EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate C - Quality of Life
ENV.C.1 – Clean Water

Brussels, February 2018

MEETING OF THE STRATEGIC CO-ORDINATION GROUP FOR THE WFD COMMON IMPLEMENTATION STRATEGY

8 FEBRUARY 2018 FROM 10:30 TO 15:30

VAN MAERLANT BUILDING, ROOM VM 2, BRUSSELS

A meeting of the Strategic Co-ordination Group (SCG) of the Common Implementation Strategy (CIS) for the Water Framework Directive (WFD) was held on 8 February 2018. The following Member States participated in the meeting: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, MT, NL, PL, PT, RO, SE, SK, and UK. In addition, delegates from IS and NO, and representatives of CEEP, CEFIC, CEMR, CONCAWE, EAA, ECPA, EEB, EMPA, EURAQUA, EurEau, EURELECTRIC, Eurometaux EWA, INBO, Wetlands International, DG ENV, JRC and ETC attended the meeting. A full list of meeting participants is provided in Annex 1.

Copies of the agenda, meeting documents and the Watch List presentation are available for download from CIRCABC:

https://circabc.europa.eu/w/browse/e43bc223-f603-45b8-a83f-201f7f8e7ce7

1 – Welcome and introduction

Commission (COM) Co-Chair Bettina Doeser (BD) welcomed the delegates to the meeting, giving apologies from Co-Chair Karl Schwaiger (AT) who could not be present.

2 – Approval of the agenda and minutes of the last SCG meeting

BD noted that the agenda only had two items, but these were for substantive discussion. BD asked to switch the order of the two items. With this the agenda was approved. The May 2018 SCG will cover the usual updates on CIS activities, etc.

On the minutes of the last SCG, SE asked for a change on page 2 on natural background conditions and requested a further follow-up with the COM on this issue. With these changes, the minutes were approved.

3 – Review of the first Surface Water Watch List (discussion on the latest proposal for updating the list)

Stéphanie Schaan (SS) (COM) gave a presentation. SCG had originally been informed that COM had aimed to cover two successive updates of the Watch List (WL) in one Commission Decision. However, this has changed to allow for further information to be gathered on some of the candidate substances. The aim now is two updates via 2 Commission Decisions, one in May 2018 and a second in 2019.

The first update, with monitoring starting 6 months after adoption, would remove substances identified as having sufficient, high quality monitoring data and replace them with new substances of interest highlighted in the JRC report. The second update of the WL would take effect in 2019 and remove substances having reached the 4-year limit and introduce new substances of interest. More work is needed within WG Chemicals before the content of the 2nd update can be discussed with the SCG.

The first update is a 2-step process, reviewing the substances in the 1st WL to assess whether substances can be removed (substances having sufficient high-quality monitoring data) and identifying new substances (substances suspected of posing a risk at EU level, but for which the monitoring data does not allow confirmation of the risk). Analysis of the 1st year of monitoring data led to identification of the following substances to be removed: diclofenac, the antioxidant, triallate and oxadiazon.

For azithromycin (one of the macrolide antibiotics) and imidacloprid and thiamethoxam (two of the neonicotinoids), additional high-quality monitoring data are still needed to assess the risk they pose. Neonicotinoids and macrolide antibiotics were introduced as two groups in the 1st WL because of their similar mode of action and possible additive effects. It is proposed that they be kept in the WL as groups. In addition, there is ongoing work at EU level on the conditions of approval of some neonicotinoids, which may lead to changes. The monitoring data gathered so far may not reflect the risk posed by some of the neonicotinoids following those changes, so keeping them in the list allows for further data to be gathered.

On the sunscreen ingredient, monitoring was initially recommended in sediment (or SPM), but not enough data were received for sediments to carry out a conclusive analysis and it is important to make sure the data gathered fully reflect the risk posed by the substance. Therefore, it is recommended to remove it from the WL and possibly re-include it for sediment monitoring in the 3rd WL, together with other substances potentially relevant in sediment.

Work has continued on updating Predicted No-Effect Concentrations (PNECs). Maximum acceptable LOD (LOD=<PNEC) have been updated for several substances and groups of substances, based on the most recent ecotoxicological information for methiocarb, neonicotinoids and macrolide antibiotics.

