Critical Perspectives

Assessing the Extent of Environmental Risks From Nickel in European Freshwaters: A Critical Reflection of the European Commission's Current Approach

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Abstract: Nickel (Ni) has a been a Priority Substance under the European Water Framework Directive since 2008. As such it is deemed to present an European Union-wide risk to surface waters. Since 2013, the Ni Environmental Quality Standard (EQS) has been bioavailability-based, and new European Guidance supports accounting for bioavailability in assessing Ni compliance with the EQS. The European Commission has developed an approach to determine whether Priority Substances present a sufficient European Union-wide risk to justify an ongoing statutory monitoring programme, effectively to deselect a substance. This is a key step to ensure that finite monitoring resources are targeted at delivering environmental benefit, when there is an ever-growing burden of determinands to measure for all regulators. When the European Commission performed this exercise for Ni without accounting for bioavailability, they concluded that Ni should not be deselected, and Ni is an European Union-wide risk. Performing this same exercise with the same methodology, using regulatory monitoring data for over 300 000 samples, from more than 19 000 sites across Europe, and accounting for bioavailability, as detailed in the Directive, >99% of sites comply with the Ni EQS. Nickel shows very low risks for all of the criteria identified by the European Commission that need to be met for deselection. Accounting for bioavailability is key in the assessment of Ni risks in surface waters to deliver ecologically relevant outcomes. *Environ Toxicol Chem* 2022;41:1604–1612. © 2022 NiPERA. *Environmental Toxicology and Chemistry* published by Wiley Periodicals LLC on behalf of SETAC.

Keywords: Nickel; Bioavailability; Compliance; Risk assessment; Environmental Quality Standard

INTRODUCTION

Environmental Quality Standards (EQSs) for Priority Substances under the European Water Framework Directive (WFD) are applied to substances where a European-wide risk to aquatic ecosystems has been identified. The risk from a substance is determined by a combination of hazard and measured environmental exposure data (e.g., Carvalho et al., 2016). An EQS is derived to preserve the structure and function of aquatic ecosystems and human health via environmental exposures (e.g., secondary poisoning or drinking water).

Nickel (Ni) was classified as a Priority Substance in Europe at the outset of the WFD through a scoring procedure that considered human health and environmental hazard classifications and environmental occurrence. The scoring mistakenly identified Ni as a human carcinogen via the oral route, and no ecological risk assessment was performed in this process. As a Priority Substance, an EQS needs to be derived and applied to all European Union Member States. A bioavailability-based EQS of 4 µg Ni L^{-1} was implemented in 2013 (European Commission [EC], 2010) in acknowledgement of the critical importance of considering bioavailability in assessing the risk of Ni in the environment, to be applied across all the European Union's freshwaters. In addition, Technical Guidance has recently been produced by the European Commission on how bioavailability-based EQSs for metals should be implemented (EC, 2021).

Under the WFD individual Member States are responsible for monitoring surface waters and biota for EQSs for 44 Priority and Priority Hazardous Substances at sites monthly.

Sites are generally selected to represent a range of pressures and impacts on the aquatic ecosystem, but are determined by the individual Member States. Compliance with respective EQSs is undertaken on a yearly or three-yearly basis. This compliance may be undertaken on face value, or through the use of other approaches that would reflect confidence in the assessment (e.g., International Organization for Standardization, 2008), and the outcomes are reported to the European Commission. Most Member States make these monitoring data publicly available on the websites of the responsible regulatory organisation (Table 1). While many of the EQSs are assessed through comparison with annual average concentrations of the substance in filtered water samples, some are assessed through other operationally defined means, such as in specific types of biota (e.g., specifically fish fillets for mercury) or bioavailable concentrations, such as for Ni.

The recent European Commission Technical Guidance reiterated that to account for bioavailability in using the Ni EQS, supporting water chemistry data for pH, dissolved organic carbon (DOC), and Ca are needed for the sample. The bioavailable Ni EQS ($EQS_{bioavailable}$) has been in place since 2013 and so these additional supporting parameters have been required since that time. The resource burden of monitoring sites 12 times a year for over 40 substances, with the likelihood of this number increasing in 2022, has led to Member States to look for ways to reduce their routine monitoring commitments (EC, 2021). Hence, the European Commission has drafted an EQS Deselection Process, whereby existing EQSs are deselected if they do not present an European-wide risk to European freshwater ecosystems (Joint Research Centre [JRC], 2021). Initially, this process was targeted to EQSs where the substance had been banned, restricted or authorisations withdrawn (e.g., for some plant protection products), but then was extended to all existing EQSs under the WFD. As some of these EQSs were derived over a decade ago, it is worth considering that use and exposure patterns of substances may have changed in that time, and so they may no longer pose a significant risk. Under those circumstances, an European-wide EQS is no longer needed, and so that substance should be deselected.

