Final RCOM for September 2014 bioavailability guidance for metals

#	From	Comment	Response
1	NL	There are two issues: 1) Derivation of EU-generic EQS(bioav); 2) Tools to derive local EQS or PNEC. The route to achieve the first is a different one than the second. One cannot use 2) to derive 1).	It is probably the case that both need to be covered in this guidance. The EQS TGD gives only broad concepts, whilst the EQS dossier for Ni includes the derivation of the $EQS_{bioavailable}$ This derivation incorporated the use of friendly tools to identify sensitive conditions in a sensitive member state.
2	NL	The target audience for the guidance should, in any case, be the water authorities; the subject of the guidance should be the available tools and how to use them for compliance checking. According to the new Directive (2013/39/EU) we have a bio-available EQS for Nickel and Lead. A suggestion might be to differentiate for the compliance check for Cd, Hg, Ni and Pb. Clarify the different "rules" for Hg (No correction), Cd (hardness correction), Pb (correction) and Ni (BLM)	The target audience probably should be all stakeholders, arguably water authorities are one the most important. Yes, in regard to the different treatment of each trace element. We will insert text or a new section on this.
3	NL	In the current draft, the view of the UK seems to be dominant of course. As other MS are expected to contribute to this guidance, this will indefinitely lead to a more balanced view in the next draft. Information on the developments in The Netherlands as regards the simplified BLM-tool PNECpro will be delivered in due course.	Out of all MS the UK has probably done the most work on bioavailability implementation. We hope that other Member State experiences will be included in future drafts to compliment those of the UK. There are now several examples from France in the text.
4	NL	It should be made clear what the role of the background concentration is for the different metals and corresponding BLM. Does adaptation to background concentrations play a role in metal toxicity once BLM's are used?	How and where backgrounds might be used is probably going to be a policy decision, although we recognise that backgrounds are more explicitly treated in some BLMs than in others e.g. Zn. Examples from MS on the treatment of backgrounds will provide additional content for this section of the guidance.
5	NL	Include text as regards compliance check for MAC.	This could be done, but would currently need to be generic as no bioavailability-based MACs have been derived under the WFD. Further, the acute BLMs in circulation now are not based on EU ecotoxicity databases (although development is underway to fit with EU compliant effects data).
6	NL	Include some text on compliance checking for transitional and coastal waters using BLM-tools	This is a good question. Perhaps some views from MS on how this might be done and where the salinity boundary might be in relation to not using the

			freshwater BLM and switching to marine-based corrections?
7	NL	Technical details of the tools should be moved to the appendix.	Presume this is in relation to Section 5? No problem. We will restructure as you've recommended.
8	NiPERA	It would be helpful to have a glossary of terms up front	Agree
9	NiPERA	The model that we are considering, i.e., the BLM, uses toxicity as the endpoint. This should be emphasized as it is the driver for the EQS.	OK
10	NiPERA	Table 1.1 is outdated and needs to be revised to reflect the current situation – currently it doesn't match the text.	OK
11	NiPERA	In Section 3.2, it should be stressed that that a main harmonizing principle is that all user friendly models should have the same basis, i.e., the same ecotoxicity databases, the same BLM parameters, inter-species extrapolation processes, and HC5(50%) determination methods.	To be added. A tool must show acceptable performance relative to HC5 predictions from these. i.e. validated against these.
12	NiPERA ILA/ILZRO	Section 4.3, can other guidance be referenced that assists in collection, preparation and preservation of samples?	Agree, this will be developed further with detailed references to these methods, e.g. CIS Guidance #19.
13	NiPERA	When using historic monitoring data in an assessment it is important to clarify the QA/QC characteristics.....	Agree, will add text to reinforce that input data quality characteristics will have an important influence on outcomes. Reference will be made to ISO 17025 and ISO 5667 series
14	NiPERA	Section 6.1.2. Can the differences between 2 and 3, in relation to options for outside the boundaries, be better explained.	Yes. Text will be added here.
15	ILA/ILZRO	The document needs information with guidance and examples on approaches for EQSbioavailable that are currently not based on BLM under WFD – for example, bioavailable Pb EQS in the 2013/39/EU Directive. This is a major deficiency of this document as all information and examples are targeted for BLM-based EQS. I think such information can be added in each section as appropriate in addition to current information or examples for BLM-based EQS, or adding completely a separate chapter for non-BLM based EQS (preferable).	Agree. See response to Comment 2.
16	FRA	Added Risk and Total Risk should really be dealt with explicitly in the text.	Agree, Section 4.5 to be updated.
17	FRA	Where the user-friendly tools are within a factor of two compared to the full BLM outputs is that under or overprotective?	Appendix 2 will show the performance of the tools compared to the full BLM outputs. It tends to vary between metal and tool.
18	FRA	In relation to the requirements for a	Good point. Yes, these data are

		user-friendly tool having clear and transparent information on the derivation and validation – what does this mean? Are the transfer functions which are embedded in simplified BLMs (Bio Met and PNEC Pro) made available? Or else, do we encourage member states to develop their own user-friendly models? In my opinion, some regulators could be reluctant to use simplified BLMs as they might be seen as "black boxes".	generally all available. For M-BAT the transfer functions are available as appendices of the EQS sheets for each metal (being key in the EQS derivation process), for PNECpro these are published and available on the website, for Bio-Met all the information and datasets are also available on the website. However, this point needs to be made clearer in the text!
19	FRA	While median DOC measures may be appropriate, or defaults in screening assessments at 25th percentiles, what are the best summary statistics for Ca and pH? Use the 90th percentile of pH values and 10th percentile of dissolves Ca concentrations of the waterbodies?	Agree, text needs to be added to 4.3.1 to make this clearer, or at least the experiences of others and potential implication of the selection.
20	FRA	Section 6, Maybe good to remind end users that all the calculation will be influenced to some extent by the value of the generic EQS (might be of importance for specific pollutants whose EQSs are set at national level)	Agree. This will be emphasised at the beginning of this section.
21	FRA	In relation to capacity of the tools, how many lines (samples) can be processed at the same time?	For tools operating stand alone there is a limit of 2000 for bio-met, 1000 for M-BAT and when M-BAT is used in LIMS then there is no limit.
22	SE	General comment: The text is often quite "wordy" and it could be made more stringent. Some parts are not specific to the implementation of BLMs, e.g. handling censored data and confidence of failure, and could be removed from the document to keep it more focused on how and when to use BLMs.	The text is aimed at practical implementation of an $EQS_{bioavailable}$, and issues such as dealing with censored data and confidence of failure clearly fall within the remit of implementation. It is perhaps also important to mention them here as they are not dealt with elsewhere in existing guidance. For example, censored datasets are often encountered when moving to an EQS which is dramatically lower than the previous and for which additional parameters is required, such as DOC and Ca.
23	SE	Chapter 1.1, 3rd section: Sweden should be deleted from the steering group since we only have been commenting on drafts.	Agreed, although given the extent and nature of the comments received you may well wish to be included as authors.
24	SE	Chapter 1.2, last section: Measuring total conc of metals is relevant to assess load (cf for example the OSPAR RID program to estimate total input to the marine env from riverine sources, but also relevant to assess load to sediment, total load from a particular emission source etc), and may also be relevant for human health (drinking water).	Agree, but the Directive does indicate the measuring of dissolved metal concentrations and as this text is in reference to the implementation of bioavailability based metal standards there is limited relevance to total metal measures. The section on permitting has yet to be finished and may well include more reference to total measures.

			In reference to the pelagic comment, total measures are not ecotoxicologically based and as the EQS is effectively the lowest for whichever matrix, i.e. EQS is derived for all compartments including sediment and lowest is chosen the $EQS_{bioavailable}$ is protective of all other compartments, not just pelagic.
25	SE	Chapter 1.3, 2nd section: Inappropriate to refer to "ecological status" here. Suggested change "to no adverse effects on pelagic organisms".	Not really. Compliance with the EQS is a metric by which to assess ecological status. If the EQS is not met then the ecological status would be less than good (especially for specific pollutants).
26	SE	Chapter 1.3, 2nd section page 13: Please mention areas in Europe (geographical and type of waters) for which the models are less appropriate/applicable. Please define "nearly all", does it refer to eg 95% of investigated waters?	The applicability of the models is determined by the applicability or validation range, as indicated in Section 6.1. The $EQS_{bioavailable}$ is set to protect 95% of the waters in the most sensitive region (in the case of nickel this was Austria), as agreed at the WG for nickel as practical way forward.
27	SE	Chapter 1.3, 4th section page 13, sentence "Therefore, the EQSbioavailable is a dissolved metal concentration, but for water conditions that result in that dissolved metal concentration **being highly (100%) bioavailable**." : ? reasonably worst case = 100 % bioavailabity? This is contradictory to the fact that 5% of the Austrian data resulted in lower EQS.	"100%" removed. Agree, that isn't all that clear, but under the conditions of the EQS the metal is effectively nearly all bioavailable, there may be 5% of sites under conditions in Austria when the metal is also highly bioavailable.
28	SE	Chapter 1.3, last section page 13-14, sentence "Where an EQSbioavailable would not protect other receptors/compartments under certain water chemistry conditions the QS for the alternative receptor would become the overall EQS for those water conditions. This would have the effect of setting an upper limit to the range of possible EQSsite-specific derived from the bioavailability relationship.": We think that a table of QSs (drinking water, MACs? – for MACs see later comment) for other receptors/protection goals should be included.	Not quite sure what this means. Is the request here to include a table that clearly shows this and gives an indication of when a site-specific PNEC calculated using bioavailability might get close to another regulatory limit?
29	SE	Figure 1.3, page 15: Section 2 does not refer to "total" vs "added risk" in the sense normally made (whether the EQS refers to a value to which background should be added or not), or? If this is what "total vs added risk" refers to, a clarification might be needed also in chapter 2,	Changes made here in the Figure to more clearly reflect the section headers.