On new substances for the 2nd WL, it is recommended to include metaflumizone, a veterinary medicine, but mainly used as a PPP, identified based on the results of the last prioritisation, and also amoxicillin and ciprofloxacin, two antibiotics, based on research projects on their ecotoxicological effects, taking account of the revised European Antimicrobial Resistance (AMR) Action Plan, and also, respectively, evidence of monitored / modelled exceedances of the PNEC.

In conclusion, the proposed substances for the 2nd WL are EE2, E2, E1, macrolide antibiotics, methiocarb, neonicotinoids (from the 1st WL) and metaflumizone, amoxicillin, ciprofloxacin (new substances).

After this SCG, the timeline for submission of the proposal for the first update of the WL is for a vote in the Article 21 Committee on 17 or 18 April 2018. For the second update, a proposal will be submitted (after further work and consultation) for a vote in the Committee in 2019.

Hans Stielstra (HS) (COM) asked for comments, firstly on the procedural issues, then on substances being removed, then on the two groups to be kept together and then the substances being added.

PL asked whether the 2nd WL would only be in force for one year, being replaced by the 3rd WL in 2019. If so, it would not be able to take account of monitoring results from the 2nd WL. SS replied that substances cannot stay more than 4 successive years in the WL, which explains why the WL needs to be updated in 2019. Member States will report the data for the 1st year of monitoring of (new) substances in the 2nd WL probably around February 2020 (21 months after inclusion of the substances in the list) so it will not be possible to use these data for the 2019 update. However, these data will inform the following update. The 2019 update of the WL is also a good opportunity to add new relevant substances.

DK stated that the timing is difficult due to the review of the WFD and asked to send written comments. HS confirmed that comments may be sent, but should be sent soon to aid the process. The WFD is being evaluated, but there is no decision to revise it, so for some years to come the current legislative framework will be in place.

IT agreed on the substances proposed to be removed and added to the WL. The regional agencies face difficulties in having reliable methods, so JRC should provide clear validated methods for the substances as was done for the 1st WL. These should be provided well before the Decision to allow for time to adjust. Is the JRC able to do this? SS replied that the Commission is aware that the EQSD requirement to start monitoring substances six months after their inclusion in the WL is challenging. The JRC is organising a workshop on 1-2 March to help MS prepare for monitoring the substances under consideration for the 2nd WL. The aim is to gather the technical experts doing the analysis and explore the difficulties encountered, etc. The deadline to register is 15 February. Teresa Lettieri (TL) (JRC) stated that published validated methods are important. JRC will obtain as much information as possible from MS on measuring each substance and develop protocols to share with MS.

BE reported encountering problems with the analysis of antibiotics, in particular reactions with solvents, adsorption, etc., thus raising questions about the sampling and analytical methods to be used. These need to be addressed before a final Decision is adopted. BE noted that DE has monitored antibiotics so it might have relevant experience. TL acknowledged that there are difficulties for antibiotics but added that it is possible to reach the proposed PNEC. The workshop will explore the difficult issues including how to validate the methods.

SE agreed with the proposed substances, but also had concerns regarding the use of the concept of LOD in the Commission Decision, which is not in line with the use of the concept of LOQ in the Quality Assurance/Quality Control (QA/QC) Directive. SE also highlighted that guidance on the sampling strategy would be useful. SS acknowledged that the concepts LOD /LOQ used in the Decision and the Directive are different (but linked). The JRC has assessed that this hasn't led to a problem in practice. Consequently, there is no immediate plan to change this requirement in the new Commission Decision, but this could be reconsidered when more monitoring data are received. The content of a sampling guidance was discussed some time ago in the WG Chemicals but it wasn't finalised due to a lack of consensus. This could be considered again.

NL stated that it was happy with the improvements made to the JRC report. NL also supports the substances for the 2nd WL provided there is consensus on the analytical methods. Thus the JRC workshop is important. Some data collected for the 1st WL could not be used due to the methods employed and this was a significant waste of resources. NL is also in favour of analysis in whole water and not in sediments as the latter are very difficult to compare. Finally, there is also work ongoing on the EQS guidance and could an update on its progress be given? HS noted that sediment monitoring will be for the 2019 update.

