

BSDA BOTTLED WATERS TECHNICAL WORKSHOP

Sampling and Testing Regimes For Bottled Waters

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WATER FOR HUMAN CONSUMPTION

Organizations that regulate water for human consumption



- *Worldwide:*



- **WHO:** issues guidelines on quality of water for human consumption. These guidelines are a worldwide reference when setting standards.
- **CODEX ALIMENTARIUS:** Organization established in 1963 by FAO and WHO. It develops harmonised international food standards, guidelines and code of practice to protect the health of the consumers and ensure fair practices in food trade.
 - *Two Standards:*
 - Packaged Water: Codex STAN 227-2001
 - Mineral Water: Codex STAN 108-1981
 - *Two Code of Practices:*
 - Code of Hygienic Practice for bottled / packaged drinking water other than Natural Mineral Water: CAC / RCP 48-2001
 - Code of Hygienic Practice for Collecting, Processing, and Marketing of Natural Mineral Waters (CAC / RCP 33-1985)

C O D E X
International Food Standards



WATER FOR HUMAN CONSUMPTION

Organizations that regulate water for human consumption:



- **US EPA:** Under the Safe Drinking Water Act, EPA establishes minimum standards to protect tap water and requires all owners or operators of public water systems to comply with these primary (health-related) standards.



- **US FDA:** Regulates bottled water in USA as packaged food under the Federal Food, Drug, and Cosmetic Act, establishing standards of identity and quality for bottled water



- **EU Commission:**
 - * Directive 98/83 EC on water for human consumption
 - * Directive 2009_54 EC on *“the exploitation and marketing of natural mineral waters”*
 - * *Directive 2003_40 EC establishing limits to certain naturally present constituents in mineral waters and use of ozone-enriched air*



REGULATORY FRAMEWORK FOR BOTTLED WATER IN EUROPEAN UNION

Directive 2009_54 EC: Establishes microbiological criteria, permitted treatments, and labelling conditions for mineral and spring waters

Directive 2003_40: Establishes limits to certain naturally present constituents in mineral waters, and conditions for use of ozone-enriched air in mineral and spring waters

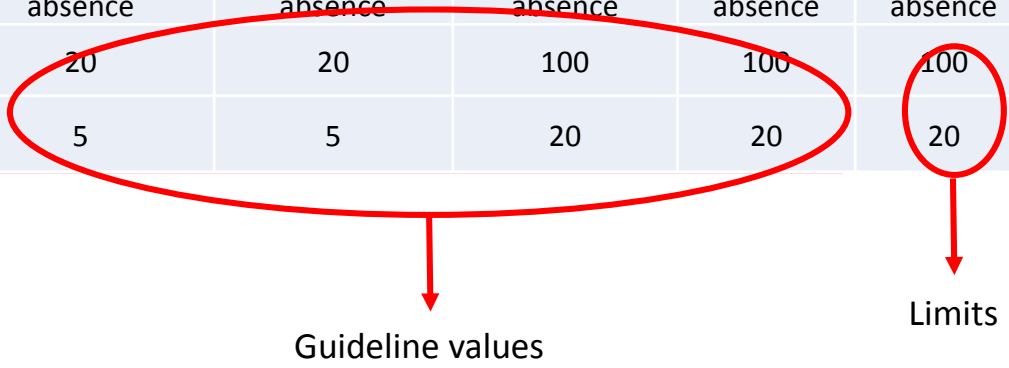
Directive 98/83 EC: Establishes physicochemical, chemical, microbiological and radiological criteria for ordinary drinking water. Spring waters are subjected to the physico-chemical, chemical and radiological criteria in this directive. Microbiological criteria for Spring waters are the same as for mineral waters

Directive 98/83 EC Establishes microbiological criteria for bottled waters which are neither mineral nor spring waters (example, the so-called table waters)



