# Definition and key points of the *De Minimis* notion in the vitivinicultural sector

OIV
International Organisation
of Vine and Wine
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# Table of contents

# 1 | Creation of an OIV Task Force on *de minimis*

At the OIV Scientific and Technical Committee meeting on 23 October 2021, Mr Dubernet gave a presentation on the principles and concept of *de minimis*. In particular, he indicated that a *de minimis* value is an analytical value below which a substance is generally considered not to be present in the analysed product. He also stated that the *de minimis* value is in no way associated with a regulatory limit or a consumer toxicity limit and is set at levels far below these regulatory or toxicity limits.

In conclusion, the OIV President noted the Scientific and Technical Committee's interest in this approach and approved the creation of a task force coordinated by the First Vice-President of the OIV, Mrs Regina Vanderlinde, to continue investigating this subject, incorporating developments relating to the precautionary principle.

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# 2 | Introduction

The concept of *de minimis* is inherited from Roman law. *De minimis* non curat praetor (the judge (the chief) does not deal with that which is insignificant).

The notion of *de minimis* is primarily concerned with the translation of regulatory criteria into analytical criteria.
Traditionally, the translation of regulatory criteria into analytical criteria takes the form of maximum content (maximum sulphite content, maximum sugar content) and sometimes minimum content (minimum ABV).

However, the search for "zero" or "absence" in many fields is an increasingly common issue, for example:

- The absence of prohibited or regulated products
- The vitivinicultural product category
- The issue of ingredient labelling
- Organic certification
- Zero Phytosanitary Residue certification
- Private law specifications between buyers and producers, containing requirements relating to the absence of residues
- Zero alcohol wine; alcohol-free wine
- .....

The translation of "absence" into an analytical criterion has not been addressed so far, or only in rare cases (total sulphur dioxide, gluten, lactose).

# 3 | Some previously defined *de minimis* values

Some *de minimis* values have already been introduced, albeit without being referred to as such:

- Absence of ethanol in dealcoholised wine (0.5% vol)[1]
- Limit on the level of natamycin in wines (5 ppb)[2]
- Total SO2 content in "sulphite-free" wines (10 ppm)[3]
- Exogenous water in wine
- Pesticide residue for organic certification (10 ppb), defined unilaterally by certifying bodies[4] (French and European in particular)

The concept of *de minimis* is mentioned in the regulations of the United States of America. The TTB has indicated that it intends to propose regulations on the use of certain "fermentation activators", and also states that "*In the interim, TTB will continue to allow, under an administrative approval pending rulemaking, the use of biotin, calcium pantothenate, folic acid, inositol, magnesium sulfate, niacin, and pyridoxine hydrochloride at levels consistent with good commercial practice, only for the purpose of providing nutrients to the yeast, and not to fortify the wine, where the level of any remaining nutrient in the wine would be* ***de minimis.***" https://content.govdelivery.com/accounts/USTTB/bulletins/32d599e

[1] Beverage obtained by dealcoholisation of wine, Resolution OIV-ECO 432-2012, https://www.oiv.int/node/3304
[2] Resolution OIV-MA-AS323-09 : 2012, Determination of natamycin in wines, https://www.oiv.int/fr/standards/annex-a-methods-of-analysis-of-wines-and-musts/section-3-chemical-analysis/section-3-2-non-organic-compounds/section-3-2-3-other-non-organic-compounds/determination-of-natamycin-in-wines-%28type-iv%29
[3] Codex Alimentarius General Standard For The Labelling Of Pre-Packaged Foods CXS 1-1985, https://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf
[4] https://www.bioagricert.org/en/certification/product-quality/zero-residue/

# 4 | Analytical issues

Analytical techniques have come a long way in recent years, and they are continuing to improve all the time. These improvements are constantly pushing analytical limits, not only in terms of measurement trueness and precision but also in terms of the limits of quantification (LOQ) and detection (LOD).