Furthermore, Ni has not yet been assessed appropriately within the European Commission's Guidance (EC, 2021) and accounting for bioavailability or using the publicly available European Member State monitoring data. The purpose of the present study is to assess the Europe-wide risks from Ni to freshwater ecosystems against the EQS using the methodology defined by the European Commission. Specifically, we characterize the risks identified and assess if there remains an environmental benefit to continued Ni monitoring across all European freshwaters. We also describe some suggested revisions to the deselection approach for metals to properly account for bioavailability, to align with the long-established scientific evidence. The findings of the deselection exercise for Ni, when performed properly against the current EQS for Ni (i.e., by utilizing a robust ecotoxicity database and by taking account of bioavailability), indicate that the vast majority of sites and samples across Europe show very low risk.

The European Commission's deselection approach

Recently published Technical Guidance on the implementation of bioavailability-based EQSs outlines the appropriate approach for assessing potential risks to freshwater ecosystems from Ni (EC, 2021). Bioavailability is implemented following a tiered approach.

Tier 1 is a direct comparison of the annual average concentration in the dissolved phase at the site (e.g., the measured concentration in the sample) with the EQS, without accounting for bioavailability (4 µg Ni L^{-1}). If the annual average or measured concentration exceeds the direct comparison with the EQS, the evaluation then proceeds to Tier 2, which takes account of bioavailability using site- or sample-specific water chemistry. At this tier, the average pH, DOC, and Ca data are entered into a simplified bioavailability tool, such as bio-met (https://bio-met.net), which then performs a series of chemical speciation calculations to generate a toxicity threshold that is calibrated for the site- or sample-specific waters. Bio-met, in particular, has been validated and is consistent with the current Ni EQS (e.g., Peters et al., 2020). If an exceedance is identified at Tier 2, Tier 3 actions may include the use of the biotic ligand model (BLM; e.g., Nys et al., 2016) and/or consideration of local ambient background concentrations at the site of interest. In present study, we have taken an exceedance at Tier 2 to represent a failure, without any additional consideration of Tier 3 refinements, effectively meaning a level of precaution in the outcomes.

The European Commission's contractors, the Joint Research Centre (JRC), conducted an analysis of existing Priority Substances to assess whether any of them could be deselected, thus removing them from the requirement for all Member States to perform routine compliance assessments against the EQS (JRC, 2021). The first part of the procedure involves the calculation of a Spatial, Temporal and Extent of predicted-no-effect concentration (PNEC) exceedances score (STE score; as detailed in Carvalho et al., 2016) and then calculation of a risk quotient (RQ). The second component of the assessment examines the EQS exceedances at the 95th percentile level and determines the number of Member States where exceedances are observed. The full approach to deselection and its constituent parts are presented in Figure 1 and the Supporting Information. The European Commission's criteria for deselection identifies substances posing a very low risk as having a low STE score (<0.6), RQ less than 1, and when measured in ≥20 countries of which fewer than four show EQS exceedances at maximum concentration (JRC, 2021). All three criteria need to be fulfilled for a substance to be deselected.

The deselection approach was conducted by the JRC on monitoring data that were mostly collected between 2006 and 2014, and were supplemented with further data collected since 2014 from the WISE database (JRC, 2021). Nickel was reported by the European Commission as having an STE score of 0.519, an RQ of 1.25, and 10 of the 20 reporting countries exceeding

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TABLE 1: Summary of publicly available datasets used to undertake the deselection approach for Ni[a]