MICROBIOLOGICAL REQUIREMENTS FOR BOTTLED WATERS

Species	Microbiology at source		Microbiology finished product		
	Mineral water	Spring water	Mineral water	Spring water	Table water
Parasites and pathogenic microorganisms	absence	absence	absence	absence	absence
E. coli, 250 ml	absence	absence	absence	absence	absence
Total coliforms, 250 ml	absence	absence	absence	absence	absence
Enterococci, 250 ml	absence	absence	absence	absence	absence
Sporulated sulphite-reducing anaerobes, 50 ml	absence	absence	absence	absence	absence
Pseudomonas aeruginosa, 250 ml	absence	absence	absence	absence	absence
Total colony count at 20-22 C, 72h, per ml	20	20	100	100	100
Total colony count at 37C, 24h, per ml	5	5	20	20	20



ELEMENTS LIMITED IN MINERAL WATERS BY DIRECTIVE 2003_40 EC

ANNEX I

Constituents naturally present in natural mineral waters and maximum limits which, if exceeded, may pose a risk to public health

Constituents	Maximum limits (mg/l)
Antimony	0,0050
Arsenic	0,010 (as total)
Barium	1,0
Boron	For the record (*)
Cadmium	0,003
Chromium	0,050
Copper	1,0
Cyanide	0,070
Fluorides	5,0
Lead	0,010
Manganese	0,50
Mercury	0,0010
Nickel	0,020
Nitrates	50
Nitrites	0,1
Selenium	0,010



Elements more likely to be found in groundwater

WHO



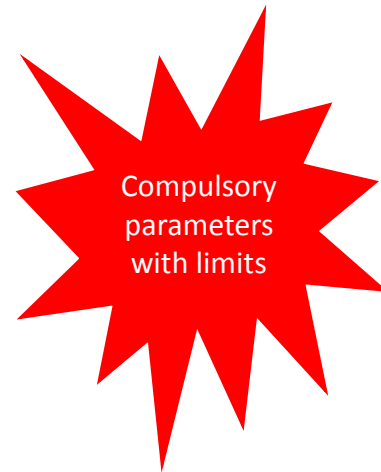
(*) The maximum limit for boron will be fixed, where necessary, following an opinion of the European Food Safety Authority and on a proposal from the Commission by 1 January 2006.



CHEMICALS LIMITED BY DIRECTIVE 98/83 EC IN SPRING AND TABLE WATERS

ANNEX I, PART B

PARAMETER	PARAMETRIC VALUE	WHO VALUE, REFERENCE	UNIT
Acrylamide	0.1	0.5 (GV)	ug/l
Antimony	5	20 (GV)	ug/l
Arsenic	10	10 (PGV)	ug/l
Benzene	1	10 (GV)	ug/l
Benzo(a)pyrene	0.01	0.7 (GV)	ug/l
Boron	1	2.4 (GV)	mg/l
Bromate	10	10 (PGV)	ug/l
Cadmium	5	3 (GV)	ug/l
Chromium, total	50	50 (PGV)	ug/l
Copper	2	2 (GV)	mg/l
Cyanide	50	No value	ug/l
1,2-dichloroethane	3	30 (GV)	ug/l
Epichlorohydrin	0.1	0.4 (PGV)	ug/l
Fluoride	1.5	1.5 (GV)	mg/l
Lead	10	10 (PGV)	ug/l
Mercury	1	6 (GV)	ug/l
Nickel	20	70 (GV)	ug/l
Nitrate	50	50 (GV)	mg/l
Nitrite	0.5	3 (GV)	mg/l
Pesticide, individual	0.1	Individual limits exist	ug/l
Pesticide, total	0.5		ug/l
PAH	0.1	0.7 (GV)	ug/l
Selenium	10	40 (PGV)	ug/l
Tetra and trichloroethylene	10	Tetrachloro: 40 (GV), Trichloro: 20 (PGV)	ug/l
Trihalomethanes, total	100	Chloroform: 300 (GV), Bromoform: 100 (GV), Dibromochloromethane: 100 (GV), Bromodichloromethane: 60 (GV)	ug/l
Vinyl chloride	0.5	0.3 (GV)	ug/l



