

**Transposition of the „Council Directive  
98/83/EC of 3.Nov.1998 on quality of water  
intended for human consumption“ into the  
national laws in the EU associated countries**

Proceedings of the workshop organized jointly by the National Institute of Public Health, Prague, and the Umweltbundesamt, Berlin, with support by the European Commission - DG-XI

**Prague, 27-29 May 1999**

Transposition of the “Council Directive 98/83/EC of 3.Nov.1998 on the quality of water intended for human consumption” into the national laws in the EU associated countries

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# Contents

Introduction.....	5
Welcoming address <i>Jaroslav Kříž</i> .....	7
Presentation of the new drinking water Directive 98/83/EC <i>Ierotheos Papadopoulos</i> .....	11
General aspect of the Council Directive 98/83/EC <i>Oven Hydes</i> .....	19
Microbiological issues of the Council Directive 98/83/EC <i>Colin Fricker</i> .....	25
Materials in Contact with Drinking Water and the Council Directive 98/83/EC <i>Wennemar Cramer</i> .....	31
Drinking water database for reporting to authorities and private persons <i>H.-J. Grummt</i> .....	47
The Transposition of the Drinking Water Directive 98/83/EC in Cyprus <i>Kyriaki Ioannou</i> .....	55
Prerequisites for the transposition and implementation of the Council Directive 98/83/EC in the Czech Republic <i>František Kožíšek</i> .....	65
Transposition and implementation of Council Directive 98/83/EC in Estonia <i>Aare Laht, Enn Lenk</i> .....	75
Problems and prospects of the 98/83/EC Directive in Hungary <i>Mihály Csanády</i> .....	79
Transposition and implementation of Council Directive 98/83/EC in Slovenia <i>Aleš Petrovič</i> .....	85
ANNEX - List of participants.....	89



## Introduction

This international workshop devoted to the new European Council Directive 98/83/EC of November 3, 1998 on the quality of water intended for human consumption was held in Prague from May 27 to 29, 1999. It was organized by the National Institute of Public Health, Prague in co-operation with the German Umweltbundesamt, Berlin and with a subsidy of the European Commission – DGXI (ref. No: B7 – 8110/98/858/JNB/XI-6) for the specialists in the fields of drinking water quality, public health and legislation of the EU associated countries (Cyprus, Czech Republic, Estonia, Hungary, Poland, Slovenia).

Thanks to the communications of the specialists invited from the EU Member States (European Commission, Germany, Netherlands, and United Kingdom) and a rich discussion, the participants had an opportunity to get familiarized in detail with all parts of the Council Directive and the requirements for its transposition. The participants of the EU associated countries reported on the situation in drinking water supply, prospects in the transposition of the Directive and problems expected in relation to its implementation in these countries. As a participant of this Workshop, I can say that this meeting was very helpful and challenging for all parties involved.

As many as 30 specialists of 10 European countries took part in this Workshop. Their contact addresses are listed in Annex.

These Proceedings, also available on the Internet (<http://www.szu.cz>) include all of the reports presented except three. The text of the presentation by A. Grohmann (Quality standards for chemical parameters in the Council Directive 98/83/EC), T. Grummt (Do we need additional parameters for particular toxic substances?) and J. Swiatczak (Transposition and implementation of Council Directive 98/83/EC in Poland) are not available.

The printed Proceedings are available on request at the following address:

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## Welcoming address

*Jaroslav Kříž*

*Director of the National Institute of Public Health*

Ladies and gentlemen,

I am convinced that this workshop is of high importance, because environmental health problems deserve permanent attention. I would like to mention at least four reasons to support this opinion:

1. Health in relation to the environment has become a powerful element of local environmental and global policy,
2. Health and environment protection has had significant economical and legal consequences,
3. The public and mass media draw great attention to both health and the environment,
4. Problems relating to health and the environment are a challenge to research.

General interest is focused on professionals in this field, particularly those working in public health, environmental epidemiology, toxicology, risk assessment and research. Their work requires a high level of professional skills. Therefore, this workshop is extraordinarily useful and important.

All history of man and civilisation is accompanied by interest in water as a resource of life and economical development. Modern society has made great progress in drinking water safety, however, for that reason it may be useful to mention our ancestors.

I would like to present you a part from an ancient document:

# **R**egiment Sanitatis Salernitatum

( on the Maintenance of Good Health, and How to Preserve it Against Sickness, as well as How Upon Illness can It be Mended ) by the noble knight HENRYCH RANTZOVIVS. CZECH TRANSLATION BY DANIEL ADAM OF VELESLAVÍN, PRAGUE, 1587

## Chapter V.

### About water

*A sign of good water is when it is clear and light. Good water is also that one which is without taste and smell and that which can be easily warmed or easily cooled, which is cooler in summer and warmer in winter. Good water is also that one which is taken from a deep brook or river, the bed of which has no silt or ooze. Approved could be also water that in a good cleaned copper kettle leaves neither spot nor dung and in which cooking is easy and boiling is quick.*

*To sum up - bad is all water which is either turbid, thick, stinking or salty and bitter.*

*Whenever you, in straits, need to drink any of better waters, do boil it at first over a small fire, because such boiling takes away thickness and crudity and rectifies all harmfulness.*

## Chapter XLII.

### About drinking of water

*I do not blame water from a well at all, except of the case when a clear flax fabric taken from a well shows spots or dirt in two hours. If it did not occur, then it is possible to drink the water, without suspicion of poisoning or infection.*

*Water can be cleaned by filtration through sand from a soil without a taste, because harmful and foul strength of water stays in the sand.*

Ladies and gentlemen,

It s a great pleasure for me to welcome the distinguished European specialists Mr. Papadopoulos from Brussels, Mrs. Hulsman and Mr. Cramer from the Netherlands, Mr. Grohman, Mr. and Mrs. Grummt from Germany, Mr. Hydes and Mr. Fricker from the UK and all distinguished delegates from other European countries.

I believe that the workshop will contribute to broad understanding of requirements for water for human consumption and to the implementation of the EU Directive in the EU associated countries.



# **Presentation of the new drinking water Directive 98/83/EC**

*Ierotheos Papadopoulos*

*European Commission, DG XI.DI, Belgium*

## **BACKGROUND OF NEW DRINKING WATER DIRECTIVE**

- Based on precautionary principle
- Based on subsidiarity principle
- Essential quality and health parameters in the whole European Union
- Member States may add secondary parameters
- Improved transparency
- Update DWD to current knowledge and scientific developments

## **SCOPE OF NEW DIRECTIVE**

### **WHICH WATER IS COVERED BY THE DIRECTIVE?**

- Water intended for human consumption (Article 2(1))
  - \* water for drinking, food preparation or other domestic uses
  - \* from distribution network, tanker, bottles or containers
  - \* water used in food undertakings

### **WHICH WATER IS NOT COVERED BY THE DIRECTIVE?**

- Natural mineral waters (Article 3(1)a)
- Medicinal products (Article 3(1)b)

### **WHICH WATER MIGHT BE EXEMPTED?**

- Water used for purposes not affecting human health (Article 3(2)a)
- Individual supplies < 10m<sup>3</sup> or fewer than 50 persons (Article 3(2)b)
- Water used in food undertaking not affecting wholesomeness of foodstuff (Article 2(1)b)

## **POINT OF COMPLIANCE**

- Tap normally used for human consumption (Art. 6(1)a)
- Point of supply from tankers (Art. 6(1)b)
- Filling point of bottles and containers (Art. 6(1)c)
- Point of use in food-production undertaking (Art. 6(1)d)

## **SHARED RESPONSIBILITY**

- Changes in water quality in domestic distribution systems (definition of domestic distribution system)
- Non-compliance due to domestic distribution system in premises and establishments (responsibility of the consumer)\*
- Non-compliance due to domestic distribution system in premises and establishments where water is supplied to the public, such as schools, hospitals and restaurants (responsibility of the authorities)

\* advice to property owners on possible remedial action

\* appropriate treatment

\* advice to consumers concerned

## **ESSENTIAL QUALITY AND HEALTH PARAMETERS**

- Minimum quality standards in all Member States
- Member States can set additional and more stringent standards than those set out in Annex I (Article 130t of the Treaty)
- Member States are obliged to set additional national standards if this is required to protect human health (Art. 5(3))
  - \* In line with the principles and Articles of the Treaty
  - \* National standards should not cause a barrier to international trade

## **SIGNIFICANCE OF PARAMETERS**

Reduction from 66 (80/778/EEC) to 48 (50 for bottled water) parameters, including 15 new parameters;

### **Significance of:**

Annex I, part A: Microbiological parameters (2)

Annex I, part B: Chemical parameters (26)

Annex I, part C: Indicator parameters (20)

Action in case of non-compliance with Part A, Part B or Part C parameters

## **SAMPLING AND MONITORING**

- **CHECK MONITORING**

- \* Organoleptic and microbiological quality
- \* Effectiveness of drinking water treatment

Parameters: Aluminium, Ammonium, Colour, Conductivity, *C.perfringens*, *E.coli*, pH, Iron, Nitrite, Odour, *Ps. Aeruginosa*, Taste, Colony counts at 22° and 37°C, Coliform bacteria, Turbidity.

- **AUDIT MONITORING**

- \* Test compliance with all parametric values
- \* Except Radioactivity: relative provisions to be determined

## **METHODS OF ANALYSIS**

- Parameters for which methods of analysis are specified:
  - \* where possible CEN/ISO methods are given for guidance
  - \* Microbiological parameters
- Parameters for which performance characteristics are specified:
  - \* trueness, precision and limit of detection as percentage of parametric value
  - \* Acrylamide, epichlorohydrin and vinyl chloride through product specifications
- Parameters for which no method of analysis is specified:
  - \* Colour, Odour, Taste, TOC, Turbidity.

## **QUALITY CONTROL**

- **WATER LABORATORIES ANALYTICAL QUALITY CONTROL**
- **REGULAR CHECKING**
- **AUTORISED PERSON**

## **IMPORTANT CHANGES TO PARAMETERS & PARAMETRIC VALUES**

### **LEAD**

- Parametric value reduced from 50 to 10 µg/l to be achieved within 15 years
- Interim value of 25 µg/l, between 5 - 15 years
- Representative sample (method to be decided upon), note 3 Exceedance due to domestic plumbing is exempted, except where water is provided to the public, such as schools, hospitals and restaurants
- Estimated cost of compliance 27 - 34 BECU (EUR 12)

### **COPPER**

- Parametric value reduced from 3 to 2 mg/l
- Representative sample (method to be decided upon), note 3

### **TRICHLOROETHENE AND TETRACHLOROETHENE**

- Parametric value of 10 µg/l for the sum of tri and tetra

### **POLYCYCLIC AROMATIC HYDROCARBONS (PAH's)**

- Exclusion of fluoranthene as not being toxic
- Subsequent reduction in parametric value to 0.10 µg/l
- Parametric value for carcinogenic Benzo(a)pyrene (0.010 µg/l)

### **NITRITE**

- Parametric value ex works 0.10 mg/l
- Parametric value at the tap 0.50 mg/l

### **ARSENIC/NICKEL**

- Reduction in parametric values
- As from 50 to 10 µg/l
- Ni from 50 to 20 µg/l representative sample (method to be decided upon), note 3

## **PRODUCT SPECIFIED PARAMETERS**

### **ACRYLAMIDE/ EPICHLOROHYDRIN/VINYL CHLORIDE**

- Parametric values 0.10/0.10/0.50 µg/l
- Values apply to residual monomer concentration
- Parametric values are below detection limit
- Compliance testing through product specification

- **Acrylamide**

Monomer present in polyacrylamide flocculant

Grouting agent (drinking water reservoirs and boreholes)

Present in some types of RO membranes

- **Epichlorohydrin**

Present in epoxy-resin coatings

- **Vinylchloride**

As monomer in PVC pipes

As degradation product of tri and tetra in groundwater

## **DISINFECTION BY PRODUCTS (DBP'S)**

### **TRIHALOMETHANES**

- Parametric value for total of four compounds 100 µg/l
- Chloroform, bromoform, dibromochloromethane, bromodichloromethane
- Parametric value to be met after 10 years
- Interim value between 5 - 10 years 150 µg/l

### **BROMATE**

- Parametric value of 10 µg/l
- Parametric value to be met after 10 years
- Interim value after 5 years of 25 µg/l

## **RADIOACTIVITY PARAMETER**

- Part C Indicator parameter
- Tritium parametric value 100 Bq/l, notes 8 and 10
- Total indicative dose parametric value 0.10 mSv/year, notes 9 and 10
  
- Note 8 Monitoring frequencies
- Note 9 Excluding tritium, potassium-40, radon and radon decay products; monitoring
- Note 10 Commission proposals on monitoring and waiving of monitoring requirements

## **LEAD PARAMETER**

PARAMETER	PARAMETRIC VALUE	COMMENTS
Lead	10 µg/l	notes 3 and 4

Note 3 The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value ingested by consumers (\*). Where appropriate the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4). Member States must take account of the occurrence of peak levels that may cause adverse effect on human health.

(\*) To be added following the outcome of the study currently being carried out.

Note 4 For water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 15 calendar years from the date of entry into force of this Directive. The parametric value for lead from five years after entry into force of this Directive until 15 years after its entry into force is 25 µg/l.

Member States must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve that value Member States must progressively give priority to where lead concentrations in water intended for human consumption are highest.

## RESULTS OF LEAD STUDY

- COMPARISON SAMPLING PROTOCOLS
  - \* Composite proportional samples (COMP)
  - \* Fully Flushed samples (FF)
  - \* Random Daytime samples (RDT)
  - \* 30 minutes stagnation samples (30MS)
- LEAD: VERY VARIABLE PARAMETER
- RDT AND 30MS CAN BE USED FOR COMPLIANCE SAMPLING
- SAMPLING FREQUENCY (DWD) MIGHT BE INSUFFICIENT

## COST OF COMPLYING WITH PARAMETRIC VALUES FOR LEAD

Prices at Dec 1993, implementation to achieve 25 µg/l within 5 years, and full implementation within 15 years; (MECU = million ECU)

Cost for household installations plus distribution pipes

Belgium	1 819 MECU	Italy*	1 960 MECU
Denmark	0 MECU	Luxembourg*	1 MECU
France	13 417 MECU	Netherlands	1 078 MECU
Germany	3 203 MECU	Portugal*	965 MECU
Greece*	20 MECU	Spain*	1 312 MECU
Ireland	732 MECU	United Kingdom	9 228 MECU

Grand Total 34 000 MECU

\* Pipe replacement only

## DEROGATIONS

- Derogations for parametric values Annex I, part B (Article 9, derogations)
- Derogations for timescale for compliance (Article 15, exceptional circumstances)

## INFORMATION AND REPORTING

- Information to the public on quality of water
- Reporting to the Commission on quality of water, every three years
- Reporting to the Commission on measures in case of non-compliance (measures on lead and THM)

### Directive 98/83/EC Time table

Entry into force DWD	25 Dec 1998
Transposition DWD by MS	25 Dec 2000
General Compliance with DWD	25 Dec 2003
Lead parameter	Compliance date
≤25 µg/l	25 Dec 2003
≤10 µg/l	25 Dec 2013
Bromate parameter	Compliance date
≤25 µg/l	25 Dec 2003
≤10 µg/l	25 Dec 2008
THM parameter	Compliance date
≤150 µg/l	25 Dec 2003
≤100 µg/l	25 Dec 2008

## ENDOCRINE DISRUPTORS

- HIGH PRIORITY FOR EUROPEAN PARLIAMENT
- INSUFFICIENT SCIENTIFIC AND CONSISTENT KNOWLEDGE AVAILABLE
- NOT YET POSSIBLE TO SET STANDARD
- STUDY TO BE CARRIED OUT

# **General aspect of the Council Directive 98/83/EC**

*Oven Hydes*

*Deputy chief inspector, Drinking Water Inspectorate,  
London, UK*

## **PRESENTATION**

- Objectives
- Waters covered and exemptions
- General obligations and standards
- Point of compliance
- Monitoring (sampling and analysis)
- Remedial action and derogations
- Exceptional circumstances
- Information and reporting
- Conclusions

## **OBJECTIVES**

- Adapt Directive 80/778/EEC
- Wholesome and clean
- Essential quality and health parameters
- Minimum monitoring framework
- Subsidiarity - parameters, monitoring
- Water protection and treatment measures
- Action to be taken when breach
- Information provided to consumers

## **WATERS COVERED**

- Water for human consumption
  - drinking, cooking, food preparation
  - other domestic purposes
  - distribution, tanker, bottles, containers
- Water for food production
  - if it can affect wholesomeness of food