SS replied that the review on technical guidance for deriving EQS has progressed, with improvements in the parts on the selection and assessment of ecotoxicological data, on EQS derivation for metals, etc. Discussions are still ongoing on the new proposed methodology for secondary poisoning for top predators. The approach to deriving quality standards to protect human health against contamination via consumption of seafood will not change. The aim is to have the TGD endorsed by WDs in June and present a revised version to the May SCG. An update will be discussed by WG Chemicals prior to this.

BE agreed with the substances to be included, but expressed concern about the new maximum acceptable method detection limits. On Cr(VI), it needs to be clear what is being monitored, but it is fine to include it. HS noted that Cr(VI) is to be addressed in the 2019 update.

FR agreed that substances should not be in the WL without agreed methods. The JRC workshop will be useful. FR experts have stated that metaflumizone should be monitored in sediment, so it should be withdrawn if it is to be monitored in water. SS replied that the log K_{ow} for metaflumizone (which is an indication of its hydrophobicity) is in the range of the Log K_{ow} for substances monitored in water in the 1st WL. There are water monitoring methods for metaflumizone and JRC has been working on these. The JRC report presents the LOQ and this is below the PNEC. Comparability is important, but methods do not need to be standardised, as long as there is reasonable evidence that they allow detection at the required level. This contributes to allowing the WL mechanism to be reactive and flexible. TL noted that JRC has reported 2-3 methods that allow metaflumizone to be measured in water.

AT agreed with the process for updating the WL, but for new substances comparable methods must also be agreed. AT suggested that instead of having the maximum number of substances in the WL, the focus should be on selecting substances with agreed methods to make the WL more effective. SS replied that this is indeed the case for the 2nd update, as only 8 substances are proposed for inclusion in the 2nd WL, which is less than the maximum possible of 11.

PL asked if LOQs/LODs will be included in the list. SS replied that the 2nd Decision will retain the approach of 1st WL – the LOD should not be higher than the PNEC derived from ecotoxicological data. The PNECs are reviewed and updated if necessary at each update of the WL.

IT stated that experts should provide input to the JRC workshop and that the workshop conclusions should set out how to proceed practically, given the tight timeline for monitoring. SS replied that the workshop conclusions will be important. SS also highlighted that substances need to be monitored at least once per monitoring year, and that the timing of monitoring should take into account the use pattern of the substance and its possible occurrence. Consequently, monitoring may not always be relevant in the first month of the monitoring year, but could potentially take place later. This can give a bit more time to MS to prepare the monitoring of some of the WL substances.

HS asked if there were comments relating to the substances being removed from the WL. Delegates had no comments.

HS asked if there were any additional comments relating to the two groups of substances proposed to be retained in the WL. Delegates had no further comments.

HS asked if there were further comments relating to the three additional substances (metaflumizone, amoxicillin, ciprofloxacin), noting that monitoring methods will be discussed at the JRC workshop. Delegates had no further comments. HS concluded that SCG was favourable to their inclusion assuming there is agreement on methods to be applied.

HS asked if there were further comments relating to the 2019 WL. Delegates had no comments.

HS asked delegates to send any further comments by early next week as there is significant time pressure to complete the work. The future timetable includes the workshop on methods, 1-2 March at JRC in Ispra and the Decision will be prepared for a vote by the Committee on 17 or 18 April.

SE asked if it is possible to have the Committee meeting back to back with a meeting of WG Chemicals. SS replied that this is the plan.

BD concluded by thanking delegates for the constructive and detailed discussion.

3 – Development of the Strategic Approach to Pharmaceuticals in the Environment (PIE)

Helen Clayton (HC) (COM) gave a presentation. The stakeholder consultation had only recently finished, and inputs are still being analysed. The public consultation is continuing until 21 February and internal consultation (in DG ENV and with other DGs/agencies) is ongoing. There will then be a need for a formal inter-service consultation before the strategic approach can be adopted. Therefore, the presentation was not a comprehensive analysis of the consultation inputs, nor of the detail of what the strategic approach may contain, but of the state of play at this point.

