RESOLUTION OIV-SECSAN 357-2011

DECISION TREE FOR TOXICOLOGICAL EVALUATION BY OIV OF PROCESSING AIDS AND ADDITIVES USED IN VINE PRODUCTS

THE GENERAL ASSEMBLY,

In view of article 2, paragraph 2 ii of the Agreement of 3 April 2001, establishing the International Organisation of Vine and Wine

Taking note of the works of the « Food safety » expert group

Taking into account Strategic Plan 2009-2012 of the OIV and action linked to assessment on food safety linked to new viticultural and oenological treatments and other innovative processes and practices,

Taking into account the work of Codex Alimentarius, in particular the one of the Codex Committee on food additives in the elaboration of the general standard on food additives,

Taking into account Strategic Plan 2009-2012 of the OIV and the result indicator which mentions that procedures used for the assessment of oenological practices shall be established,

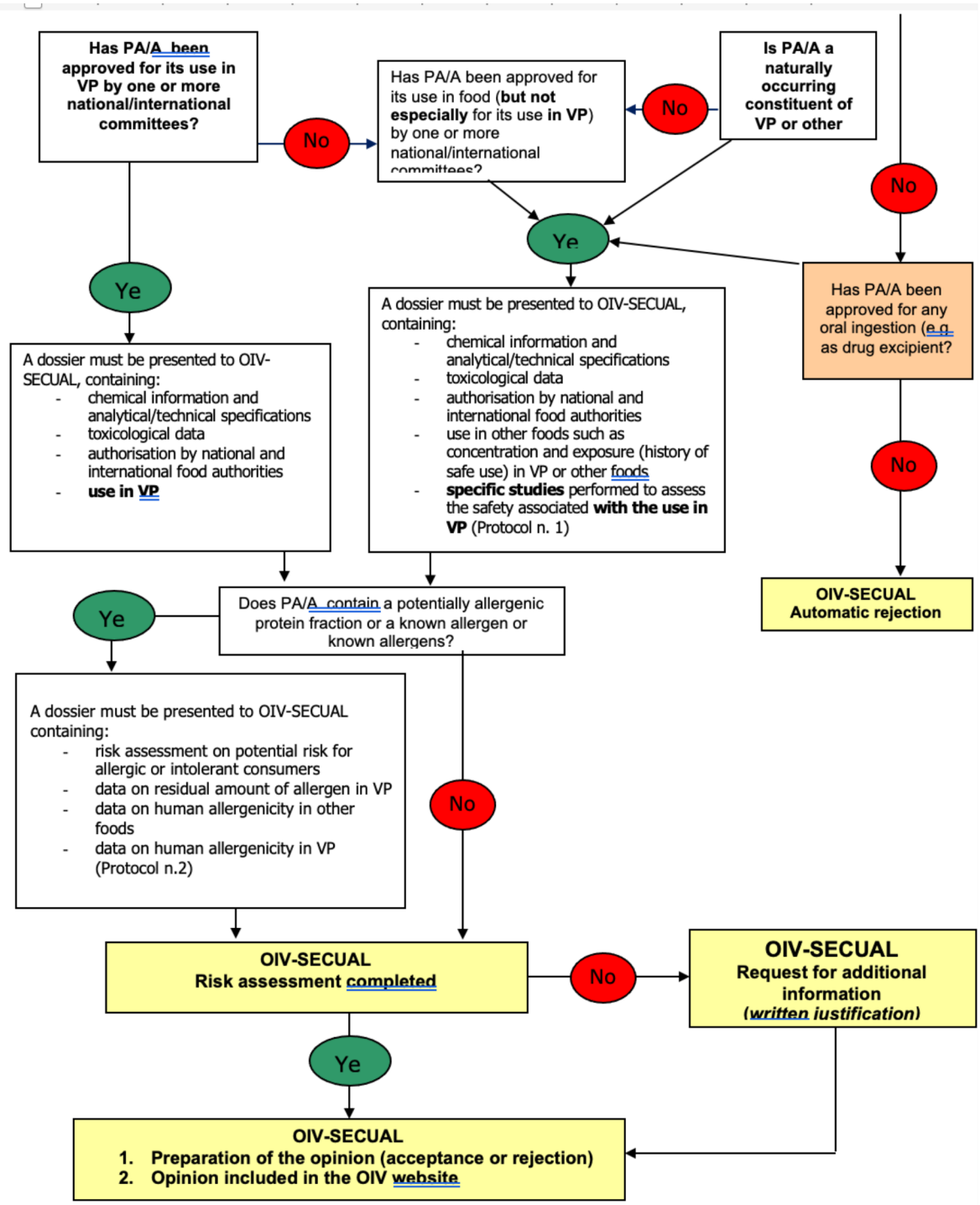
In order to aid in the assessment on food safety related to a new oenological practice,

DECIDES during the procedure for adoption of an oenological practice related to processing aids or additives, to adopt an assessment procedure based on the following decision trees.