## **WATERS EXEMPTED**

- Natural mineral waters - 80/777/EEC
- Medicinal waters - 65/65/EEC
- **MAY** exempt
- Waters - no influence on health of consumers
- Water supplies less than 10 m<sup>3</sup>/d or fewer than 50 people
- unless commercial or public activity

## **GENERAL OBLIGATIONS**

- Ensure water wholesome and clean
- meets standards for microbiological and chemical parameters
- free from micro-organisms/parasites in numbers and substances in concentrations potential danger to public health
- Comply with other requirements
- No deterioration of quality or increase in pollution of sources

## **QUALITY STANDARDS**

- Mandatory standards - not less stringent
- Annex 1A - microbiological
- Annex 1B - chemical
- Non - mandatory values for monitoring
- if exceed - investigate cause - take action if risk to public health
- Additional parameters where needed to protect human health

## **POINT OF COMPLIANCE**

- Taps normally used for human consumption
- No breach if exceedance due to domestic distribution system
- Except where water supplied to public - schools, hospitals, restaurants
- Reduce/eliminate non - compliance at taps by treatment, suppliers' pipe replacement and advice to consumers'

## **MONITORING -GENERAL**

- No point in setting standards unless
- samples are representative of water supplied to consumers
- samples are adequately taken, transported and stored (no change in concentration and not contaminated)
- analysis is carried out using methods of established performance
- analysis is subject to AQC (Analytical Quality Control)

## **MONITORING - SAMPLING**

- Regular to ensure standards met
- Samples representative of water consumed throughout the year
- Monitoring programmes established - meet minimum frequencies in Annex II
- Additional monitoring for other substances if potential danger to public health
- Sampling points - consumers' taps and in some cases treatment works
- Two types of monitoring
- **CHECK** - frequently to establish compliance
  - organoleptic (aesthetic) quality
  - microbiological quality
  - treatment effectiveness, mainly disinfection
- **AUDIT** - less frequently
- compliance with other parameters
  - no monitoring if established parameter absent or present in low concentrations

## **MONITORING - ANALYSIS**

- At laboratory with system of AQC
  - subject to checks by person not under control of laboratory
  - accreditation organisation or inspectorate
- Analysis methods specified
  - microbiological, generally ISO
  - use other method if demonstrate equivalent performance
- Performance characteristics specified
  - trueness % PV - systematic error
  - precision % PV - random error
  - limit of detection % PV
- No methods of analysis specified
  - colour, odour, taste, TOC, turbidity
- performance specified for turbidity
  - any method may be used

## **MONITORING - NOTES**

- Lead monitoring methods to be harmonised
- Monitoring frequencies for radioactivity to be set
- Decisions to be made using Committee procedure under Article 12

## **REMEDIAL ACTION**

- Mandatory standard breached
  - immediate investigation of cause
  - remedial action as soon as possible
  - if potential danger to human health, restrict/prohibit supply or other action
  - may issue guidance to suppliers
- Non-mandatory indicator value exceeded
  - immediate investigation of cause
  - remedial action only if risk to human health
- Consumers informed of remedial action

## **DEROGATIONS**

- Applies only to chemical parameters in Annex 1, Part B
- No potential danger to human health
- Short time as possible
  - 3 years, 3 more years tell Commission, Commission 3 more years exceptionally
- Derogation not needed
  - if breach trivial
- if remedial action within 30 days
- breach lasts less than 30 days per year
  - A derogation must specify
    - grounds
    - parameter, previous results, maximum permitted value
    - area, volume/day, population, food production undertaking
    - monitoring, increased if needed
    - action plan, timetable, costs and review
- duration
  - Commission informed within 2 months of any affecting over 1000 m<sup>3</sup>/day or 5000 people

## **EXCEPTIONAL CIRCUMSTANCES**

- Request Commission for longer period to comply in exceptional circumstances
  - geographically defined areas
  - grounds and difficulties given
  - information as for derogations
- Commission will examine and determine
- Maximum period three years
- Further three years possible after review
- Inform consumers and provide advice

## **INFORMATION AND REPORTING**

- Adequate up-to-date information available to consumers - public record ?
- Publish report every three years
  - first for 2002-4 by end 2005
  - all supplies over 1000 m<sup>3</sup>/day or 5000 people
  - format determined by Article 12 procedure
  - send to Commission within 2 months
- Commission will publish synthesis report by end 2006
  - Report to Commission on measures to reduce lead and THMs

## **CONCLUSIONS**

- New Directive much better than old
  - standards up-dated, irrelevant parameters deleted
  - sampling method/ points better defined
  - analysis, methods/performance and AQC specified
  - appropriate derogation provisions
  - sensible information and reporting
- Subsidiarity when appropriate
- Better drinking water quality in EU



# **Microbiological issues of the Council Directive 98/83/EC**

*Colin Fricker*

*Thames Water Utilities, Reading, UK*

## ***Escherichia coli***

*E.coli* vs Faecal coliforms

What are faecal coliforms??

Method detects “faecal coliforms“

## **Enterococci**

Enterococci vs Faecal streptococci

What are faecal streptococci?

ISO method detects “faecal streptococci”

## **Coliforms**

What is a coliform?

What is its significance?

## **Plate counts**

- What do they mean?
- What does “no abnormal change” mean?
- Which temperature, medium etc?

## ***Clostridium perfringens***

- Why look for it?
- Correlation with parasites???
- Method is poor
- What do positive findings mean?

### **Why look for new methods?**

- Existing methods slow and laborious
- New organisms emerging
- New technologies available
- Increased awareness of waterborne disease
- Public perception

### **Existing methods (indicators)**

- Definitions often defined by methodology
- Often taxonomically inaccurate
- Long lead time for result
- Reliant upon culture
- Little scope for improvement

### **Current coliform methods (MF)**

- Often based on lactose fermentation
- 10-15% coliforms do not ferment lactose
- May take 72 hours for a result
- All results retrospective
- Labour intensive

### **Current *E.coli* methods (MF)**

- Based on lactose fermentation and indole production
- 10% *E.coli* do not ferment lactose
- 5-10% *E.coli* do not produce indole
- 1-5% *E.coli* are not thermotolerant
- 10-15% of organisms which are thermotolerant, ferment lactose and produce indole are NOT *E.coli*

### **Some “new” methods**

- Based on specific substrates
- Detect galactosidase activity (coliforms)
- Detect glucuronidase activity (*E.coli*)
- Give results in 18 hours or less
- Less labour intensive

### **Benefits of enzymatic methods**

- Faster result (no confirmation)
- Less labour intensive
- “One protein, one gene”
- Provide basis for “molecular methods”
- More taxonomically defined?

### **Problems with enzymatic methods**

- Not widely accepted by regulators??
- Reliant on culture
- Occasional “false negatives”
- Occasional “false positives”
- Results remain retrospective

## **PCR for coliforms & *E.coli***

- Based on DNA
- Interferences from iron, humics, etc.
- Lacks sensitivity
- Does not discriminate between “live” and “dead”

## **Other options for PCR**

- Target mRNA
- Technically difficult
- Should discriminate between “live” and “dead”

## **Use of 16S rRNA**

- Genus or species specific probes can be produced
- Directly linked to bacterial taxonomy
- Variation in signal dependant on physiological activity
- Signal related to viability????

## **Validation of methods**

- Not based on science
- Not uniform world-wide
- Disagreement between researchers and regulators
- Different methods detect different things!!

## **How can we implement new methods?**

- By member states?
- Across Europe?
- Single study?
- Multiple studies?

## **What's happening now?**

- UK has a working group looking at validation of new methods
- Independent European group has formed a working group
- ISO has a working group

## **Problems**

- What constitutes equivalence?
- Must new methods be “as good” or “better”?
- Who makes the final decision?

## **Likely outcome**

- Multicentre study
- At least five member states
- Chlorinated and non-chlorinated samples
- Two phase study
- Full statistical evaluation
- Will member states accept it

## **Disadvantages of “new” methods**

- No correlation with existing methods??
- Detecting different things
- Perceived as always being “better”
- Often not suitable for “developing countries”
- Often expensive and time-consuming

## **Conclusions**

- Validation of new methods may be problematic
- Some regulators unwilling to accept change
- New methods treated with suspicion, especially if developed by commercial organisations)
- As “new” organisms emerge, new methods will emerge
- Current methods are for reference purposes
- Better methods exist
- No good validation data exists for any of the ISO methods
- Molecular methods will eventually take over!!!!

# **Materials in Contact with Drinking Water and the Council Directive 98/83/EC**

*Wennemar Cramer*

*Ministry of Housing, Spatial Planning and the Environment,  
The Hague, Netherlands*

## **1. Introduction**

It is a well known and established fact that materials for installations used in the preparation or distribution of water intended for human consumption could lead to deterioration of the water quality and consequently cause a risk to human health. The same holds for chemicals used in water treatment. This has been recognised during the revision process of the 'old' Drinking Water Directive 80/778/EEC. Therefore, the new Council Directive 98/83/EC on the quality of water intended for human consumption has a specific provision on materials and chemicals in contact with water intended for human consumption. When implementing the new directive, the Member States have to decide on the way they transpose the obligation put on the Member States by this provision into national legislation.

Today, the Member States operate different approval schemes for materials and chemicals in contact with water intended for human consumption. Within the framework of the Construction Products Directive (89/106/EEC), working groups of the Comité Européen de Normalisation (CEN) have been attempting to develop harmonised test methods since 1990. But little progress has been made so far. Mainly due to the fact that harmonising the test methods in this field is not possible without harmonising the acceptance criteria, which is however not in the competence of CEN. To overcome this deadlock, and in view of the new Drinking Water Directive, the European Commission initiated a study last year to establish the feasibility of a European Approval Scheme for construction products in contact with water intended for human consumption. This study, undertaken together with water regulators of France, the UK, Germany and the Netherlands, has been concluded recently, and on the basis of the positive results, it has been decided by the Member States and the European Commission to develop such a European Approval Scheme.

This contribution to the workshop deals with

- requirements of the new Drinking Water Directive with respect to materials and chemicals in contact with water,
- current approval scheme in the Netherlands and the way the Netherlands will implement the requirements of the new directive with respect to materials and chemicals
- development of a European Approval Scheme.

## **2. Requirements of Council Directive 98/83/EC with respect to materials and chemicals**

According to Article 10 of Council Directive 98/83/EC, the Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive. The interpretative document and technical specifications pursuant to Article 3(1) and Article 4(1) of Council Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to constructions products (Construction Products Directive) shall respect the requirements of this Directive.

Furthermore, it should be emphasised that the new Drinking Water Directive also puts an obligation on the Member States that goes further than complying with a (minimum) set of quality standards. Article 4(1) requires from the Member States to take all measures to ensure that water intended for human consumption is free from any micro-organisms, parasites and from any substances, which in certain numbers or concentrations, constitute a potential danger to human health.

In case a material is part of a construction product as defined in the Construction Products Directive, it is also subject to possible future harmonisation of technical specifications related to the essential requirements (specified in Annex to this Directive) for buildings and constructions. Products satisfying the technical specifications and the appropriate level of conformity will be allowed to carry the CE mark and to be sold throughout the EU, without prejudice to the national performance requirements. One of the essential requirements deals with hygiene, health and environment. This requirement is elaborated in the Interpretative Document No C 62/75 (28 December 1994). It is important to note that this document states that technical specifications should be harmonised to identify the relevant characteristics related to the control of the water supply, including migration of contaminants from materials in contact with water intended for human consumption and the enhancement of microbiological growth.

Observations:

- According to the new Drinking Water Directive, Member States have to consider all substances, micro-organisms and parasites and not only the set of parameters in Annex I of the Drinking Water Directive.
- The scope of Article 10 of the Drinking Water Directive (all materials and substances) is wider than the construction products as defined in the Construction Products Directive.

- Article 10 of the Drinking Water Directive requires from the Member States to operate a formalised system for assessment and approval of materials and chemicals in contact with water intended for human consumption (national approval scheme).
- The Drinking Water Directive gives no guidance on the outline and the operation of such an approval scheme. Apparently this is left to the Member States.
- Technical specifications based on the Construction Products Directive should be in line with the implementation of obligations/requirements of the Drinking Water Directive at the national level.
- Given the number of substances and the complexity of test and field conditions, it is a laborious and long term task to harmonise all relevant technical specifications at the EU level.

### **3. Approval of materials and chemicals in the Netherlands**

#### *Guideline*

The legal framework for water supply in the Netherlands is provided by the Water Supply Act (see Box 1). The drinking water quality requirements are elaborated in the Drinking Water Quality Decree. According to this decree, materials and chemicals coming into contact with drinking water may not adversely affect its quality during production and distribution from the point of view of public health.

In this context, the Inspector General for the Environment, in charge of the statutory supervision of drinking water supply, published in 1986 a guideline for the systematic health-related evaluation of materials and chemicals used by water supply companies. This guideline was revised in 1994.

#### *Background*

In the production and distribution of drinking water, many chemicals and materials are used which come into contact with drinking water. In theory these may affect the quality of the drinking water by releasing substances into it. The Drinking Water Quality Decree lays down the requirements for drinking water quality by means of standards for a large number of parameters. However, this is not enough to enable the evaluation of all chemicals and materials in use with regard to their toxicological aspects and their possible influence on drinking water quality. Therefore, it is necessary to evaluate the chemicals and materials to be used by water supply companies with reference to their composition.

Evaluation of all the relevant aspects by each individual water supplier would be time-consuming and inefficient. Therefore, a central evaluation and control system was set up in 1988 (and revised in 1994) for the products in question by the national government in collaboration with the Netherlands Water Works Association, Kiwa, and the producers. This Approval Scheme has been applied since to complete satisfaction of all parties.

### *Evaluation procedure*

An essential element of the Dutch approval scheme is the use of the so-called positive lists of substances/materials with migration requirements based on toxicological evaluations. The enactment, revision and extension of the positive lists and evaluation of the products (chemicals and materials) which do not (yet) appear on a positive list are handled by the Inspector General for the Environment. He is advised by the Committee on Health Aspects of Chemicals and Materials for Drinking Water Supplies (CGCMD). This committee is assisted by the Toxicity Sub-Committee consisting of experts from Kiwa, industry and central government.

Applications for a Toxicological Aspects Certificate (ATA) are handled by Kiwa, taking into account the composition of the product as well as the production process (Factory Production Control). If Kiwa decides that the product satisfies the requirements of the relevant positive list(s), it handles an application for an ATA directly, i.e. without the intervention of the CGCMD. The Positive lists therefore allow to shorten the approval procedure and to give the applicant a better understanding of the minimum requirements that a product has to satisfy. If it is found during the evaluation of an application for an ATA that a material contains one or more substances which do not appear in a positive list, or that a positive list does not yet exist, or that a chemical substance has not yet been included on the positive list of "chemicals", the applicant may request to extend or amend the positive lists or to make an individual assessment. For this he is required to supply data on the toxicological aspects of the substance(s) in question. If a product does not satisfy the positive list(s), the CGCMD has to evaluate the product before an ATA-Certificate can be issued.

Applications are handled by Kiwa and the CGCMD on the basis of confidentiality of the data supplied by the applicant.

Other than toxicological aspects (e.g. organoleptic and physical aspects) are covered by a Kiwa-Certificate according to the so called Assessment Guidelines agreed upon by producers and Kiwa (Third Party Certification).

### *ATA-Agreement and auditing*

If a product satisfies the requirements, Kiwa concludes an agreement with the applicant in which the latter declares that the product to be produced is nominally identical in appearance and composition to the evaluated specimen or test sample. This means that the products manufactured under an ATA agreement with Kiwa conform to the characteristic properties described in the agreement and meet the relevant ATA criteria laid down by Kiwa. In the agreement, Kiwa declares its willingness to grant the applicant the right to use the ATA issued by Kiwa as proof of quality assurance on toxicological grounds.

The ATA records the characteristic features of the product. It may also contain information about the aspects relevant to public health (e.g. instructions on maximum

dosage). The ATA additionally offers scope for recording detailed relevant information if necessary (e.g. ATA criteria laid down by Kiwa, results of laboratory testing).

Part of the approval is a visit of the factory to audit the Internal Quality Control Scheme of the producer of the material (pre-certificate auditing). The IQC scheme guarantees (to an acceptable degree) that the producer continuously will comply with the requirements laid down in the approval criteria. The IQC scheme is part of the agreement between the producer and the certifying body (Kiwa).

The scope of the IQC scheme includes control of the raw materials of the product, process control, testing of the final product for relevant properties, control on internal storage and transport of raw materials and final product, maintenance and calibration of the test equipment and procedure for handling of complaints of the users of the product. Finally the IQC scheme also mentions those staff members who are responsible for the critical stages in the production process.