Country	2006 onwards						2013 onwards						2018–2020					
	Sites	Samples	Sites that can be assessed at Tier 2	Tier 1 exceedances (samples)	Sites that cannot be assessed at Tier 2	Tier 2 failures	Sites	Samples	Sites that can be assessed at Tier 2	Tier 1 exceedances (samples)	Sites that cannot be assessed at Tier 2	Tier 2 failures	Sites	Samples	Sites that can be assessed at Tier 2	Tier 1 exceedances (samples)	Cannot be assessed at Tier 2	Tier 2 failures
Austria	94	1464	94	22	1	21	94	1464	94	22	1	16	13	104	10	0	0	0
Belgium	44	1915	0	270	270	0	44	1915	0	270	270	0	0	0	0	0	0	0
Bulgaria	9	283	0	7	7	0	9	283	0	7	7	0	8	144	0	3	3	0
Croatia	8	457	0	5	0	5	8	457	0	5	0	1	8	23	0	0	0	0
Cyprus	21	101	0	15	15	0	21	101	0	15	15	2	0	0	0	0	0	0
Czech Republic	36	98	34	52	2	50	36	98	34	52	2	2	2	24	0	2	2	0
Estonia	140	1227	35	70	69	1	121	1008	35	43	42	0	35	160	8	7	7	0
Finland	215	3534	73	1471	1273	198	185	3246	42	1413	1255	28	75	531	10	281	220	0
France	6076	167 365	4627	4781	2966	1815	5757	131 930	4449	3158	1701	246	3770	45 883	3415	1192	256	123
Germany	6	349	4	3	1	2	6	161	3	1	0	0	3	52	1	0	0	0
Hungary	14	508	0	39	39	0	14	508	0	39	39	0	14	256	0	7	7	0
Iceland	4	12	0	0	0	0	4	12	0	0	0	0	0	0	0	0	0	0
Ireland	1431	11 898	1394	138	89	49	1431	11 898	1394	138	89	9	176	1413	79	68	42	5
Italy	318	4710	157	489	273	216	318	4710	157	489	273	88	103	1592	65	84	3	30
Latvia	28	504	27	37	7	30	28	504	27	37	7	11	0	0	0	0	0	0
Lithuania	14	38	13	1	0	1	14	38	13	1	0	0	0	0	0	0	0	0
Netherlands	6240	82 385	1841	26 920	12 395	14 525	4675	64 174	1460	21 226	9784	1908	3033	30 889	321	9736	8275	279
Poland	865	874	0	43	43	0	404	408	0	21	21	0	0	0	0	0	0	0
Portugal	816	2656	8	216	206	10	816	2656	8	216	206	6	665	1564	8	116	106	6
Romania	21	915	20	110	1	109	21	915	20	110	1	61	21	456	20	83	0	55
Slovak Republic	21	622	0	5	5	0	21	622	0	5	5	0	6	133	0	0	0	0
Slovenia	121	1443	0	50	50	0	121	1443	0	50	50	0	121	1419	0	50	50	0
Spain	2989	42 833	72	11 123	11 097	26	2989	42 833	72	11 123	11 097	14	2581	17 547	44	1793	1774	10
Sweden	17	70	1	3	3	0	16	54	1	3	3	0	0	0	0	0	0	0
Switzerland	1	125	1	5	0	5	1	6	1	0	0	0	0	0	0	0	0	0
Total	19 549	326 386	8401	45 875	28 812	17 063	17 154	271 444	7809	38 444	24 868	2390	10 634	102 190	3981	13 422	10 745	508

[a]Full datasets are in the Supporting Information.
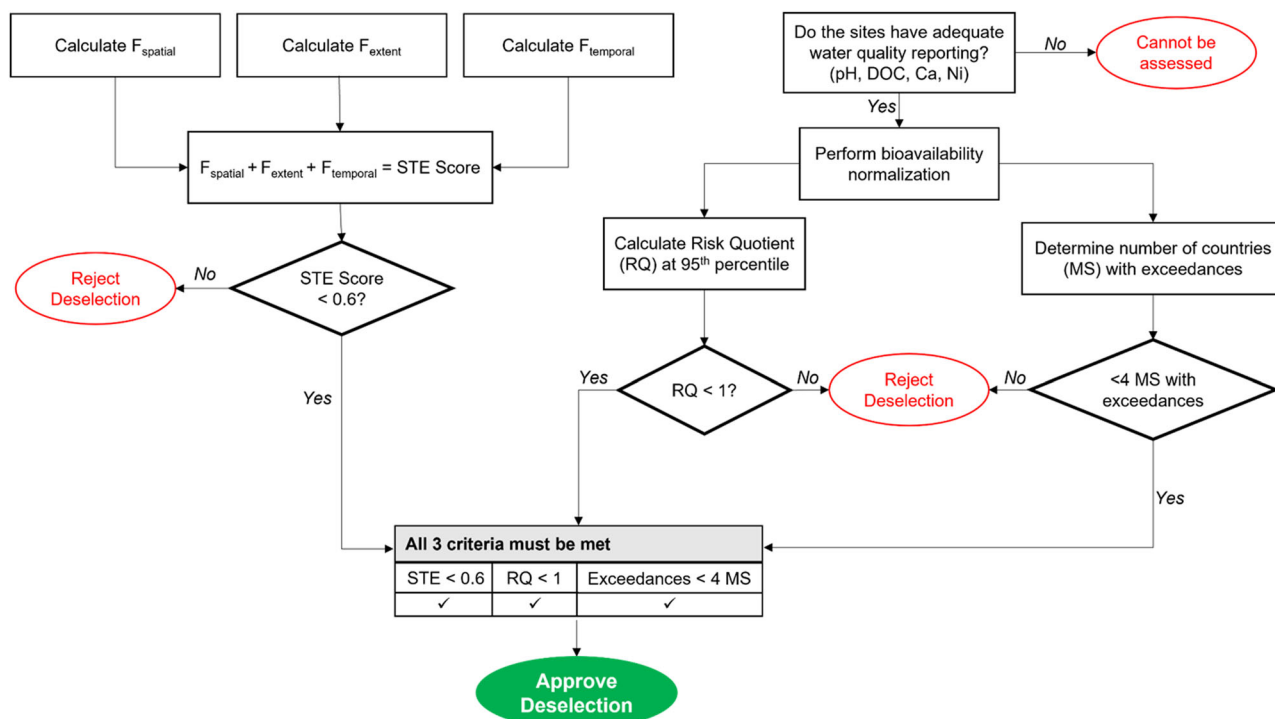Some sites may be able to be assessed at Tier 2 even when some samples cannot (see Supporting Information).