OFFICIAL DECISION TREE FOR TOXICOLOGICAL EVALUATION BY OIV-SECUAL ABOUT THE USE OF A PA OR A IN VP

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Secretary of the General Assembly
Frederico CASTELLUCCI

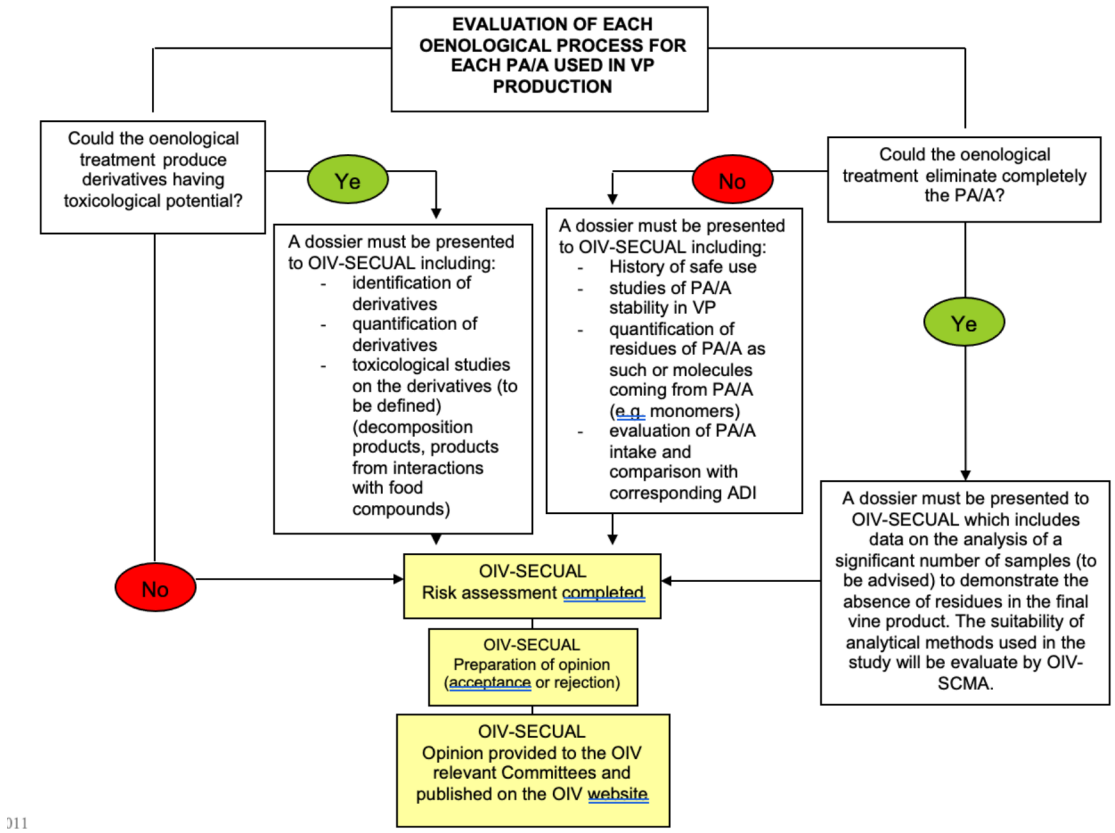
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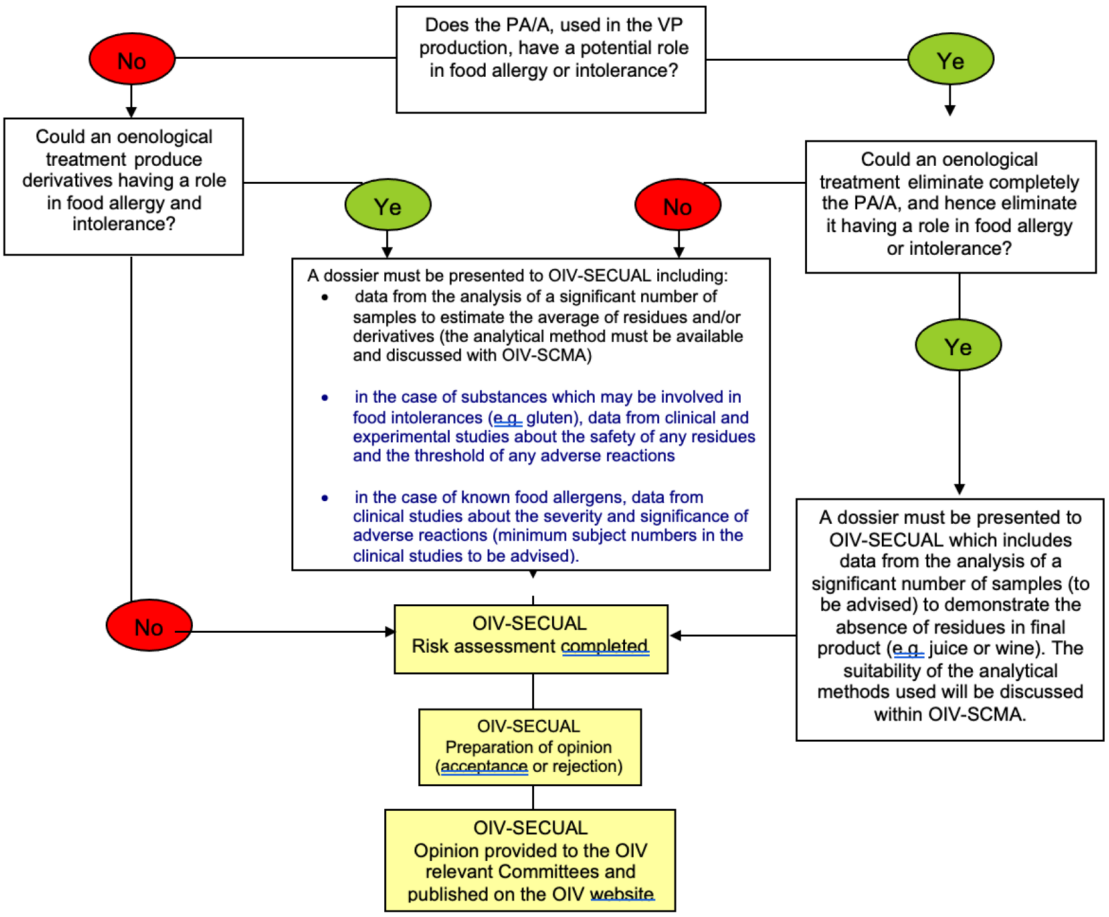
PROTOCOL 1 – EVALUATION OF SAFETY OF PA/A APPROVED FOR FOOD OR FOR ORAL USE, BUT NOT APPROVED FOR VINE PRODUCTS