Post-certificate auditing includes a factory inspection visit once a year. During his visit the inspector checks the production on the basis of the IQC scheme. The inspector checks especially the use of the raw materials on the basis of the approval agreement, takes samples which will be tested in the laboratory for the criteria as laid down in the approval agreement. The test results are compared with the criteria. In case the results of the tests and/or the factory inspection do not comply the producer is given an opportunity to take measures to improve his performance. When he fails to do so, the approval will be withdrawn immediately.

Every three to five years the full IQC scheme will be checked during a factory visit to the same level of detail as during the pre-certification audit.

### *New developments*

In view of the EU internal market, it has been decided by the Government to strengthen the legal basis of the Dutch approval scheme. The scheme is now a Guideline of the Inspectorate for the Environment which is in strict legal terms a voluntary arrangement between Government, water supply companies and producers. The ATA Certificate has a private law basis. The Guideline will become a formal Decree (public law) on the basis of the Water Supply Act. This will improve transparency for all parties. In particular for producers, water suppliers, contractors and plumbers. It will also make it easier for the drinking water quality regulator to enforce the use of approved materials and chemicals.

The legal work is now underway as part of the implementation of the new drinking Water Directive. The scope will be made wider to include materials used for domestic distribution systems and for hot water systems. At the same time the approval scheme will be extended to testing for enhancement of microbiological growth because of health risks related to microbiological deterioration of drinking water and because of consumer complaints.

## **4. Development of a European Approval Scheme for construction products in contact with drinking water**

### *Current situation*

Most Member States have systems for approval of construction products for use in contact with drinking water. These systems usually involve carrying out leaching tests in which the product is exposed to water under controlled conditions. The leachates are then analysed to establish whether substances leaching from the product might have an adverse effect on water quality or cause a risk to the health of consumers. There is little consistency between the different approval systems in terms of application requirements, toxicological evaluation, choice of parameters to be tested, test procedures, conversion of test results, pre test and post test auditing, approval criteria and approval procedures. Approval systems could therefore constitute a barrier to trade because the Member States reserve the right to re-test products which have already been tested and approved elsewhere within the European Community. A unique European certification process would promote transparency and decrease the “multi-certification” cost that is borne by the producers at present.

The CEN working groups have been attempting to develop harmonised test methods since 1990 but little progress has been made. The 1994 Vienna seminar, organised by CEN Programme Committee 6, identified that the key components of the approval systems such as setting approval criteria and the legal/administrative framework can not be dealt with by the CEN. The seminar concluded that these issues are the responsibility of the European Commission and the national regulatory authorities.

### *Feasibility study*

Willing to avoid further lengthy and sometimes useless discussions, the EC proposed last year to the Standing Committee on Construction to invite the drinking water regulators from France, Germany, the Netherlands and the United Kingdom (being the Member States with the more sophisticated approval schemes) to verify, prior to further development, whether these 4 Member States could agree to harmonise their schemes and to assess the feasibility of a European Approval Scheme (EAS). This EC proposal was unanimously agreed by the 15 Member States in July 1998.

The feasibility study started in September 1998 and was concluded in March 1999. The working group of the EC and the 4 Member States

- identified the major difficulties of harmonisation (see Box 3)
- agreed on the feasibility of the possible convergence of the national approval schemes of the 4 Member States
- defined the baseline conditions for a European Approval Scheme
- developed the framework of a European Approval Scheme (prototype)

The feasibility study has been successful. The outcome suggests that it is indeed feasible to harmonise the approval schemes of France, Germany, the Netherlands and the UK without compromising the high protection level of any of these schemes. In fact, harmonisation of these four schemes constitutes a prototype for a future European Approval Scheme.

The baseline conditions for a EAS, as suggested in the report on the feasibility study, are given in Box 4. The EAS- prototype (see Box 5) consists of the following elements, taking into account 'a level playing field' for all types of materials:

- uniform principles for submission of applications for approval
- pre-certificate auditing by notified bodies
- positive lists of substances with specific migration levels
- uniform principles for case-by-case evaluation
- harmonised test procedures (in stages) to be carried out by approved test laboratories
- conversion factors
- acceptance criteria (reflecting a high level of protection)
- certification by notified bodies
- post certificate auditing by notified bodies

It is of paramount importance that the EAS has a sound legal and institutional basis to be developed further from both the Construction Products Directive and the Drinking Water Directive. This could lead to an adjustment of the latter to accommodate e.g. a European Positive List.

Although the work undertaken by the Commission and the regulators/experts of the four Member States has been successful, it is only the first step on the road to an operational EAS that is acceptable. A lot of effort has to be put into the development of a EAS. Moreover, this development could only be successful if there is a broad support from the Member States as well as from industry for a EAS along the lines of the prototype as defined in our feasibility study .

The Standing Committee on Construction agreed in April 1999 to the proposal of the EC to create a Regulators Group for Construction Products in contact with Drinking Water (RG-CPDW) in order to develop a EAS. This group is a working group of both the regulatory Standing Committee on Construction (89/106/EEC) and the Standing Committee on Drinking Water (98/83/EC) and shall also have its scientific options validated by the EC Scientific Committee on Food and the Scientific Committee on Toxicology, Ecotoxicology and Environment.

## References

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## Annexes

Box 1: Overview of the legal and institutional framework of the water supply in the Netherlands.

Box 2: Dutch Approval Scheme. Principles for the evaluation of chemicals and materials in contact with drinking water.

Box 3: Some difficulties to deal with when harmonising national approval schemes.

Box 4: Baseline conditions for the development of a European Approval Scheme.

## Box 5: Prototype of European Approval Scheme - Step by Step

## Box 1: Overview of the legal and institutional framework of water supply in the Netherlands

### Legal and institutional framework of water supply in the Netherlands

*Water Supply Act (now under revision to implement Council Directive 98/83/EC)*

The legal framework for water supply is provided by the Water Supply Act *cum annexes* (1957, latest partial revision in 1997). This act deals with

- drinking water quality standards, quality assurance, control and enforcement,
- re-organisation of the water industry (up scaling through mergers on the basis of provincial re-organisation plans)
- planning of infra-structural works (national policy and framework set by government, elaborated by water supply companies in an operational 10 year plan) .

Based on the Water Supply Act there are 2 Decrees:

- Decree on Protection of Drinking Water Installations (1989), with regulations on drawing up and implementation by the water supply companies of plans to protect drinking water installations against acts of war, sabotage, terrorism and disasters.
- Drinking Water Quality Decree (latest partial revision in 1994), with regulations on drinking water quality standards and monitoring (implementation of Drinking Water Directive, 80/778/EEC) and inspection and enforcement (by the Inspectorate for the Environment)

Furthermore there are 3 Inspection Guidelines issued by the Inspector General for the Environment:

- Guideline on the approval of chemicals and materials in contact with drinking water
- Guideline on the quality of emergency water supplies
- Guideline on the permeation of pipes in case of soil pollution

At the national political and administrative level the Minister of Housing, Spatial Planning and the Environment is responsible for the drinking water supply. Drinking water is produced and supplied by water supply companies. According to the Water Supply Act, the water supply companies have the legal duty to produce and distribute drinking water of good quality, under sufficient pressure and in sufficient quantity.

There are 22 water supply companies (1999). Nearly all water supply companies are (public) companies under civil law (limited liability companies) with shares held by provinces and municipalities (20). There is one water supply company operated by the municipality (Amsterdam) and there is one water supply company in private hands. The water supply companies work together in VEWIN, the Netherlands Water Works Association. Kiwa, owned by the water supply sector, offers certification, testing, research and consultancy services to the water supply sector and others.

### *Standards for drinking water quality, monitoring, reporting and enforcement*

Legally binding standards for drinking water quality are set in the Drinking Water Quality Decree, which is an administrative order on basis of the Water Supply Act. The current standards are in conformity with the standards set in the EU Drinking Water Directive 80/778/EEC (to be adjusted according to 98/83/EC). For other substances the Inspectorate for the Environment, acting on behalf of the Minister of Housing, Spatial Planning and the Environment, may set guide values on the basis of assessment of potential risk to human health to be respected by the water supply companies.

Drinking water quality is monitored according to programmes based on the Drinking Water Quality Decree and in compliance with the requirements of the Directive 80/778/EEC (to be adjusted according to 98/83/EC). The monitoring is done by the water supply companies and supervised by the Inspectorate for the Environment. Analyses have to be carried out by the laboratories approved by the Minister of Housing, Spatial Planning and the Environment. Part of the formal approval is the accreditation by a certifying body.

To be continued.

### Box 1 (continued)

All monitoring results have to be reported on a yearly basis to the Inspectorate for the Environment that publishes a yearly report which is sent to Parliament and to the European Commission by the Minister of Housing, Spatial Planning and the Environment. The yearly number of analyses is approximately 1 million (at a drinking water production of 1200 million m<sup>3</sup>/year); 25% are taken at the tap or in the distribution network and 75% are taken ex water works. The compliance rate (percentage of analyses complying with the standard) over the last five years was between 99.5 and 99.9 %.

Water supply companies have to report non-compliance with standards immediately to the Inspectorate for the Environment, unless it is trivial. The Inspectorate will then in consultation with the water supply company decide on the basis of the potential health risks what has to be undertaken by the water supply company to comply. The Inspectorate checks the actions of the water supply company. Consumers are informed about any non-trivial breach of standards, its meaning in terms of potential health risks, the actions that will be undertaken and are given advice in case of any temporary restrictions in the use of the water supplied.

### *Implementation of Council Directive 98/83/EC*

Work is underway to implement the Council Directive 98/83/EC into Dutch legislation. The legislative work will be completed before the end of the year 2000. The focus is on

- exemptions (Article 3.2)
- quality standards and monitoring (Annexes)
- regime of derogations (Article 9)
- responsibilities regarding domestic distribution systems (Articles 2.2, 6.2 & 6.3)
- approval of materials and chemicals in contact with drinking water (Article 10)

## **Box 2: Dutch Approval Scheme. Principles for the evaluation of chemicals and materials in contact with drinking water**

### Dutch Approval Scheme

#### *General basic principles*

In view of the possibility of drinking water pollution, the materials and chemicals to be used are evaluated with regard to the nature of the substances from which they are made and the quantities of these substances which migrate or dissolve in drinking water under standardised conditions (temperature, migration time, surface-to-volume ratio). The no-effect-level (NEL) established in toxicity testing generally serves as the basis for the toxicological standardisation. The NEL may be used to calculate the maximum tolerable concentration (MTC) in drinking water. As many of the substances used in materials and chemicals may also be absorbed as food additives or via food through migration from packaging materials, the following basic principles are also applied:

- The contribution from drinking water to the intake of substance must not exceed 10% of the maximum tolerable daily quantity stipulated for this substance.
- Limits for drinking water quality laid down in the Drinking Water Quality Decree shall not be exceeded.
- From the point of view of public health and environmental protection, exposure of people to toxic substances, even in concentrations lower than those regarded as the maximum tolerable levels, shall be avoided as far as possible. This implies, among other things, that additives should not be used in larger than strictly necessary amounts and that these substances should be of high technical quality.

The maximum tolerable concentration is determined as follows:

- If it is clear that a substance is not mutagenic and there is no suspicion of carcinogenic potential or any other property which makes further investigation desirable, it is investigated whether semi-chronic testing produces a NEL. This is generally the case when the effects found in the highest dosage group no longer occur at a lower dosage.
- The NEL can be used to calculate the maximum tolerable concentration in drinking water. Here a safety factor of at least 100 is used, due among other things to the differences in sensitivity between human beings and rats and between one human being and another.
- Based on a body weight of 60 kg, a daily consumption level of 2 litres of drinking water and a 10% contribution by drinking water to the tolerable daily intake, the relationship between the MTC in drinking water and the NEL in (semi-)chronic testing can be calculated.

#### *Evaluation of materials; migration limits*

The tolerable migration is dependent upon the surface-to-volume ratio and is expressed in  $\text{mg}/\text{dm}^2$ . The migration limit applicable to an actual product application is established by means of a conversion factor. The migration limit values as stated on the positive lists are expressed in  $\text{mg}/\text{l}$  in order to enable comparison with other evaluation systems which generally refer to the maximum tolerable concentration. In connection with the problems of the migration, the migration limits on the positive lists, expressed in concentration units, have to be interpreted as the maximum tolerable average concentration calculated in relation to the daily level of drinking water consumption.

#### *Evaluation of chemicals*

In addition to the general basic principles stated above, the following also apply:

- In establishing the limits, for safety reasons removal of a pollutant during treatment to drinking water quality is not taken into account.
- The contribution of impurities in drinking water treatment chemicals to the concentration in the water to be treated must in principle not exceed 10% of the limit stated in the Drinking Water Quality Decree.
- For chemicals dosed during the production of drinking water, the maximum dosage to which the limit applies must be stated.

### **Box 3: Some difficulties to deal with when harmonising national approval schemes (identified in the feasibility study)**

#### Some difficulties in harmonising national approval schemes

- Different legal and institutional framework
- Different types of products. There is a big difference between a small ring and a large diameter pipe. The National Approval Schemes deal differently with these differences. The EAS might establish a policy to deal with “minor” products. A reasonable approach, that takes into consideration the major health and environment requirements, has to be established
- Different drinking water quality. Different European areas have different water, in terms of acidity, corrosiveness, hardness, etc.. Furthermore, the water is very often treated. Two possibilities are offered to the water regulators and water suppliers: either to adapt the water characteristics (pH, hardness, et c.) to the materials already installed in the distribution network, or to adapt the materials to the water characteristics. Furthermore there are differences in disinfection practices (especially the use of chlorine). It could therefore be necessary to define in the EAS different “categories” of water.
- Different parameters that are tested.
- Different types of Positive Lists for substances that have been toxicologically evaluated (alphabetical list or material-specific list). The EAS should include rules to set up and update these Positive Lists.
- Different ways of testing procedures and conversion factors for the same parameters.
- Different order for carrying out the tests.
- Different acceptance criteria
- Different levels of certification, either with different levels of Attestation of Conformity, and/or by different approach to different materials. Certification levels range from the manufacturer’s declaration to full certification, including pre and post auditing procedures.

**Box 4: Baseline conditions for a European Approval Scheme (as suggested in the feasibility study).**

Baseline conditions for a European Approval Scheme (to be approved by the Member States)

- The European Approval Scheme (EAS), that includes all the certification processes for fitness of the construction products for contact with water intended for human consumption (98/83/EC), will apply to all construction products in contact with water intended for human consumption from the treatment plant to the consumer taps. The Member States will remain free to apply the EAS also to products used for other parts of the system (e.g. intake, raw water transport, storage reservoirs, treatment works). The Member States should also decide whether the EAS requirements have to apply to products that would not fall under the CPD requirements and/or whether to apply the EAS to hot water systems.
- The EAS should offer a level playing field for all materials and products, using the same high level of consumer protection. This does not mean, however, that each material will have to pass the same test methods.
- The EAS acceptance criteria will be developed from, *inter alia*, the Council Directive 98/83/EC, the EC Synoptic Document for Plastics in contact with Foodstuffs and World Health Organisation Recommendations.
- The EAS can only be accepted as a whole package, when the full process (e.g. auditing, uniform principles for case by case assessments, test procedures, conversion factors, acceptance criteria, Notified Laboratories, etc.) will be operational for all materials and products of the same sub-family (e.g. pipes, tanks, valves, “minor” products, etc.). The Member States will keep/preserve their National Approval Schemes until the EAS, in its modular implementation, can be considered as fully operational in all its options.
- The EAS will be set up taking into consideration the existing protection level in use among the different Member States. In doing so, the high level of protection in some of the existing National Approval Schemes must not be compromised. In particular, it might lead to accept a request from a Member State to change the prototype EAS only if and when it can be proved that this request will not compromise the high level of protection.
- All stages of the EAS process and of the resulting CE Marking should be transparent. Confidentiality of product formulations shall not lead to the introduction of an unclear certification processes. A partial CE Marking, if any, that could be satisfactory for the use of the product in some Member States (during transitional periods, for instance), shall clearly show the EAS tests that have been carried out, and those that are missing to satisfy the full EAS requirements.
- It is expected that the EAS will be fully operational within 4 to 5 years. Meanwhile, if any National Scheme had to be improved, it should be made in accordance with the EAS main features.