FIGURE 1: A summary schematic of the overall deselection approach developed by the European Commission. Schemes for calculating $F_{spatial}$, $F_{temporal}$, and F_{extent} are given in the Supporting Information. DOC = dissolved organic carbon; STE = Spatial, Temporal and Extent of PNEC exceedances score; MS = Member States.

the EQS based on the 95th percentile of monitoring data. Unfortunately, despite Ni being a bioavailability-based EQS, the JRC analysis was limited to comparing dissolved Ni concentrations against the EQS for bioavailable Ni. We present an alternative evaluation of the deselection approach for Ni based on the EQS of $4\,\mu g\,L^{-1}$ and accounting for bioavailability, that is, appropriately applying the EQS as it is set out in the legislation and guidance.

Accounting for bioavailability in the deselection approach

To perform the deselection procedure accounting for bioavailability, a monitoring dataset including pH, DOC, and dissolved calcium, as well as dissolved Ni, is required. Initially all available dissolved Ni data for Member States were collected from publicly available sources; subsequently, the bioavailability parameters were obtained where available and were matched to the dissolved Ni data based on sample location and date of sampling. Data were collected from Member States from 2006 onwards in accordance with the European Commission's approach (see Supporting Information, S1). Once these data had been collated, samples where the result was less than the limit of quantification (LOQ) and the LOQ was greater than twice the EQS were removed; any other samples less than the LOQ were treated as LOQ × 0.5, following the SC3 approach proposed by the JRC (2021). After data treatment, two further subsets of the data were extracted for

assessment alongside the complete dataset: data from 2013 to present, to assess the effect of only using data since the implementation of the current EQSs, and data from 2018 to 2020, to assess the effect of using the most recent data only. This was undertaken to investigate the temporal influence on the potential Ni risks. The numbers of countries, samples, and sites in each of these datasets are presented in Table 1.

To assess samples (and sites) while appropriately accounting for Ni bioavailability, bio-met v5 (bio-met 2019) was used as it has been demonstrated to provide reliable results that are fully consistent with the Ni EQS (Peters et al., 2020). Any samples with at least one bioavailability parameter (pH, DOC, Ca) missing (Table 1) could not be assessed for bioavailable Ni concentrations and therefore had to be excluded from the assessment to ensure that the EQS is applied in accordance with the way in which it was set (EC, 2010). Where samples were outside of the water chemistry ranges of the bioavailability correction that is used for the Ni EQS, and therefore also the bio-met tool, the Tier 1 RQ was used for calculation purposes, delivering a worst case assessment and introducing a degree of conservatism in the assessment. After calculation of the bioavailable Ni concentrations, the $F_{spatial}$, $F_{temporal}$, and F_{extent} were calculated (Supporting Information, Figures S1–S3) and the STE score was calculated (Figure 1), with calculations performed for all three datasets and the 95th percentile RQ calculated in line with the European Commission's methodology.

