils/fats	With hydrogenated vegetable oils/fats with the analysed Ni concentration			With hydrogenated vegetable oils/fats with the maximum Ni concentration assumed from good manufacturing practice		
		Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$	Dietary concentration, $\mu\text{g Ni}/\text{kg DM}$	Ni intake $\mu\text{g}/\text{day}$	Ni intake $\mu\text{g}/\text{kg bw}$
Cats	LB	10	703	42	11	2,018	121	30
	UB	10	705	42	11	2,020	121	30
Dogs	LB	11	831	299	12	2,385	858	34
	UB	11	833	300	12	2,387	859	34

LB: lower bound; UB upper bound; DM: dry matter; bw: body weight.

Table 10: Estimated high LB and UB dietary concentrations and chronic exposure of fish (salmonids) to Ni

Animal species	Scenario	Without hydrogenated vegetable oils/fats
		Ni intake $\mu\text{g}/\text{kg bw}$
Fish(salmonids)	LB	18
	UB	18

LB: lower bound; UB upper bound; bw: body weight.

3.5. Exposure to Ni from sources other than feed

3.5.1. Exposure to Ni from water

Ni may be present in drinking water and in the atmosphere, but generally at very low levels, unlikely adding substantially to the overall exposure. No occurrence data on Ni content in water consumed by animals were identified. In order to estimate a Ni intake from water, the mean UB concentration of Ni in tap water of 1.8 µg/L retrieved from the EFSA database on chemical occurrence data and the total water intakes retrieved from the literature (ARC, 1980; OMAFRA, 2007) were considered. For example, the Agricultural Research Council suggested that the total water intake of a lactating dairy cow (600 kg bw, 30 kg/day milk production, environmental temperature 21–25°C) is 133 kg/day. Assuming a mean UB concentration of Ni in tap water of 1.8 µg/L, exposure from this source would be 239 µg/day, equivalent to 0.40 µg/kg bw, which compares with an estimated exposure from feed of 21 µg/kg bw (Table 3). Estimates for other livestock and companion animals (see Appendix C for details) suggest that water is likely to account for 1% on average of total exposure.

3.5.2. Exposure to Ni from other sources

Ni is naturally present in soil, and for grazing animals soil ingestion may be an important route for Ni intake. Thornton and Abrahams (1983) found that grazing cattle involuntarily ingest from 1% to nearly 18% of their DM intake as soil; sheep may ingest up to 30%. However, soil ingestion varies seasonally and with farm management practices. It might be assumed that non-ruminants (e.g. free-range pigs and poultry) also consume soil during the course of their foraging, but no data have been identified to quantify this. Ni concentrations in soils vary widely. It was estimated that under conditions of high soil intake or high contamination levels, soil may represent a substantial contribution to Ni exposure by grazing livestock (EFSA CONTAM Panel, 2015a).

Also, the sludge which is widely used for agricultural use may contain appreciable levels of Ni. This clearly represents a potential additional source of exposure. Grazing livestock might also potentially be at risk from sludge physically adhering to the surface of the leaves. The amount of sewage sludge that adheres to grassland or forage crops is influenced by both the amount applied and subsequent rainfall before grazing commences.

As mentioned in Section 3.3, the potential migration of Ni from feed manufacturing equipment has to be considered as an additional route of Ni exposure in animals. Machinery used in the manufacture of livestock feeds is frequently made of stainless steel, and it is possible that traces of Ni may occur in feed as a result of processing using this equipment.

4. Uncertainties

A qualitative evaluation of the uncertainties of the animal exposure assessment to Ni from feed was performed following the guidance of the Opinion of the Scientific Committee related to Uncertainties in Dietary Exposure Assessment (EFSA, 2007).

The occurrence data used for the animal exposure assessment were mainly reported by one country (Slovakia) while other countries submitted only limited number of data. There is an overall uncertainty in possible regional differences in Ni contamination of feed commodities and it is evident that the data set is not fully representative for feed in the EU.

The animal exposure assessment was hampered by limited occurrence data on Ni in compound feed for which the species/categories was traceable. Limited data were also available on certain feed material categories. In addition, for mineral feeds-likely to be the most important contributor to Ni content in compound feed-relatively limited and disperse data were available.