There were 92 stakeholder consultation responses and currently 244 public consultation responses have been received. Of the stakeholder consultation respondents, the largest group was water and wastewater service providers (private, public, associations of water authorities), followed by authorities responsible for environment/water and then authorities responsible for health/medicine. One third were from Germany (mainly water service respondents).

COM aims to avoid drawing superficial conclusions from statistics on closed questions as they are not fully representative. A significant amount of additional text and documents had been submitted, which still need to be examined. Differences of opinion are inevitable and it is particularly important to differentiate between the responses from human and veterinary health stakeholders because of their different concerns. There is a high level of concern about the link between AMR and environment. Analysis of the stakeholder responses will be complemented by analysis of the public consultation inputs and other information (study, etc).

Policy options being considered relate to the whole life cycle of pharmaceuticals. This means that water policy is not the only area, but the policies cover other environmental policies, agriculture, health, trade etc. Hence DG ENV is working closely with DG SANTE and other DGs. The aim is to include concrete actions if possible, but there is no impact assessment (IA) at this stage. So, if there were a need for legislative action, a full IA would be required subsequently. There is no fixed number of options – the aim is to include those that are most feasible/cost-effective and there is a need for each to have "ownership" for effective follow-up.

In discussion, FR noted that the number of organisations consulted and replies is very limited compared to the actions to be taken. HS replied that the public consultation is still open and responses to these tend to be last minute. However, it is also important to note that these are not the only sources of information contributing to the strategic approach. HC added that the proposals would be based on reasonable evidence and any concrete actions would require further analysis, e.g. an IA.

Actions could be grouped in ten areas. HC introduced them and several possible actions under each, with a separate discussion of each area in turn.

1. Reduce the problem by addressing the unnecessary use of pharmaceuticals.

Delegates had no specific comments on the possible actions under this theme.

2. Favour the use of "greener" pharmaceuticals, i.e. pharmaceuticals intrinsically less harmful for the environment.

HS noted that the emphasis is on actions to move the market to greener pharmaceuticals.

NL agreed that actions should cover the whole life cycle, from source to emissions and also including all actors. On source issues, there is a clear role for COM in providing information and sharing best practice. HC agreed COM could take a lead.

DE asked if there was discussion about banning the more environmentally unfriendly pharmaceuticals. HC replied that the actions do not mention banning, but do consider precluding authorisation where suitable alternatives exist. This is controversial, but not allowing an authorisation for some uses is further than some stakeholders want to go.

3. Improve environmental risk assessment and its review.

LU noted that it has many small rivers, so ERA should consider several different scenarios according to the level of emissions and extent of dilution. HC agreed that it is necessary to have good information on these. The guidelines on ERA for human medicinal products are under review and might be able to address some issues. For water treatment, the information available to water treatment companies on substances that might appear at UWWTPs should also be improved.

4. Favour the use of pharmaceuticals manufactured in a greener way.

CEFIC noted that a new chemicals BREF will be agreed soon, so a further revision in the near future is unlikely. Therefore, it is important not to miss the current opportunity. HC replied that the new BREF only covers air emissions. Neither it nor the completed BREF on common waste water in the chemicals sector covers all the points in the existing Fine Chemicals BREF, which will be retained as it is for the moment. But future revision might take the Fine Chemicals BREF and other aspects relevant to pharmaceuticals into account.

FR noted that it is important to take account of the specificities of different MS. For example, in FR hospitals are the only public bodies procuring pharmaceuticals. HC replied that any guidance on procurement would need to look carefully at MS specificities.

AT asked if the two actions (2 and 4) concerning production of pharmaceuticals could be merged. HC replied that there is some overlap and that actions might be merged or otherwise reformulated.

5. Improve waste water treatment.

Eureau stated that it supported COM in taking the initiative and in particular the whole life cycle approach. WWTPs can have a role to play, such as in addressing hot spots. However, there is no perfect technology and no 100% removal from waste water. Also treatment is energy intensive and costly. The question is who pays and Extended Producer Responsibility has a role. Control at source is preferred as this internalises impacts in the costs of a product. Eureau is working on this and will submit its proposals to COM. It is not acceptable that pharmaceutical companies make money, but that waste water operators have to charge consumers to remove their products.

