

**Annex to the minutes of the**

**PAFF meeting of 16 October 2017**

**Point A.01: Exchange of views on a**

**DOCUMENT PROVIDING INDICATIONS FOR COMPETENT AUTHORITIES  
AND FOOD BUSINESS OPERATORS ON COMPLIANCE OF NATURAL  
MINERAL WATER  
WITH THE DEFINITION LAID DOWN BY ANNEX I TO DIRECTIVE 2009/54/EC  
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 18 JUNE 2009  
ON THE EXPLOITATION AND MARKETING OF NATURAL MINERAL  
WATERS<sup>(1)</sup>**

This document was developed in collaboration between the experts of the Member States under the technical coordination of the Commission services. It has not been adopted or endorsed by the European Commission. Any views expressed in this document may not in any circumstances be regarded as stating an official position of the Commission. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex I to Directive 2009/54/EC or any case law developed with regard to these provisions. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

<p><b>Note:</b> This document is an evolving document and may be updated to take account of the experience of the competent authorities or of information provided.</p>
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**BACKGROUND AND OBJECTIVES**

According to the definition for a ‘natural mineral water’ provided by Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (hereafter “the Directive”), a natural mineral water must be protected from all risk of pollution in order to preserve its ‘*original purity*’.

Accordingly, the Directive does not provide maximum levels for contaminants in natural mineral waters. Nowadays, due to technological progress in analysis methods, even trace amounts of contaminants can be detected with modern sensitive laboratory methods.

It is therefore not excluded that, even where all conditions set by the relevant legislation are met with a view to preserving the hydro-geological systems and the springs from where the natural mineral water originate, such trace amounts of contaminants could be detected in those waters.

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<sup>1</sup> OJ L 164, p. 45.

Therefore, with a view to ensure common application, enforcement and control of the compliance of a natural mineral water with the definition mentioned above, there is a need to set an agreed list of substances to be taken into account, together with the parameters and values that could be considered as compatible with the definition of a natural mineral water as laid down in Annex I of the Directive.

This document has been drawn up by mutual agreement between the representatives of the Member States, under the coordination of the Commission services. The indications given in this document have no legally binding effect. National rules may continue to be applied, in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), on the territory of the Member State in which the natural mineral water is exploited.

The aim of this document is to provide indications to Member States' control authorities and to food business operators with regards to the compliance of a 'natural mineral water' with the definition laid down by Annex I to the Directive, in particular the requirement for 'original purity' of a natural mineral water at source.

The aim is to ensure a clear common approach throughout the EU in the assessment of whether a 'natural mineral water' complies with the definition laid down by the Directive, thereby ensuring that the primary purposes of the Directive i.e. to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading, are met.

This document may be used as a tool by operators exploiting natural mineral water springs and by national control authorities, including where they set multi-annual national control plans in accordance with Regulation (EC) No 882/2004.

It does not apply to spring waters as defined by the Directive.

## **THE LEGISLATIVE FRAMEWORK RELATED TO THE DEFINITION OF A 'NATURAL MINERAL WATER'**

### **i. Definition**

The primary purpose of the Directive is to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading.

Annex I of Directive 2009/54/EC on the exploitation and marketing of natural mineral waters provides a definition for a '*natural mineral water*' as follows:

*“Natural mineral water’ means microbiologically wholesome water, within the meaning of Article 5, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.*

*Natural mineral water can be clearly distinguished from ordinary drinking water:*

*(a) by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;*

*(b) by its original purity,*

*both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.”*

Unlike for other categories of drinking waters, no parameters or values for anthropogenic substances have been laid down by the Directive for natural mineral waters, as they must have the highest level of quality, as reflected by the concept of ‘original purity’ included in the definition.

This is because at the time of adoption of the Directive, i.e in 1980, standard laboratory analytical methods could not detect very low levels of anthropogenic substances and this was considered to be satisfactory for measuring the absence of man-made contaminants in natural mineral waters and thus compliance of the natural mineral water with the requirement for ‘original purity’.

However, technological progress in analytical methods has made it possible to detect even trace levels of such contaminants, for which there is no associated health risk, but that could, beyond given levels, question the quality of the natural mineral water concerned. This presents certain difficulties for food business operators when ensuring compliance with the purity and quality requirements for natural mineral waters and for control authorities in the Member States when verifying that compliance.

#### ii. Safety and quality criteria

A ‘natural mineral water’ must comply with specific safety and quality criteria that are laid down by the Directive and by other relevant pieces of EU legislation.