The limited representative feed consumption data for livestock and fish (salmonids) across Europe added a considerable uncertainty regarding the total animal exposure to Ni.

Due to the lack of information on recovery rates, a part of data was not corrected for recovery which might have introduced an additional uncertainty.

Samples with LC data introduced uncertainties to the overall exposure estimate since the use of the LB in this assessment tends to underestimate, while UB tends to overestimate the dietary exposure. In addition, several analytical results were reported with relatively high LOQs which may have an impact on the UB estimations when dealing with LC data. However, the impact resulted to be minor since the data set comprised only low proportion of LC data.

The use of a worst-case scenario based on the maximum concentration assumed from good manufacturing practice of Ni in hydrogenated vegetable oils/fats (50 mg Ni/kg) has led to a considerable overestimation of the real animal exposure to Ni.

It was assumed that all animal species can be exposed to Ni from the hydrogenated vegetable oils/fats (with exception of fish ((salmonids))). This may have led to overestimation of the real exposure to Ni for the animal species not consuming or consuming rarely the hydrogenated vegetable oils/fats.

The feed processing may have an influence, due to migration of metallic Ni from the stainless steel present in the processing equipment. Due to the lack of data, it was not possible to quantitatively assess the contribution of feed processing. However, it is believed that the contribution to the exposure from this source is rather negligible compared to the contribution from Ni naturally present in feed.

It was not possible to quantify exposure from other routes, nevertheless it is known that livestock take in Ni from sources other than feed (e.g. soil, sewage sludge). Under some foraging conditions, the intake of Ni from soil might be substantial and is influenced by factors such as soil Ni content, herbage type and density, grazing intensity and rainfall. Therefore, the exposure calculated only from feed and without considering other sources is likely to have underestimated total exposure to Ni.

Table 11 shows a summary of the uncertainty evaluation indicating an estimate of whether the respective source of uncertainty might have led to an over- or underestimation of the exposure.

Table 11: Summary of the qualitative evaluation of the impact of uncertainties on the animal exposure to Ni in feed

Sources of uncertainty	Direction ^(a)
Extrapolation of occurrence data from few Member States (mainly one country only) to whole EU	+/-
Limited occurrence data from several compound feed groups/feed materials	+/-
Use of feed ingredients instead of compound feed data due to lack of information of the target animal for compound feed	+/-
High variability of feedstuffs used and feeding systems for livestock	+/-
Limited occurrence data from mineral feeds/mineral premixtures	-
Limited consumption data for certain animal species	+/-
Using the substitution method at the LB scenario	-
Using the substitution method at the UB scenario	+
Use of the worst-case scenario with highest occurrence Ni values for hydrogenated vegetable oils/fats	+
The consumption of the hydrogenated vegetable oils/fats assumed for all animal species (with exception of fish ((salmonids)))	+
Contribution of feed processing not considered (e.g. migration of metallic Ni from the stainless steel)	-
Exposure from other routes (e.g. soil, sewage sludge) not considered	-

UB: upper bound; LB: lower bound.

(a): + = uncertainty with potential to cause over-estimation of exposure; - = uncertainty with potential to cause under-estimation of exposure.

Overall, the animal dietary exposure to Ni presented in this report is likely to overestimate the exposure levels of the animals living in the European region, in particular, a worst-case scenario considering the highest occurrence Ni values for hydrogenated vegetable oils/fats.

5. Conclusions

Recent data on Ni (2007–2018) in feed (2,212 analytical results) were reported by Member States to EFSA, however, mainly by only one European country. After applying the exclusion criteria, a total of 2,198 analytical results were included in the final data set used for the animal dietary exposure. In addition, 663 Ni analytical results on hydrogenated vegetable oils/fats were reported by industry.

- Among the feed categories at FoodEx level 1, the highest mean Ni levels were measured in 'Minerals and products derived thereof' (n = 72) reported at the mean level of 3,896 µg/kg for LB and 3,905 µg/kg for UB.