### Box 5: Prototype of European Approval Scheme - Step by Step

STEPS	WHO	EAS REGULATORY DOCUMENTS	COMMENTS
1. Application, with full formulation and production process	Producer	Guidance Paper	
2. Check requirements of application	Notified Body	Guidance Paper & Uniform Principles	In case of minor products, the approval procedure may be adjusted according to Guidance Paper
3. Check on conformity with EAS Positive List	Notified Body	EAS Positive List & Guidance Paper	If in full conformity, then step 6
4. Toxicological evaluation of new substances	MS Regulatory Committee	Uniform Principles for case by case assessment	If toxicological data are insufficient, then producer should provide additional data based on toxicological tests. Back to step 1
5. Set migration levels / acceptance criteria for new substances	MS Regulatory Committee	Uniform Principles for case by case assessment	Outcome of steps 4 and 5 forms input in periodical review of EAS Positive List
6. Pre-certificate auditing	Notified Body	Uniform Principles	Producer could fail to meet quality assurance requirements
7. Laying down of test protocol	Notified Body	Uniform Principles	
8. Level 1 testing (screening organoleptic parameters and TOC)	Accredited Laboratory	Harmonised test procedures (EN)	If product fails, then step 11
9. Level 2 testing (relevant parameters DWD and substances specified in steps 3 & 4)	Accredited Laboratory	Harmonised test procedures (EN)	If product fails, then step 11
10. Level 3 testing (final screening unexpected substances and microbiological growth)	Accredited Laboratory	Harmonised test procedures (EN)	
11. Report of test results	Accredited Laboratory	Guidance Paper	
12. Evaluation of test results. Check against acceptance criteria	Notified Body	Harmonised acceptance criteria & Uniform Principles	
13. Approval	MS Regulatory Committee	Uniform Principles	If product fails, then <b>no</b> 2 <sup>nd</sup> application in other MSs.
14. Certification, with protocol post-certificate auditing	Notified Body	EAS Certificate	Publication

Notes:

Step 3 & 12: The EC Scientific Committee on Food and the Scientific Committee for Toxicity, Ecotoxicity and the Environment will be involved in preparing the EAS Positive List and the harmonised acceptance criteria.

Step 8,9 & 10: These 3 steps could proceed together if the applicant wishes to do so.



# **Drinking water database for reporting to authorities and private persons**

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Everybody, who is dealing with drinking water, knows that the high standards and quality of drinking water reached are supported by two columns (Fig. 1).

The first column describes the requirements to be met in drinking water for human consumption. Drinking water shall be wholesome and clear. The objectives of a good water quality are reached by an appropriate source protection and water treatment. The water quality is defined by quality standards for microbiological, chemical and physical parameters.

The second column, which guarantees a good drinking water quality too, consists of regular monitoring of drinking water to find out whether the fixed parametric values are fulfilled. Additionally, in this second part, we can also range the duties of and rights to reporting and information.

In Germany for instance, both of these columns have been built upon the drinking water ordinance. In the European Community, the Council directive on the quality of drinking water has existed since 1980, as we know, being the basis for the supply of drinking water at the European level.

In many points such a drinking water guideline can be seen as a kind of quality monitoring programme, also containing Hinweise for generation of reliable data. That data reflect the actual status of the variables which influence drinking water quality. It is acknowledged that simply generating good data is not enough to meet the objectives. The data must be processed and presented in a manner that aids understanding of the spatial and temporal patterns in drinking water quality. The intent is to use the information to explain water quality, furthermore, to control water quality and to communicate the information more widely. The resulting data are to be used in fulfilling these objectives.

Today a database offers the best means of data logging and handling, and so we find databases in nearly all social life. The computer software we use in data handling and management falls mainly into four principal classes: the first is the statistical software which processes numerical data and performs test and analyses, secondly, spreadsheets handle both numerical data and text, and usually include powerful graphical and statistical capabilities. The third class of software is designed to manage the input, editing and retrieval of numerical data and text. The power of the programming language allows the user enormous scope for data manipulation, sorting and display. The fourth class is specifically designed to relate data to geographical locations and output of them in the form of maps. Data of different aspects, in this case, related to drinking water quality can be overlaid with data on land. This allowed to represent the relationship between the selected aspects and a map.

Now we are in a nearly ideal situation, that all four classes of software can be used together in a complementary fashion. Today the former constraints on the use of such information system software, as costs and need for sophisticated hardware, have been more or less solved. Good software and hardware are available on the market for a relatively accessible price, and one can have recourse to a lot of excellent skilled and experienced programmers for installation and preparation for special use. The databases, used today, are relational database management systems. Such systems allow creation of data tables that can be related to other, associated data tables. A data table is a collection of data records and a record comprises a series of information variables. In case of drinking water there are records about quality standards, measuring values, water production, distribution and consumption.

In the following, a database will be presented, which has been created in the Federal Environmental Agency (Umweltbundesamt, UBA) and is being extended continuously at present, as well about the historical development and up-date-problems.

The UBA-database called BIBIDAT (in Latin *bibo* = I drink) has been built upon an elder database, created in the seventies and eighties by the former Federal Health Agency. In 1980, using these databases, a survey of the state of drinking water in the old Federal Republic was published. Based on the values measured in the regional districts, a description of the drinking water quality was given for the old federal states (*Länder*).

In the eighties, further data were collected and stored for updating the drinking water parameters, but the values were not processed and published.

After the German reunification there were a transition period characterised by different legal systems in West and East Germany in wide fields of political, social and economic regulations. For instance, the drinking water ordinance of the GDR differed in some parameter values permitted. Within the first five years after reunification the German drinking water ordinance, in force since 1990, has not been extended to the five new *Länder*. To be able to manage the adjustment properly, in 1991 the Federal Ministry of Health and the authorities of the new states agreed on a project to analyse the situation of drinking water in the new federal countries. The intent was to get an overview of 6500 central water supply plants and to characterise the drinking water quality in each of about 7.600 communities. These information had to provide the background for setting priorities for improving the water supply.

In creating a database, the first questions to ask are: which type of information is required and what amount of data is to manage. With reference to the agreement, the task was to create a collection of drinking water data, coming from about 200 East German local boards of health. The water supply plants were requested to provide data on localities, water production, capacities, distribution and so on. The quality parameters for drinking water were assessed according to the drinking water ordinance. About 60 particular parametric values were selected for the database.

The database consisted of two computer programmes. For the data input a programme was used, developed in the former Federal Health Agency mainly for collecting and storing data on drinking water. This programme was combined with a powerful graphical programme for statistical and geographical presentation called Personal Computer Interacting Programming, and allowed to adapt the data structure to our own requirements.

Upon the agreement between the Federal Government and the new *Länder* and according to the technical opportunities the following structure of the database was chosen (Fig. 2):

The central table is concerned with the water supply plants, including plant number, plant name, location of the plant, production capacity and daily output. The water supply plant is linked with the water company. Here one can find name, address, telephone number, contact person. Another table is concerned with the water distribution from water work to the area of supply. In this manner it is possible to get information about pipe net and the way of water from the plant to the consumer. A further table describes the sampling sites: the type of sample, freshwater or drinking water, the location before or behind the supply plant, between the plant and the consumer or the tap outlet. Tables concerned with details on water quality are files of the parameters including the parametric or limit values set in the drinking water ordinance. The chemical and microbiological variables are stored in a particular record and can be combined with the name and locality of the laboratory responsible for measuring. At least, the table for results is used for the output of the data and their appropriate presentation.

In the following, I want to mention some examples of data presentation.

Using several macros, written by the programmer, the analysed values of water works can be processed statistically and described in tables or figures. For each particular water works the values assessed can be presented together with the period and site of sampling, the frequency with which the parameter was measured, the mean value, minimum and maximum values, standard deviation and so on. For such presentation a series of forms has been designed.

Using the interactive system programming it is possible to provide not only basic statistical data but also a diagrammatical representation of the results. The general objective when constructing graphs is to concentrate a large amount of quantitative information in a small space for a comprehensive overview.

In the following you can see two examples of a geographical representation. Using the parameters of water distribution it is possible to summarise geographical distribution of water in an area. In Figure 3, a new federal state, Saxony, has been selected. In this example, we can see the supply areas of some water works and we are able to assess the amounts of drinking water supplied by the water works.

In more detail, it is possible to show the volumes of drinking water expressed as percentages which each community gets from one or more water supply plants.

A very useful overview technique for data survey is a map of the study area. This enables to see the parameter differences in a geographical perspective. This is illustrated for the nitrate parameter in two maps. We can see nitrate concentrations in drinking water in different areas of supply (Fig. 4). The results measured have been divided into four classes, from a very low level to the concentrations above the limit value of 50 mg nitrate per litre. Another pattern represents the water quality at the end of water treatment (Fig. 5). Here the data have been related to the water works. In both pictures we can observe that higher concentrations of nitrate are more frequent in the southern part of the new *Länder*.

It should be emphasised that there are much more possibilities for data processing and presenting, more possibilities than a non-mathematician can suggest.

Modern software and computer techniques offer an almost unlimited data handling. A good database can be used for many kinds of reports. Nevertheless, in practice a report should be easy to understand for different audiences. According to the requirements, one can combine a lot of parameters, and screen the needed data in a database.

With a database for drinking water we could give information at three important levels.

1. Information on the quality of drinking water has to be given to the national authorities, to the government or to working groups of parliament. Such duty of providing information is regulated at the national level and depends on the national legal system.

2. Private consumers have got the right to get information about the drinking water which they consume. Now, this point is also fixed in the new Council Directive. In article 13 paragraph 1 we read "The Member States shall take the measures necessary to ensure that adequate and up-to-date information on the quality of water intended for human consumption is available to consumers." For the future, creating a central database does not seem of a priority importance. In most cases, the consumers are interested in the quality parameter of their drinking water locally supplied, and they may ask the data from the local boards of health or the water suppliers. The water works have begun to present the information on the quality of water on the Internet. So it will become easier and easier to reach knowledge about the drinking water supplied.

3. The third direction for flow of information is the EC. The duties of reporting at regular intervals to the Commission are fixed in article 13 paragraph 2 of the Directive, saying "...each Member State shall publish a report every three years on the quality of water... Each report shall include, as a minimum, all individual supplies of water exceeding 1000 m<sup>3</sup> a day as an average or serving more than 5000 persons ... The Member States shall send their reports to the Commission ..."

The Commission demands detailed information on:

- the quality standards set in accordance with the parameters of the Directive
- appropriate monitoring programmes established by the competent authorities. Those monitoring programmes shall meet the minimum required
- the report shall include facts about remedial actions and restriction in use
- the Commission demands reports on derogation in fulfilment of the Directive. In case of derogation a report is required on the mode of information provided to the affected population and on managing the situation.

All these details can be given by a suitable and up-dated database. The technical basis exists.

From our point of view, the difficulties that we have in creating a central database are associated with the input of valid data on quality of drinking water into the system. Here I will shortly touch a German problem. Our aim is to built up an up-dated database concerning all federal countries. You remember, the old BIBIDAT comprised only the western federal states, and that database, created after 1991, contains only data from the new *Länder*. According to the federative structure and constitutional regulation the particular *Länder* themselves are responsible for fulfilment of the drinking water ordinance. It includes monitoring, controlling, managing and reporting. Until now a lot of the states have created their own databases mostly using different types of software. A particular database is designed for the tasks of the authorities at the state level. The transfer of the data from the database of the *Länder* to that of the

Federal Agency is not a technical difficulty. In BIBIDAT there are enough points of intersection for data transfer. Our problem is of a political nature. At present, the federal institutions discuss with the boards of the *Länder* to come to an agreement on data transfer in the field of drinking water. We hope the states could be convinced that there are advantages resulting from creation of a central database for drinking water.

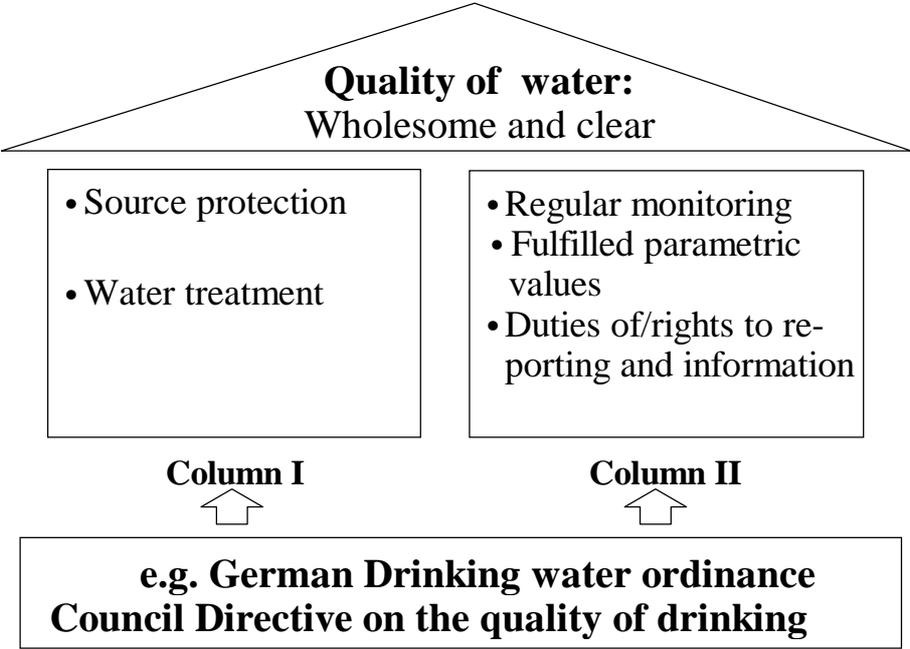


Fig. 1: Basis for a good drinking water quality: high standards in source protection and water treatment and regular monitoring of drinking water



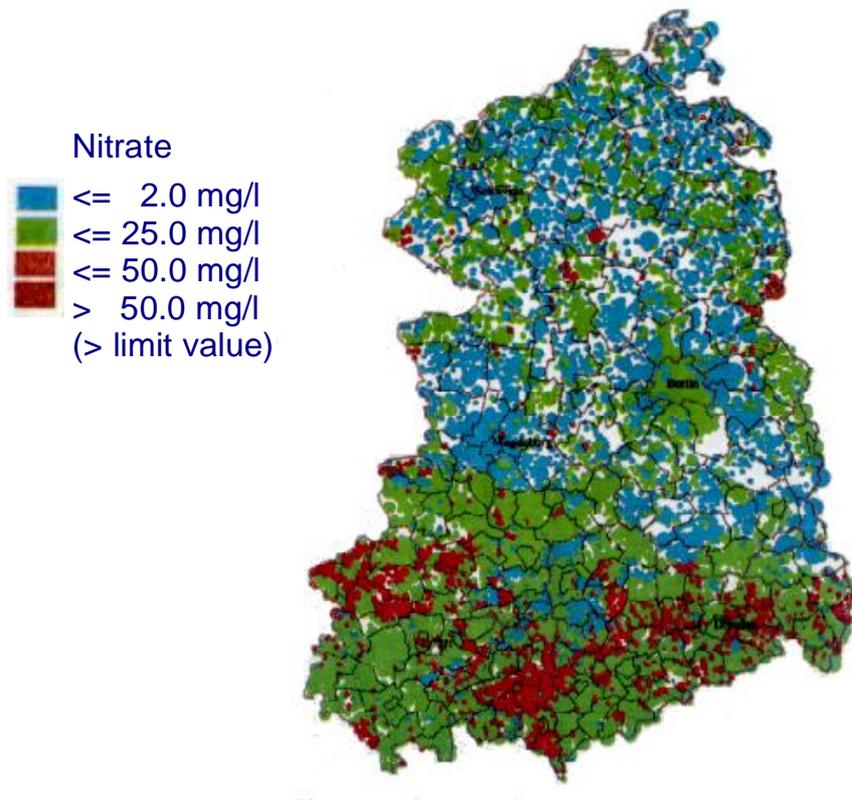


Fig. 4: Quality of drinking water in the new *Länder*  
Concentration of nitrate in area of supply

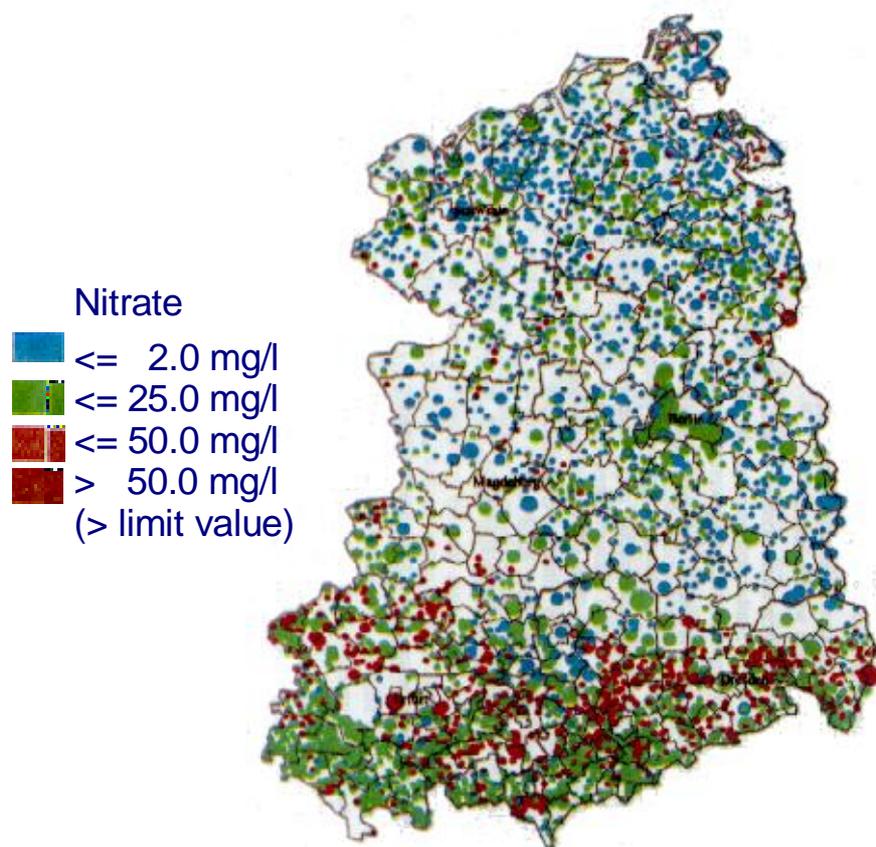


Fig. 5: Quality of drinking water in the new *Länder*  
Concentration of nitrate at the works outlet

# **The Transposition of the Drinking Water Directive 98/83/EC in Cyprus**

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## **The Cyprus Profile**

### **Geography and Climate**

Cyprus is located at the north-eastern end of the Mediterranean Sea. It is the third largest island of this basin with a population of about 736000 and an area of 9251 km<sup>2</sup>, out of which 47% is arable land, 19% is forest and 34% uncultivated land.