To determine exceedances of the Ni EQS at the 95th percentile level as well as the number of reporting Member States

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where exceedances were observed, the average pH, Ca, and dissolved Ni concentration for each site and the median DOC concentration were calculated and all sites were then assessed following the tiered approach (EC, 2021). Samples that exhibited exceedances at Tier 1 proceeded to Tier 2; any sites that had a bioavailability parameter missing could not be further assessed against the EQS and therefore were not included in the assessment further (Table 1). The 95th percentile RQ was then calculated for the entire dataset and for each country following the European Commission's criteria (Figure 1). It is possible to assess sites that exhibit exceedances at Tier 2 further by using the full BLM or by accounting for background concentrations (EC, 2021), although these exercises have not been performed in this assessment and therefore Tier 2 exceedances are considered to represent a failure against the EQS.

OUTCOMES OF THE DESELECTION APPROACH

The total dataset consists of 326 386 samples from 19 549 sites from 24 Member States plus Switzerland. The 2013 subset is of a similar size with 271 444 samples from 17 154 sites from 25 countries. The 2018–2020 dataset is significantly smaller than the other datasets due to the removal of older data (102 190 samples from 10 634 sites from 17 countries; Table 1). Each dataset has samples and sites that cannot be assessed at Tier 2 due to a lack of bioavailability parameters (Table 1).

The results of the various calculation components that contribute to the overall result of the deselection approach for Ni are summarized in Table 2 for each of the datasets covering the three time periods. The results for each dataset evaluated are very similar, not only in the individual components that summarize the spatial, temporal, and extent aspects of the STE score, but also in terms of the calculated RQs and the number of countries with potential EQS failures.

$F_{spatial}$, the spatial extent score of EQS exceedances for each of the three datasets was determined to be 0.01 (Table 2). This indicates that the spatial extent of exceedances is unchanged over the three periods assessed (2006 onwards, 2013 onwards, 2018–2020). The dataset used for the analysis is included in Supporting Information, S1.

$F_{temporal}$ shows some variation between the three datasets for the temporal extent of exceedances, with values ranging from 0.19 (from 2006 onwards) to 0.22 (from 2013 onwards) when bioavailability is accounted for. However, the limited variation in the values indicates that the most important aspect for calculation of the $F_{temporal}$ is to account for the bioavailability of Ni.

F_{extent} is calculated from a look-up table of the EXC_{extent} values reported in Carvalho et al. (2016). The EXC_{extent} values were calculated to be 0.975 for the 2006 onwards and 2013 onwards datasets, and 0.96 for the 2018–2020 datasets. This indicates that although there is some limited variation in these EXC_{extent} values, the overall F_{extent} score is 0 for all datasets, based on the look-up table EXC_{extent} values <1 provide an F_{extent} score of 0.

To calculate the overall STE score the three calculated factors are summed together (Figure 1). The overall STE scores were 0.21, 0.22, and 0.21 for the 2006 onwards, 2013 onwards, and 2018–2020 datasets, respectively. As with the $F_{temporal}$ and F_{extent} scores, this indicates that the age of the data is less important than accounting for bioavailability; this is particularly highlighted when compared to the STE score calculated by the European Commission of 0.519, in which bioavailability was not taken into account.

For the RQ calculation, two methods were used to assess the influence of data treatment on the overall calculation. Initially the RQ was calculated with substitution of the Tier 1 RQ where the Tier 2 RQ could not be calculated due to one or more of the bioavailability parameters being either missing or out of range of the bioavailability correction that is used for the Ni EQS and so also is the user-friendly bioavailability tool, biomet (see Supporting Information). A second assessment was performed where these missing or out-of-range data were excluded from the calculations. In both cases samples that could not be assessed at Tier 2, due to the lack of one or more of the bioavailability parameters, were excluded as these do not allow for the EQS to be appropriately applied as set out in the WFD (see Supporting Information, S1). Overall, the proportion of sites that could be assessed at Tier 2 was 43%, 46%, and 37% for the 2006 onwards, 2013 onwards, and 2018 onwards datasets, respectively. Although the percentage of sites removed is relatively large, this process ensures that the EQS is applied

TABLE 2: Summary of the results of the metrics from the deselection approach for the present study when accounting for Ni bioavailability and the European Commission's outputs

Deselection metric	2006–2020	2013–2020	2018–2020	European Commission's outputs
$F_{spatial}$	0.01	0.01	0.01	–
$F_{temporal}$	0.19	0.21	0.20	–
F_{extent}	0	0	0	–
STE score	0.21	0.22	0.21	0.52
RQ (95th percentile; with substitution approach)	0.48	0.45	0.46	1.25
RQ (95th percentile; excluded OoR)	0.43	0.41	0.41	–
Countries	25	25	17	20
Countries that can be assessed at Tier 2	16	15	11	-
Countries Exceedances (with substitution approach)	3	3	3	10[a]
Countries exceedances (excluded OoR)	0	0	2	-