- High mean Ni concentrations were observed in 'Compound feed' (n = 516), in particular in complementary feeds for fattening cattles (n = 26; LB and UB mean = 6,813 µg/kg), unspecified complementary feed (n = 9; LB and UB mean = 5,270 µg/kg) and complementary feeds for fattening pigs (n = 6; LB and UB mean = 4,344 µg/kg).
- Within grains (n = 597), the Ni highest mean concentrations were measured in oats (n = 26; LB mean = 1,690 µg/kg; UB mean = 1,702 µg/kg).
- Among the forages and roughage feed commodities (n = 712), the highest mean Ni concentrations were observed in unspecified forages and roughage (n = 18; LB and UB mean = 1,606 µg/kg) and in lucerne (n = 119; LB and UB mean = 1,167 µg/kg).
- The feed category 'Oil seeds, oil fruits, and products derived thereof' (n = 204) was mainly covered by rape seeds with Ni concentration levels being for both LB and UB mean at a level of 762 µg/kg. Higher Ni concentration levels were reported for toasted soya (n = 13; LB and UB mean = 4,462 µg/kg) and sunflower seeds (n = 39; LB and UB mean = 1,566 µg/kg).
- Within the feed category 'Miscellaneous' (n = 68), a substantial number of data was available only for glycerine (n = 36; LB mean = 350 µg/kg and UB mean = 358 µg/kg) and unspecified miscellaneous feed commodities (n = 29; LB and UB mean = 836 µg/kg).
- For other feed categories, including 'Land animal products and products derived', 'Legume seeds and products derived thereof', 'Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed', 'Fish, other aquatic animals and products derived thereof', 'Tubers, roots, and products derived thereof' and 'Other plants, algae and products derived thereof' only a limited number of analytical results were available.
- Ni analytical results on hydrogenated vegetable oils/fats (n = 663) reported by the industry had the LB and UB mean Ni level of 527 and 530 µg/kg, respectively. These data were used only for the exposure scenario including hydrogenated vegetable oils/fats with the analysed Ni concentration.
- Compared to the 2015 EFSA opinion, Ni occurrence in feed is within the same order of magnitude for all feed categories with exception of 'Oats', 'Toasted soya' and 'Complementary feed' for which the current mean Ni concentrations are higher.
- When considering the diets with hydrogenated vegetable oils/fats based on the reported Ni concentrations, the mean exposures varied between 6.0 µg/kg bw per day in cats and 79 µg/kg bw per day in laying hens and the high exposure levels varied between 11 µg/kg bw per day in cats and 127 µg/kg bw per day in rabbits.
- Mean exposure estimates based on a worst-case scenario considering the maximum concentration of Ni assumed from good manufacturing practice in hydrogenated vegetable oils/fats (50 mg Ni/kg) varied between 27 µg/kg bw per day in cats and 255 µg/kg bw per day in rabbits. For the high concentration scenarios, exposures varied between 30 µg/kg bw per day and 307 µg/kg bw per day in the same species.
- The use of a worst-case scenario has led to a considerable overestimation of the real animal exposure to Ni. For this scenario, the estimated exposure to Ni for livestock and companion animals is in line with that previously reported by EFSA in 2015.
- The calculated exposure levels of livestock and companion animals for the realistic scenario (based on the reported Ni concentrations in feed) are lower (approximately from 1.5 to 6 times, depending on the species) than those estimated in the 2015 assessment.
- Due to lack of data it was not possible to also estimate other additional exposure to Ni as a result of processing (e.g. migration of metallic Ni from the stainless steel) or from other routes (in particular as a result of soil, sewage sludge ingestion).

Recommendations

- Member States should be encouraged to collect occurrence data on Ni in feed in order to improve the representativeness of data for the EU as well as for the feed categories.
- Studies on quantification of Ni ingestion from sources other than feed (e.g. water, soil, sewage sludge) and studies on possible increase of Ni levels as a result of feed processing should be performed in order to evaluate additional exposure sources.
- More data on mineral feeds and mineral premixtures should be collected since these materials are those contributing mostly to the Ni content in feed.
- Where applicable, the analytical data on compound/complete feed should be accurately classified according to the corresponding target animal/category.