The topography of Cyprus (Fig.1) reflects the main geological formations including:

- a) two mountain regions, the Kyrenia or Pentadactylos in the north, a hard limestone range (carboniferous-cartaceous) rising at 1024 m high, and the Troodos ophiolite complex (precretaceous) massif in the northwest-southeast with the highest peak of 1951 m.
- b) Central or Mesaoria and Morphou fertile plains, which lie in between the two mountain ranges and the narrow alluvial plains along the coast of the island.

The climate of Cyprus is typical Mediterranean, with long hot, dry summers and short, mild winters. The average daily temperature is 36<sup>0</sup> C in summer and 6<sup>0</sup> C in winter with abundant sunshine during the whole year.

### **The Water Situation Analysis**

Cyprus being an island without hydrologic connection with neighboring countries relays entirely for its water requirements on the rainwater.

The average annual rainfall is about 500 mm, is uneven with spatial and temporal variations and corresponds to about 4600 MCM of water (Fig.2). About 80% of this water is lost to the atmosphere through evapotranspiration and the remaining 20% or 900 MCM of renewable water resources are offered for development.

- (a) About 2/3 of this water or 600 MCM are surface runoff, of which up to 150 MCM is distributed in the irrigation network and up to 190 MCM is stored in more than 100 dams of Cyprus. It has to be mentioned that Cyprus is ranked as first in Europe

in the number of dams per km<sup>2</sup> with a total storage capacity of 300 MCM. This was the goal of all Cyprus Governments since the establishment of the Cyprus Republic in 1960 for the development to the highest degree of the water resources and their allocation between the various users, on the basis of the recognition of the water shortage problem.

- (b) The other third or 300 MCM of renewable water penetrates the sedimentary rocks and alluvial soils and is either stored as groundwater or is lost to the sea. About 270 MCM of this natural aquifer recharge is pumped out or emerges from springs (Fig.3). Unfortunately, in some areas the overexploitation of these aquifers led to a lowering of the water table or sea intrusion and the consequent degradation of water quality.

In addition to the regional and seasonal variation in the precipitation and the occurrence of two or more year consecutive droughts, the annual rainfall is gradually declining in the last fifty years (Fig.4). Therefore, in order to satisfy the demand, water is not only stored and supplied, but is also transferred from one catchment area a long way to the drier eastern areas. The largest of these projects being the Southern Conveyor Project, which covers the southern coast between the Diarizos River in the west and the Kokkinochoria area in the east. This project includes the Kourris dam (with a storage capacity of 115 MCM), the main pipeline of 110 km long, the Achna terminal reservoir and the Limassol and Tersefanou Water Treatment Plants.

## **The Water Policy**

Water resources in Cyprus are scarce due to the infrequent and declining rainfall. The rate of their exploitation is unequal and the availability of fresh water in some regions is critical. Partly, because it is dependent upon the temporal and areal distribution of rainfall and because of their rapid urbanization and tourist industry growth.

The increasing demand for fresh water is a real pressure on the public agencies, which are forced to manage effectively the limited water resources among the various socioeconomic sectors or to use costly treatments like desalination. Since 1998 a private desalination plant with a total daily capacity of 40000 CM is supporting the drinking water supply.

The water policy is mainly based on the requirements for protection and development of these resources, as well as on the protection of public health. However, the implementation of conservation and water saving measures or the techniques for reducing water losses, the long distance transfer or reuse of treated wastewater are not sufficient to balance supply and demand. There is still space for improvements and integrated water utilization planning.

## **The Water Supply System**

The water supply system has been designed and adjusted to respond to the existing geographical and climatic conditions of the island. It is a mixed/combined system that

involves the use of all types of resources, thus groundwater, treated surface water or desalinated water. Through an extensive pipeline network the drinking water reaches all consumer premises. The distribution network is managed by the WDD as the bulk distributor, providing the water to the distributors, i.e., the Town or Village or Community Water Boards, which then distribute the drinking water to the various users.

The drinking water sources are either: i) **groundwater** from boreholes or springs, which is used with or without disinfection as per se or after being blended with water from other sources, or ii) **treated surface water** from the conventional type treatment plants, and/or iii) **desalinated water** from the private desalination plant.

There are four state water treatment plants in Cyprus at present, servicing the major towns of Nicosia, Limassol, Larnaca and their surrounding populated areas. A fifth one is under construction to satisfy the demand of Paphos town and area.

The raw water for these plants is abstracted from the reservoirs of the major dams and is processed in the conventional way. So, after pre-sedimentation and pre-chlorination, the water is treated by coagulation with aluminium sulphate and hydrated lime, rapid-gravity sand filtration preceded by sedimentation and flocculation with polyelectrolyte. Finally, it is disinfected with chlorine. The process provides operational flexibility, while maintaining the cost effectiveness and high quality of treated water.

The quality of all types of water that is used in the supply systems is monitored throughout all stages, from the source to the consumption, so that the water used for human consumption meets the limits set in the Drinking Water Directive. The monitoring is extensive and is performed by the WDD, the General State Laboratory and the Public Health Department. The main principle governing this activity is the prevention of pollution, with various water resources protection measures and public awareness programs, rather than the expensive curing techniques.

The management and maintenance of the distribution system is shared between the WDD as the bulk supplier and the regional Water Boards. The former is responsible for the distribution network lying between all the above sources and the main water reservoirs of the towns or villages, while the latter is responsible for the network that is extended within the populated areas, in addition to the billing process.

Drinking water is also supplied to the consumers in bottles or trunks and containers from licensed producers/distributors. The type of water used for this purpose is groundwater with fine quality characteristics.

## **Water Legislation**

There are various laws dealing with the administration, operation and management of the distribution of water (Table 1). All these will be evaluated to be covered by a unified law in relation to the establishment of the Water Authority.

The quality of water for human consumption is officially subject to the WHO Guidelines and to the Foods (Sales and Hygiene) law. Since 1991 it is indirectly influenced by the Water Pollution law. Unofficially, the European standards and Directives 80/778/EE and 80/779/EE were also taken into account. In addition, some EPA standards were considered to complete as many essential parameters as possible.

Since 1996 the Cyprus National Standard for the Bottled Water (CYS 109/96) is in force, while the relevant one for the Potable Water, although prepared by the same Technical Committee, was not published. The reasons for this delay were the clarifications for some parametric values and the announcement of the preparation of this Drinking Water Directive.

The base used for the above CYS Standards included the WHO Guidelines, the previous Water European Directives, the EPA and some National Standards of other countries. They have to be adjusted to reflect the reality of Cyprus water. Therefore, the transposition of the new Directive into the Cyprus law will not be difficult.

It has to be pointed out that, the enforcement of the Water Pollution law (69/91) in 1991 facilitated the implementation of this Directive in terms of meeting the quality values. Great attention has been given to the protection of water sources used for the abstraction of water for treatment plants, in accordance with the Directive 75/440/EE and the zone protection of boreholes connected with the distribution network. Furthermore, the measures to eliminate contamination, the control of waste discharge, the application of Good Agricultural Practice etc. are also steps in the same direction.

## **Comparing the Cyprus Standards with the Drinking Water Directive**

### **Quality Standards**

The Cyprus Standards concerning the quality of potable and bottled water include 131 and 133 parameters, respectively, which are grouped in nine tables with their maximum permissible values (Table 2). The microbiological parameters in Tables 1 and 2 of the CYS Standards are extended to some more supplementary parameters if needed. The aesthetic and physicochemical or operational ones are shown in Tables 3 and 4, whereas the chemical parameters are given in Tables 5,6 and 8. Pesticides, within the local agricultural practice, are grouped separately in Table 7 and the radioactivity indicators are shown in Table 9.

The Drinking Water Directive 98/83/EC is definitely handier in terms of parameters 48 or 51 (Table 3) and the analytical work involved, even if this is referred to a minimum

set of parameters. Of course we must have in mind the necessity of the application of quality assurance programs, the accreditation of laboratories performing the analyses, the quality of service in addition to the quality of water (as product) offered for consumption. All these must be fulfilled for the implementation of this Directive and obtention of reliable and accurate analytical results.

When comparing the two sets of standards, there are differences in terms of the parametric concentration limits and in terms of the parameters used:

i) Parameters that are not included in the Cyprus Standards: These are Copper, in part B and *Clostridium perfringens*, Conductivity, Oxidisability and Total Organic Carbon (TOC), in part C of Annex 1 of the Directive. Two of them, i.e., Conductivity and Oxidisability, were performed in the routine monitoring, while Copper and TOC upon request. The other parameter is a new one.

ii) Parametric values: These have been found higher, lower or the same regarding the Directive values. The values in the first category are differentiated into those that have not been experienced in real samples, according to our records, and into those that have been recorded as high. Therefore, the former can be adjusted to the reference values of the Directive without difficulty.

The preliminary investigation of the available data indicated that problematic might be three parameters of part C in Annex 1, namely Chloride, Sulphate and Sodium. These have been found to show higher values in some groundwater samples supplying rural areas, either because of the geological formation or the overexploitation of the aquifers of the region.

The magnitude of the problem has to be quantified for each case, according to the criteria given by the Directive for tap rather than source water samples. The remedial action best for each case is under consideration. These involve the use of alternative supply or the mixing of water from various sources or a small-scale treatment. It seems that unless water shortage this will be feasible within the given time limits.

### **Monitoring and Sampling**

In general, the water quality is monitored in an extensive and comprehensive manner, covering nearly all aspects of the Drinking Water Directive. The monitoring programs have been designed and implemented to satisfy the needs of maintaining the quality characteristics of water with regards to the type of parameters under investigation. The peculiarities of the status of water, as well as the consumption mode on a local or national basis, or other limitations have been also considered, so that monitoring is regular throughout the year as requested in Annex II.

However, there is a need to differentiate and clarify the activities and responsibilities undertaken by the implicated agencies, on the basis of the performance of the check or the audit monitoring consistent with the new Directive. In particular, the legal establishment and redesign of these programs is needed to include and facilitate the collection of tap samples from private premises.

The sampling of water from various points at the source, the treatment or bottling plants, the distribution line, the containers or trunks, the market and governmental buildings (e.g. hospitals, schools etc.) is performed by trained technicians of the WDD and Public Health Departments. The frequency and representative sample collection technique is in agreement with the requirements of WHO and the relevant European Guidelines.

The necessary analytical methods used for determination of the quality of water are those stated in the manuals of ISO, CEN or EPA Standard Methods of Analysis and are in compliance with Annex III. Well-trained scientific personnel, of the General State Laboratory and the WDD's Water Treatment Works Laboratories execute these analyses. The accreditation process for all the analytical laboratories involved in the determination of the water quality and the adoption of quality control and assurance programs is now in progress. This will support the reliability and the comparability of the results.

### **Quality Assurance of Treatment, Equipment and Materials**

The various chemicals used in the treatment of water or the equipment and materials in contact with water are supplied according to specifications. There is a need for re-evaluation of the technical specifications, the relevant methods for their determination and acceptance, in terms of the present Directive. The selection of the appropriate measures to be taken and the legislative formulation should ensure the absence of any immediate or potential contamination during treatment or distribution and storage.