		under the tier 2 text. Rename the box for section 2 to "A tiered approach" or "A suggested tiered approach".	
30	SE	Chapter 2.2: This chapter should be rephrased to describe a suggested approach and not the UK approach.	One of the key aspects to the guidance is to clearly demonstrate to MS and stakeholders, that while the use of an $EQS_{bioavailable}$ does represent a step change in the way compliance works for metals, it does not represent an insurmountable and impractical task. Therefore, to clearly provide examples of MS who have made the system work and who use the approach in an automated and straight-forward way is probably very important. Implementation is not an abstract hope but a clearly readily achieved.
31	SE	Chapter 2.2, tier 1: Before step 2, we suggest to add a check against "maximum" values too (MAC/drinking water).	Do you mean to check *after* accounting for bioavailability to ensure that the site-specific PNEC does not get near these other values? That would perhaps make a bit more sense?
32	SE	Chapter 2.2, tier 2, sentence on LIMS: Informative but not relevant in this section, could be deleted.	See response to comment 30 for reasoning for keeping included.
33	SE	Chapter 2.2, tier 2, last sentence: Perhaps this is yet another tier instead? Is this "total and added risk" (as referred to in fig 1.3?) Should this step be performed before or after BLM model? (might consider to clarify this in the fig 2.1. too)	All the discussions, unless specifically noted, are for total risk approaches. The considerable challenge with trying to account for ambient background concentrations of trace elements is estimating what they are. This tends to be less than scientific in its approach, and so added risk approaches are considered post accounting for bioavailability (following a total risk approach). Local ambient background concentrations might be elevated compared to the rest of a water body perhaps due to natural enrichment and the ecology may have adapted to these exposures in some cases.
34	SE	Chapter 2.2, tier 4, last sentence: Unclear sentence. In what way do the application of BLMs help identification of causal factors? This sentence should be deleted.	It is possible to establish whether the waters are relatively sensitive to low level of exposures, i.e. specific water chemistries or impacted via other factors. Line deleted.
35	SE	Chapter 2.2, figure 2.1: The right bar "No further action necessary" gives the impression that it is OK to pollute up to this level….We strongly suggest that you replace with "Good WFD status" or similar instead.	Change made, although it should be clear that was never the impression intended as to achieve the EQS, based on no effect, and low effect concentrations, would suggest it is OK to pollute.

		Also the Tier 4 bar: "Remedial measures" should be rephrased: "Not good WFD status" or at least "Water body to be included in Program of Measures". Using the word "remedial" might give the impression that "clean up" is needed, but this is not necessarily the most appropriate measure.	Tier 4 bar has been changed to "Failing to achieve good chemical status".
36	SE	Chapter 3, 1st section, last sentence: It is unclear what this second approach refers to, any references?	Example given. This is the approach taken for the existing lead EQS in the Directive.
37	SE	Chapter 3, 2nd section: Unclear. What about the second approach above? "accounting for availability through the development of relationships, based on scientific evidence and supporting ecotoxicity data, to account for the mitigating effects of water chemistry parameters upon chronic toxicity." Unclear what it refers to but seem to link to availability and toxicological endpoints….	The 'availability' approaches, as used in the lead EQS use empirical relations derived from ecotoxicity data to derive reasonable worst case corrections (in the case of lead this is DOC). BLMs account for complexation in the water and competition at the biotic ligand (such as the fish gill). It is this consideration of the chemistry and the biology across taxa that can be regarded as bioavailability.
38	SE	Chapter 3.2, box, fist bullet: Quality controlled is perhaps better to use here – a peer reviewed publication does not necessary fulfil the regulatory requirements; refer to CIS 27?	Agreed
39	SE	Chapter 3.2, box, bullet 6: What is the difference between boundary conditions, validation range, applicability range, consider rephrasing for consistency.	Agree, consistency required with Section 6.1.
40	SE	Chapter 4.1.1, title: We don't think the title reflects the content of this section, furthermore we miss a conclusion maybe because the conclusion is unclear. What we learn from the section is that averaged data can be used under some circumstances, but the description of these circumstances is quite diffuse.	Title changed. I think the conclusion is that, it depends and that it needs to be assessed on a Waterbody by water body basis. Text added here to try and clarify.
41	SE	Chapter 4.1.1, 2nd section: Shouldn't this be moved down further; the preferred approach is to handle each data point individually. To use "average pH" etc is only a second choice?	See above, it depends on the variability noted in the waterbody and may also be down to costs and sampling and analysis resource.
42	SE	Chapter 4.1.1, 4th section "Where data for physico-chemical supporting parameters are only available as annual averages these should only be applied to correct an annual average dissolved metal concentration.": Why? Will an annual average calculated by applying default physico-chemical data to	The issue here is to ensure similar summary statistics are used in the calculations. Default data tend to be set to relatively low percentiles of frequency distributions and so would generally give lower site-specific PNECs and are more precautionary.

		monthly metal data differ?	
43	SE	Chapter 4.2, 2nd section "There is little point in undertaking an assessment of potential risks from metals accounting for bioavailability if the limit of quantitation or detection of the metal in question is greater than the EQSbioavailable.": In this case a measured concentration still is posing a risk.	No, clearly not. The value recorded in the dataset will be < LoD, which means the value is less than the LoD, but what the value is not know. It means that if the LoD of the analytical assessment is 10 ppb but the Ni EQS is 4 ppb any comparison is valueless, unless the values are recorded above the LoD. The QA/QC Directive states the need for the LoQ to be 30% of the EQS. The measured concentration could still be corrected for bioavailability, so will not necessarily fail a bioavailable EQS if the dissolved concentration is measureable.
44	SE	Chapter 4.2, 1st section page 27: The directive says: "the water EQS refer to the dissolved concentration, i.e. the dissolved phase of a water sample obtained by filtration through a 0,45 µm filter or any equivalent pre-treatment, or, where specifically indicated, to the bioavailable concentration." It states what the EQSs refers to, but not that it is required to measure dissolved concentrations.	Text amended. This is of course a Member State choice, the implications of which are clear and would no doubt be dealt with by the Member State.
45	SE	Chapter 4.2, 1st section page 27, last sentence: Doesn't really matter for Tier 1 if total concentrations are below EQSbioavailable. Further, total concentrations could be used as a first step also at tier 2 as a screen to reduce number of water bodies potentially at risk, and to identify those for which dissolved data may affect the assessment.	Agree, text inserted for first comment here, good point. Yes, very true. A proportionate and precautionary step to take. Text added.
46	SE	Chapter 4.2, box page 28: See previous comment.	Agree, text added.
47	SE	Chapter 4.4.1: How come this chapter in this report? Is not specifically related to metals (or BLM)? Other – more scientific – tools also exist, should be mentioned in this context, if this chapter kept…Kaplan Meier mentioned later on for example). Guidance that is covered elsewhere need not to be included in this report. At least it should be clear what the status of this text is in comparison to the QA/QC etc.	Good question. The reasoning behind this is that often MS who are starting on this journey find that the datasets needed to adopt this approach are not complete, because this is a new way of working. Also, as we see from EIONET and MS datasets, metal LoDs are often way too high to facilitate a proper feasibility study (e.g. previously the UK, France). As such there is a need to be able to deal with 'patchy data'. As was shown in the previous prioritisation exercise, the technical understanding to do this in MS do not always exist and while reference is made to methods (one that really should be avoided, unless fully aware

			of implications, is that given in the QA/QC Directive of ½ LoD!) details are rarely given. Would welcome assistance in identifying where else this methods may described in existing guidance, we struggled to find it. Some text has been added on KM method, although it is outwith the scope of the guidance.
48	SE	Chapter 4.4.1, 2nd section "The recommended way forward in the QA/QC Directive is…": Rather required. The QA/QC directive says: "Where the amounts of physico-chemical or chemical measurands in a given sample are below the limit of quantification, the measurement results **shall** be set to half of the value of the limit of quantification concerned for the calculation of mean values.".	Text changed to "required". This is really poor approach though and the implications of which really need to be understood before its adoption.
49	SE	Chapter 4.4.2, figure 4.2: The figure, figure legend and text are a little bit unclear. In legend it says "Pale blue squares indicate water body default DOC concentrations and pale blue lines indicate hydrometric area default concentrations" but there seem to be both large and small pale blue squares (and line) in the figure.	Corrected
50	SE	Chapter 4.4.3, title: Unclear title.	Rephrased.
51	SE	Chapter 4.4.3, 1st section: Consider moving 1st section to beginning of 4.4, and rephrase title to describe the content of the other important section, eg "identification of sensitive waters".	Section moved to beginning of Section 4.4. It is perhaps worth noting that these exercises often don't identify many sensitive waters.
52	SE	Chapter 4.5: Should be clear that 2008/105/EC actually refers only to NATURAL background. Ambient background is only mentioned in non legally binding CIS 27. How to identify /natural/background is part of CIS 27 – why this description also here? Please double check for any contradictory statements….and focus perhaps primarily on how to take background into account in using BLMs, and perhaps the ecotoxicological relevance of taking background into account, given that the BLMs focus on assessing bioavailability (toxicological effects).	I'm sure this is correct. However, this is a practical guidance and for all practical purposes 'natural', certainly for the metals being considered here is a bit of a stretch. The identification of natural backgrounds is from a practical and regulatory perspective very difficult and almost always moves away from scientific considerations towards policy pragmatism.
53	SE	Chapter 4.5, 2nd sentence:	

		This depend on metal. For some there might be areas free of anthropogenic influence, but for metals subject to long range atmospheric transport there are no" free" areas.	Agree
54	SE	Chapter 4.5, section 4: According to the dossier for Cd the AA-EQS is derived as a maximal permissible addition (thus ARA), but MPA + Cbackground not to exceed 0,26 µg/l (to also be protective of sec. pois.)	Text corrected
55	SE	Backgroundconcentrations and BLMs: The guidence could be more clear regarding recommendations on when (TRA vs ARA, at what tier) and how (eg BLM first without consideration of BC, next step subtract BC from measured conc and run BLM again) to consider both bioavailablity and backgroundconcentrations.	The only metal for which backgrounds might be considered before accounting for bioavailability is for zinc. In the new version of bio-met there is an opportunity to account for zinc ambient background concentrations. Effectively, a background may be subtracted from the exposure data before this is entered into the tool for bioavailability consideration.
56	SE	Chapter 5: A description on how to evaluate data when a national EQS different from the generic would be valuable, eg for metals where there´s no EU agreement on generic EQS, would be valuable. EG to compare the national EQS with bioavailable concentration obtained by the BLM.	This is a good question. Only a bioavailable-based EQS can be used in the tools really, representing RWC conditions. The current or former national EQS for metals such as Cu and Zn tend to be hardness based, for which the ecotoxiciological evidence is very limited making comparisons quite difficult. Compliance comparisons might be more appropriate, as performed in France, UK and Denmark.
57	SE	Chapter 5, bullet 5: How specific are these flags? Is it enough that one of the parameters are outside the boundaries ?	Yes, just one of the parameters needs to be out and it is flagged.
58	SE	Chapter 6.1.1: Clarify which that have been developed from Industry voluntary risk assessments and which from EU risk assessments	Text added.
59	SE	Table 6.1: Shouldn´t there be an interval also for DOC?	The relationship for DOC is linear. MS asked for this to be topped at a reasonable EU maxima. The value of 30 mg/L represents this value.
60	SE	Chapter 6.1.2, page 41, point 4: Toxicity test usually refers to water spiked with substances, bioassays refer to tests performed on samples collected from the field… Please point out that the current BLMs refer to effects on chronic levels, so any bioassays to "confirm" or "exclude"	The samples collected from the field would be water samples in the case of the validation exercises and also field-based ecological data (see Ni and Pb EQS dossiers for examples). The use of ecological monitoring in weight of evidence approaches and for even deriving limit values is quite

