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SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

Opinion

on the

Proposed health standards for a revised bathing Water Directive

expressed at the 23rd CSTEE plenary meeting

Brussels, 24 April 2001

In the context of the revision of the Bathing Water Directive 76/160/EC, the Commission intends to propose two new microbiological indicators, namely intestinal *Enterococci* (IE) and *Escherichia coli* (EC) for coastal and fresh waters, respectively. This is based on two epidemiological studies. The Commission is now requesting the opinion of the CSTEE on the appropriateness of these two indicators and the limit values to ensure acceptable protection of human health.

Terms of reference

<u>The CSTEE is asked to answer the following issues:</u>

a) **Does the CSTEE consider that the two epidemiological studies present a scientifically sound basis for the determination of health indicators and limit values?**
b) **Does the CSTEE consider that the two chosen indicators and the suggested limit values are appropriate for the protection of humans? If not, which indicators and/or limit values does the CSTEE suggest?**
c) **The Commission is aware that the two chosen indicators are of little help in the "assessment of the presence" of viruses in the bathing water and would therefore welcome any information on any new developments that the CSTEE could provide to help tackle the "presence of virus" issue.**

Background

At the time it was published, Directive 76/160/CE had fixed some parameters to which bathing areas should comply in order to be recognised as 'safe'. Because concerns have been expressed regarding the soundness of the scientific basis upon which these parameters had been set and in order to acknowledge 25 years of improvements in knowledge and technology, this directive is currently under revision. Major goals of the revision are to provide the consumers with protection and information when they are bathing in open waters, either fresh or coastal, swimming pools being not considered in the directive.

Given the available information and considering the absence of indisputable analytic methods together with the uselessness of some of the parameters that are required by the current directive, the Commission, in the revision process, has chosen to limit the microbiological monitoring of bathing waters to two indicator micro-organisms. These microorganisms have been chosen on the basis that they are, indeed, indicators on the following basis:

➢ They reflect a pollution

➢ They represent a health concern

➢ Reliable, standardised methods of analysis are available

➢ Enough data are available in order to allow scientific experts to agree on a range for a value that should achieve human health protection.

The two chosen micro-organisms are: intestinal *enterococci* (formerly fecal *streptococci*), considered as representative of coastal waters contamination, and *Escherichia coli,* thought to be more relevant for fresh waters microbiological assessment.

It is the understanding of the CSTEE that non-microbiological parameters of bathing waters that may be relevant to human health concerns (mostly chemicals) are dealt with by the Water Framework Directive.

Question A:
Does the CSTEE consider that the two epidemiological studies present a scientifically sound basis for the determination of health indicators and limit values?

To answer this question, the following issues have been examined:

1. *In order to assess correct exposure of the swimmers were sampling conditions and analytical procedures adequate?*
As can be judged from the information provided by the publications, sampling conditions seem to be correct; on the other hand, as far as microbiological analytic procedures are concerned, the information is more scarce. A more precise description of the methods and a discussion of their reliability and sensitivity would have been appreciated.

2. *Are the study populations large enough to allow appropriate statistical analysis?*
Appropriate statistical tests and the data were adequately used. Therefore the conclusions are scientifically sound. However, it is difficult to understand why use of all the available data has not been made, especially regarding coastal waters. A recent study carried out in France (see Bibliography) has shown that the outcome would not have been basically changed, but the results would have been more robust and some interpretation slightly modified. As an example, the existence of a threshold in the relationship between intestinal *enterococci* number and morbidity, found in the study by Van Asperen, is no longer supported if the data from 18 studies are gathered in a meta analysis.

3. *Are the study populations representative of the general population? Did they take into consideration or were they capable of identifying 'sensitive populations'?*
The subjects in the study by Van Asperen do not adequately represent the general population of bathers. Both the Kay and Van Asperen studies were not designed in order to consider possible 'sensitive' populations. The characteristics responsible for an increased sensitivity and the candidate populations (young children, elderly, immunocompromised patients) have to be identified in order to provide them with special warnings.