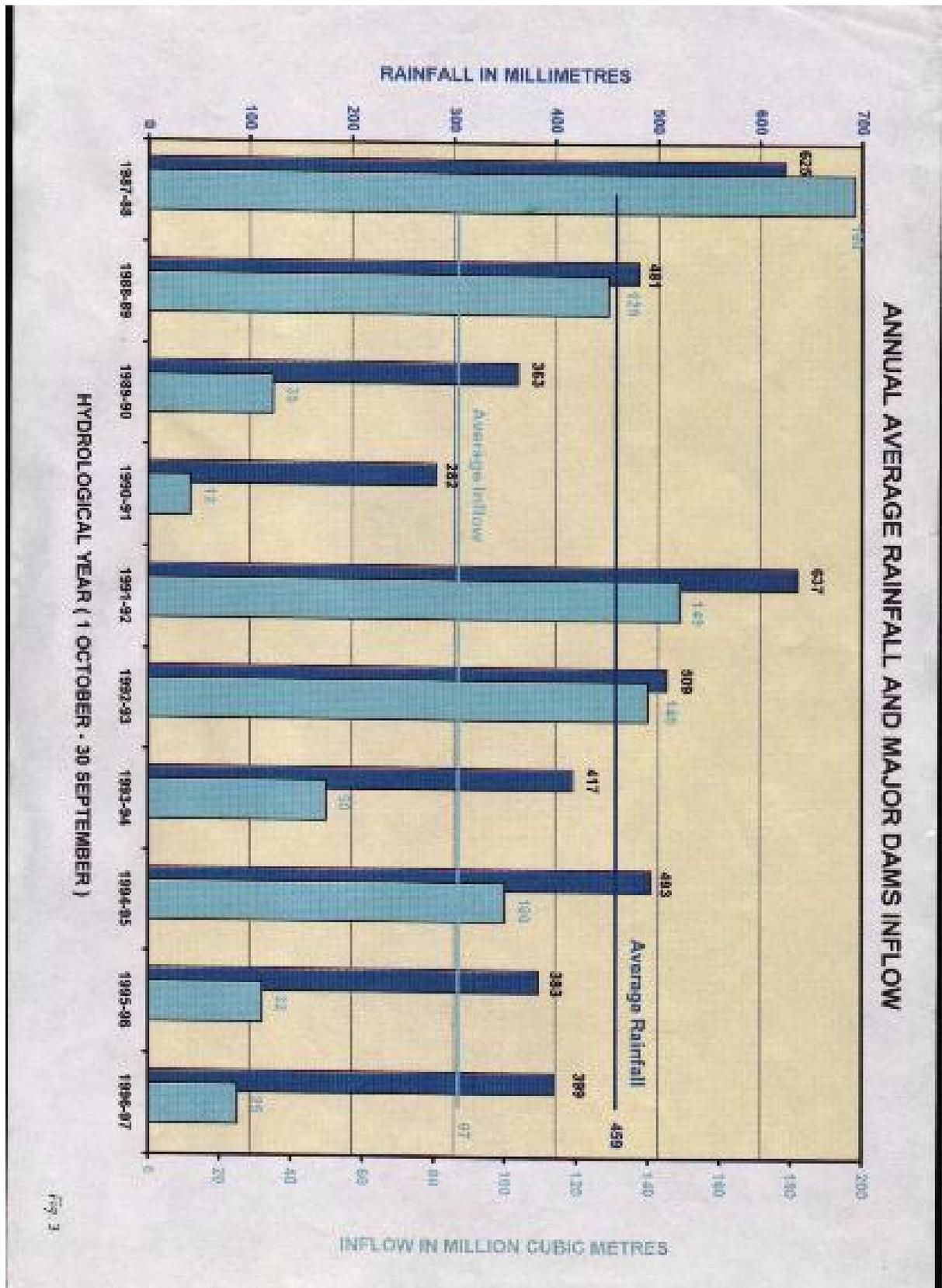


Fig. 3

# WATER BALANCE FOR CYPRUS

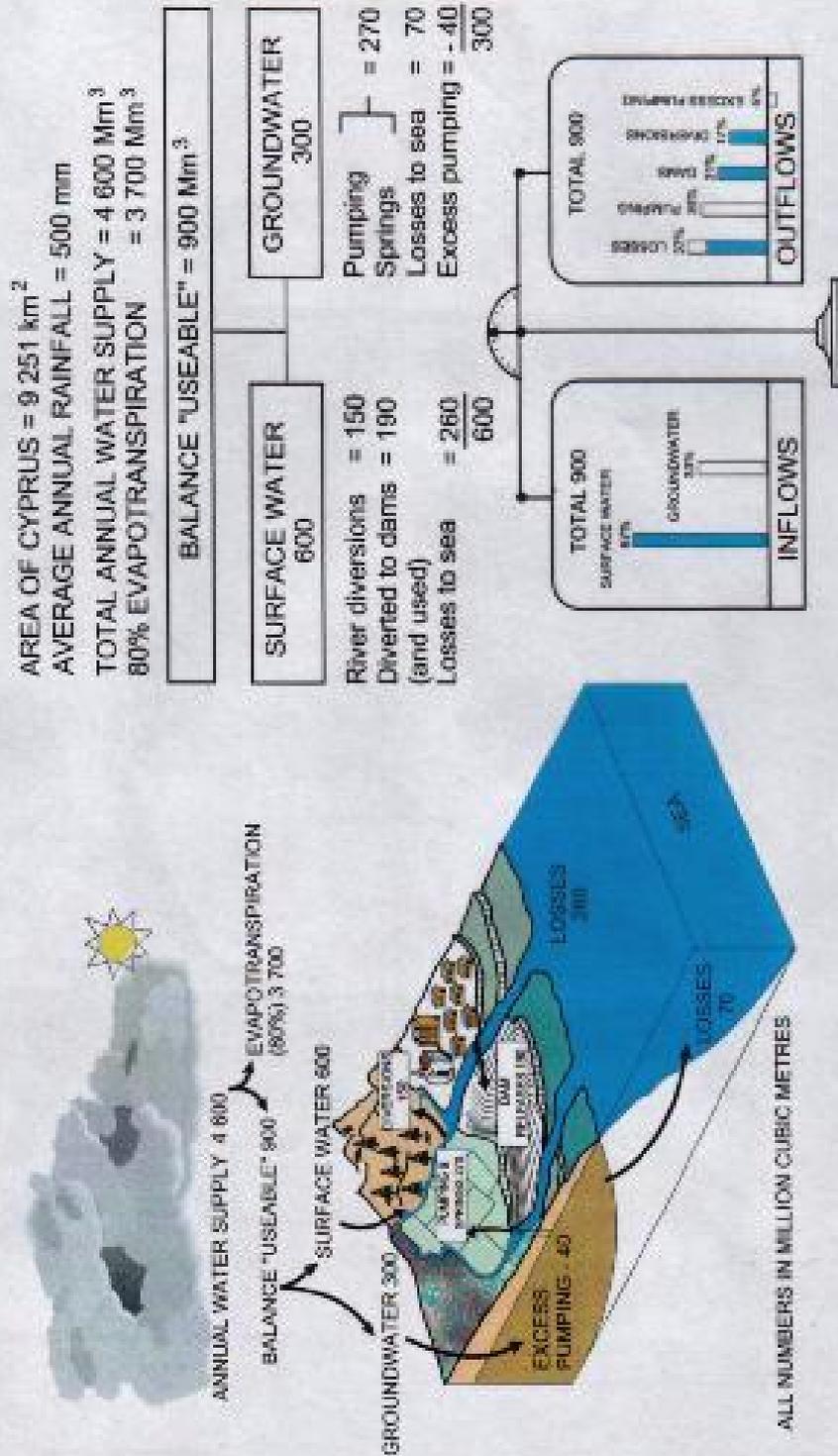


Fig.2

Fig. 3



# **Prerequisites for the transposition and implementation of the Council Directive 98/83/EC in the Czech Republic**

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This report on the current situation and prospects in the transposition of the Council Directive 98/83/EC in the Czech Republic is divided into three parts. The first part briefly describes the present state in legislation related to drinking water, authorities and responsibilities in drinking water quality assurance, drinking water quality monitoring and its main results. In the second part, the regulations which are being prepared to allow the full transposition of the Directive are listed including the time schedule of the measures to be taken. In the third part, the problems expected in the practical implementation of the Directive and in meeting its requirements are discussed.

## **Present state**

At present, most Czech regulations related to drinking water are of the nature of standards rather than laws. These standards are listed bellow.

ČSN 75 7111 “Drinking water quality”. It establishes requirements for drinking water quality. The standard has been in force since 1991 and is based mainly on the WHO Guidelines for Drinking Water Quality (1984). It gives about 80 parameters, i.e. microbiological, biological, physical, chemical and sensorial parameters, that can be divided into three groups:

- a) parameters with the “limit value”, “recommended value” and “indicative value”, that are mostly of minor concern for human health (a total of 39 parameters),
- b) parameters with the so called “maximal limit value” to be used for microbiological agents and toxic chemicals with the threshold effect (a total of 34 parameters),
- c) parameters with the so called “limit value of reference risk” for the chemicals in which the no-threshold effect is expected (a total of 10 parameters).

In addition, three radiological parameters are given in this standard, which are not valid any more, since this area has been newly arranged by Act No 18/1997 or by Regulation No 184/1997 of the State Office for Nuclear Safety on requirements for radiation protection assurance.

ČSN 75 7211 “Drinking water. Surveillance of the quality by transport, storage and distribution”. This standard of 1993 establishes the monitoring rules for the producer: number of sampling points, sampling frequency, and range of the quality parameters controlled according to the quantity of water supplied in m<sup>3</sup>/day.

Apart from these two standards, the latter of which only is mandatory in some provisions, there are dozens of technical standards of no force for analytical methods, operating surveillance of water quality in water treatment, etc.

Act No 20/1966 on population health care and Regulation No 45/1966 on creation and protection of healthy living conditions (both in the wording of later regulations) are also important to ensure the distribution of safe drinking water. The Act establishes the responsibilities of the Ministry of Health and the Public Health Service as the competent and control bodies that approve the use of water sources for supplying the population with drinking and domestic waters, approve the production and importation of materials and objects coming directly into contact with drinking water and establish requirements for drinking water quality and safety. The Public Health Service supervises the drinking water quality from the public supply. The obligation of controlling drinking water quality does not apply to the owners of individual sources of drinking water, if not used for commercial purposes, only recommendations are given. Requirements on bottled waters (both natural mineral and drinking waters) are given in Regulation 292/1997 (as amended by Regulation 241/1997) on requirements for bottled water safety and treatment and in Act No 110/1997 on foods and tobacco products. This Act says that the water used for production of foods and drinks has to be of such a quality to allow the final product to meet the qualitative requirements for the given commodity. The necessity for using drinking water is not explicitly stated.

Drinking water supply. At present, about 86 % of the population of the Czech Republic are supplied with drinking water from the public water distribution systems, the others are supplied from individual sources. According to the data of 1997, 55.4 % and 44.6 % of water for the public supply are taken from the surface and ground sources, respectively.

Although all public water systems in the Czech Republic are systematically controlled for water quality by the producers and supervised by the Public Health Service, and theoretically, a lot of data are available, most of these data are not centrally collected and processed. Exceptional in this regard are 30 districts in which a governmental project “System of Monitoring the Environmental Impact on Population Health in the Czech Republic” has been conducted since 1991.

The central towns of the monitored areas (district towns, former central regional cities and the capital Prague) provide water supplies for almost 3.5 million population, i.e. more than 60 % of the people living in towns with more than 20, 000 population. The monitoring of the district towns covers 40 % of 8.87 million population whose water supplies are from the public water systems. The monitoring of all districts covers approximately 50 % of the population. The data on the drinking water quality in public

water supplies issues from the routine monitoring of drinking water quality conducted by the Public Health Service and from the obligatory analyses executed by the operators of the water-supply engineering.

From the total number of almost 188 thousand specified data on drinking water quality obtained in 1998, the limits of significant quality factors (i.e. maximal limit value (NMH) and limit value of reference risk (MHPR)) were exceeded in 597 cases. The limit values of the parameters characterising mainly the aesthetic properties of drinking water were not achieved in 3,370 findings (2.11 %). In a total of 10,420 cases (5.54 %), the limit values of the quality factors were exceeded. See figure 1. From comparison of the values obtained between 1994 and 1998, it is evident that the proportion of the limit values exceeded for the health risk parameters (NMH, MHPR) decreased from 0.8 % to 0.32 % and other parameters did not show any marked changes.

The data available from the epidemiological information system EPIDAT and direct reports of the co-operating Public Health Institutes proved that there had been no case of infection or infection outbreak caused by drinking water from the supervised public water supplies in the districts monitored in 1998. There was no case of intoxication due to chemical contamination of the drinking water of the public water supplies in the districts monitored.

#### Transposition

The full transposition of the Directive 98/83/EC into Czech legislation will be achieved before the Czech Republic joins the EU, and will be based on the following regulations:

- a) Law on public health protection (will replace Act No. 20/1966) – its bill was recently discussed by the government and submitted to the members of Czech Parliament. The law and elementary regulations are expected to be in force by January 1, 2000. Apart from the law itself which will establish the responsibilities of the national health inspection, the extending regulations of the Ministry of Health will be presented: Regulation of the Ministry of Health which will specify the requirements for drinking water quality and Regulation of the Ministry of Health which will specify the hygiene requirements for materials and objects coming into direct contact with drinking water, and chemicals used in water treatment technologies. These regulations will contain most requirements given in the Directive 98/83/EC.
- b) Law on water systems and waste water disposal systems and the extending regulation. It will establish, among others, the conditions for implementation of a general monitoring of drinking water quality and central data collection for the purposes of assessment and reporting. It is expected to be in force since 2001.
- c) Amendment to Act No 110/1997 on foods, which will establish, among others, the obligation of using drinking water in production of foods. Furthermore, amendment to Regulation No 292/1997 (or No 241/1998) on bottled waters. Expected to be in force since 2001.

- d) Amendment to Regulation No 184/1997 on requirements on providing radiation protection where the requirements for drinking water radiological safety will be modified to be consistent with those of the EC Directive. Expected to be in force since 2000.

In the light of the “revolutionary” requirement of the Directive 98/83/EC, i.e. that the point of compliance for the public water supply does not mean the distribution system outlet but the consumer’s tap (including the domestic distribution system for which the water supplier is not responsible!), it is not clear how to establish the legal responsibility for meeting this requirement not only in public, but also in private buildings.

Drinking water quality parameters in the Czech regulation which is being prepared. Since most drinking water in the Czech Republic comes from the surface sources, determination of certain parameters has a long tradition in this country and there are local problems due to some specific natural contaminants; when transposing the European Directive, the Czech Republic is expected to use some additional parameters (according to article 5) or quantitative limits of some parameters where the EU Directive only suggests qualitative assessment (e.g. no abnormal change). The following parameters are to be taken into account in this regard: beryllium, colourless flagellates, live algae, dead algae, magnesium + calcium (hardness), free residual chlorine, acidity to pH = 4,5, crude oil products, total dissolved solids, PCBs, silver; or quantitative assessment for colour, odour, turbidity, TOC, and colony count 22°C.

For the same reason, in contrast to the Directive 98/83/EC, Annex II, Table A-1, the range of the obligatory parameters for the check monitoring will be broadened in the Czech legislation. Additional parameters proposed are as follows: enterococci, colony count 22°C, oxidisability (or TOC), nitrate, nitrite,  $\Sigma$  Ca+Mg, chloride, iron, manganese, free residual chlorine (if used).

So far it is not completely clear who should perform the so called audit monitoring according to Annex II, Table A-2, since the audit monitoring is understood as a producer independent control. On the other hand, we suppose that the producer should not conduct only the check monitoring but the whole range of analyses required.

Conversely, some parameters included in the Czech standard so far, but not required by the Directive 98/83/EC and not presenting a current problem in the Czech Republic, will be excluded in the future. This would concern the following items: faecal coliform bacteria, asbestos, ammonium ions (NH<sub>3</sub>), barium, dichlorobenzenes, dichlorophenols, phenols, humic acid, hydrogen sulfide, anionic surfactants, temperature, tetrachloromethane, vanadium, zinc, 1,1-dichlorethene, 2,4,5,-trichlorophenol, 2,4,6-trichlorophenol.

Establishment of more strict limit values is considered only in case of copper and oxidisability, if implementation of a more strict quantitative limit in the following parameters is not regarded as such: colour, odour, turbidity, TOC, colony count 22°C. Comparison of the current Czech standard and the Directive is presented in Annex I.

## Implementation

As for the institutional assurance of the Directive, it is not completely clear who will conduct the monitoring (water quality testing) in the private buildings (impact of the domestic distribution system on water quality) and who will be charged with the monitoring audits. Other problems should not arise.

The prescribed and recommended methods for microbiological and chemical analysis of water should not cause any problems, since ISO or CEN standards have been currently used in the Czech Republic for this purpose. Laboratory equipment will need to be complemented in some places to allow ion chromatography for bromate detection and total organic carbon analysis; such equipment is not currently available in all laboratories.

Problems resulting from water quality monitoring are not expected to arise since the present frequency and range of controls (sampling) as performed in the Czech Republic are either fully consistent with the requirements of the Directive 98/83/EC or even more severe. Nevertheless, it is necessary to create an effective central system of data collection and a central database of results for all water systems supplying more than 5000 population (or providing more than 1000 m<sup>3</sup> water per day) to meet the requirement of article 13 (paragraphs 2 to 6) of the Directive. The existing system covers only about 50 % of the population supplied from these water systems.

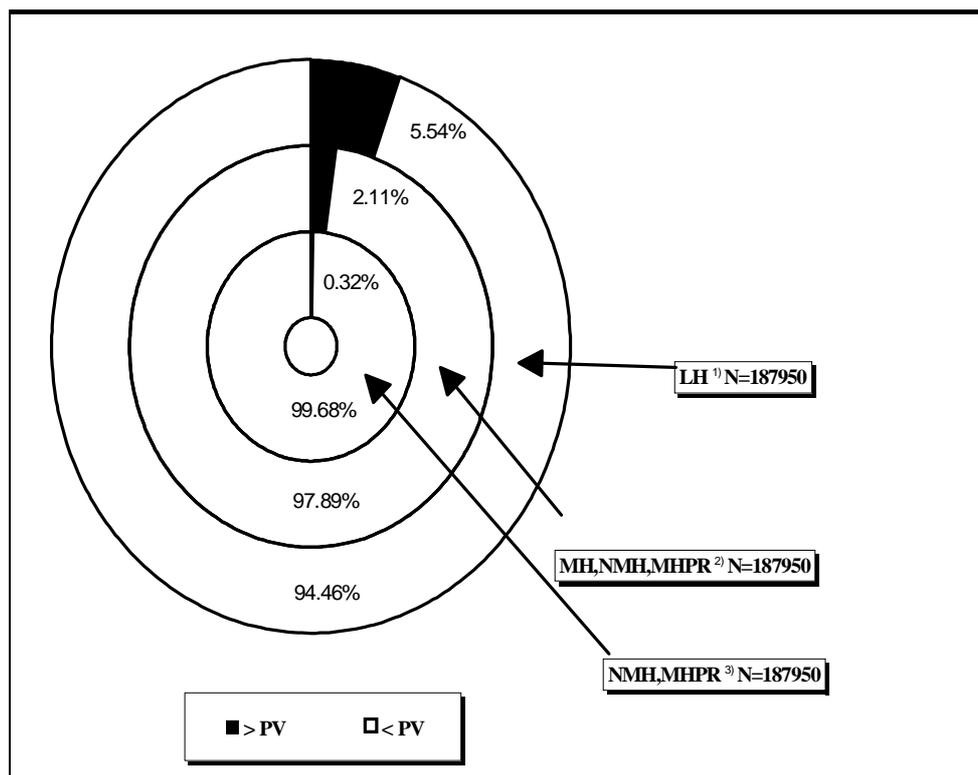
As for the water quality parameters given by the Directive 98/83/EC, compliance with the limits prescribed is expected, and when the Czech Republic joins the EU, the situation should be satisfactory. Nevertheless, there is an uncertainty as to the parameters not included yet in the Czech standards or analysed with a low frequency: sufficient data is not available to have an accurate idea of the situation in the Czech Republic. This is true of the following parameters: chlorethene, acrylamid, epichlorohydrin, natrium, and some pesticides, and to a certain extent also bromate, boron, and antimony. A detailed study will be necessary in this regard.