[a]No account taken of bioavailability, EQS not applied appropriately.
OoR = out of range; STE = Spatial, Temporal and Extent of PNEC exceedances score; RQ = risk quotient.

as detailed in the legislation and all sites are assessed at Tier 1, which ensures that sites without the required bioavailability parameters but that do not have dissolved Ni concentrations above the EQS$_{ompromised}$ are not treated inappropriately. When the substitution approach to handling data reported as <LOQ was utilized, RQs ranged from 0.45 to 0.48, and with the exclusion approach, from 0.41 to 0.43 (Table 2). All of the calculated 95th percentile RQs were approximately three times below the value of 1.25 calculated by the European Commission. Critically, this highlights that if the EQS does not follow legislative direction and account for bioavailability, the outcome erroneously overestimates the potential risk of Ni to European freshwater ecosystems.

The ompromiseon approach and the exclusion approach were also applied for calculation of the country 95th percentile RQ and the number of countries exhibiting exceedances (Table 3). Where a site passes at Tier 1, the RQ was reported for the purpose of calculations with account taken of bioavailability where possible. In all cases the RQ is lower when the exclusion approach is utilized, but neither the substitution nor the exclusion datasets resulted in more than three countries with exceedances (Table 2). Based on the deselection approach proposed by the European Commission (Figure 1) and the calculated STE scores, RQs, and extent of exceedances, it can be concluded that Ni meets the criteria for deselection for all three datasets when the EQS is applied appropriately.

Assessing the risks of Ni to European freshwaters, through accounting for bioavailability as defined by the EQS (EC, 2010) and using the annual average Ni concentrations at sites (and samples), that is, in line with how compliance is to be determined in the WFD, we see low levels of exceedance. Indeed, greater than 99% of sites show compliance with the Ni EQS when accounting for bioavailability. Figure 2 shows an example for France (n = 142 137 samples from 4535 sites from 2006 to 2021), where just 122 sites had at least one sample fail over the EQS but passed at average values (the compliance measure under the WFD). However, 23 sites had at least one sample fail and failed at average values. Effectively, >99% of sites passed the Ni EQS in France over the time range considered when accounting for bioavailability. As can be seen from the datasets in the Supporting Information, this is a close reflection of the compliance picture across Europe where the Ni EQS has been implemented appropriately. Were natural background concentrations to be accounted for, an even lower exceedance rate would likely be expected.

Is the European Commission's deselection approach fit for purpose?

The relevant data from which to assess current exposures of Ni to European freshwaters are likely those collected most recently. The European Commission's approach to deselection has been to use monitoring data predominantly from 2006 to 2014. Importantly, the Europe-wide EQS for Ni from 2005 to 2013 was 20 µg L^{-1}. Consequently, the assessment performed by the European Commission largely focused on a time period prior to the current EQS taking effect, therefore it would be unreasonable to expect the bioavailable EQS of 4 µg L^{-1} to have been complied during this time span. Furthermore, the WFD states that the LOQ should be set at a third of the value of the EQS, therefore, up until 2013, the LOQ for Ni could reasonably have been 6.67 µg L^{-1}. This means that in following the European Commission's LOQ × 0.5 approach to the treatment of censored monitoring data in this time, if this value is less than the EQS (not the LOQ, i.e., 3.35 µg L^{-1}) these data are then included in their assessment, although this could introduce some unquantifiable bias in monitoring summary statistics. Identifying a need for improved analytical performance in areas where LOQ values are insufficient to assess compliance

TABLE 3: Country-specific results, as summarized in Table 2, rows 5 and 6, of the RQ of the 95th percentile of concentrations compared with the EQS, accounting for Ni bioavailability

Country	2006–2020		2013–2020		2018–2020	
	RQ with substitution approach	RQ with out of range excluded	RQ with substitution approach	RQ with out of range excluded	RQ with substitution approach	RQ with out of range excluded
Ireland	0.13	0.12	0.13	0.12	0.55	0.40
Romania	0.58	0.58	0.58	0.58	0.75	0.75
Germany	0.30	0.30	0.31	0.31	0.35	0.35
Austria	0.32	0.26	0.32	0.26	0.16	0.13
France	0.31	0.28	0.29	0.25	0.30	0.25
Estonia	0.18	0.11	0.17	0.07	0.09	0.04
Czech Republic	0.89	0.89	0.89	0.89	–	–
Finland	**36**	0.59	**58**	0.52	0.49	0.45
Italy	0.80	0.80	0.80	0.80	0.83	0.79
Latvia	0.23	0.23	0.23	0.23	–	–
Lithuania	0.59	0.13	0.59	0.13	–	–
Netherlands	0.80	0.73	0.88	0.77	**1.1**	**1.0**
Switzerland	0.13	0.13	0.15	0.15	–	–
Portugal	**3.2**	0.90	**3.2**	0.90	**3.3**	**1.0**
Spain	**1.9**	0.63	**1.9**	0.63	**1.3**	0.62
Sweden	0.16	0.16	–	–	–	–