		negative impacts would need to be performed using chronic bioassays (on pelagic organisms).	widespread and techniques to do this are given in the EQS dossiers. This can be for fish, algae, diatoms, molluscs and benthic and epibenthic invertebrates. These data have been collected in the UK for over 25 years and in other MS too (e.g. Czech Republic, Norway).
61	SE	Chapter 6.2.1: Exceedance and failure (what is a failure?) is not at BLM-specific question and could be left out of this guidance.	We were asked by MS to identify when in the tired approach they had finished in relation to compliance. That is why this section is here.
62	SE	Chapter 6.2.1, 2nd section, 1st sentence: Disagree. It needs to possible to make the conclusion "not good status" even if not being able to complete a tier 3 assessment. For example if the deviation from EQS is high. In this case, to obtain sufficient data and proceed to tier 3 should reasonably be a matter of polluter pay principle (as an alternative to implementing measures).	This comment seems to suggest that it should be acceptable to assess compliance against the EQS by making the assumption that all of the metal is bioavailable. We believe that this is not likely to be acceptable for a standard which is expressed in terms of a "bioavailable metal" concentration, although greater flexibility is likely to be possible at a national level for standards set for specific pollutants than for Priority Substances.
63	SE	Chapter 6.2.1, 3rd section: This maybe not only relevant for water bodies presently used for drinking water but also those that may be subject to future use. Further if considering the overall aims of the WFD we find it questionable to state good status for a water body if the water is not suitable for drinking water production (although the EQS-TGD state that QSdwhh only can be adopted for waters intended for drinking water use).	I recall this being a political argument as to whether all waters in the EU should all be of drinking water quality. There are arguments that the WFD was never intended to require all waters to meet potable criteria and that the drinking water directive obligations did not apply to controlled waters "per se" but should be applied at the point of abstraction.
64	SE	Chapter 6.2.1, 3rd section: Recit 37 of 2000/60/EC reads "Member States should identify waters used for the abstraction of drinking water and ensure compliance with Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (2)." 80/778/EEC have been replaced by 98/83/EC. 98/83/EC give the values 10 µg/l and 20 µg/l for lead and nickel respectively (also presented as QShh drinking water in the dossiers). For lead and nickel, this is thus an issue.	See response to comment 31. The point of compliance mentioned in 98/83/EC applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap (see Article 6). Furthermore, the footnote to the lead value states "For water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 15 calendar years after the entry into force of this Directive. The parametric value for lead from five years after the entry into force of this Directive until 15 years after its entry into force is 25 µg/l." However, perhaps some text is required in which there is account taken of whether the water in a MS is identified for the abstraction of drinking water?

65	SE	Chapter 6.2.3: What about the MAC-EQSs given in 2013/39/EU? How should they be implemented? Nothing is stated in the directive that imply that they refer to bioavailable concentrations, and we cannot find any guidance regarding their implementation in the dossiers. So, should they be considered in the assessment of chemical status? If so, that would imply that they give an upper limit for the application of BLMs. This could result in strange situations where the MACs fail but application of BLM would give the result that there´s no risk for chronic effects.	Agree. It is possible that the chronic EQS for Ni, when expressed on a dissolved basis, could exceed the MAC. This situation would only be likely to occur in a relatively insensitive water. It is unlikely that acute effects would be observed, although the MAC would be failed.
66	SE	Chapter 6.3: This guide should not be about "permitting" but rather about WFD use to evaluate surface water data....? ELVs should, at least for substances that could accumulate in the environment, ideally be expressed both on total amount basis (based on total conc) and conc basis. Only include this topic if referring to modelling bioavailable conc in the surface water (but disagree to include the suggestion to use BLM on effluent samples themselves to establish ELVs expressed on a dissolved basis).	The guidance is about the implementation of an $EQS_{bioavailable}$ and for some MS that will mean compliance assessment and permitting as both currently use EQS. If MS chose to do this and have an example for doing so then it is relevant to include, agree, only if modelling bioavailable concs.
67	SE	Chapter 7: There is information in some of the answers that maybe should be included in the previous chapters. See comments given as track changes.	Will check and include where appropriate.
68	SE	Appendix 2, page 56, point 2 "All BLM predictions less then EQSbioavailable were removed.": Why? An illustration that show amount of predictions of site specific EQSs by the full BLM below the generic EQSs could be quite interesting related to discussions regarding the relevance/validity of the generic EQSs.	To reduce bias in the analysis a full report, from which this is an extract is now available.
69	SE	Appendix 2, performance criteria, "No predictions below generic EQSbioavailable": If this is relevant depend on if the there is an agreement regarding the generic EQSs and this might not always be the case.	This is an MS decision for specific pollutants and an EU wide one for PS and PHS. Of course a MS can set a lower value if it wishes.

70	SE	Appendix 2, Interpretation: Pnec-pro does not always seem to be more precautionary according to the comparisons above (eg when full BLM predict low EQSs for Cu).	Agree, see response to comment 68.
71	FI	In relation to the datasets supporting the user-friendly tools; Finland has performed chronic Ni toxicity tests using P. *subcapitata* (algae) in a range of typical Finnish freshwaters. The results will be published and appear to support the role of DOC and pH in the derivation of local EQS (user-friendly model).	
72	FI	Where an EQS has been derived using a BLM, the user-friendly tool should be based upon that same full BLM - As the nickel EQS is now based on the Bio-Met tool, it would be easier for users/assessors to apply correct model for Ni if that had been clearly stated in this guide.	Agree or at least other models should be based on the same ecotoxicity dataset as used for the EQS and/or achieve the same level of agreement with field validation data.
73	FI	In reference to: "Outside these ranges, user-friendly tools and the BLMs on which they are based, do not necessarily make incorrect predictions of bioavailability...." Would be wise to note concerning the Bio-met model that it is conservative/precautionary for the nickel local EQS derivation below pH validation range due to increase of H+ as the situation is quite common in Fennoscandia. Therefore, the flag is not a "problem" if problem at all.	Agree, this is certainly the case for nickel.
74	FI	Calcium appears to have no effect on nickel results when using Bio-Met model. This should be dealt with in this guide or at least in the model specific instructions (Bio-Met manual).	Agree. Text has been added to Section 4.3.1, explaining the importance of Ca in the nickel calculations.
75	FI	Why is there no range for the DOC? Is 30 mg/L a max value and all below are ok for a model (Bio-Met)?	The relationship between the binding of the metals and DOC concentration tends to be a linear one. MS requested that the DOC was held at a reasonable EU maxima for freshwaters – this is the value of 30 mg/L (See response to comment 59). The model will still work with DOC values above 30 mg/L, although the DOC value used in the calculation will be held at 30 mg/L.
76	FI	What next in relation to confirmation of failure with the user-friendly tools? Since this option is likely to take place, this guide should give references for the correct full BLMs for each metal and, preferably, give an example on such an exercise.	Agree. This is straight-forward for copper, perhaps less so for zinc and nickel, but does need to be addressed in the guidance.
77	FI	What about MACs?	Agree.

		Finland has conducted Ni & Pb acute toxicity tests (L. *variegatus* & D. *rerio*) in a range of typical Finnish freshwaters. The data will be published and probably useful for development of MACs and acute BLMs.	
78	DE	So far this guidance is not a CIS Guidance. This should be reflected in the foreword to the guidance.	From the previous WG Chemicals meetings it was agreed that this would not be CIS until a majority of MS agreed to it. Nowhere in the document is it suggested that this is CIS Guidance. However, to ensure absolutely no confusion it is clearly stated in the forward that this is NOT CIS Guidance.
79	DE	Contents: 1.3 … delete sentence "* The EQS …"	Corrected
80	DE	Glossary: AA-EQS is the official acronym for the EQS expressed as an annual average.	Corrected
81	DE	Chapter 1, first section "Across ... ecological impacts." as well the last section "Regulatory implementation ... regulatory certainty." Both section are of little relevance and may therefore be excluded. Figure 1.1 (caption is missing) could be deleted as well.	The sections are both factually correct though and perhaps there is a need to detail this information as the use of the bioavailability based approach does represent a step change in working from hardness-based limits. Caption is on the figure, which does shows why the hardness-based limits are not appropriate?
82	DE	Chapter 1.1, first sentence may be deleted. Last section: replace representatives by experts	Deleted. Replacement made
83	DE	Chapter 2.2, tier 4, last sentence should be deleted. BLMs account for metal bioavailability under present water chemistry conditions. But do they really help to identify causes of the failure?	Deleted
84	DE	Chapter 2.2, figure 2.1: Please replace "No further action necessary" with "Good chemical status" because the flow diagram describes the compliance checking against EQS. Tier 4 bar: "Remedial measures" should be replaced by "Failing to achieve good chemical status"	Changes made to the diagram.
85	DE	Chapter 3, first section, last sentence: Please add references or link to the relevant chapter in this guidance. Second approach is unclear.	Text added referring to the current Pb EQS, which uses this approach, reference also made to Section 3.3 where this is detailed.
86	DE	Chapter 3.2, box, bullet 6: Please explain boundary conditions and applicability range.	Reference made to Section 6.1 where this is discussed in detail.
87	DE	Chapter 3.2, box, bullet 7: Why a factor of two?	The factor of two was used under the ESR programme and under REACH as an acceptance criteria for predictions,