Documentation provided to EFSA

FEDIOL (The European Vegetable Oil and Protein Meal Industry Federation), 2015. Analytical results of nickel in hydrogenated vegetable oil/fat. Submitted to EFSA on 23 April 2015.

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Abbreviations

AAS	atomic absorption spectrometry
BMDL	benchmark dose level
bw	body weight
CAS	Chemical Abstracts Service
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
DM	dry matter
DATA Unit	EFSA Evidence Management Unit
ET AAS	electrothermal atomic absorption spectrometry
FEDIOL	The European Vegetable Oil and Protein Meal Industry Federation
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
GF AAS	graphite furnace atomic absorption spectrometry
ICP-OES	inductively coupled plasma optic emission spectroscopy
ICP-MS	inductively coupled plasma mass spectrometry
LB	lower-bound
LC	left-censored
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
Ni	nickel
NOAEL	no observed adverse effect level
SOPs	standard operational procedures
TDI	tolerable daily intake
UB	upper-bound

Appendix A – Intakes and composition of diets used estimating animal exposure to Ni

The feed intake and the diet composition used to estimate the exposure to Ni of the animal species considered in this report are those extensively described in the by the CONTAM Panel in the Scientific Opinion on the risks to animal and public health and the environment related to the presence of Ni in feed (EFSA CONTAM Panel, 2015a). They are summarised in this appendix.

A.1. Feed intake

A.1.1. Live weights, dry matter intake for cattle, sheep, goats and horses, and the proportions of the diet as non-forage

	Live weight (kg)	Dry matter intake (kg/day)	% of diet as non-forage feed	Reference
Dairy cows, lactating	650	20.7	40	AFRC (1993)
Beef: cereal-based	400	8.4	85	AFRC (1993)
Beef: forage-based	400	9.6	50	AFRC (1993)
Sheep: lactating	60	2.8	50	AFRC (1993)
Goats: lactating	60	3.4	75	NRC (2007a)
Goats: fattening	40	1.5	40	NRC (2007a)
Horses	450	9	50	NRC (2007b)

A.1.2. Live weights and feed intake for pigs, poultry, rabbits and fish

	Live weight (kg)	Feed intake (kg/day)	Reference
Pigs: piglets	20	1.0	EFSA FEEDAP Panel (2012)
Pigs: fattening pigs	100	3.0	EFSA FEEDAP Panel (2012)
Pigs: lactating sows	200	6.0	EFSA FEEDAP Panel (2012)
Poultry: broilers	2	0.12	EFSA FEEDAP Panel (2012)
Poultry: laying hens	2	0.12	EFSA FEEDAP Panel (2012)
Turkeys: fattening turkeys	12	0.40	EFSA FEEDAP Panel (2012)
Ducks: fattening ducks	3	0.14	Leeson and Summers (2008)
Rabbits	2	0.15	Carabano and Piquer (1998)
Salmonids	2	0.04	EFSA FEEDAP Panel (2012)

A.1.3. Live weights and feed intake for dogs and cats

	Live weight (kg)	Feed intake (kg/day)	% of diet as cereal based feed	Reference
Dogs	25	0.36	65	NRC (2006)
Cats	4	0.06	55	NRC (2006)

A.2. Diets composition

A.2.1. Diet compositions of non-forage feed for cattle, sheep, goats and horses

Feeds(%)	Dairy cow	Beef cattle		Sheep	Goats	Goats	Horses
		Cereal-based	Forage-based	Lactating	Dairy	Fattening	
Wheat	15	–	–	14	–	–	–
Barley	19	55	36	16	24	20	–
Oats	–	–	–	–	33	37	40
Soybean meal	5	–	–	5	10	10	–
Rapeseed meal	20	5	20	10	10	10	–
Sunflower meal	–	5	–	5	–	–	–
Beans	5	–	–	10	–	–	10
Maize gluten feed	9	10	11	–	–	–	–
Wheat feed	8	5	10	13	10	10	30
Sugar beet pulp	8	10	12	15	–	–	–
Oat feed	–	–	–	–	–	–	12
Molasses	3	3	3	4	4	4	–
Hydrolysed vegetable oils	5	5	5	5	5	5	5
Mineral–vitamins premix	3	3	3	3	3	3	3