Values in bold show exceedances at the P95.
EQS = Environmental Quality Standard; RQ = risk quotient; – = country cannot be assessed.

FIGURE 2: Assessment of potential Ni risks in France ($n = 142137$ samples from 4535 sites from 2006 to 2021), where green dots are samples that pass at either Tier 1 or Tier 2 and site average data passes at Tier 1 or Tier 2, purple dots indicate at least one sample fails at Tier 2 but site average data pass at Tier 1 or Tier 2, and black dots indicate at least one sample fails at Tier 2 and site average data fail at Tier 2.

against the EQS may be more appropriate than excluding data from the assessment.

It is important that the EQS used for the assessment was applicable during the time period that the exposure data represent. If this is not the case, then it is not possible to assess the appropriateness or adequacy of the EQS that has been used in the assessment. If the purpose of the assessment is to establish if an EQS is required for Ni, or any other substance, then there should be a strong preference for using the most recent monitoring data as the basis for the assessment. If the assessment is conducted on historic data, it will not be possible to evaluate whether there is a current need for the EQS. The assessment performed by the European Commission does not provide a clear indication of whether current Ni exposures in Europe comply with the EQS because they are not based on sufficiently recent exposure datasets. An evaluation of whether or not an EQS may have been

required a decade ago is not necessarily a reliable indicator of whether the same EQS will still be required for the next 10 years. Therefore, the measured Ni data from 2018 onwards should be used in the deselection approach. There are, however, good reasons for conducting evaluations based on historic data because although such information is not useful for compliance assessments it is useful for purposes such as environmental status reporting. Similarly, evaluating longer-term trends in contaminant concentrations or risks requires historical data, and comparing shorter periods of time against each other could indicate whether risks were decreasing over time or if extreme weather conditions were influencing the results, such as concentrations being reduced due to additional dilution during exceptionally wet periods. Such an evaluation of differences over time could improve the certainty of the conclusion based on the most recent monitoring data.

Taking account of bioavailability is extremely important in understanding the potential risks posed by trace metals such as Ni to aquatic ecosystems (EC, 2021). The importance of bioavailability is recognized by the European Commission in setting the EQS for Ni as a bioavailable Ni concentration, rather than as a dissolved Ni concentration (EC, 2010). Simple, user-friendly tools are available for performing assessments of Ni bioavailability such as bio-met. Bio-met has been demonstrated to provide reliable predictions (Peters et al., 2020) of the local bioavailable Ni concentration and the local HC5 value based on the dissolved Ni concentration from data for the local water chemistry conditions (pH, DOC, and Ca). If bioavailability is not considered, it is possible to identify some of the sites at which there is very low potential risk due to Ni, but it is not possible to reliably estimate RQs for sites at which dissolved Ni exposures are elevated.

There are some limitations with the overall approach toward deselection, particularly with regard to the treatment of data that is reported as below the LOQ, and more importantly to distinguishing between isolated local risks in a limited number of places and a continent-wide problem. However, the use of data that was collected before the EQS being evaluated came into force, and the failure to assess compliance against the EQS for Ni as it was set by the European Commission (EC, 2010), that is, as bioavailable Ni concentrations, have ompromised the assessment performed by the European Commission to a much greater degree.

Is Ni a continent-wide risk?

The identification of Ni as a Priority Substance, which was largely weighted on a scoring approach that considered human health classifications, presumes that it is expected to pose widespread risk on a continental scale and therefore needs to be widely monitored. However, the findings of the deselection exercise, when performed against the current EQS for Ni as it was set (EC, 2010; i.e., by utilizing a robust ecotoxicity database and by taking account of bioavailability), indicate that the vast majority of sites show very low risk. Exceptions where Ni may pose a risk are localized issues in a limited number of areas, for example in the vicinity of Ni mines in Finland (Heikkinen et al., 2002). The very high levels of compliance against the EQS for Ni observed in the present study demonstrate that Ni is very clearly not a continent-wide risk in freshwaters, based on the European Commission's own metrics.