			as this was considered to be the typical variation in the ecotoxicity test results performed on the same organism in the same water in different laboratories.
88	DE	Chapter 3.3: delete "... and as scientific ... very robust."	Text altered, reference added.
89	DE	**Chapter 4** Chapter 4.1 (including sub-chapters), 4.2, 4.3 and 4.4 should be merged and shortened. Practical instructions as step-by-step approach would be helpful. Please describe exactly the requirements on the monitoring data: data quantity (which water parameter, spatial and temporal distribution) and quality (units, analysis – QA/QC). It should be clearly described in which way the existing monitoring data have to be "matched" for the BLM calculations. How to handle data sets with another spatial and temporal resolution than the required ones? Please describe first the preference of matched data and how to summarize (average) them? What does it mean - ... physico-chemical parameters are only available as annual averages? When and how to consider natural background concentration? As written before: According to our understanding, *bioavailable metal concentrations have to be calculated using appropriate BLM tools for each single dissolved metal concentration in combination with the corresponding physico-chemical parameters (pH, DOC, Ca) determined in the respective monthly taken water sample. From the resulting 12 bioavailable metal concentrations the annual average can be calculated and assessed against the relevant AA-EQS.* Thus, temporal and spatial variations are taken into account.	This section has been amended to be more explicit in its instruction. The section of spatial variation has been updated and reference is made to the QA/QC Directive, although this clearly does not represent 'best practice'. A text box has been added describing the meaning of 'matched'. Backgrounds are discussed in greater detail in Section 6. Effectively the user-friendly tools correct the exposure (measured metal concentrations) to allow comparison with the EQSbioavailable, using the parameters listed. As you detail, this is the best place to start and the ideal. However, for very low variability conditions it may be possible to reduce the measures of supporting parameters, once it has been established that variance is low.
90	DE	Chapter 4.2 could be merged with chapter 4.1 Only the following aspect is relevant for this guidance: Dissolved metal concentrations has to be determined in water by filtration through a 0.45 µm filter or any equivalent pre-treatment, as noted in the Directive 2013/39/EU. Methods used for the analysis of dissolved metal concentrations have to	While this is correct and DE are very clear on this, other MS are much less so and we have been asked to include this level of detail and also (see comments above from SE) make reference to total metal measures. Further detail will also be added here on filtration, which for some MS is not

		fulfill the requirements of the Directive 2009/90/EC.	something routinely undertaken.
91	DE	Chapter 4.3 could be merged with chapter 4.1 and 4.2.	As with comment 90, this level of detail has been requested by MS both via emails and through requests at WG
92	DE	Chapter 4.4 should be merged with chapter 4.1, 4.2 and 4.3.	See response to comment 91.
93	DE	Chapter 4.4.1 may be deleted: Directive 2009/90/EC sets in article 4 requirements on the limit of quantification (LOQ) not on the LOD. Any discussion on LOD is not relevant. The Directive also specifies how to calculate the mean value when the results are below LOQ.	There are many ways to treat censored data and the method outlined in the QA/QC is but one. The implications of treating data in this way need to be understood. As MS move to considerably lower EQS for metals it is very common to have inappropriate LOQs and highly censored datasets. In dealing with these, it is important to have an understanding of what it will mean for compliance assessment. Response to comment 48.
94	DE	Chapter 4.4.3: Delete this chapter.	Germany performed a feasibility study, on the adoption of BLM approaches (Hommen U, Rüdel H. 2012. Sensitivity analysis of existing concepts for application of biotic ligand models (BLM) for the derivation and application of environmental quality standards for metals and evaluation of the approaches with appropriate monitoring data sets from German waters. Fraunhofer Institute for Molecular Biology and Applied Ecology, Schmallenberg. Report produced on behalf of the Umweltbundesamt (FKZ 363 01 352). This is a first step in the investigation of the approach for MS waters and has been undertaken recently by other MS. It is acknowledged in this report that the data used in the assessment are not ideal, primarily because not all the required inputs were available. This section highlights what can be undertaken if not all of these data are available.....which at the feasibility assessment stage they are often not.
95	DE	Chapter 4.5: Revise this chapter. Please describe when and how to consider natural background concentrations when accounting for bioavailability.	Examples have been added here including when these backgrounds are considered in compliance, how they might be derived (Response to comment 52). Effectively, at the moment they should only be considered for zinc in the early tiers of compliance and latterly at Tier 3 or 4. Background derivation and use is largely a MS specific decision as it is heavily reliant upon policy makers.

96	DE	Chapter 5: Some words on the software design and functionality of the user-friendly tools would be helpful. (e.g. excel based spreadsheet for data entry, designed for use on PCs running Microsoft Office.	Agree. Text added.
97	DE	Chapter 6: It would be helpful to clarify the terms validation ranges, boundary conditions and applicability ranges. Table 6.1: Why a concentration of 30 mg/l has been chosen for DOC? Chapter 6.1.2: delete bullet point 4. no common practice	Agree, greater consistency of terms used throughout the report. Response to comment 79. Explanatory text added. Not common practice in Germany? But collection of ecological monitoring data for WFD requirements common practice in UK, Czech Republic, Norway, France.....?
98	DE	Chapter 6.2.1: Delete this chapter	Again, MS have specifically asked when they can declare a failure in the Tiered Aproach.....that is why this section is here
99	DE	Chapter 6.2.2 delete Bullet point 2 – incomplete monitoring data - stays in contradiction to chapter 4	See above. Incomplete monitoring data are a regulatory reality in many MS. For those working in monitoring and assessment units this is a routine occurrence.
100	DE	Chapter 6.2.3: Delete	See previous comments on MACs. MS have specifically asked for detailed information on MACs
101	DE	Chapter 6.3: Delete Not within the scope of this guidance	In some MS EQS have two uses, compliance assessment and for setting discharge limits.
102	DE	Appendix 2 It would be interesting to see and understand the mentioned differences of underlying toxicity database and BLM binding co-efficients in the compared BLM tools. How does the water chemistry influence the mentioned differences between the predictions?	Agree. The full report will be circulated in time, only two tools are currently available for the comparison..
For June 2014 Draft			
103	ILA/ILZRO	Page 11, line 229: lead is listed in the box but not in lines 224 or 226. There is also some inconsistency in the body of the document as to the existence of the Pb BLM. Whilst we argue that a chronic BLM is now available (as highlighted at the recent SETAC EU meeting), in the context of this document it may be better to include Pb as one of the metals for which a BLM will "soon be available". I therefore suggest adding lead to line 226 and removing from line 229.	This has been amended.
104	ILA/ILZRO	page 23, lines 625 - 627: The slope for	Text changed.

		relationship between lead toxicity and DOC for *Philodina rapida* was used, but the EQS derivation was not entirely dependent on the data from this species, as it sounds by this sentence. I suggest to amend to the following: "The EQS for lead is based upon data showing strong relationship between observed toxicity and DOC concentration for freshwater organisms and was derived using the DOC slope for *Philodina rapida*, a species of freshwater rotifer that displays limited influence of DOC on lead toxicity. The EQS (EC2010b) assumes that there will not be any species in natural freshwater ecosystems for which the relationship between DOC concentration and EC10 would have a lower slope that that derived for *P.rapida* and thus is precautionary in nature"	
105		P42, lines 1237-1238. Something wrong with this sentence. Should it read "The results of any compliance assessment will obviously be influenced by the value of the EQS bioavailable. For nickel and lead these are applied Europe-wide. However , for specific pollutants…"	Corrected
106		P48 ,line 1470. Lead also has an acute BLM and should be included in the list	Noted now in text
107	NIVA	Line 1387-1388: Should the unit be µg/l instead of mg/l? There are not many water types exceeding 3 ppm of dissolved Al or Fe.	Correct, change made.
108	NIVA	Line 1402-1404: Would not copper and lead be more affected by competition from other ions than nickel and zinc? The humic fraction of copper tend to be much higher than for e.g. zinc and the relative change in free ion activity could potentially be much higher.	The degree to which competition for binding to DOC from other cations (e.g. H+, Ca2+, Zn2+) is important depends upon the relative binding affinities of the different cations. Because Cu2+ and Pb2+ bind very strongly to DOC they will outcompete many other cations for occupancy of binding sites. Dissolved trivalent ions are most likely to be of importance in these cases. These competitive effects are generally well described by current humic binding models such as WHAM6.
109	SE	Line 157 (and 629) - EC10 not explained	Added to glossary from the EQS TDG
110	SE	Line 272-274 (and 269), Statement slightly incorrect – form or speciation of certain synthetics also change in response to water chemistry conditions, and this can have an impact on bioavailability and subsequent ecotoxicity (e.g. organic acids, such as PCP). Rephrase – perhaps just by adding the word "usually" before "not" in row 269	Agree, re-phrased.
111	SE	Lines 424-425 (and 447, 1115 and 1118), "suggested" vs "described"	The title has been changed to indicate that this is the UK approach, but could

		Please state clearly whether this IS the suggested approach OR a description of the UK approach. In particular, it is unclear at which step a correction for background concentration is made in the UK or "is suggested" – cf Tier 1 and/or 2 according to text on line 447 but according to line 1115 and 1118, this is rather done at tier 2 or 3 (depending on metal?) in the UK….See also related comment below) Maybe change title to "A tiered approach". That it is based on an approach implemented in UK is clarified in the first paragraph.	be readily used elsewhere. In the UK the background concentration is considered in the first tier, only for zinc, as in the UK this specific pollutant is derived as 'added'. For the other metals ABCs may be considered at tier 3. Further text has been added to clarify that this is the case in the UK.
112	SE	Lines 443-445. The sentence "There is a requirement at this tier to have matched data.." should be changed since options if not the case are presented later on in the document (chapter 4).	Change made to this text.
113	SE	Lines 447 (1198; 1445-1448), Unclear: so one can take background into account at any step ? (see also 1445-1448 regarding both tier 1 and 3). Does it have an impact on the results, whether background is subtracted at tier 1, 2 or 3? If so, what would be the most "scientifically sound" approach? Does it depend on the metal? Perhaps actually tier 3 would be more appropriate for most metals (also seems to be the case in UK), but after tier 1 and before tier 2 (before the BLM is run) for Zn? If so, please explain why this difference in approach between metals? A clear suggestion on when to take background into account, would be greatly appreciated.	Text has been added here to make this clearer. This will depend on the approach for derivation and at the moment it only applied to zinc. As discussed earlier, the use of backgrounds is generally not scientifically sound (response to comment 52). Yes agree. See revised text Section 4.5 covers this.
114	SE	Line 456, Classification comprises tier 1 and 2 in the figure, whereas in 1423-1424 it says that "failure" can only be determined in the latter tiers. It should be recognized that there may also be uncertainty in the conclusion "compliance" depending on data availability and quality at tier 2. We would suggest that the classification	Lines 1423 and 1424 have been deleted, agreed this is confusing. The whole scheme is leading to a decision about classification, not just Tiers 1 and 2, so Figure 2.1. has been adjusted. The text box "classification" has been replaced by "assessment". Tier 3 is an optional step – you can still make a classification decision without doing anything at Tier 3 … it just probably won't be as good a decision! Correct, but that uncertainty is no different to assessing compliance with any other EQS.....not just metals. Yes, you could but, although Tier 3 is