In particular, it must comply with the microbiological requirements that are defined by Article 4 of the Directive, and with the chemical parameters and values for certain constituents that are naturally present in natural mineral waters as laid down in Commission Directive 2003/40/EC of 16 May 2003<sup>2</sup>.

Commission Directive 2003/40/EC was adopted on the basis of Article 12 of the Directive; it provides a list of certain constituents that may be present in the natural state in certain natural mineral waters because of their hydrogeological origin and that may present a risk to public health above a certain concentration. Annex I thereof lays down maximum limits for these natural constituents and Annex III lays down limits for residues resulting from the use of ozone enriched air, that is permitted for the separation of iron, manganese, sulphur and arsenic in natural mineral waters.

A natural mineral water may not be subject to any treatment other than those authorised by the Directive or by Commission Directive 2003/40/EC. Furthermore, any treatment must not modify the natural mineral water’s composition with regard to its essential constituents or its microbiological characteristics.

Regarding contaminants, Article 12 of the Directive enables the Commission to adopt methods of analysis, including methods of detection, to verify the absence of pollution of a natural mineral water. However, those tools are not adapted to the continuous progress and increase in sensitivity of laboratory methods.

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<sup>2</sup> Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentrations limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters (OJ L 126, p. 34))

It is therefore necessary to set, on a common understanding and for a limited list of anthropogenic substances in natural mineral waters, guidance values to be used by the Member States' control authorities and by food business operators in their operations.

Those guidance values are set at the lowest possible level, so that the presence of the substances concerned up to those levels would not put into question the quality of the natural mineral water with regard to the requirement laid down by the definition of a 'natural mineral water' that it must be clearly distinguished from ordinary drinking water.

### SPECIFIC PARAMETERS

For the purpose of assessing compliance of a natural mineral water with the requirement for 'original purity' as laid down in the definition in Annex I to the Directive, the following specific parameters and their values should be taken into account:

<b>Parameter</b>	<b>Guidance value</b>
Polynuclear aromatic hydrocarbons (PAHs)	0.01ug/L for individual substances <sup>3</sup>
Volatile organic compounds (VOCs)	1.0ug/L for individual substances <sup>4</sup>
Trihalomethanes (THMs)	1ug/L for individual substances
Pesticides	0.1ug/L for the sum of all individual pesticides and their relevant metabolites <sup>5 6</sup> ; 0.03ug/L for aldrin, dieldrin, heptachlor and heptachlor epoxide <sup>7</sup>  Member States may set individual limits for those pesticides considered to be relevant in the local, regional or national context.

<sup>3</sup> As fluoranthene and naphthalene may be formed naturally in the environment and may therefore be detected at high levels than the guidance value, hydrogeological assessments are required on a case-by-case basis to clarify that any natural origin does not affect the original purity of the natural mineral water.

<sup>4</sup> Certain VOCs may be found naturally in the environment. Therefore a case-by-case hydrogeological assessment may be required if higher levels of these substances are found in a natural mineral water.

<sup>5</sup> As defined in the Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances regulated under Council Directive 91/414/EEC, [http://ec.europa.eu/food/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_fate\\_metabolites-groundwtr.pdf](http://ec.europa.eu/food/plant/docs/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr.pdf).

<sup>6</sup> Member State authorities may establish lists of pesticides considered to be relevant at local, regional or national level for the purpose of assessing compliance of the natural mineral water with the parameter of 0.1ug/L for the sum of all individual pesticides.

<sup>7</sup> A case-by-case hydrogeological investigation and analysis of the causes may be required if higher levels of any pesticide and/or its metabolites are detected in a natural mineral water.

Member States agree that:

- the presence of the above substances below the corresponding guidance value does not affect the level of quality of the natural mineral water concerned in a way that would make it incompatible with the definition of natural mineral water by reference to the concept of "original purity";
- in cases where a specific natural mineral water does not comply with the above guidance values, the competent authorities may assess on a case-by-case basis what action to take, taking into account relevant factors such as hydrogeological variations and potential shortcomings in the protection of the spring or the aquifer. The operator exploiting the spring must investigate the cause of the pollution and take appropriate measures to eradicate it;
- as hydrogeological variations may occur at a local or regional level, it is the responsibility of the Member States' competent authorities to assess on a local, regional or national level whether additional criteria are to be included when assessing the compliance of a natural mineral water with the definition laid down by the Directive. This is because certain local factors may influence the presence of other substances and this is best dealt with at a local level.