GV: Guideline value
PGV: Provisional guideline value

Inorganic mercury

Short-term exposure

Benzo(a)Pyrene



PARAMETRIC VALUES IN DIRECTIVE 98/83 EC APPLICABLE TO SPRING AND TABLE WATERS

ANNEX I, PART C

PARAMETER	PARAMETRIC VALUE	WHO VALUE, REFERENCE	UNIT
Aluminum	200	No health value	ug/l
Ammonium	0.5	No health value	mg/l
Chloride	250	No health value	mg/l
Clostridium perfringens (spores)	0	No value	0/100 ml
Colour	Acceptable to consumers and no abnormal change	No value	
Conductivity	2500	No value	uS/cm, 20C
Hydrogen ion concentration	6.5 to 9.5	No value	pH units
Iron	200	No health value	ug/l
Manganese	50	No health value	ug/l
Odour	Acceptable to consumers and no abnormal change	No value	
Oxidisability	5	No value	mg/l O ₂
Sulphate	250	No health value	mg/l
Sodium	200	No health value	mg/l
Taste	Acceptable to consumers and no abnormal change	No value	
Colony count 22 C	No abnormal change	No value	
Coliform bacteria	0	0/10 ml (GV)	0/100 ml
Total Organic Carbon	No abnormal change	No value	
Turbidity	Acceptable to consumers and no abnormal change	No value	

} Taste & color reasons

→ Taste & color reasons

Taste reasons

Taste reasons



RADIOLOGICAL PARAMETRIC VALUES IN DIRECTIVE 98/83 EC FOR SPRING AND TABLE WATERS

ANNEX I, PART C

RADIOACTIVITY PARAMETERS

PARAMETER	PARAMETRIC VALUE	WHO VALUE, REFERENCE	UNIT
Tritium	100	No value	Bq/l
ID	0.1	0.1	mSv/an
Radon	100	No value	Bq/l



ALFA AND BETA CRITERIA

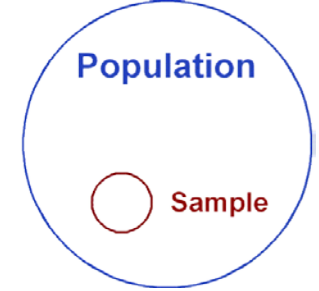
	EU	WHO VALUE, REFERENCE	UNIT
total alfa	0.1	0.5	Bq/l
total beta	1	1	Bq/l



Although not applicable to mineral waters, these values are used for monitoring purposes in these waters



SAMPLING



- Mineral water directive does not give any sample pattern. When adapted to national legislation, the regulators may include sampling frequencies for water at the source and bottled water
- Drinking water is sampled according to water distribution and population patterns. Spring waters were subjected to this type of sampling until recent modification of drinking water directive where it is now considered that spring water is a food stuff and sampling and control frequencies shall be set according to HACCP principles. The same is valid for bottled table waters
- Sampling and analytical frequencies should then be defined according to a HACCP plan, where critical points are identified and parameters and frequencies are established
- Food industries apply now FSSC 22000 as tool to manage Food Safety. HACCP is an important part of it