		(and thus conclusion ”failure” or ”compliance”) could end already after tier 2. ”Investigation” (tier 3) should then represent a step undertaken if the classification ”failure” or ”compliance” is considered to be uncertain to reduce the uncertainty. Information obtained under Tier 3, such as statistical confidence in the assessment if considered, may yield valuable information of relevance for prioritizations and when/if considering measures under the Programmes of Measures.	really a refinement step – Tiers 1 and 2 give you an answer … but tier 3 gives you a chance to make it more robust. I suppose that amounts to the same thing – it's just where you say you reach a 'classification' decision. The tiered approach is just a suggestion for organizing resources, not a prescriptive rule..... Agreed
115	SE	Lines 560-577. The comparison with PNECpro is not in the annex now. Thus these sentences should be changed (if PNECpro will be out of the guidance)	Agreed. There have been delays from the Dutch authorities in performing this exercise.
116	SE	Line 619, I think that a sentence reminding on the difference between bioavailability corrections by BLMs and the availability corrections for Pb, Cd and maybe Cu (marine waters) should be included in the beginning of this chapter. Otherwise it might get confusing for the reader.	OK, text added for clarity.
117	SE	Lines 701-704, 1423. Since the aim is to obtain good chemical/ecological status it would be more logic to consider confidence of compliance, i.e. to show that a WB has reached good status with confidence - not confidence that it does not comply with the target, if considering statistics in the status assessment. Confidence of compliance would further be more in line with the precautionary principle and PPP. Considering "confidence of failure" for the outcome of the assessment would mean that a higher annual average is accepted if the temporal variation in concentrations increase.	Text added to the end of this paragraph including reference to the ISO Guidance, ISO 667-20:2008.
118	SE	Line 921, footnote 11. Two references in footnote. Add to reference list instead, cite both in the main text	Done
119	SE	Lines 968-983, Description of how to assess censored data: The most suitable choice between different options may not only depend on ”policy” but also on the data distribution. Could be mentioned shortly… Nevertheless, option 6 in the table should perhaps be listed first, since it is indeed the required option in a WFD context. And if deviating from this approach (and we agree that the ½LOD approach may	OK, table is changed. Yes, this is a reasonable and robust

		be unsuitable for datasets with large proportion of censored data)– KM would probably be the most appropriate (and scientifically sound) option than any of the other choices?	choice.
120	SE	Line 1095, In CIS 27, the 10th percentile is suggested. This should maybe be mentioned here.	Agree. Text and reference added.
121	SE	Lines 1277-1280, 1560-1561 (Answer Q26), It is unclear if these validation ranges refer to full BLMs or eg bio-met. For the latest version of bio-met that I can find on the webpage (v2.3_04_12_2013) the lower range for Ca for Zn is 5 mg/l according to info in spreadsheet and outcome of runs.	The validation ranges refer to the BLMs and so also user-friendly tools. Correct, text amended the Ca lower validation boundary is 5 mg/L. The anticipated change in relation to zinc, from recent testing at low Ca levels, is not yet supported by these data.
122	SE	Line 1347, The sentence should be changed since EQSbioavailable does not mean 100% bioavailable. For Zn, the lower validation ranges result in the generic EQS but give a BioF of 0,92, thus not 100% bioavailable. We suggest that the first part of the sentence is deleted and instead write "Apply the EQSbioavailable and assume…."	Text amended.
123	SE	Lines 1423-1424, We do not agree. First we are of the opinion that compliance or failure can be determined at earlier tiers, e.g if the data is limited but clearly show that the bioavailable concentration is far above or below the generic EQS. There might eg be enough knowledge to conclude by expert judgment that the water chemistry result in relatively insensitive conditions, or the opposite, for the metal under consideration even though matched data is missing. Depending on metal conc this may be enough to conclude compliance or failure. Second, compliance or failure does not have to involve considerations of confidence. We think that the confidence in the classification may be considered when deciding if and what action to take in response to the outcome of the classification. "Should" should thus be replaced with "can" or "may".	This has now been covered in earlier comments. Agree, text has been amended.
124	SE	Line 1449, "inputted" strange language Replace with "entered"	Text amended.
125	SE	Lines 1532-1537, Risk for sediment build up (increasing trends downstream and at sea, and eventually also concentrations above QSsed or national sediment criteria) is neglected in this statement. Also, these are preliminary studies (and only based on modelling?). No reference is included. Field validation of such a conclusion would be desirable, before making the conclusion that the	Correct, because risks to sediment would be addressed separately. The bioavailable EQSs don't deal with risks to sediment quality. Agree, would SE be interested in funding such a programme? This approach is an example of what the UK is doing going forward and this is

		undissolved fraction can be ignored in the permitting process. Delete or rephrase; at least rewrite the last sentence into "If this is a general pattern, this would simplify the introduction of bioavailability-based approaches to permitting because the undissolved fraction is unlikely to contribute to risk to pelagic organisms. [delete "and should be ignored]"	made clear in the text. Changed text to reflect concern.
126	IT	In the Foreword, the presence of EQS bioavailable for Ni and Pb is mentioned as a regulatory requirement. However, our tool is for Cu, Ni and Zn. Maybe explain how this anticipates forthcoming issues or give a reason for being interested in elements currently not included in the list of priority substances at EU levels. This is actually said at page 11, lines 227–235.	Text added.
127	IT	Note that the document is not consistent in the use of the symbol for litres. Sometimes it is 'µg l^{-1}' and elsewhere 'mg L^{-1}'	Changes made.
128	IT	Page 7, Definition of EQS dissolved: add 'filter' after 0.45 µm	Addition made.
129	IT	Line 324, does the BLM identify the 'high bioavailability conditions' or rather does the BLM calculate a bioavailable concentration depending of specific conditions ?	The latter. Some text added to clarify this.
130	IT	Line 767–793: I am not sure it is clear for a first-time reader. Consider the attached changes.....	Changes made as described.
131	IT	Section 4.4.2.: one important point is the re-oligotrophication of several European waters following improvements in water treatment. Reduction in the organic load can paradoxically result in an increased risk from element contamination due to reduced complexing capacity by DOC. Consider if this cautionary comment is needed to further stimulate the collection of recent DOC data by regulatory bodies.	Text added
132	IT	Lines 1164-1168: this is an important point. From a regulatory point of view, a non compliance due to high ABC would not require mitigating actions. However, high ABC may impair some water uses. This issue is clearly beyond the purposes of the guidance. However, it may be worth mentioning that the possibility of impaired water uses due to high ABC should be reported when needed.	Agree
133	NL	Page 7 and 17. The introduction of the term EQSbioavailable for tier 1 is unnecessarily confusing, it suggests a site-specific property, but in the first tier it is used as a generic value. In the definitions it is explained as EQSgeneric or generic EQS. The EQSgeneric may be	The text is currently set to try and be consistent with the Directive, EQS Dossier for nickel and lead and the EQS TGD. In the Directive, the footnote for nickel and lead states: "These EQS refer to bioavailable concentrations of the

		derived in several different ways, but is ultimately a fixed value, set by policy makers in a negotiating process, eventually adjusted with safety factors et cetra. What is wrong with the original term EQSgeneric. We suggest to use EQSbioavailable for site-specific assessments only.	substances". In the Dossier for nickel, it is stated in the header for the first table, at the very beginning of the document that "The Generic Environmental Quality Standard for nickel is an EQSbioavailable". In the TGD, for metals there is reference to EQS generic or reference So, we would suggest a need for consistency across the documents and the guidance currently tries to reflect this. The EQSbioavailable is therefore a fixed value, for nickel it is 4 µg/L. Now, you may wish to take account of local water conditions, but the EQSbioavailable is still 4 µg/L. The corrections are to exposures, not effects, hence the need for single EQS value. A site-specific PNEC may be generated for the waters of interest BUT this is still equivalent to the EQSbioavailable of, in the case of nickel 4 µg/L.
134	NL	Page 15, Table 1.1. Which model version was used for generation of the EQS values in table 1.1, with reference to EC, 2010a? We compared a Biomet version distributed during a workshop in 2011, with an update of Biomet in 2013, using 1668 samples of The Netherlands (within applicability domain), and observed that EQS-values of the latest version are considerable higher than in the 2011 version. Is this due to the change of the assessment factor from 2 to 1? The mean ratio between the two model versions is 1.5. Beside the overall difference of a factor 1.5, small unexplained deviations of certain data points are observed. We are not aware of documention that explains the differences between model versions.	The EQS was generated using the available version of the model at the time the EQS dossier was completed in 2010. Updates for Bio-met continue, as presented at WG Chemical, specifically in relation to the extension of the boundary conditions. The EQS values have remained the same in Bio-met, except for nickel, which was changed to reflect the use of 4 µg/L rather than 2 µg/L. All the alterations in the model performance and changes in latest versions of the models are given in the Bio-met website and are communicated to registered users when an update of the model is released, e.g. the mail from the latest release read: "....that an updated version (2.3) of the bio-met bioavailability tool (user-friendly BLM) has been released on the bio-met website (http://bio-met.net). Version 2.3 of the bio-met tool includes predictions of nickel bioavailability for a greater range of water physico-chemistry (pH 6.5 – 8.7, Ca 2.0 – 88.0 mg/L) compared to the previous version of the tool (pH 6.5 – 8.2, Ca 3.8 – 88.0 mg/L) and also explicitly incorporates the use of zinc ambient