"0" does not exist in analysis. In the absence of an analytical "0", the unfettered application of the precautionary principle in the search for "absence" could lead to litigious, controversial, or arbitrary situations and situations in which the application of the law by States and magistrates is subject to multiple divergent interpretations.

"0" cannot be an analytical result. At a concentration of "0", analytical uncertainty increases to infinity (Figure 1). In reality, no laboratory would or could publish "0" as the result of an analysis.

For a long time, the limits of detection for analytical methods were not low enough to reach insignificant concentration levels.

However, improvements in analytical tools could lead to increasingly frequent positive analysis results that are based on extremely low concentrations. In many cases, the limits of detection and quantification are reaching levels at which the analytical result is no longer correlated with any significant cause.

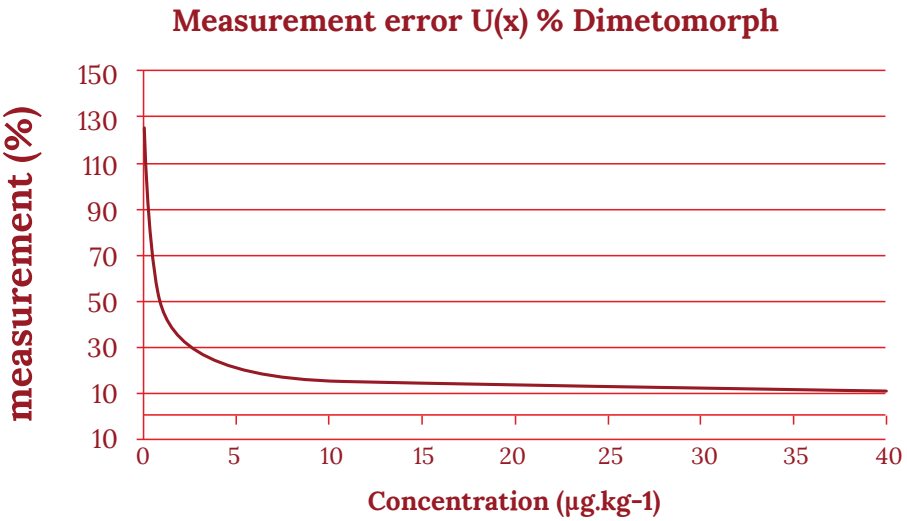


**FIGURE 1 -** Relationship between analytical level and analytical measurement error

In the absence of an analytical "0", therefore, it is necessary to provide a translation for the precautionary principle and, in particular, the management of risks associated with the search for the absence of compounds.

As yet, there have very been few attempts to translate "absence" into an analytical criterion (total sulphur dioxide, pesticides for organic wines). If a laboratory cannot return a result of "0", a new category of analytical thresholds must be defined in order to establish an irrelevant level. This category of analytical thresholds is called *de minimis*.

The limit of quantification for a given method is not a suitable approach. The *de minimis* value and the limit of quantification for a specific method must be distinct.

- The limit of quantification can vary from one laboratory to another and changes over time as laboratories develop.
- The methodologies for calculating limits of quantification are not standardised and could lead to significant disparities between the results obtained.

For a long time, the limits of detection for analytical methods were not low enough to reach insignificant concentration levels. A practical "0" was therefore established at these limits of detection.

Therefore, a *de minimis* value could be considered as an Analytical threshold, below which a result must be considered in practice as irrelevant.

**We must not confuse *de minimis* values with method limits.**

- The limits of performance for given methods are not fixed or stable.
- Different laboratories operate with different levels of performance, depending on the methods and equipment used.
- Therefore, the performance of a method is not a relevant criterion for the establishment of a *de minimis* value.
- However, a *de minimis* value should not be defined if the analytical performance is incapable of reaching levels at which the concentrations may be considered insignificant.
- In order to operate using *de minimis* values, a laboratory must validate its analytical method with a detection limit below that of the *de minimis* value.
- The concept of the limit of quantification is mutable, whereas the concept of *de minimis* should be immutable, and based on broad consensus amongst all stakeholders..
- A *de minimis* value can be defined if there is an analytical method for which the limit of quantification is below the expected *de minimis* value.