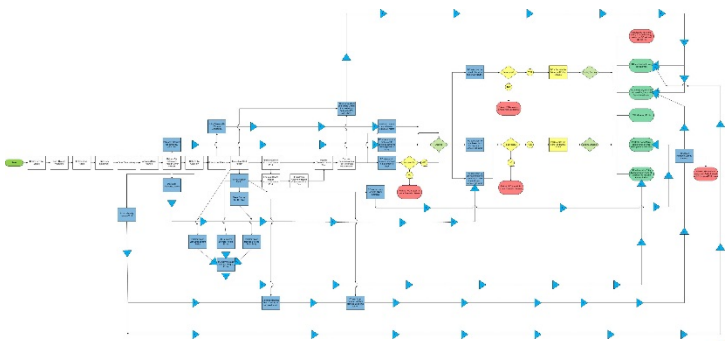
SAMPLING

Always based
on risk
evaluation

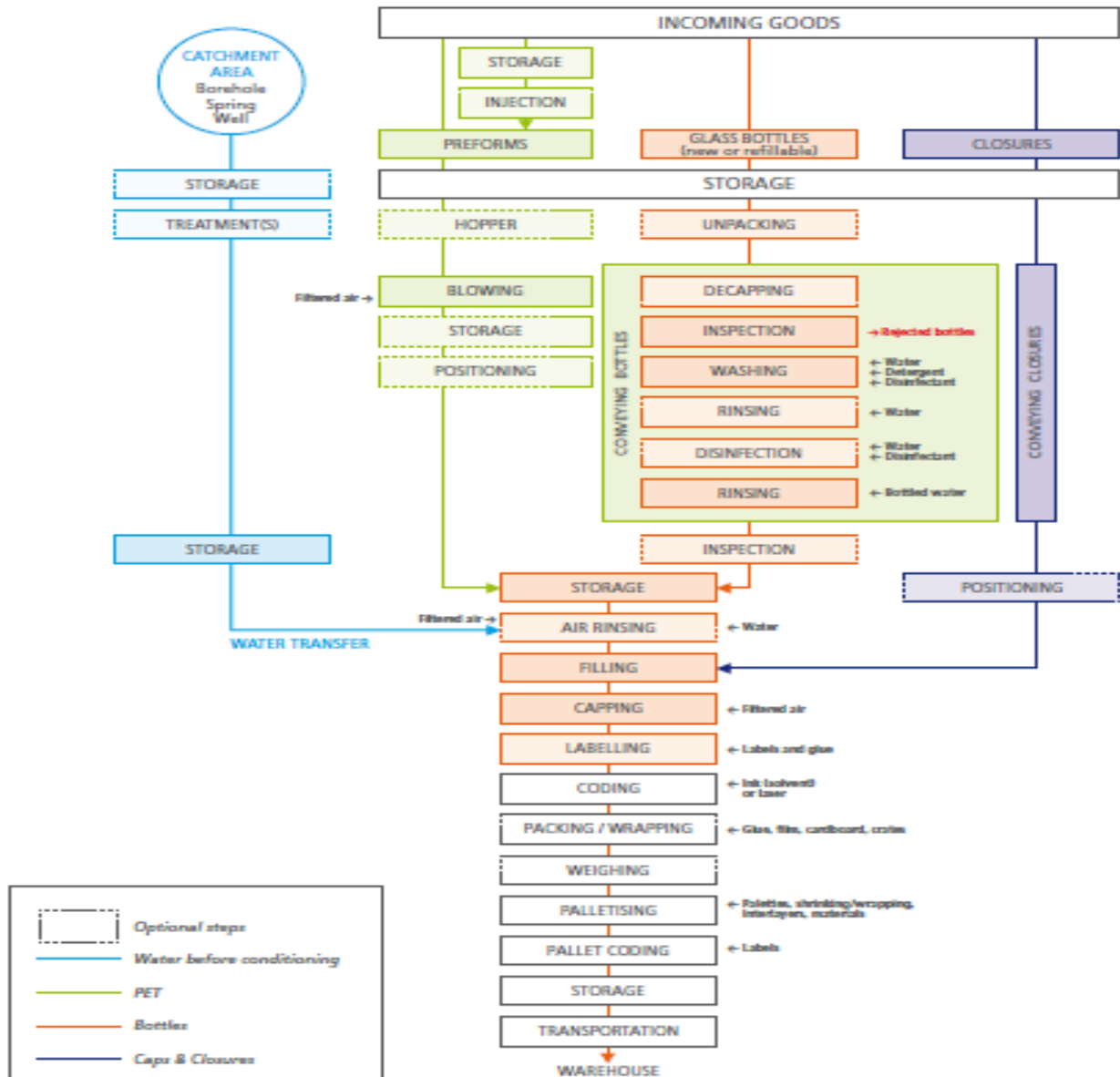
- First step is to draw the flowchart for your processes. Mineral / Spring waters are simple processes where microbiology and aquifer protection are of significant importance
- Example of a generic flowchart can be found in the EFBW Community Guidelines adopted by DG Sanco in 2012, and downloadable from the link below:

http://ec.europa.eu/food/safety/docs/biosafety_fh_guidance_eu_guide_wholesale_market_management_2012_en.pdf

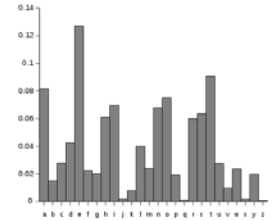
- Flowchart for mineral waters from this guide is presented in the next slide. The flowchart can be found on page 75 of the document