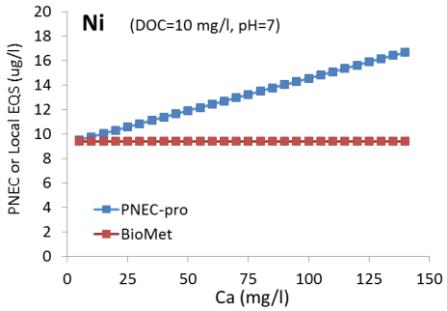
			background concentrations (ABCs) in the derivation of local EQS, BioF and during compliance assessment. The validation of the tool predictions for Zn, Cu and Ni has also been completely updated based on an enhanced underpinning dataset of Member State water chemistry data from across the UK, Netherlands, Austria and France. Version 2.3 of the bio-met bioavailability tool is also now available in an "online" format allowing users to submit data directly to the bio-met servers for processing. This development will directly aid users who have previously been unable to access the bio-met bioavailability tool due to IT security considerations within corporate or government IT networks. The bio-met project partners hope that these improvements will allow the concept of bioavailability to more accessible to those responsible for the environmental management of metals in order that the aquatic environment is adequately protected for potential risks. If you have any queries regarding Bio-met or the updated version please complete the contact us section of the website (http://bio-met.net/contact) and we will respond to your query".
135	NL	Page 17. (par 2.1) We recommend to narrow the scope (and the title)of the guidance document by focusing on the site-specific assessment of monitoring data. The paragraph suggests that the generic EQS's in tier 1 are routinely being derived, and that simplified tools may be used. The derivation of a generic EQS is however, done once in maybe 10 years or even less. Depending on the available data and knowledge at that time, a generic EQS is inevitably derived on a case-by-case basis. The deriviation of generic EQS with simplified tools is therefore not appropriate, because the BLM simplification introduces extra	In a compliance assessment, it may not be necessary to use or even measure site-specific information, aside from the dissolved metals concentration if that concentration is below the EQSbioavailable. To do this will potentially save a great deal of physical and financial resource. No, the EQSbioavailable is a value that does not change, unless detailed through a daughter directive. This is very clear in Figure 2.1 and in Section 2.2. The EQS generic, is the EQSbioavailable and this is not derived on a case by case basis. See the EQS dossier for nickel. Indeed, the user-friendly tools are not the BLMs. However, it is clear that the simplification process is predominantly precautionary (hence the need for the

		uncertainty. Moreover, the deriviation of generic EQS with simplified tools is not necessary because, several science groups have implemented the full BLMs, and are able to propose generic EQS values based on full BLMs. Please include these remarks for clarification. Page 21, line 530 Change the title of paragraph 3.3. The term "user friendly tools" is meaningless, and very dependent on the perception and experience of the user. Suggest replacing it by "simplified BLM tools".	information contained in Annex 2) and allows large quantities of monitoring data to be used in the derivation. This last point is important when deriving an EQS that is implementable across the EU. Disagree. While science groups may have used full BLMs, this approach is the first time chronic models and derivations of those models, have been included for routine regulatory implementation. The USEPA use of acute model for Cu is of limited relevance here, and has seen very limited application in the US. Disagree. This is explained fully in the text below and references and examples given. The user-friendly tools are based on BLMs but are not BLMs.
136	NL	Page 21, line 545-555 This paragraph solely describes developments from a UK point of view. In the same period, the same developments took place in other parts of Europe, for the same reasons. Better to delete this paragraph and provide a more neutral description of reasons to develop simplified tools.	Rather than delete this, as it provides useful context and the process that was followed to end up at the user-friendly tools, perhaps other examples of the processes followed in those other parts of Europe could be given too?
137	NL	Page 22. Line 581-582 It is impossible and maybe undesirable to include the most contemporary, quality controlled ecotoxicity data. This would require continuous adjustments of the simplified models. Instead, a process of version control is recommended, where a certain version is "frozen" and will be used for a certain period. Authorized updates may be provided, for instance parallel to the Water Framework Directives 6 year's revision cycle. Changes to the version compared to the previous one should be clearly described, and demonstrated on a reference dataset.	Agree, in-part, but it should include the most recent data at the time of development. Please see response to #134. The 'frozen' concept while a useful one is probably only appropriate for priority substances or priority hazardous substances, as specific pollutants maybe added in a different time frame depending on national interests. Agree with this point.
138	NL	Page 22 Line 589-593 It is a misunderstanding that the higher tier models should be the same as the first tier. Although the EQS values are proposed by scientists, the generic EQS ultimately is just a value set by policy makers (see my comments in line 10-12). The setting of generic EQS values is a process that takes several years, upto more than a decade, and consequently it is based on relatively old data and models. Whereas the generic EQS is not likely to change on a short notice, the	See revisions in text and response #114.

		higher tiers offers the opportunity to include new scientific insights and data. In the higher tiers, more advanced and site-specific assessments are allowed. Simplified BLM models are just one of the options for higher tier assessments.	
139	NL	Page 23 Line615-616 Use a fixed generic EQS, instead of the confusing EQSbioavaialable	See response to #133
140	NL	Page 23 paragraph 3.3. The distinction between compliance tools and user friendly tools is not clear. Suggest to refer to it as "Other compliance tools"	Text has been added here to improve clarity, response to comment #116.
141	NL	Page 40, Line 1190-1196 These lines are not an instruction, it is redundant. Seems more or less a bio-met features promotion. If you want to describe run-times, then use a reference dataset and report different run-times!	Agree, they are not an instruction, but they are relevant for MS trying to establish the most efficient and effective was to resource the implementation of bioavailability-based EQS. M-BAT is run in an automated way in the UK, Bio-met can be run online.....these are facts rather than promotion of any specific tool or methodology.
142	NL	Page 40 Line 1200-1214 The use of a bioavailability coefficient is not transparent, and can be missed. Suggest to delete these lines. What do you mean by specific pollutants (line 1201)? This seems to be a method for a hypothetical case, that probably requires its own specific approach, that cannot be included in this guidance in advance.	Text has been added here to clarify what this means. Specific Pollutants are defined as substances that can have a harmful effect on biological quality, and which may be identified by Member States as being discharged to water in "significant quantities" See the description of quality elements in Section 1.1 and 1.2 of Annex V of the Water Framework Directive. Agree, but the text does make this very clear that this is an area that is in development and the role of this is to flag the issues.
143	NL	Page 42, line 1225-1227 BioF is a redundant parameter, and can easily be missed.	The BioF is critical if there is to be one EQSbioavailable for the whole of Europe and corrections for bioavailability are to be made on the exposure data.
144	NL	Page 42, line 1228-1231 Bioavailable metal concentration is also redundant. The only output you need for the risk assessment is a local, site-specific EQS (dissolved) and a RCR.	Disagree. These additional information can be used to inform decision making processes and potentially programmes of measures. Furthermore, these outputs are also very useful when explaining to non-experts how water chemistry effects the ecotoxicity of metals.
145	NL	Page 46, paragraph 6.2.1 First explain what failure means, before you describe the confidence of failure.	This is dealt with in-part in Section 4.1.2 and also 6.3.3. Compliance using these EQS is the

		How do you have to deal with failures of individual samples, how to deal with time-series where some samples fail and some don't? How do you deal with water-bodies where some samples fail, and some don't? How does the "confidence of failure" relate to the "precautionary principle"? It seems that in this paragraph economic motivations prevail and that protection of ecosystems is considered a less important goal.	same as for when dealing with any other chemicals for which EQS are available. This is not a specific metals related issue and each MS will have its own methods for dealing with these. The ISO guidance provides an outline of these options. Different MS will have different views on how this is treated.
146	NL	Page 48, paragraph 6.2.3 Have you considered the use of an acute/chronic ratio, instead of implementation of acute BLMs?	Not really. Challenges can occur when switching between chronic acute effects, which respond differently to water chemistries. For example, for copper the response to calcium concentrations is different between acute and chronic exposures.
147	NL	Page 49 paragraph 6.3 This is the tricky part, and probably outside the scope of the guidance document. The option to use the bioavailability concept for permitting discharges needs careful consideration. You correctly mentioned the challenge of dealing with variability in place and time. The chronic BLMs provide a clue at what level individual species are affected when exposed to a single metal in dissolved form. Discharges are mostly a cocktail of contaminants, and may pose additive or more than additive risks. The single metal BLMs are not protective in that case, as was demonstrated in several studies. Additionally, some crucial processes are not covered: for example, what is the effect of metal bioaccumulation and biomagnification in the food chain, over more than one generation. How large is the effect of metal uptake via food and suspended matter? What is the effect of metal exposure in a real ecosystem, with multiple other stressors? There are too many uncertainties to simply allow discharges to "fill" the gap that was created by bioavailability corrections.	I agree, but as some MS will use EQS to derive permits, this is part of the implementation process. The other exposure routes are covered in the original derivation process.
148	NL	Page 49, Line 1519-1525 What about the stability of anthropogenic DOC, does it degrade, does the binding capacity change?	Evidence suggests that the DOC is different, but perhaps has a greater affinity than NOM – but this may depend upon the metal (e.g. Baken, S., Degryse, F., Verheyen, L., Merckx, R. and Smolders, E. (2011) "Metal Complexation Properties of Freshwater Dissolved Organic Matter Are Explained by Its Aromaticity and by Anthropogenic Ligands", Environmental Science and Technology, vol. 45, no. 7, pp. 2584-

			2590.)
150	NL	Page 63. We suggest to delete the comparison of the tools, and write a separate report with a thorough comparison of the three tools, with the full BLM	The full validated BLMs, as agreed at TCNES and used for the EQS derivation for nickel, are the basis of two of the user-friendly tools discussed in Annex 2. MS and Stakeholders have asked at WG Chemicals and in this document (e.g. #17, 68, 102) for a comparison of the performance of user-friendly tools against full, validated against field waters, BLMs. This section therefore remains.
151	NL	Line 169, If the purpose of this figure is to illustrate the non-relationship between hardness and toxicity, (and another non-explained parameter represented by squares and triangles), I would skip it. The inserted text above is sufficiently convincing.	The figure shows that the relationship between hardness and ecotoxicity is poor. It is important to show this as many MS will be familiar with hardness-based limits and will have used them for a very long time.....this figure demonstrably shows that this is not a robust approach.
152	NL	Line 292, Rephrase the sentence: "Under sensitive conditions…." Suggestion: "If a large part of metals is bioavailable, the toxicological effects will mostly be high and the water will consequently be classified as "sensitive"	Text amended
153	NL	Line 318. Calculations with this user-friendly tool do not result in these "stylized" relations, but yield choppy lines. Anyone who tries to reproduce these graphs will notice this, and will be puzzled. Suggestion: Either use original (reproducible) outcome of Bio-met, or use PNECpro results (=straight lines) to visualize the statement	This figure has been reproduced from the nickel EQS dossier and so forms a reference of continuity for those seeking guidance across the relevant documentation. Bio-met is based on 'look up' tables and will produce a stepped response, M-BAT, based on the same data provides a 'smoothed' response. As bio-met was used in the EQS process it would seem appropriate to use that tool.
154	NL	Line 514, What's the point? Isn't that always the case for innovative science and subsequent implementation in policy? Delete this sentence.	Agree, it is correct, but many may have heard of BLMs, but like unicorns, no one had ever seen one. The reason for this is they were never in a form that fitted with the regulatory frameworks in which they could be used.
155	NL	Line 557, I can find 27 references to the Bio-met tool, but not a single one to PNECpro. At least mention the website in a footnote or so (www.pnec-pro.com), as was done for Bio-met on many occasions.	pnec-pro now mentioned in a footnote. The reason that bio-met (and M-BAT) are mentioned is that they are, currently, the only user-friendly tools based on BLMs that have been validated under field conditions and that have received robust regulatory scrutiny. This is not to say they will be the last, and no doubt in time this document will be updated to