# 5 | Technological issues

Definition of an additive (Resolution OIV-OENO 567A-2016)
This term means "any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose, in the manufacture, processing, preparation, treatment, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities."

Definition of a processing aid (Resolution OIV-OENO 567A-2016)
This term means "any substance or material, not including apparatus or utensils, and not consumed as a food ingredient itself, intentionally used in the processing of raw materials, food or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues".

The concept of *de minimis* is directly relevant to the issue of additives and processing aids.

The concept of *de minimis* is directly relevant to the use of permitted winemaking additives and processing aids. All, when used as prescribed, can leave traces behind in wine which may be detected by suitably sensitive analytical methods and such insignificant traces may not represent "contaminants" requiring reporting.

Compounds (such as additives), which are required to appear on labels, could therefore use this concept of *de minimis* so that products contained in insignificant amounts equivalent to "0" might be exempted from labelling requirements.

A similar approach would also be required in relation to processing aids because in certain circumstances non-intentional but unavoidable traces of processing aids might also be detectable in wine.

There are already examples of *de minimis* values for ingredients.

The Codex Alimentarius general standard for the labelling of prepackaged foods, CXS 1-1985, states that foods and ingredients that are known to cause hypersensitivity shall always be declared, including sulphites in concentrations of 10 mg/kg or more. This limit constitutes a value for "sulphite-free" wines.

In addition, some vitivinicultural product categories are potentially defined by *de minimis* values. A prime example is that of de-alcoholised wines (or beverages obtained by the dealcoholisation of wines). A de-alcoholised wine is specifically defined as such when its alcohol content is below 0.5% vol.

Therefore it seems, on the one hand, that the concept of *de minimis* could enhance the concepts of "additive" and "processing aids" and on the other, that the only question is whether there is an analysable trace left after a treatment. And this trace threshold is inherently defined by a *de minimis* value.

# 6 | Health issues

In toxicological terms, thresholds are expressed as maximum intake values that must not be exceeded in a certain period of time (usually referring to daily intake).
Toxicological issues are governed by the Acceptable Daily Intakes (ADI), Tolerable Daily Intake (TDI), with its variants for weekly exposure TWI, and the provisional nature of the established value PTDI/PTWI set by national or international health bodies (JECFA, JMPR, EFSA) and adopted by the various countries.
An important class of molecules for which the concept of *de minimis* could be applied is that of pesticides. For these compounds, maximum residue levels (MRL) are established; MRL is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (Good Agricultural Practice). It is not a toxicological limit but a value that considers the degradability of the single compound and guarantees a daily intake well below the established ADI.

The *de minimis* value should be lower than the MRLs established at national or international level and consequently, is not a toxicological concept that affects consumers.

In any case, a *de minimis* value should not be defined in the context of an uncontrolled toxicology situation, and specifically:

- The *de minimis* principle should not be interpreted as a toxicological limit. If there are no indications for a certain compound regarding the consumers' safety, a *de minimis* value should not be established.
- As a consequence, *de minimis* values are placed outside the scope of safety problems and are outside any "dose" risk level.
- *De minimis* thresholds cannot be defined if no toxicological references (e.g. ADI) and/or regulatory limits have been established. The concept of *de minimis*, "minimum significant value" is, therefore, inherently separate from questions of safety.

When setting *de minimis* thresholds that mean "irrelevant", it is important to account for the effect of endocrine disruptors and different molecules. Allergens are in this group of molecules.

# 7 | Legal issues

In law, the concept of "0" is still very poorly defined. It frequently depends on the assessment of an expert, and assessments differ.