As can be seen from Table 1, comparing the frequency with which the limits are exceeded with reference to the current Czech standard and the European Directive, more strict limit values of certain parameters may cause problems.

In view of this fact and uncertainty as to some “new” parameters, the Czech Republic intends to apply to be allowed a transient period of 3 years starting from the moment when the Directive comes into force (December 25, 2003) to the end of 2006.

With this possible exception, the practical implementation of the Directive should be achieved by the year 2003.

Figure 1. Exceeded limits in the public drinking water supply monitored in 1998 in the Czech Republic



1) General limit value (LH)

2) Limit value (MH), maximal limit value (NMH), limit value of reference risk (MHPR)

3) Maximal limit value (NMH), limit value of reference risk (MHPR)

PV ... parametric value

**Table 1. Comparison of the frequency with which the limit is exceeded with reference to the current Czech standard and new Council Directive. Czech Republic - public drinking water systems 1994 – 1998.**

PARAMETER	TOTAL N	ČSN		EC		EC- CSN	
		Above PV		above PV		above PV	
		N	%	N	%	N	%
1,1,2,2-tetrachloroethene	2527	3	0.12	3	0.12	0	0.00
1,1,2-trichloroethene	2562	12	0.47	89	3.47	77	3.01
1,2-dichloroethane	1018	5	0.49	29	2.85	24	2.36
Arsenic	2097	2	0.10	45	2.15	43	2.05
Benzene	1652	3	0.18	174	10.53	171	10.35
Chloroethene	102	0	0.00	53	51.96	53	51.96
Manganese	19240	706	3.67	2973	15.45	2267	11.78
Nickel	2179	5	0.23	107	4.91	102	4.68
Lead	3811	17	0.45	286	7.50	269	7.06
Iron	30613	2847	9.30	6094	19.91	3247	10.61

CSN ... CZECH NATIONAL STANDARD ( ČSN 75 7111

Drinking water quality)

EC ... COUNCIL DIRECTIVE 98/83/EC

PV ... PARAMETRIC VALUE

## **Annex 1. Comparison of the parameters of the Czech standard ČSN 75 7111 „Drinking water“ with those of the Council Directive 98/83/EC.**

### 1) Parameters included in both of these regulations with the same limit values:

faecal streptococci (= enterococci), coliform bacteria  
ammonium, nitrate, fluoride, aluminium, chromium, cadmium, mercury, selenium,  
sulphate, benzo(a)pyrene

### 2) Parameters included in both of these regulations, but with more strict limit values in the Council Directive 98/83/EC: (data in brackets: ČSN 75 7111 ⇒ Council Directive 98/83/EC):

arsenic (50 ⇒ 10) µg/l  
manganese (100 ⇒ 50) µg/l  
nickel (100 ⇒ 20) µg/l  
lead (50 ⇒ 10) µg/l  
iron (300 ⇒ 200) µg/l  
tetrachloroethene (10 ⇒ 10 [sum of PCE + TCE]) µg/l  
trichloroethene (30 ⇒ 10 [sum of PCE + TCE]) µg/l  
1,2-dichloroethane (10 ⇒ 3) µg/l  
benzene (10 ⇒ 1) µg/l  
chloroethene = vinyl chloride (20 ⇒ 0,5) µg/l

### 3) Parameters included in both of these regulations, but with less strict limit values in the Council Directive 98/83/EC: (data in brackets: ČSN 75 7111 ⇒ Council Directive 98/83/EC):

nitrite (0,1 ⇒ 0,5) mg/l  
chloride (100 ⇒ 250) mg/l  
cyanide (10 ⇒ 50) µg/l  
copper (0,1 ⇒ 2,0) mg/l  
pH (6-8 ⇒ 6,5-9,5)  
conductivity (100 ⇒ 250) mS/m  
chloroform - see below  
pesticides - see below  
COD-Mn = oxidisability (3,0 ⇒ 5,0) mg/l

### 4) Parameters included in both of these regulations, showing changes in conception of either the limit or the parameter:

colour, taste, odour, colony count 22°C, turbidity ⇒ quantitative assessment replaced in the Directive by qualitative assessment („acceptable to consumers“ or „no abnormal change“),

fluoranthene ⇒ omitted in the Directive to be replaced with a sum of specific PAU (0,1 µg/l),

chloroform (30 µg/l ⇒ 100 µg/l [sum of four specified THMs]),

PESTICIDES: 2,4-dichlorophenoxyacetic acid (100 µg/l), DDT (1 µg/l), hexachlorobenzene (0,01 µg/l), heptachlor (0,1 µg/l), lindane (3 µg/l), methoxychlor (30 µg/l), pentachlorophenol (10 µg/l) ⇒ replaced with two parameters in the Council Directive: individual pesticide (0,1 µg/l) and total pesticides (0,5 µg/l),

5) Parameters given in ČSN 75 7111 but not included in the Council Directive 98/83/EC:

faecal coliform bacteria, colony count 37°C, colourless flagellates, live algae, dead algae,

abioseston, asbestos, ammonium ions (NH<sub>3</sub>), beryllium, phenols, magnesium, humic acids, free residual chlorine, silver, hydrogen sulfide, anionic surfactants, temperature, acidity to pH=4,5, oxygen dissolved, total dissolved solids, vanadium, calcium, ΣCa+Mg (hardness), zinc, barium, dichlorobenzenes, dichlorophenols, tetrachloromethane, 1,1-dichloroethene, 2,4,5,-trichlorophenol, 2,4,6-trichlorophenol, absorbance, EOX, chlorobenzene, crude oil products, PCBs, pentachlorophenol,

6) Parameters given in the Council Directive 98/83/EC but not included in ČSN 75 7111 (limit values given in brackets):

E.coli (0 KTJ/100 ml)  
Clostridium perfringens (0 KTJ/100 ml)  
acrylamide (0,1 µg/l)  
antimony (5 µg/l)  
boron (1,0 mg/l)  
bromate (10 µg/l)  
epichlorohydrin (0,1 µg/l)  
pesticide (0,1 µg/l)  
pesticide - total (0,5 µg/l)  
PAH [sum of specified compounds] (0,1 µg/l)  
THMs - total [sum of specified compounds] (100 µg/l)  
sodium (200 mg/l)  
TOC (no abnormal change).



# Transposition and implementation of Council Directive 98/83/EC in Estonia

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## Present legislation

The Ministry of the Environment and Ministry of Social Affairs are responsible for supervision of the use and protection of water resources in Estonia. Their activities are regulated by the Water Act and the Public Health Act, that came into force in recent years. These legislative acts establish both the principles for co-operation and the arrangement of work between the two Ministries and with other bodies. According to these laws the protection of groundwater and water sources falls within the competence of the institutions of environmental protection. Health protection institutions have to monitor the quality of water directly used by people.

On the basis of the above mentioned laws, the Standard of Drinking Water came into force in 1995. This Standard was compiled taking into account the WHO Recommendations of 1993, the Soviet GOST of 1982, the Position of the Commission of the European Communities on Foodstuffs of 1993 and the existing situation and possibilities to meet the values proposed in the standard. **Therefore, most of the norms in this Standard are the same as or quite close to the Council Directive 98/83 EEC parametric values.**

Radiological parameters for drinking water are fixed in the directive of the Minister of the Environment "Radiation doses to the population caused by natural radiation, sources of radiation, and accidents". Special activity factor should be calculated on the basis of <sup>210</sup>Pb, <sup>210</sup>Po, <sup>226</sup>Ra, <sup>228</sup>Ra, <sup>234</sup>U, <sup>238</sup>U and <sup>222</sup>Rn radiation.

## Present situation

### Consumption

Estonia is quite well supplied with water for human consumption. Approximately 75 % of the population use water from the central supply systems, although there are differences between urban and rural areas. In towns up to 90% of the inhabitants use water from the central supply systems, but in rural communities this over-all percentage is only 60.

In 1996, the total consumption of drinking water from the central supply systems was 175 million m<sup>3</sup> in Estonia.

### Water sources

There are three kinds of sources of water for human consumption in Estonia:

Source of water	Main users	% of consumption
Surface water	Tallinn (about 450,000 population), in part, and Narva (70,000 population)	34
Groundwater from deep wells	Tallinn, in part and 56 other towns and communities	37
Groundwater from pit-shaft wells	Farms, villages, suburbs in towns	29

### Surface water

In Tallinn and Narva surface water is treated in water treatment works using classical purification technologies including micro-strainers, clarifiers, coagulation, ozonisation and chlorination. The water supplied by treatment works meets the requirements of the Standard for Drinking Water, but the quality of water often deteriorates in the supply systems.

### Groundwater

It is supplied from many geological strata:

*Cambrian-Vendi and Cambrian-Ordovician sandstones - North-Estonia.*

These strata are naturally protected against pollution. The quality of water is good, except that water from deeper deposits has a high **radiation level**. As a rule, it does not need purification.

*Silurian and Ordovician limestones - Central and Western Estonia.*

These strata are covered by a thin layer of moraine and are easily affected by anthropogenic influences.

A high content **nitrate**s can be recorded in this water which also may contain **H<sub>2</sub>S**.

*Devonian sandstones - South-East Estonia.*

Water is rich in **iron**, (up to 5 mg/l).

In Estonia, groundwater used as drinking water is depleted of iron via aeration in only a few plants.

*Quaternarian moraine - Pit-shaft wells - all Estonia.*

This stratum is very sensitive to human activities. Typical problems are **microbiological contamination** and a high content of **nitrate**s.

According to the 1997 data from the Ministry of Social Affairs, there was no case of non-compliance with the standards for arsenic and pesticides.

Although the percentage of analyses which exceeded the standard for **nitrate, fluoride and total coliforms** is high, the population that has to consume the poor-quality water only represents a few per cent.

The fluoride content widely varies with different regions. In some small regions in the South-West and South the fluoride content of water exceeds the limit (up to 6 mg/l), but in other regions in the South-East there is near-total deficiency of it.

A very serious problem encountered in different kind of waters are high **iron** and **chlorides** contents of groundwater in the coastal regions. There are two ways to meet the EU directive norms: to start with purification or to drill new wells nearby where the quality of water meets the EU norms. Both scenarios are quite expensive.

The experts estimate that to meet the EU demands 40 - 50 new iron removal plants should be established at a cost of about 30 million EUR.

Another problem is the **aggressiveness** of water. This kind of water seriously damages metal pipelines of the distribution networks.

#### Water-borne outbreaks

During the period 1945 - 1996 there were 167 water-borne outbreaks, causing illness to about 8500 population; the situation dramatically improved during the past few decades. The last outbreak of typhoid fever was reported in 1984, an outbreak of E. coli intestinal infection in 1971, that of **viral hepatitis A** in 1993 and that of **shigellosis** in 1997. In 1998, there were no outbreaks. On the other hand, the microbiological testing of drinking water shows a high percentage of cases where the limit values were exceeded. One conclusion could be drawn that there is a high potential risk of water-borne outbreaks, however, as there are not infection carriers, the real situation is good at the moment. Nevertheless, appropriate activities should be taken to eliminate potential risks.

#### Radiological situation

The level of 0.1  $\mu\text{Sv}/\text{year}$  (the norm given in the Directive) is exceeded in the lower layers of cambrium-vened deposits (up to 1.0  $\mu\text{Sv}/\text{year}$ ). There are some ways to solve the problem, but no decision has been taken yet.

### **Present activities**

Officials in the Ministry of Social Affairs and the Ministry of the Environment have compiled two documents dealing with water for human consumption:

1. Action plan for sustainable use of groundwater.

Action plan for sustainable use of groundwater is built up of specific measures which should be taken to meet the goal of the Action Plan. Each measure is specified by a timetable, estimated cost, financial source, responsible organization, way of measuring the result, possibilities for support from other organizations, and probable risks.

2. Action plan of the Estonian Environmental Health (ENEHAP)

The Action plan of the ENEHAP describes the present situation and the targets for the years 2000 and 2010.

3. Revision of the Estonian Standard for Drinking Water.

In March 1999, the Ministry of Social Affairs organized a commission for harmonisation of Estonian law with the "Council Directive 98/83/EC on the quality of water intended for human consumption".

To implement the Directive, some amendments should be made to the Water Act and in the Public Health Act. The main part of the Directive will be incorporated into the new Standard for Drinking Water. A detailed scheme has been compiled following the articles of the Directive to suggest where to include each of them.

The Government of the Republic of Estonia has determined already that 2003 laboratories concerned should be capable of determining all parameters listed in the Directive.

The parameters form four groups.

1. Parameters that have a stricter parametric value in the Estonian Standard for Drinking Water than in the Directive 98/83/EC:

**B; Cd; nitrate; nitrite; COD**

2. Parameters, that have the same parametric value in the Estonian Standard for Drinking Water as in the Directive 98/83/EC:

**Al; As; Cr; Pb; Cu; Hg; Ni; Se; fluoride; sum of pesticides; pesticide, E. coli, enterococci.**

3. Parameters that have more lenient parametric values in the Estonian Standard for Drinking Water than in the Directive 98/83/EC:

**Mn; Fe; cyanide; ammonium; chloride; sulfate; trihalomethanes; PAH-s**

4. Parameters that are not listed in the Estonian Standard for Drinking Water:

**bromate; Na; Sb; acrylamide; benzene; 1,2-dichloromethane; epichlorohydrin; tetrachloro- and trichloroethene; vinyl chloride, tritium, total indicative dose.**

Estonian chemists and microbiologists can determine most of the parameters listed in groups 1 to 3 according to the specifications in Annex III of the Directive.

Costs for refitting the laboratories to be capable to perform the analyses according to all the requirements of the Directive are estimated to be one million EUR.

As the parameters in group 4 have not been determined in Estonia yet, we cannot estimate whether there are any failures to meet the parametric values of the Directive and whether any measures are needed in this regard. Information is needed from the EU countries about these matters to allow the Estonian authorities to set the action plan and time schedule.

The list of most urgent activities for 1998 -2010 in the largest communities:

- to build 500 km of the water supply systems.
- to reconstruct 600 km of the water supply systems.
- to build or to reconstruct 30 water treatment works.
- to reconstruct 130 deep wells.
- to drill 33 new deep wells.
- to close 73 deep wells.
- to build and to reconstruct 64 pumping stations.
- **to increase the percentage of the population using water from the central supply systems from 75 to 85.**

To fulfil this first-step plan in Estonia, the expert estimations propose total investments of **250 to 500 million EUR during the next 10 years.**

# Problems and prospects of the 98/83/EC Directive in Hungary

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## 1. Present situation in Hungary

In Hungary the quality of drinking water has been regulated by national standards since 1955. Earlier the standards were obligatory. Since 1994 standards have not been generally compulsory, therefore the last versions of these standards (issued in 1989 and 1991 on chemical and microbiological requirements, respectively) were made obligatory by a decree of the Minister of health. The limit values are similar to the national standards in other countries, limit values for toxic substance are based on WHO guidelines. The quality of drinking water is regularly monitored by the suppliers (water works) and by the laboratories at the Regional Institutes of the National Public Health and Medical Officers's Service (NPHMOS).

## 2. Differences between the EU and the Hungarian limit values

During the last decade the WHO modified a considerable part of the limit values, the EU values are not identical with the WHO values in many cases, this way there are many differences between the EU and the Hungarian parametric values.

In the Hungarian standard, the list of the microbiological parameters is longer: coliforms, fecal coliforms, fecal Streptococci, total plate counts at 22 and 37°C are to be tested and evaluated.

Among the chemical parameters:

The EU is stricter for As, benzene, B, CN<sup>-</sup>, Pb, NO<sub>2</sub><sup>-</sup>, pesticides, tri- and tetrachloroethane); NH<sub>4</sub><sup>+</sup>, Cl<sup>-</sup>, Fe, Mn, oxidisablity, SO<sub>4</sub><sup>2-</sup>, (Na).

The Hungarian standard is stricter for Cu, NO<sub>3</sub><sup>-</sup>, (THM); conductivity, pH.

There is no difference in case of benzo(a)pyrene, Cd, Hg, Se; Al.

The followings are not included in the Hungarian standard: acrylamide, Sb, BrO<sub>3</sub><sup>-</sup>, 1,2-dichloroethane, epichlorohydrin, Ni, PAHs, vinyl chloride; TOC.