			reflect further changes.
156	NL	Line 560-562, PNECpro was left out of the comparison since the underlying full BLMs/WHAM speciation algorithms were slightly modified, so simplified tools cannot be compared one-on-one. The text should therefore be changed into (something like): "Appendix 2 gives a comparison of two user friendly tools which share the same underlying BLMs, but use different simplification routines"	PNECpro was left out the comparison exercise because the BLMs/tools on which it is based are different to those validated BLMs used as the basis for the other user-friendly tools. Text amended here, see #115.
157	NL	Line 872, The text states: "For example, both Ca2+ and H+ compete with nickel for occupancy of binding sites at the biotic ligand..". This implies that increasing Ca2+ concentrations affect NOEC/LC values; the higher [Ca], the higher NOEC/LC or EQS. This is indeed reflected by PNEC-pro, but not by the Bio-met tool. See below.  As long as mechanistic processes are not reflected in the tool, it renders the comparison (appendix 2) quite useless, since it is not necessarily a measure of mechanistic quality.	Within the Ni BLMs H+, Ca2+, and Mg2+ are all competing ions for the toxicity models. The Bio-met database upon which predictions for nickel are based is currently relatively limited and does not fully reflect the performance of the BLM in regard to the effect of Ca. Within natural waters, however, there is a tendency for both pH and Ca concentrations to co-vary. Consequently the decreasing proton competition due to increasing pH is compensated by increasing Ca competition from the increased hardness. This co-variation between pH and hardness means that the overriding effect on nickel toxicity tends to come from the DOC concentrations. It is anticipated that updates to Bio-met will improve its performance compared to the underlying mechanistic models over time.
158	NL	Line 1864, Text is incorrect: "This comparison exercise has been performed between two user friendly tools". -Explicit note: There are more tools, also readily available; see comment line 557. -Explicit note: The results are merely a measure of agreement, not per- se a measure of mechanistic quality (see remark 873). The overall usefulness of this comparison in appendix 2 is therefore doubtful.	Text has been amended to reiterate the comparison is between the outputs from the user-friendly tools and the full, validated BLMs on which they are based. There are more tools, this is true and it was agreed with the Dutch authorities that a comparison exercise would be undertaken including PNECpro once the validation of the underlying BLMs for PNECpro were assessed against the same field validation ecotoxicity data that were used to validate the existing BLMs from the ESR process. This has not yet happened as scheduled (summer 2014). This annex is important because it shows how the tools perform against the validated BLMs within reasonable regulatory criteria.

159	DK	.....For this reason it is important to avoid that the draft guidance document uses EQS-terms that at the best are just confusing. We are especially concerned about the use of EQSsite specific and EQSlocal because this might imply that local EQSs would as well be legally binding, so that you for each metal could get a whole array of legally binding values. We suggest to replace the two terms with "compliance concentration", and to mention it only in connection with discharge permits. In the draft bioavailability guidance document the terms "EQSbioavailable", "EQSgeneric", and "EQSreference" are used for the same thing. We suggest being consistent and use "EQSbioavailable" in all cases.	Agree. The terms EQSsite-specific and EQSlocal have been replaced with PNEC site-specific and PNEC local, there is only one EQS. The desire here is to reduce the number of terms used, rather than introduce more. Therefore, removing EQS and sticking with PNEC is perhaps the way forward here. Agree, but see response to#133. This is an attempt to try and be consistent with the terminology across the Directive, guidance and dossiers.
160	DK	In section 3.3 the term "EQSavailable" can be found. For consistency reasons it should be considered replacing it by "EQSbioavailable"	The reason it was used is that it does not consider full bioavailability, only partially. So the reason for its use was to draw a distinction between those EQS derived using BLMs, or such like, and those EQS derived using less fulsome levels of scientific rigour. However, EQSbioavailable, is used in the Directive.....but EQSavailable in the dossier, see Section 1.3 of this Guidance, where this distinction is made.
161	DK	In the glossary: We suggest amending "This is a predictive tool that can account for variations in metal toxicity and calculates a site-specific PNEC using information on the chemistry of local water sources, …." to "This is a predictive tool that can account for variations in metal toxicity that is due to water chemistry. The tool calculates a site-specific concentration of bioavailable metal (compliance conctration) and PNEC using information on the chemistry of local water sources, …."	Text has been amended, but the BLMs will calculate dissolved concentrations....
162	DK	In the glossary: We suggest rephrasing to "The so called hazardous concentration 5%, where the NOEC or EC10 for 5% of the species will be lower than that concentration"	Changed to; hazardous concentration for 5% of the species (based on the SSD), which is from the glossary in the EQS TGD.
163	DK	In the glossary: AA-EQS: The term is not used anywhere in the text, so we suggest to delete it.	It is, just once, on page 50.
164	DK	EQSdissolved: We suggest inserting a	OK.

		"total": "…measured as a total dissolved concentration, …" Generic EQS: We suggest deleting this entry	This term is also used in the EQS TGD, it is also used in the text (response to comment 133)
165	DK	We suggest introducing a new paragraph. : EQS: "EQS: Environmental quality standard. Concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment. Legally binding environmental quality standards for priority substances and certain other pollutants are laid down in part A of annex I to Directive 2008/105/EU as amended by Directive 2013/39/EU. EU Member States lay down environmental quality standards for river basin specific pollutants in accordance with the procedure in section 1.2.6 of annex V to Directive 2000/60/EC. Environmental quality standards are set as an annual average AA-EQS or a maximum allowable concentration MAC-EQS. Water EQS laid down in part A of annex I to Directive 2008/105/EU as amended by Directive 2013/39/EU are expressed as total concentrations in the whole water sample except in the case of cadmium, lead, mercury and nickel where the water EQS refer to the dissolved concentration, i.e. the dissolved phase of a water sample obtained by filtration through a 0,45 µm filter or any equivalent pre-treatment, or, where specifically indicated, to the bioavailable concentration. In this guidance an environmental quality standard referring to the bioavailable concentration is denoted EQSbioavailable	Text inserted, in-part (it is rather long!).
166	DK	Under 1.1 Purpose and scope of guidance, line 201, page 10, we suggest: "This guidance is concerned with the issue of checking compliance with EQS set with reference to dissolved bioavailable concentrations (EQSbioavailable) which in Directive 2008/105/EU as amended by Directive 2013/39/EU currently are set for certain metals (Ni, Pb). It does not deal with the issue of setting an EQS or EQSbioavailable. It should be emphasized that in the cases where an EQSbioavailable has been set in EU this is the only legally binding EQS, here the EQSbioavailable, for each	Text added.

		substance which applies to all waters after bioavailability corrections of monitoring data. Thus when the concentration of bioavailable metal has been measured or calculated at a given site it can be compared directly to the EQSbioavailable. " In the case of permitting discharges to a given water body it could be a possibility to use bioavailability corrections to set a local compliance concentration. Such local compliance concentration shall not be exceeded as a consequence of the discharge"	
167	DK	Under 1.3, line 298, page 12: We suggest: "Alternatively, especially in connection with permitting discharges to a given water body, the bioavailable fraction of dissolved metal in a sample can be expressed as a compliance concentration. This metric is expressed as total dissolved metal concentration and describe …". In the following lines of the same paragraph replace "EQSlocal" with "compliance concentration".	The terms EQSlocal and EQSsite-specific have been replaced, as agreed these could be a source of confusion, as there is only one EQS.
168	DK	Under 1.3, line306-316, page 13: We don't understand why the EQSbioavailable should be derived for a reference water. Because then it is not an EQSbioavailable, but an EQSreference-water. If the EC10 and NOEC values upon which the SSD is based refer to the bioavailable fraction in the test media, then the EQS will be an EQSbioavailable not referring to any specific reference locality.	The water chemistry ranges are important as it is necessary to derive an EQS representing conditions of the high bioavailability. Ah, now this is why the EQSreference and EQSgeneric where probably used in the EQS TGD. The conditions under which the tests were carried out vary enormously and don't always represent the high bioavailable conditions. Reductions in intraspecies variability in laboratory tests show the importance of the water chemistry. The use of the BLMs facilitates normalising the effect concentrations in the tests to a specific water condition.
169	DK	Under 1.3, line316, page 13: "The y-axis is the calculated HC5, or hazardous concentration protecting 95% of the population". This sentence is nonsense. You cannot speak of a hazardous concentration being protective! What was originally meant by the HC5 was that the concentration was only hazardous to 5% of the species (not the population). This, however, is also misleading as the HC5 is a concentration which, for 95% of the species, is expected to be lower than or equal to their NOEC or EC10, and for 5% of the species is expected to be greater than	This is probably broadening the debate out significantly beyond this guidance, but the text has now been amended to remove the reference to populations.