Following the European Commission's own approach to assessing risks Ni is shown to be of low risk, with STE score ≈ 0.22, RQ ≈ 0.41, and limited to three countries showing exceedances of the 95th percentile of EQS. Consistency of results for datasets based on differing timescales could reasonably suggest that overall these results tend to reflect background levels of Ni exposures, rather than sources of anthropogenic contamination.

The tiered approach to compliance assessment provides a staged framework within which sites where Ni does not pose a potential risk can be identified easily and efficiently in the first tier based only on the measurement of dissolved Ni concentrations. However, it is important to note that this preliminary stage of the approach cannot reliably identify sites that are at risk and is therefore not a proper assessment of compliance against the EQS for Ni. The first tier of the approach identifies those sites where monitoring of additional supporting parameters (pH, DOC, and Ca) is required to enable compliance against the EQS for bioavailable Ni to be assessed. This ensures that resources are targeted toward those sites where they are required to properly evaluate the potential risks due to Ni.

It should be recognized that to determine whether Ni is a continent-wide risk, the Ni EQS needs to be appropriately implemented. Specifically, not all Member States are collecting the required supporting parameters to undertake the tiered approach, but most are monitoring dissolved Ni, facilitating an assessment at Tier 1 only. However, approximately 25% of Member States should also be performing assessments at Tier 2, for sites that fail at Tier 1, but they are currently not doing these Tier 2 assessments. The European Commission's central reporting repositories still do not require the supporting data that is required to assess bioavailability (pH and DOC) to be submitted, and it is unclear whether the measured Ni concentrations detailed have been corrected for bioavailability. The new guidance (EC, 2021) will no doubt provide an opportunity to recognize the importance of collecting these data to deliver better environmental protection. However, it is clear that nearly 10 years after the adoption of a bioavailable Ni EQS under the European WFD over one-quarter of European Member States appear not to have collected data that are sufficient to assess the potential risks from Ni in line with the EQS (EC, 2010) in their surface waters, despite having other data indicating a need to perform such an assessment.

CONCLUSIONS

Levels of compliance with the Ni EQS exceed 99% in freshwaters across European countries that implement bioavailability in accordance with the guidance and for which data are publicly available. This demonstrates the very low levels of risk from Ni and that routine wide-scale monitoring of Ni in European freshwaters is unlikely to deliver any environmental improvement but does entail considerable costs in time and resources. Specifically, considering the number of samples analyzed between 2018 and 2020 in implementing the Ni EQS as it was set (EC, 2010), and assuming the proportions would be similar for all Member States, over a 5-year period deselection of Ni would provide a saving in monitoring budgets in the region of €15 million. It is notable that there still appear to be some areas where the EQS for Ni is not being properly implemented by taking account of bioavailability, although recently published guidance (EC, 2021) should see this situation improve in the future.

Nickel should be a candidate for deselection as a Priority Substance due to the very low level of risks identified on an

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European-wide basis when evaluated against the existing EQS for bioavailable Ni. It is important to take account of Ni bioavailability in the assessment process to avoid drawing inappropriate conclusions about the scale and extent of the risks posed. A recent amendment to the European Commission's deselection approach is that a single exceedance of an EQS means that a substance cannot be considered for deselecting. Although one exceedance across Europe hardly seems to confirm a continent-wide risk, for naturally occurring substances, such as metals that may be geogenically enriched locally or have been sought at sites since pre-history, consequently considering more evidence-based approaches would be beneficial.

We have considered regulatory monitoring data for over 300 000 samples from more than 19 000 sites across Europe. However, it is clear that there are some significant shortcomings in the implementation of the current EQS for Ni in some Member States, particularly in terms of performing bioavailability assessments. Evidence- and science-driven approaches to the assessment of Ni risks must account for bioavailability appropriately and in accordance with the recent guidance.

Supporting Information—The Supporting Information is available on the Wiley Online Library at https://doi.org/10.1002/etc.5352.

Disclaimer—The authors work for, or are subcontractors to, NiPERA. This work was funded by NiPERA.

Author Contributions Statement—**Adam Peters**: Writing—original draft. **Iain Wilson**: Writing—original draft. **Graham Merrington**: Writing—original draft. **Christian Schlekat**: Writing—review & editing. **Ellie Middleton**: Writing—review & editing. **Emily Garman**: Writing—review & editing.

Data Availability Statement—All of the data used in this analysis are included in the Supporting Information. Associated metadata and calculation tools are available from the corresponding author (graham.merrington@wca-consulting.com).

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