4. *Did the study conditions take into consideration the diversity of bathing water conditions within Europe?*
Due to a broad variety of conditions throughout Europe, this issue is a complicated one. However, it is to be noted that the studies are representative of the conditions of a limited part of Europe. It is difficult to know if similar studies carried out under different conditions *e.g.* in southern or northern Europe, should have reached similar conclusions. In addition to climate features such as: temperature, rainfall characteristics, pH, amplitude of tide and of flows in coastal rivers, local geological conditions are also of importance in the microbiological 'reactivity' of a beach. Depending on whether the beach is made of

sand, shingles, rocks, or muddy, bacterial absorption is likely to be different and as a result a different temporal release is to be expected following contamination. In addition, the presence of specific factors capable of influencing bacterial release and growth either directly, such as a treatment plant breakdown or indirectly, such as the local presence of a power plant through modification of water physical parameters (*e.g.* temperature) has to be considered.

Conclusion:

The conclusions drawn from the two studies are sound and justified. However concern is expressed on the capacity of these studies to address properly human health issues relevant to all the European population. The conclusions should have been more robust if all the data available in the scientific literature had been used. Sensitive populations were also not taken into consideration. Finally, important local factors capable of influencing the characteristics of the contamination should have been discussed more thoroughly.

<u>**Question B:**</u>
<u>**Does the CSTEE consider that the two chosen indicators and the suggested limit values are appropriate for the protection of humans? If not, which indicators and/or limit values does the CSTEE suggest?**</u>

The rationale underlying the choice of intestinal *enterococci* and *Escherichia coli* as indicators is that they are representative of the most frequent reported episodes of contamination and that they are correlated with health problems, mainly diarrhoea.

This question addresses, on the one hand, the issue of the relevance of the indicators *i.e.*: on which criteria is it based to decide that they are preferable to others, and, on the other hand, the issue of the fixation of the limit values, *i.e.*: on what criteria were they set and, was the methodology used for measuring the bacterial contamination reliable?

<u>To answer question B, the following issues have been examined:</u>

1. *What are the other candidate indicators and why could they be relevant in terms of either health effects or information?*
   From the other candidate micro-organisms very few fulfil the criteria of: reflecting a pollution, representing a health concern, availability of reliable methods of analysis and of enough data in order to allow scientific experts to agree on a range for a limit value that should achieve health protection. Most of the pollution arises from failure (absence) of neighbouring treatment plants or flooding after storm or heavy rain episodes. Under these conditions, the selected indicators are always present even if this is in association with others. Under specific circumstances, unusual pollution may happen involving other microorganisms such as hepatitis, rota- or calici- viruses, which justify their being specifically searched for. The frequency of these specific episodes of pollution is low and their occurrence is often predictable, as for instance during a community epidemic. Also, if wastewaters from treatment plants (discharges) are disinfected using for example chlorine or UV, the chosen indicators are killed whereas some viruses may not be. In that case research of a viral indicator(s) is necessary.

Regarding other agents responsible for health concerns possibly including health effects other than gastrointestinal ones and that may not be of fecal origin, *e.g.* *Vibrio sp.*, *Leptospira*, *Naegleira*, algal toxins, cyanobateria, parasites, their low and sporadic occurrence does not justify a generalised, constant monitoring. However, it is of importance to identify the 'at risk' situations were such monitoring could be justified.

From an information (predictive) point of view, apart from microorganisms, it would be interesting to find out the origin and/or the mechanisms through which pollution appears. In that connection, elucidation of the physicochemical characteristics in water (*e.g.* temperature, pH, amount and nature of suspended matter, nutrients concentration, presence of nitrates) that are linked to the abundance of microorganisms should be significant. The possibility to be rapidly informed of failure in a treatment plant should also be crucial in avoidance of health problems.

2. ***Are the limit values adequate vis à vis the reliability of the method of assay? What are the differences relative to previous limit values?***
The limit values included in Directive 76/160/CE were not set based on scientifically sound data. On the basis of the available data, it is currently difficult to decide on a limit value for either IE or EC.

The 1 to 8 ratio that is proposed between the limit values for IE and EC, respectively, does not reflect the complexity and the variability of data due to local specific situations. Taking into account this complexity, a 1 to 4 ratio, as suggested in the French meta-analysis, seems more appropriate to cover most of the situations, leading to better ensuring human health protection.

It appears from the data made available to the CSTEE that the correlation between health effects and microbiological contamination is widely hampered by the use of different assay methods, which lead to inconsistencies in the results. The proposed values seem in an acceptable range but relying on data obtained from different assay methods to fix limit values is questionable. In order to be in a position to make an optimum use of the results obtained from different Member States the CSTEE strongly recommends to adopt as references the ISO CEN methods which have already been submitted to extensive intercalibration between several European laboratories (the microbath project). Only under such conditions will a relevant dose/effect relationship be expected to be scientifically sound. The CSTEE draws also the attention to the need to determine operating procedures for sampling, which is a crucial stage in the identification of contaminating microorganisms.