		their NOEC or EC10. Calling such a level "protective" to 95% of the species implies that you feel certain that 10 % effect on, say reproduction of, a species population is negligible, which I really don't think there is any good evidence for. I suggest something like this: "The y-axis is the calculated HC5, or the so called hazardous concentration 5%, where the NOEC or EC10 for 5% of the species will be lower than that concentration."	
170	DK	Under 1.3, line 325-327, page 14: We suggest to change to "…, and calculates a site-specific Predicted No Effect Concentration (PNECsite-specific) using information on the local water chemistry…" to "…, and calculates a site-specific bioavailable concentration as well as the Compliance Concentration using information on the EQSbioavailable and local water chemistry…"	See response to comment #159.
171	DK	Under 2.2, line 424-460, page 17-18: After each tier the exceedance arrow should actually lead to a socio-economic analysis. If this analysis leads to an insignificant impact of a refused permission then the authorities may choose not to proceed to the next tier.	The diagram has been altered and the title of this section also, to reflect this way forward is only a suggestion and that MS may chose a different way forward.
172	DK	Under 2.2, Tier 2, line 440-441, page 18: The most important value that the BIO-MET returns is the concentration of bioavailable metal, which can be compared to the EQSbioavailable. So we would include that in the parenthesis: "…(returning values of the concentration of bioavailable metal, compliance concentration (called "local EQS"in BIO-MET and PNEC (local) in PNEC-PRO), and/or bioavailability factor (BioF))".	Text inserted stating the models give the bioavailable metal concentration.
173	DK	Under 2.2, Tier 3, line 449, page 18: Under this tier the possibility of doing a full BLM could be mentioned	Agree. Mention made of this.
174	DK	Under 4.1.1, page 26-27: One of the greatest challenges might be the daily variation in pH which in some water bodies may be very pronounced.	Agree, this may be an issue. The challenge in these situations will be to determine a summary statistic for this or trying to find an resource efficient way of reflecting these changes (using reasonable worst case?).
175	DK	Under 4.1.1, line 695-696 page 26: With a log-normal distribution I would think the right measure of central tendency would be the geometric mean, not the median.	I think this is a useful discussion point. The belief is that the median perhaps provides a more precautionary statistic for DOC. The best way forward, as recommended is to always use matched and measured values.
176	DK	Under 4.1.1, line 701-702, page 26: Something is missing in the sentence "Using these data ….".	Agree, text corrected.
177	DK	Under 4.2, line 752-806, page 27-29: As the guidance is not on analytical	See previous comments from Italy. It was felt that there is potential to

		methods, most of this section seems irrelevant. It is however relevant to point out the uncertainties associated with the data from such analyses, but this could be expressed in a much shorter paragraph.	introduce a great deal of error at this critical stage of sample treatment and so details, not found elsewhere in guidance, have been given here.
178	DK	Section 4.4. The purpose and use of this section is not clear. In particular section 4.4.2 on the use of historic data is difficult to understand and use in practice.	This section is especially important for those undertaking a feasibility study on the implementation of bioavailability approaches. In these situations the ideal data is often not available (as in the UK, Germany, Denmark, France) and so this section highlights ways forward with less than ideal data which is likely to be important for those MS starting on this journey.
179	DK	Under 5, line 1200 - 1215, page 40-41: The generic EQS, i.e. EQSbioavailable, is not an "alternative" EQS, it is the EQS. We suggest to rephrase the paragraph telling how compliance is checked (i.e. using the formula). We suggest using "EQSbioavailable" instead of "generic EQS" to be consistent. It should be mentioned that BIOMET in fact calculates the PECbioavailable, and you need not do any calculations.	Text has been changed, PNEC and not EQS has been used.
180	DK	Under 6, line 1220 – 1224, page 42: We suggest rephrasing from: "Local or site-specific EQS/PNEC (dissolved) [µg l-1] – this is the calculated concentration of dissolved metal that is equivalent to the EQSbioavailable (generic EQS) based on the local water conditions at the site. Under "sensitive conditions" (conditions of high bioavailability) the user friendly tool should return the EQSbioavailable as the local or site-specific EQS, so for nickel this would be 4 µg l-1." To: "Local or site specific EQS/PNEC (dissolved([µg l-1] – this is the Compliance Concentration, i.e. the calculated concentration of dissolved metal that is equivalent to the EQSbioavailable based on local water conditions at the site. Under "sensitive conditions" (conditions of high bioavailability) the user friendly tool should return the EQSbioavailable as the Compliance Concentration, so for nickel this would be 4 µg l-1."	Text amended.
181	DK	Under 6, line 1238 – 1240, page 42: "However, for Specific Pollutants these will be derived at a national level and could vary considerably between Member States."	Agree, but this is the reality. See work of Marion Jungens and Paul Whitehouse on variability of values for specific pollutants across MS (not just

		Is it wise to write this? It could look like an acceptance of such great variability?	metals)
182	DK	Under Appendix 2, line 1883, page 63: HC5 is not the same as neither PNEC nor EQS, except in those cases where AF = 1. For zinc, for example, the AF = 2 in the RAR (we are aware that UK is operating with an AF = 1 and that they have derived an HC5 which is different from the HC5 in the RAR. However, consensus in EU has been reached with the RAR, whilst this is not the case with the UK approach). There is also a problem here with PNEC-PRO that doesn't seem to distinguish between HC5 and EQS/PNEC. But appendix 2 doesn't deal with PNEC-PRO. Actually there ought to be a note on the reason for not comparing with PNEC-PRO.	Agree. The explanation for the EQS being used in Bio-met are given on the website. It is correct that the EQS used for Cu and Zn in Bio-met are those from the UK, this has now been made clear in the text. The RAR had its last literature search in 2003, a great deal of new data are now available for Zn now (including mesocosm data). These have been reviewed by the UK Competent Authority and accounted for in the EQS used here. Further, the SCHER opinion on the RAR (2007) criticised the PNECs in the RAR, including that for water. PNECpro does not appear in the appendix, see response to comment #158.
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183	DK	Section 4.2, Comment #177. We would like to suggest alternative text for the 7 bullets on page 30-31 in the guidance: •Be sure to use only filters, syringes and sample containers that have passed quality control at the laboratory that will receive the samples for analysis •Keep the filters and syringes in tight packaging until use. If sample containers are not in tight packaging, be sure that the caps are on, so no dust can enter the containers before use. •Discard the first 4-5 ml, and filter 10-15 ml sample for analysis. •Filter the sample at the earliest convenience after collection (ideally, filter it in the field). If possible, filter into sample containers with preservation acid already added, so the samples are preserved immediately after filtration. •If a second aliquot is needed for storage for further verification of the analytical results, collect it from the same primary bulk sample but filter it with a second filter following the procedure above; •Perform a filtration blank, or ask the laboratory that will analyze the samples to do so. The water used for blank filtration shall have no measureable content of the metals of interest. Ultraclean water can be used, but preferable the water shall contain matrix components (e.g. Ca, Na, Mg, K, sulphate, chloride, hydrogencarbonate) in representative levels.	Text has been modified to more closely reflect these views and be somewhat less prescriptive.
184	SE	Chapter 6.3.2, last sentence "If this is a	Not sure this is too clear. Aquatic is

		general pattern, this would simplify the introduction of bioavailability-based approaches to permitting because the undissolved fraction is unlikely to contribute to risk to aquatic.": We suggest that "aquatic" to be replaced by "pelagic organisms". We suppose that these preliminary modelling studies concern the proportion of dissolved and undissolved concentrations in the water column, not the accumulation of deposited metals in sediments and the potential associated risks for benthic organisms.	the term used in the EQS TGD. Agreed these do not include the sediment concentrations, although the risks to benthic organisms are covered in regard to the lowest EQS for all compartments (including sediment) being the driving EQS. In the case of the trace elements copper, nickel and zinc this is the aquatic EQS.
185	SE	Chapter 6.4, last sentence: This section could maybe be expanded. Does it refer to the SEV/SEM concept or other approaches being developed?	More text added here. Both sediment testing with metals and also factors that influence bioavailability of metals, especially AVS/SEM
186	BE-W	There is a defined range of physicochemical conditions (especially pH and Calcium) over which the BLM has been validated, linked to ecotoxicity testing conditions. The Fraunhofer Institute (Hommen, U. and Rüdel, H., 2012 [1]) showed that a high percentage (24-45 %) of the data from 3 federal states in Germany were outside the validity ranges. They recommended improving the boundaries of BLM-validity for pH. This question is addressed by the Technical Guidance with case studies in UK and Finland. It concludes that Calcium concentrations and pH outside of validated boundary conditions are not a threat for the application of the BLM, but this should be better documented, completed and tested with a large set of data from other European countries.	Disagree. This report has been read out of context. It is perhaps worth stating that the German feasibility report also states that the waters used for the test are NOT typical. Neither were the data ideal in this regard. There are currently available feasibility studies from Denmark, France, UK, Germany and The Netherlands. Perhaps Belgium should undertake it's own feasibility study? Options are also given to assist those situations that are outside the validated ranges.
187	BE-W	Moreover, the same Fraunhofer Institute report (Hommen, U. and Rüdel, H., 2012 1) points out that accumulation of metals in the sediment or biomagnification in the food chain are not taken into account. Even though the exposure via the water seems to be the most relevant pathway, this question is not addressed in the technical guidance. There are therefore some open questions that need to be discussed or developed in the document.	The driving EQS for all the chemicals is the lowest derived from consideration of sediments, water column, secondary poisoning and human health. See response #184.
188	BE-W	Finally, the use of BLM in relation to effluent discharge permitting instead of total (with undissolved) metals concentrations is not documented at all and seems to be unsafe for the aquatic environment. The emission of particulate metals is a risk for the contamination of sediments and could also give rise to bioavailable metals (through a change of	In this section it is stated at the very beginning: "Permitting of discharges using an $EQS_{bioavailable}$ is a considerable challenge and remains an area for which options are still in development". Ideas have been presented here as

		speciation in the receiving water). The introduction of bioavailability-based approaches to permitting is not precautionary (only preliminary studies). This section 6.3 and more especially sub-section 6.3.2. seems to be partial and not documented. Therefore it should be suspended until scientific and robust studies are carried out on this topic.	points for discussion and challenge. In relation to scientific and robust studies, it would be useful if BE-W could present the data where permitted discharges resulted in "the contamination of sediments and could also give rise to bioavailable metals (through a change of speciation in the receiving water)"? Such evidence would be helpful in removing the speculative nature of these comments.
189	FR	Taking account the bioavailibilty of metals should be restricted to the assessment of the status of water. One seeks to evaluate an environmental risk to the aquatic ecosystem with specific conditions. And any changes in these conditions may lead to an increase of the bioavailibility.	Bioavailability may be used in all assessments of potential risks. The specific conditions may change, such as DOC or pH, and how these changes may be accounted for are addressed in the guidance (Section 4.1.2). Changes may lead to an increase or a decrease in bioavailability, hence the need to have matched data when undertaking monitoring.
190	FR	Although the text clearly indicates that is not yet technically possible, we do not support the inclusion of a dedicated chapter on "permitting and bioavailability" in a European guidance on the implementation of the WFD. This guidance is not a CIS guidance for now on but as there is a need for a common use of BLM in the context of assessing water chemical status, we have no doubt this guidance will sooner or later become such.	For some Member States permitting remains an important function of the EQS. We acknowledge that this remains a challenging aspect of implementing bioavailability in the text, but it is important to acknowledge what progress has been made to date in this area.