### 3. Situation in drinking water supply in Hungary

Drinking water supply developed considerably in the last decades, so nowadays practically all the settlements are supplied by public works, so about 96 % of the population is supplied with piped water at least by public standposts.

The great majority of water works use underground water; the direct surface water intake accounts for only about 7 %. The main source of water is the bank filtered water (along the river Danube) using the natural process which is effective in removing pollutants. About one third of the sources is deep aquifer (100-500 m), naturally protected from any man-made pollution, but in some cases containing unpleasant (or even hazardous) natural constituents. The proportion of the most vulnerable aquifers (karstic and shallow groundwater) is relatively low, but may cause quality problems.

One special problem of waters from deep aquifers is the biologically unstable state: meaning high tendency to secondary pollution (bacterial aftergrow and nitrite formation in the distribution system).

### 4. Problems of drinking water quality

#### 4.1 General situation

The great majority of the supplied drinking water meets the Hungarian standard requirements. The main problems of quality are due to the presence of iron and manganese and exceedance of the limit of the total plate count (number of bacteria). The latter is one of the consequences of the above mentioned secondary pollution process but does not have direct impact on health. Many plants removing iron and manganese operate but the efficacy is not always good, especially in case of manganese. (The Hungarian limits for these parameters are not so strict as the EU ones).

More than half of the water sources are vulnerable and need protection. From the legal point of view the protection is ensured, a new regulation (a governmental decree) was issued in 1997 and the implementation is in progress.

The quality problems of health significance (like arsenic, nitrate, nitrite, toxic micropollutants, fecal bacteria) are rare. In 1998, the percentage of such samples was lower than 9 % according to the results of the tests performed by the laboratories at the National Public Health Service. This data can refer to 2-3 % of the total population (calculated according to the Hungarian standard, where the limit for arsenic is 50 µg/L and that for nitrite 1 mg/L).

More than half of the water works operate without treatment technology and these waters really do not need treatment (according to the Hungarian standard).

Chlorination is used in great towns and regional distribution systems where other technologies are used as well. It is done at much less than half of the water works (in number, but not in population served).

#### 4.2 Priority problems

The presence of arsenic of natural origin has the very first priority in many waters. The problem was recognised in 1981 when more than 400 000 population were supplied with water the As content of which was higher than 50 µg/L. A countrywide project was designed and accomplished (within 15 years) to reduce the concentration below 50 µg/L. The intervention was really successful: at the end of 1998, the number of population exposed (>50 µg/L) was below 15 000 (the majority of them living outside villages).

The great problem is, however, that the new EU limit is five times stricter: 10 µg/L and the majority of the newly established water works do not meet this new requirement and the removal technology is unable to reduce the concentration below this limit either. Additionally: in other areas of the country arsenic in a concentration range between 10-50 µg/L occurs as well so the exposed population is numerous. Because it is the most significant problem I will return to it later (chapter 5).

Secondary pollution in the distribution system is considered the next important problem, including nitrite formation and bacterial aftergrow. The root of the problem is the unpleasant composition of water in deep wells: high ammonium and organic content, the presence of methane gas, high temperature. To prevent the explosion hazard, methane has to be removed, the aeration initiates bacterial processes, including nitrite formation. High temperature promotes this process. In the presence of ammonium chlorine cannot control this process. The nitrite concentration can reach 5-6 mg/L.

The nitrate may be the next problem. It was present in more Water Works earlier but in the majority of the cases this problem was solved successfully mainly in the 1970-80's. A considerable part of the shallow groundwater sources had to be taken out of operation (replaced by deep aquifers). In other places the preventive steps were successful (prevention zones, mixing with other types of water).

Some natural microelements like fluoride and boron exceeding the EU limit values occur in drinking water as well, in case of boron the limit is much stricter than the Hungarian one. The exposed population is not very numerous although the solution is practically nothing else but using alternative water source to comply with the limit value.

There are not enough data available to evaluate exactly the possible hazard caused by micropollutants.

In case of chlorination by-products there are enough data available and - as a result of the activity of the Public Health Service - the situation is good: even the stricter Hungarian limits for THM's are met.

Limited data are available for the presence of other organic micropollutants like pesticides, chlorinated solvents, PAHs, other aromatic hydrocarbons, but based on the representative data (several hundreds) the situation seems to be good. In some cases the laboratories detected such compounds but in the course of the repeated (control) examinations, the majority of the higher results did not prove to be valid. (Close to the detection limit the uncertainty of the analytical methods is high).

Herbicides (2,4-D, atrazine) were present occasionally exceeding the strict EU limit, but not exceeding the WHO and Hungarian limits (determined on the toxicological basis), however, such occurrence is rather rare. Chlorinated solvents (tri and tetrachloroethene) are sometimes present in the water of the Danube as well as in the bank filtered drinking water but the concentrations are far below the limits.

Cis-1,2-dichloroethene is however present at a Water Works in a town and in an other karstic aquifer as one of the degradation products of tri and tetrachloroethane. This compound will be included into the Hungarian regulation.

Benzene, its derivatives and PAHs can be detected in some deep aquifers but their water (thermal water) is not used as drinking water.

Heavy metals are detected as well, but not frequently. The aquifers seem to be free of such pollution (arsenic is not a heavy metal). Stagnant water from the consumer tap contains sometimes lead, copper and zinc but after flushing some minutes the cold water is usually free of higher concentrations. (Lead pipes are very rare in Hungary, except some small flexible parts in old houses). Lead occurs in water stagnating in new PVC pipes, but after some months the concentration gets lower. (PVC pipes of better quality do not cause such problem, because they do not contain lead stabilizer or at least not in a soluble form).

#### 4.3 Parameters of secondary importance

The problem of iron and manganese which has already been mentioned, influences a considerable part of the population supplied mainly in small villages. To meet the EU limits, stricter than the Hungarian ones, would need many treatment plants and improved removal technology.

The case of ammonium is different. Ammonium (disregarding its pollution indicator role in shallow aquifers) does not cause health problem, but has important role in the secondary pollution process mentioned above. This problem influences many Waterworks and a considerable part of the population supplied. To eliminate the possibility of secondary pollution, ammonium removal can be a good solution, but it is not only expensive, but also technically difficult. In the majority of cases high amounts

of iron, manganese, humic material (or even arsenic) are present beside the high ammonium content, so combined (individual?) technology is necessary. Therefore, this problem needs not only financial support but also technological development.

#### 4.4 Materials used in water supply

In this area, the Hungarian situation is good. A ministerial decree was published as early as in 1971 regulating the issue. Beside the listed conventional materials, each new material needs special examination as well as a permit from the Public Health Authority.

The regulation proved to be good. Based on this experience, Hungary is a member of the CEN committee elaborating the EU regulations in this field.

### 5. The problem of arsenic

Hungary has got experience in this field as it was mentioned in subchapter 4.2. An epidemiological survey was conducted among population exposed earlier. Particular symptoms (hyperkeratosis, hyperpigmentation) were detected where the concentration was close to 200 µg/L. The new findings show that the rates of stillbirth and spontaneous abortions were significantly higher in the areas exposed (>100 µg/L) than in the control area. However, no significant elevation in the incidence of skin cancer could be detected in spite of the high probability predicted by the WHO's risk assessment. The recent literature also states that the risk of skin cancer calculated on the basis of extrapolation of the Taiwan data is not correct. So the cancer risk based on this calculation of the WHO's 10 µg/L limit value is not correct either.

The other calculation based on the usual ADI value can be considered correct. According to this calculation, the allowable daily exposure (adult) is 100 µg/capita. If the contribution of food is 80 µg, water can add 20 µg. This - calculating with 2 litres water consumption a day - justifies the 10 µg/L limit value.

In Hungary, however, the As exposure from food is - on average - only 20 µg/day/capita. In this case, water can add 80 µg/day to it. Exposure to the 40 µg/L limit would mean the same risk as in case of the WHO calculation. (The calculations are based on inorganic arsenic: this way the comparison is correct). In Hungary - to decrease the risk by 33% - a 30 µg/L limit value was proposed based on the mentioned arguments. In case of accepting this value, the risk will not increase and many unnecessary investments could be avoided. The 30 µg/L limit can be reached by improving the removal technology or slight modification of the mixing ratio or establishing some new removal plants.

From the hygiene and toxicological points of view, this argument is correct, pragmatic and consistent with the WHO strategy taking into account local conditions as well.

The legal system of the EU, however, does not allow such exception. If this opinion does not change, to cope with this problem Hungary can apply for temporary derogation in order to develop an appropriate removal technology for arsenic and to find funds to implement a widespread project for reducing the arsenic content of drinking water below 10 µg/L.

**Comparison of the limit values**  
of the 98/83 EC Directive and the Hungarian  
standard (MSZ 450-1)

The EC is stricter:

As, benzene, B, CN, F, Pb, NO<sub>2</sub><sup>-</sup>, pesticides, (tri- and tetrachloroethene);  
NH<sub>4</sub><sup>+</sup>, Cl<sup>-</sup>,  
Fe, Mn, oxidisability, SO<sub>4</sub><sup>-</sup>, (Na).

The MSZ is stricter:

Cu, NO<sub>3</sub><sup>-</sup>, (THM); *conductivity, pH*

No difference:

benzo(a)pyrene, Cd, Cr, Hg, Se; *Al*

New parametres in EC:

Sb, BrO<sub>3</sub><sup>-</sup>, 1,2-dichloroethane, Ni, PAHs; *TOC*

# **Transposition and implementation of Council Directive 98/83/EC in Slovenia**

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## **Introduction**

Safe drinking water is one of the basic elements of health quality. Water is so universally and normally present in our life that the importance of permanent preventive measures is often forgotten. The classic public health requirements regarding drinking water are: to all, always, anywhere, enough, of adequate quality and cheap. To achieve these goals, we have to develop a systematic approach to the phases of planning, operation and monitoring of water supply systems. The principles of this approach should be incorporated in the drinking water regulations and we tried to do so.

## **Water supply in Slovenia**

In Slovenia, there are nearly 1000 public water supply systems. According to Slovenian legislation, a public water supply system is a system which serves at least 5 households or 20 persons, public premises, food production undertakings and public transport vehicles.

According to the size of the population supplied, three types of public water supply systems are distinguished. In Slovenia, 84 % of the systems serve less than 1000 population (called small systems), 13 % of the systems are medium sized (serving 1000 to 10000 population) and only 3 % are large systems serving more than 10000 population. However, if we look at the coverage of the population, according to the written criteria, we can state that 59 % of the population is connected to the large systems, 19 % to the medium ones and only 8 % to the small systems. The remaining 14 % of the population is not served by the public water supply systems. In most instances data on volume of distributed water are not available.

Only 33% of the systems, which in turn serve 82 % of the population, are operated by qualified suppliers. Altogether 58 % of the systems use groundwater; these systems supply 73 % of the population. As many as 38 % of the systems or 23 % of the population are supplied from the so called karst water, which has quality characteristics of surface water. According to our data, 82 % of the systems which serve 30 % of the population have no official water protection areas. The quantity of water supplied is sufficient in 80 % of the systems; only 7 % of the population has insufficient supply regarding quantity.

In 45 % of the systems that cover 60 % of the population, water needs to be treated before distribution. The decision whether to treat or not to treat raw water must be taken on the individual basis by the Public Health Institute. This fact has to be stressed because raw groundwater is still of good quality and in many instances no treatment neither disinfection are needed; such is, for example, also the situation in the Slovenian capital Ljubljana with approximately 350000 inhabitants. Treatment is represented in 94 % solely by disinfection which is in turn mainly chlorination. Nevertheless, out of the systems where disinfection is required, it is regularly practised only in 36 %.

## **Results of the laboratory analysis**

Only results related to the samples taken from the distribution networks are presented. Microbiologically, 11 % of the samples were not in compliance with the criteria of the former national regulation in check monitoring; for the chemical analysis, this proportion was 7 %. A detailed presentation shows differences according to the size of the water supply system, type of raw water, water protection areas etc. It is obvious that the system characteristics which are responsible for such results are frequently aggregated. In audit monitoring we found elevated atrazine levels in some systems; elevated nitrate levels are less frequently detected, as most of the contaminated wells were abandoned.

## **Legislation**

The basic act is Wholesomeness of Foodstuffs and Consumer Product Act, as drinking water is considered a foodstuff in Slovenia. Drinking water quality is regulated by Rules on the quality of Drinking Water (OJ RS 46/97, 52/97, 54/98). These Rules are almost completely in compliance with the Council Directive 98/83/EC. This is due to the fact, that the basis for our regulation was the Proposal of Council Directive of 1995. The Rules were issued in August 1997 and came into force one year later. Until now two amendments were added. In the near future, we are going to include separate values for aldrin, dieldrin, heptachlor and heptachlor epoxide (0,030 µg/l). We are also going to include the impact of domestic distribution systems on water quality through the demand on sampling points, which would be the taps that are normally used for human consumption. Of course we can add some amendments if needed in the future. The translation of the Rules into English will soon be available.

Although the Rules should deal only with some parameters and their values, we have decided to include a few aspects of prevention also, as we have realized the importance of the environmental and organisational conditions, the water quality is so closely linked with.

According to the Rules, drinking water is the water from public water supply systems and water offered for sale in bottles. For the individual supply, Rules may be used only as guidelines. The Rules do not apply to mineral waters. After the introductory general statements, selection of water source is discussed; the quality of raw water has the highest priority for the decision makers. The present quality of raw water must always

be protected and the levels of contaminants must be kept as low as they are; deterioration is not allowed. The definitions of various types of raw water are included because a uniform approach to the treatment is necessary, which in turn must be based also on raw water type; hydrogeological judgement is obligatory. The Rules stress the importance of the water protection areas and of the materials which come into contact with drinking water; demands for chemicals used in the treatment process are mentioned. Treatment must be approved by the Public Health Institute; mixing is allowed as a method of treatment. Every system must be managed by a qualified operator, whose responsibilities are defined, for example, providing information regarding water quality, treatment, monitoring, emergency supply etc.

The list of the parameters and their values is almost equal to the list of the Council Directive 98/83/EC. For some values the WHO Guidelines for drinking water quality were taken into account. In comparison with the Council Directive 98/83/EC, more parameters are included. The list is divided into the microbiological and chemical parts. The so called indicator parameters are also included; their values do not represent health hazard, but indicate possible problems. Radioactivity will be considered in a separate regulation. Biological analysis are optional; one article deals with parasites and demands mechanical methods for their removal.

Monitoring is divided into check and audit activities, special or emergency examinations and research programmes. Monitoring must be carried out by the Public Health Institutes; they must determine sampling points, perform laboratory analysis and assess the results. For the sampling procedures, ISO standards are used. But this is only one topic. The Public Health Institutes must also be involved in regular field inspection in the so called water supply safety assessment. This includes all relevant elements of the supply system, from a water source including situation in the water protection area, through treatment, distribution network, storage facilities, to the taps.

In the assessment, drinking water is safe, when the results of laboratory analysis are in compliance with the parametric values. When they are not in compliance with the parametric values, the Public Health Institute has to assess in a second step what are the health hazards to the population. Suggestions for remedial actions must be part of the Public Health Institute expert opinion, which must accompany the results.

A part regarding derogations is included. It is nearly the same as in the Council Directive 98/83/EC. Prohibition or restriction in the use of water must take into account problems which could arise following them. The so called trivial non compliance of the values is not specifically included.

The role of the Health Inspectorate is defined in these regulations; it is to inspect, whether all the demands of the Rules are met.

In the second part of the Rules, Annexes A, B, C, D, E, F and G are added. Annex A covers the microbiological parameters and values, separately for the check and audit monitoring of water from a distribution network, in Annex B, similar laid down are

the parameters and values separate for the check and audit monitoring of water, offered for sale in bottles. Chemical parameters and their values for check monitoring and audit monitoring are listed in Annex C and Annex D, respectively. Annex E defines the minimum frequency of sampling according to volume of distributed water or water bottled. (In general, the Slovenian regulation requires more frequent sampling, especially in case of microbiological check monitoring). Annex F lists all methods of laboratory analysis. The record which must accompany every sample is added at the end as Annex G.

## **Conclusion**

In the Slovenian NEHAP, we declare three goals, which we consider to be essential in providing safe drinking water in Slovenia: shift towards larger systems, defined water protection areas and professional operation. We expect the new regulation to support our efforts to improve drinking water quality and consequently to protect and promote human health.

# **ANNEX**

## **List of participants**



# List of participants

## Transposition of the “Council Directive 98/83/EC of Nov. 3, 1998 on the quality of water intended for human consumption” into the national laws in the EU associated countries

Prague, May 27-29,1999

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