A.2.2. Diet compositions of feed for pigs and poultry

Feeds(%)	Piglets	Pigs for fattening	Lactating sow	Broilers	Laying hens	Turkeys for fattening	Ducks for fattening
Wheat	48	48	50	36	30	30	40
Barley	14	18	10	–	–	34	15
Maize	–	–	–	36	32	–	–
Soybean meal	22	11	16	15	22	15	25
Rapeseed meal	3	4	–	–	–	–	–
Lucerne meal	–	–	–	–	4	9	5
Wheat feed	2	7	12	1	–	–	7
Molasses	3	4	4	3	3	3	–
Hydrolysed vegetable oils	5	5	5	5	5	5	5
Minerals and vitamins	3	3	3	3	3	3	3

A.2.3. Diet composition for rabbits

Feeds(%)	Rabbit
Sunflower meal	20
Dried lucerne	17
Wheat bran	17
Barley	17
Sugar beet pulp	11
Beans	10

Feeds(%)	Rabbit
Hydrogenated vegetable oils	5
Minerals and vitamins	3

A.2.4. Diet composition for fish

Feeds(%)	Salmonids
Fishmeal	30.5
Wheat	13.2
Soybean meal	12.3
Maize gluten feed	11.5
Fish oils	31.9
Mineral–vitamins premix	0.6

A.2.5. Diet compositions for dogs and cats

Feeds(%)	Dogs	Cats
Wheat	18	18
Maize	18.5	18.5
Barley	18.5	18.5
Rice	18.5	18.5
Maize gluten feed	18.5	18.5
Hydrogenated vegetable oil	5	5
Mineral–vitamins premix	3	3

Appendix B – Statistical description of the concentrations of Ni across the feed categories

B.1. Statistical description of the concentrations ($\mu\text{g}/\text{kg}$) of Ni across the feed categories (cleaned final data set, data as reported)

Appendix B.1 can be found in the online version of this output ('Supporting information' Section).

B.2. Statistical description of the concentrations ($\mu\text{g}/\text{kg}$) of Ni across the feed categories as used to estimate animal dietary exposure

Appendix B.2 can be found in the online version of this output ('Supporting information' Section).

Appendix C – Exposure of livestock and companion animals to Ni from water consumed

The mean UB Ni concentration of 1.8 µg/L reported in 20,715 samples of tap water has been retrieved from the EFSA database on chemical occurrence data. Within species water consumption can vary considerably, influenced largely by ambient temperature but also to diet composition and level of activity and productivity. However, data for livestock have been published by a number of national authorities and summarised in OMAFRA (2007).

C.1. Water intake and its contribution to overall Ni exposure by livestock and companion animals

Animal species	Water intake (L/day)	Ni exposure from water (µg/day)	Dietary feed Ni intake (µg/day) ^(a)	Ni from water as % of total exposure
Dairy: high yielding	133	239	13,890	1.7
Beef: intensive cereal	41	73.8	3,875	1.9
Beef: fattening	41	73.8	4,949	1.5
Sheep: lactating	32.5	58.5	1,941	3.0
Goats: lactating	10	18.0	3,907	0.5
Goats: fattening	10	18.0	1,389	1.3
Horses	7	12.6	7,958	0.2
Pig starter	2	3.60	1,223	0.3
Pig finisher	9	16.2	2,491	0.7
Lactating sow	20	36.0	6,041	0.6
Chickens for fattening	0.4	0.72	124	0.6
Laying hens	0.25	0.45	158	0.3
Turkeys for fattening	0.75	1.35	417	0.3
Ducks for fattening	1.1	1.98	192	1.0
Rabbits	0.64	1.16	140	0.8
Cats	0.15	0.27	25	1.1
Dogs	1.2	2.16	177	1.2

(a): Dietary feed Ni intakes based on the exposure scenario considering the hydrogenated vegetable oils/fats with the analysed Ni concentration as reported to EFSA (Tables 3–5).