EXAMPLE OF PROCESS FLOWCHART FOR BOTTLED WATERS



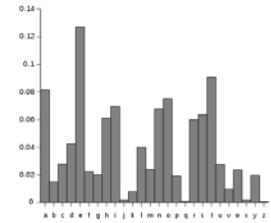
EXAMPLES OF SAMPLING FREQUENCIES



Sampling point	Microbiology	Chemistry	Frequency	Other controls
Source or mixture of sources	E. coli, Total Coliforms, Ps aeruginosa, total plate count 22C	pH, taste / odour, conductivity, TH, alkalinity, Ca, Mg, Nitrate, Nitrite, Ammonia, other characteristic elements in the system (Fluoride, iron, manganese, arsenic, CO2, etc.)	Daily	Residues of disinfectants in case of cleaning / sanitizing operations when the operation is performed
In case of treatments, before treatment		specific element to be removed	Daily	
In case of treatments, after treatment		specific element to be removed	Daily	
Storage of the water after treatment	E. coli, Total Coliforms, Ps aeruginosa, total plate count 22C		Daily	Residues of disinfectants in case of cleaning / sanitizing operations when the operation is performed
After bottling / finished product	E. coli, Total Coliforms, Ps aeruginosa, total plate 22C	pH, taste / odour, conductivity, TH, alkalinity, Ca, Mg, Nitrate, Nitrite, Ammonia, other characteristic elements in the system (Fluoride, iron, manganese, arsenic, CO2, etc.).	After shift change, after cleaning & disinfection operations	Residues of disinfectants in case of cleaning / sanitizing operations when the operation is performed. Caustic and detergent residues in case of glass bottles to be performed hourly



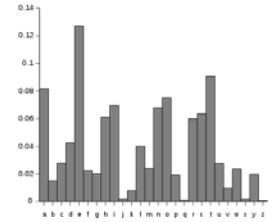
EXAMPLES OF SAMPLING FREQUENCIES



Sampling point	Microbiology	Chemistry	Frequency	Other controls
After bottling / finished product	E. coli, Total Coliforms, Ps aeruginosa, Enterococci, sporulated anaerobes, total plate 22 & 37 C	pH, taste / odour, conductivity, TH, alkalinity, Ca, Mg, Nitrate, Nitrite, Ammonia, other characteristic elements in the system (Fluoride, iron, manganese, arsenic, CO2, etc.)	Weekly	
Finished product	E. coli, Total Coliforms, Ps aeruginosa, Enterococci, sporulated anaerobes, total plate 22 & 37 C	pH, taste / odour, conductivity, TH, alkalinity, Ca, Mg, Na, K, Cl, Sulphate, Silica, Nitrate, Nitrite, Ammonia, other characteristic elements in the system (Fluoride, iron, manganese, arsenic, CO2, etc.), trace elements	Quarterly	Correct coding, labeling, tamper evidence, hourly
Source / mixture of sources	E. coli, Total Coliforms, Ps aeruginosa, Enterococci, sporulated anaerobes, total plate 22 & 37 C	Complete physico-chemical analysis with pesticide, PAH, VOC, THMs and other organics which presence can be suspected, and radioactivity	Annually	



EXAMPLES OF SAMPLING FREQUENCIES



Some other important controls:

a) Wells:

- * Piezometric levels of the wells: continuous automated monitoring
- * Water abstracted volumes: continuous automated monitoring
- * Inspection of perimeters of protection: weekly

b) Glass bottles:

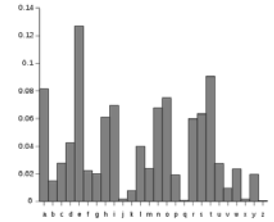
- * continuous monitoring of the sanitized bottles for foreign materials

c) PET:

- * acetaldehyde in preforms from critical cavities



EXAMPLES OF SAMPLING FREQUENCIES



Some other important controls:

d) CO₂:

- * Control of carbonation in finished products, per shift or daily. Can also be automatized and performed on-line

e) Contents (volume):

- * According to regulation





**THANKS FOR YOUR ATTENTION.
ANY QUESTIONS?**

