OIV-MA-AS1-05a Provisions on the use of proprietary methods that should be adopted by the OIV

Definition of a Proprietary Method of Analysis

For OIV purposes, a proprietary method of analysis is one that contains protected intellectual property preventing full disclosure of information about the method and/or where the intellectual property owner restricts the use or distribution of the method or materials for its performance such that no alternative source of these would be available. It does not extend to a method which is subject only to copyright.

Requirements

The OIV requires the method sponsors to provide relevant data to enable the SCMA ("Methods of Analysis" Sub-Commission) or another expert group to carry out an assessment. Following assessment, the SCMA, or another expert group, may submit methods of analysis that are proprietary, or are based on proprietary aspects, to the OIV General Assembly, for their approval, according to the following procedures.

a) A proprietary method should not be endorsed if a suitable non-proprietary method of analysis is available that has been or could be endorsed and that has similar or better performance characteristics. This should ensure that no approach is taken that could suggest that a proprietary method is endorsed by the OIV to the detriment of other potential methods; where possible preference should be given to adopting appropriate method criteria rather than endorsing a specific proprietary method of analysis.

b) Whilst respecting the necessity for reasonable protection of intellectual property, sufficient information should be available to enable reliable use of the method by analysts and to enable evaluation of the performance of the method by the SCMA or another expert group. In particular cases this may extend beyond performance data, for example, including details of the operating principle, at the sole discretion of the SCMA or another expert group.

c) Preference should be given to endorsing those methods of analysis where the reagents and/or apparatus are described in the method, to the extent that either laboratories or other manufacturers could produce these themselves; alternatively, details enabling them to acquire these themselves would also suffice.

d) Method performance criteria required for proprietary methods are the same as those for non-proprietary methods. The performance criteria should be those stipulated above. If appropriate, information about the effect of variability of the reagents used should be provided.

e) After endorsing, any changes that may influence performance characteristics must be reported to the SCMA or another expert group for consideration.

f) A method with some parts that constitute protected proprietary information should be fully and collaboratively validated according to the OIV standards appearing in Annex A of the Compendium of International Methods of Analysis of Wines and Musts. The results of such studies will be made available for the SCMA or another expert group.

g) The manufacturer or the party submitting for evaluation a proprietary method should demonstrate to the satisfaction of the SCMA or another expert group that the fundamental principles and characteristics for the execution of the method may be made available to all interested parties.

h) The SCMA or another expert group may decline to assess a proprietary method if intellectual property restrictions unduly limit research into determining the method properties, scope and validity or development of improvements to the technology.

i) If suitable non-proprietary methods become available and endorsed, the status of the previously endorsed proprietary method should be reviewed and revised if necessary.