3. ***What is the scientific rationale underlying the selection of Escherichia coli for fresh waters and* intestinal *enteroccoci for coastal waters ?***
The CSTEE does not see any scientifically sound reason for not assaying the two indicators in the two situations. On the contrary, assaying both indicators in the two situations will provide more useful information and could help identify the sources of pollution, which could trigger action in view of their reduction. In addition, intermediate situations such as estuaries could be adequately treated.

Conclusion:
There is no discussion about the relation between health effects and the episodes of microbiological contamination of bathing waters.

Given the limited number and the differences in the methodologies that have been used in the sampling and in the determination of the number of microorganisms contaminating the water, there is doubt about the concentrations of microorganisms capable of producing a given health effect. Therefore the CSTEE considers that setting scientifically sound limit values is not currently possible.

Both intestinal *enterococci* and *Escherischia Coli* should be assayed in both conditions (fresh and coastal waters). A ratio of 1 to 4, between IE and EC seems more appropriate than the 1 to 8 suggested by the Directive. In case of a ratio largely different, the origin of the discrepancy should be elucidated: specific contamination or difficulties with the methodology. In order to obtain comparable data, the CSTEE recommends the use of the same methodology (MPN or membrane filtration) for measuring IE and EC.

Question C :
The Commission is aware that the two chosen indicators are of little help in the « assessment of the presence » of viruses in the bathing water and would therefore welcome any information on any new developments that the CSTEE could provide to help tackle the « presence of virus » issue.

To answer this question, the following issues have been examined:

1. *What is the relevance of monitoring viruses and which ones should be monitored?*
   Because the most commonly encountered viruses during bathing waters contamination are usually found in association with intestinal *enteroccoci* and *Escherichia coli*, monitoring viruses is deemed relevant only when conditions where an outbalanced ratio of bacterial indicators to viral pathogens (community epidemics, disinfected discharges) has been identified.

   It is to be noted that under viral contamination of bathing waters, people with skin scratches may represent a specific sensitive population.

2. *Are the assay methods reliable (feasible) in term of capacity to provide useable (on health effects and quick information) results?*
   At present, there are no methods for isolating and assaying viruses that are sufficiently reliable, not costly and easy to perform for being recommended.

   Special attention should be paid to bacteriophages. If, today, they do not fulfil all the conditions required for being good indicators, there is enough evidence for recommending that more efforts should be put on the validation of established determination methods against epidemiological data.

General conclusions

➢ *Regarding the epidemiological studies, even if the two studies taken into consideration by the Commission are recognised as scientifically sound, the CSTEE recommends to make use of all the available information. In addition, because more bathing conditions would be considered, the consequences of their variability within Europe should be better assessed than they are in the present proposal,*

➢ *The CSTEE recommends to assay Escherichia coli together with* intestinal *enteroccoci in both fresh and coastal waters. In the case where a local source of contamination that does not involve such microorganisms can be detected, a specific monitoring is required,*

➢ *Indicator micro-organisms should be assayed using intercalibrated, standardised procedures such as the ISO CEN methods,*

➢ *Sampling procedures and the frequency of assays should be tailor-made and linked to local conditions (e.g. sediments, hydrology, climate). Furthermore, conditions under which the indicator capacity of the two micro-organisms could be affected (e.g. disinfecting of waste waters from treatment plants) should be identified and understood,*

➢ *Further studies in order to identify sensitive human populations are needed,*

➢ *In order to provide more 'predictive' information, efforts should be put on identifying 'at risk' situations or mechanisms responsible for appearance (e.g. presence of water treatment or power plant, epidemics, sewage sludge application) or growth (e.g. nutrient load in waters, pH, temperature) of microorganisms. This is especially the case for algal and cyanobacteria blooms,*

➢ *Research on the possible use of bacteriophages as viral indicator should be encouraged,*

➢ *Microorganisms other than the two indicators should be assayed on a case by case basis depending on known risks, especially when existing local sources can be identified,*

➢ *Results from monitoring should be used to establish trends and observation of recurrent events should lead to the identification of local sources of contamination and trigger actions in view of their reduction,*

➢ *The question of the sanitary status of waters for thalassoterapy, spa and swimming pools should be examined at the European level*

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