- It is often the laboratory that carries out the analyses that is responsible for the "presence" or "absence" of a regulated product in a matrix. From one laboratory to another, analytical performances and expertise differ.
- This means that magistrates sometimes have to arbitrate on questions on which the scientific consensus is not established.

There are many de facto *de minimis* criteria in use in the wine sector. They are defined in various ways by:

- Certification bodies (organic farming, "0" residue labels), which unilaterally define applicable thresholds for their controls.
- Private or control laboratories, on the basis of their own data.
- In rare cases, regulatory definitions, motivated by labelling issues (potential allergens).

The *de minimis* definition must meet sufficient scientific and legal criteria, such as:

- Scientific consensus
- Respect for the right to be heard

In the first two situations, these criteria are not necessarily met.

Certification bodies should not be responsible for defining control criteria (e.g. threshold values, which are *de minimis*) on phytosanitary residue analysis in organic production.

## 8 | Environmental issues

Independent of their toxicity, the presence of some contaminants can be the consequence of their ubiquitous presence, at trace levels, in the environment.

It is precisely this issue that underlines the need for *de minimis* values. An analytic signal that results from environmental background noise or unintentional exposure to permitted agrochemicals well below established MRLs (for example through spray drift), should not be interpreted in the same way as an analytic signal resulting from a specified technological process.

*De minimis* values should therefore be positioned precisely between the level of an analytic signal resulting from a specified technological cause and the level of an analytic signal resulting from environmental background noise.

## 9 | Societal and consumer-related issues

What consumers want to know is whether a substance is “absent”. Even if it is impossible to produce an analytical “0”, a layperson may consider a *de minimis* value as indicating the irrelevant level of a substance

Therefore, work is needed to educate and inform the general public to help them understand the concept of *de minimis*.

# 10 | Key Points and Practical Objectives of the *De Minimis* Notion

**Terminology**

The concept of "analytical zero" does not exist. In absolute terms, it is unrealistic to ask a laboratory to produce an analytical result that guarantees the absence of a compound in a given matrix or environment.

Strictly speaking, when an analytical signal for a certain compound is not detectable, the laboratory should report "not detected" rather than "0". However, "not detected" does not mean "absent," even though, in practice, it is often interpreted that way. This misunderstanding can lead to technical, contractual, and regulatory challenges.

The purpose of the *de minimis* threshold is to establish a low limit that does not indicate absence but rather that a result is no longer interpretable because it does not provide relevant information regarding:

- Technological causes explaining the presence of trace amounts, apart from environmental or analytical background noise.
- Technological and/or compliance consequences that could be derived from such an analytical result.

This notion of non-relevance is therefore established in terms of both causality and consequences concerning the presence of residual traces detected in the analysis of a given substance.

**Harmonising the Interpretation of Trace Analyses**

The interpretation of trace analysis is a highly specific technical issue, as it deals with the infinitely small, which is not absolutely accessible.

Significant distortions have been observed in the wine sector, leading to divergent conclusions among operators, which negatively impact the fluidity of trade and the homogeneous application of the law.

Depending on the circumstances, these interpretations may be conducted by the laboratory performing the analyses, if it has the necessary expertise, or by competent third parties.

The purpose of *de minimis* thresholds is to create a common interpretative foundation for all stakeholders generating and using trace analysis data by establishing a universally accepted limit, for each compound where *de minimis* reporting principles apply.

Below this threshold, a consensus is reached that the result no longer provides relevant information and should not be interpreted, whether in terms of the causes of the result or its consequences.

**Scientific, Legal, and Societal Consensus on *De Minimis* Values**

On a case-by-case basis, *de minimis* values can be defined based on a consensus among all stakeholders.

Once established *de minimis* values must be regularly reviewed, taking into account:

- Advances in scientific knowledge and technology.
- Legal data.
- Societal expectations and consumer demands.

# 11 | Definition

Therefore the following definition may be considered

A *de minimis* value is defined by consensus as an analytical threshold for reporting purposes, below which a result should not be considered for interpretation regarding the measurand.

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