NL stated that WWTPs are important to help control pharmaceuticals. However, it is necessary to examine new methods, such as effect-based tests, to assess the risks to health and the environment and, therefore, which WWTPs to select for additional treatment.

FR stated that this issue is controversial and FR prefers to remove substances at source as even after treatment, they will still persist in sludge, etc. HC agreed that source control is preferable.

6. Reduce wastage and improve the management of solid waste.

FR stated that pharmaceutical disposal is important. In FR there is a system where pharmacists take back old medicines. However, after people take medicines, the substances are metabolised and what enters the environment may differ from the sold substance. It is therefore important to identify and then focus on the most critical issues/substances. HC replied that the final strategy document will be clearer as to how the problems and solutions fit together, including on the issue of metabolites.

7. Tackle diffuse emissions.

Delegates had no specific comments on the possible actions under this theme.

8. Expand environmental monitoring.

Delegates had no specific comments on the possible actions under this theme.

9. Fill other knowledge gaps.

HS noted that further discussion with colleagues dealing with research is to take place.

BE stated that generic pharmaceuticals for humans do not require an ERA, but that generic veterinary medicines do. HC replied that for human medicines there is an argument to share data with generic producers to help reduce animal testing. However, if there is an expansion in the production of an active substance, the ERA should be redone as the risks to the environment will change. For veterinary medicines, the assessment takes a worst case scenario on the maximum numbers of animals that could be treated, so this does not seem to be consistent with the point made by BE.

10. Promote EU action on PiE.

Delegates had no specific comments on the possible action under this theme.

In concluding the discussion, EAA noted that it supported the proposals presented.

AT stated that the danger is to focus on one type of measure. A broad approach to measures is important and as many stakeholders as possible need to be involved so that all feel responsible. HS agreed on the need to look for measures on all issues, not just for water. It will, therefore, be important for each action to be owned by an actor in COM to ensure it is taken forward.

UK asked about the process going forward and the opportunity for MS to consider the draft. HS replied that the next steps will involve internal meetings (ENV and COM-wide) in February and March. The strategy will go to inter-service consultation in March with the aim of adoption by the end of May, probably in the form of a Communication supported by the study report with a revised background document, along with a report of the public consultation. The final document is likely to have more condensed actions. HC added there will be no further significant consultation with stakeholders/MS, except where specific information is requested.

BE asked if a formal response can be sent. HS stated that this is fine as the public consultation is running to 21 February.

IT stated that it is working with other competent authorities and will provide feedback, but when would be the deadline? HS replied that as the public consultation ends on 21 February, a response by this date would be best.

In conclusion, HC stressed to delegates that the actions set out in the presentation are preliminary, so some may develop further as evidence and views are analysed.

5 – Other issues/AOB

a) AOB

FR stated it is planning a seminar on 28-29 June on eutrophication bringing together scientists and policy makers. BD thanked FR and asked for information to be circulated.

CZ asked about the status of the draft assessment of the RBMPs. BD replied that COM is in the process of finalising the MS reports and this has taken a bit longer than expected. MS will hear from COM soon. UK asked if MS will still have time to review them. BD confirmed that they would. CEFIC asked if they will only be sent to MS. BD confirmed that they would, as the purpose is to check the facts contained within them.

IS thanked COM for the facility to join SCG virtually and noted that this is more environmentally friendly. BD thanked all those delegates that joined remotely.

a) Next SCG meeting: 16-17 May 2018

BD informed delegates of the dates of the next meeting.

6 - Key actions and conclusions

The key actions/conclusions agreed at the meeting included the following:

Nr	Topic	Action/conclusion	Deadline
3	Review of the first Surface Water Watch List	Delegates to send comments on any aspects of the watch list	Within a week of SCG
		Delegates to identify experts to contribute to the JRC workshop on methods on 1-2 March	Registration deadline 15 February
4	Development of the Strategic Approach to Pharmaceuticals in the Environment	Delegates to provide feedback on the options, in the consultation background document	By 21 February

Annex 1: List of participants

MEMBER STATES	PARTICIPANTS
Austria	Egon Bäumel Ernst Überreiter
Belgium	Wendy Bonne Catherine Latour
Bulgaria	Mariya Babukchieva
Croatia	Danko Biondić
Cyprus	Angeliki Larcou Yiannakou * Rodothea Moleski * Maria Philippou *
Czech Republic	Ladislav Faigl Jaroslav Kinkor
Denmark	Line Andersen
Estonia	Reet Ulm
Finland	Juhani Gustafsson
France	Jean-Marie Quemener
Germany	Meike Gierk * Michael Trepel
Greece	Evangelia Stamouli
Hungary	Gabriella Jelinek * Zsuzsanna Magosanyi *
Ireland	Donal Grant
Italy	Lucia Fiumi *
Luxembourg	Anne-Marie Reckinger * Luc Zwank *
Malta	Annabelle Haber **
Poland	Małgorzata Bogucka-Szymalska Przemyslaw Gruszecki
Portugal	Maria Fernanda Gomes * Maria Quadrado * Paula Viana *
Romania	Gheorghe Constantin
Slovak Republic	Ivana Rešutíková
Spain	Victor Manuel Arqued Esquia
Sweden	Marie Berghult Anneli Harlén
The Netherlands	Gerrit Niebeek Diederik van der Molen
UK	Rhonda Scobie-Crago

STAKEHOLDERS	**PARTICIPANTS**
CEEP - European Centre of Employers and Enterprises providing Public services	Christiane Barth
CEFIC – European Chemical Industry Council	Steven Van de Broeck
CEMR- Council of European Municipalities and Regions	Heinz Brandenburg
CONCAWE – CONservation of Clean Air and Water in Europe	Michael Spence
EAA - European Anglers Alliance	Mark Owen
ECPA – European Crop Protection Association	Stuart Rutherford
EEB – European Environmental Bureau	Leonardo Mazza
EMPA – European Mollusc Producers Association (AEMP - Association européenne de producteurs de mollusques)	Sarah Horsfall
EURAQUA	Antonio Lo Porto
EurEau – European Union of National Associations of Water Suppliers	Oliver Loebel
EURELECTRIC-Union of the Electricity Industry	Hélène Lavray
Eurometaux – European Association of Metals	Annalisa Bortoluzzi
EWA – European Water Association	Andrea Barbieri
INBO – International Network of Basin Organisations	Yannick Pochon
Wetlands International	Eef Silver

EFTA COUNTRIES	PARTICIPANTS
Iceland	Aðalbjorg Birna Guttormsdóttir *
Norway	Rune Pettersen *

EUROPEAN COMMISSION	PARTICIPANTS
Directorate-General for the Environment (DG ENV) **Unit C1 – Clean Water**	Joaquim Capitão Helen Clayton Bettina Doeser (Head of Unit ENV.C1 and SCG Co-Chair) Helen Jolly (Meeting Secretary) Stéphanie Schaan Hans Stielstra (Deputy Head of Unit ENV.C1)
Joint Research Centre (JRC)	Teresa Lettieri

ETC	PARTICIPANTS
European Topic Centre (ETC)	Volker Mohaupt * Ursula Schmedtje *

OTHERS	PARTICIPANTS
IEEP – Institute for European Environmental Policy	Andrew Farmer (Consultant for DG ENV)

* Via video link

** Via audio call

Annex 2: Agenda

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate C - Quality of Life
ENV.C.1 – Clean Water

Brussels, 19 December 2017
ENV-SCG 08022018

MEETING OF THE STRATEGIC CO-ORDINATION GROUP FOR THE WFD COMMON IMPLEMENTATION STRATEGY

8 FEBRUARY 2018 FROM 10:30 TO 15:30

PLEASE NOTE: DIFFERENT VENUE!!:
VAN MAERLANT BUILDING, ROOM VM 2, BRUSSELS

DRAFT AGENDA

1 – Welcome and introduction	Co-Chairs
2 – Approval of the agenda and minutes of the last SCG meeting	Co-Chairs
3 – Development of the Strategic Approach to Pharmaceuticals in the Environment (PIE)	COM
4 – Review of the first Surface Water Watch List (discussion on the latest proposal for updating the list)	COM
5 – Other issues/AOB a) Next SCG meeting: 16-17 May 2018	COM