PROTOCOL 2 - EVALUATION OF THE SAFETY OF PA/A FOR FOOD ALLERGIC OR FOOD INTOLERANT CONSUMERS

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NOTES TO TOXICOLOGICAL PROTOCOLS

DEFINITIONS

FOOD ADDITIVE[1]

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

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the characteristics of such foods"

PROCESSING AID [2]

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, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product."

FOOD ALLERGY AND INTOLERANCE

The European Academy of Allergy and Clinical Immunology (EAACI) presented two Position Papers on the nomenclature of adverse reactions to food. These two documents are integrated in Figure 1.

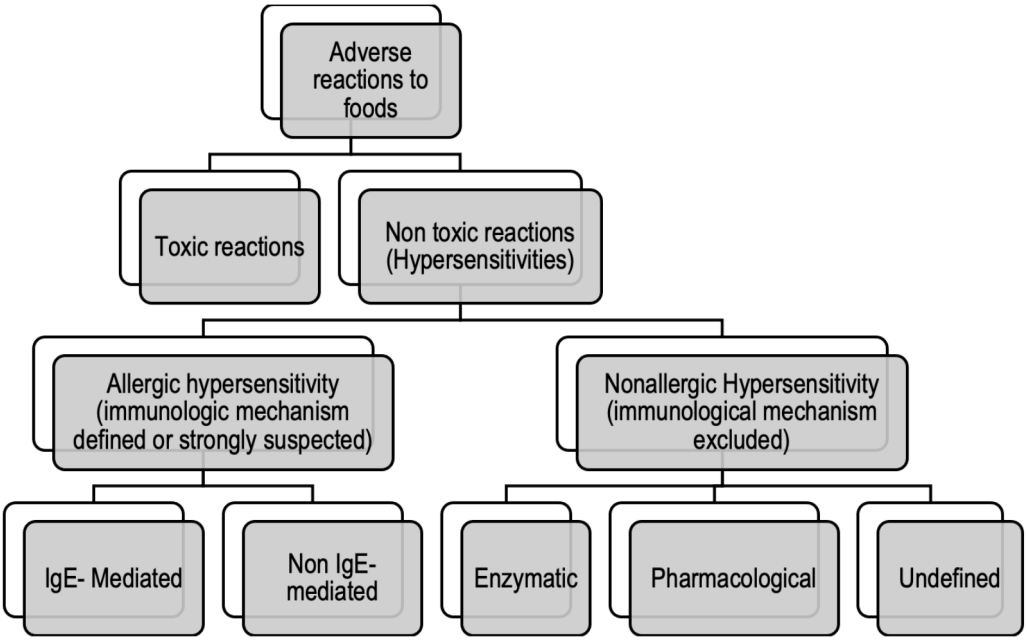


Figure 1 - A classification of adverse reactions to foods

First of all, adverse reactions to foods are divided into toxic and non-toxic reactions.Toxic food reactions derive from the general toxicity to humans of some substances that contaminate foods or that are naturally present, e.g. poison in non-

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edible mushrooms.

Non-toxic food reactions depend on an individual's susceptibility to certain foodstuffs.

The term **food allergy** is commonly used for immune-mediated reactions, while non immune-mediated reactions are referred to as **food intolerance**.

Food allergy can be further divided into IgE-mediated and non IgE-mediated reactions.

Non immune-mediated food adverse reactions, or food intolerances, are definitions used when the history and/or the provocative tests clearly prove the causative role of a food but there is no evidence of an immunological mechanism. They are caused mainly by enzymatic defects (lactose intlerance, phenylketonuria, etc) or pharmacological actions of compounds or other pharmacologically active substances added to the food or naturally present in it (caffeine, teobromine, tyramine, etc.).

REFERENCES

1. Bruijnzeel-Koomen C, Ortolani C, Aas K, Bindslev-Jensen C, Bjorksten B, Moneret-Vautrin D, Wuthrich B. Adverse reactions to food. European Academy of Allergology and Clinical Immunology Subcommittee. Allergy 1995;50:623–35.
2. Johansson SGO, Hourihane JO'B, Bousquest J, Bruijnzeel-Koomen C, Dreborg S, Haahtela T, Kowalski ML, Mygind N, Ring J, van Cauwenberge P, van Hage-Hamsten, Wuthrich B. A revised nomenclature for allergy. An EAACI position statement from the EAACI nomenclature task force. Allergy 2001; 56:813-824.

ABBREVIATIONS

- DT= Decision Tree
- VP = Vine Products (chosen in agreement with OIV definition)
- PA = Processing aids (and additives) used in Vine Products
- A = additives used in Vine Products

Comments to the Decision Tree

1. OIV-SECUAL prepares opinions on the safety of all compounds used in VP but the

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decision tree (DT) could be applied only to some categories (for examples microorganisms could be evaluated differently).

2. The request of opinion on a specific WPA must be based on a dossier where the main technological procedures (dose and time of treatment, secondary treatments such as fining agents; etc.) are clearly indicated.
3. Toxicological data must relate to the substance as well as potential decomposition products and products resulting from interaction with food compounds.
4. These indications are critical to assess:

   - possible interactions between WPA and VP (natural or other added compounds) with the production of new substances whose toxicological risk must be evaluated when necessary
   - possible interactions responsible for the reduction of natural potentially healthy VP compounds (antioxidants, etc.)
   - the residues of WPA when the safety for allergic and intolerant subjects must be ensured

5. Specific analytical method/methods capable to detect WPA in suitable amount must be available and presented in the file. The relevance of the method must be discussed within the OIV-SCMA taking into account the recommendation of the "Food safety" expert group.
6. WPA never approved for their use in food could be considered only if toxicological studies by oral administration are strong enough to ensure consumers' safety (for example in the case of drug excipients)

Comments to the Protocol 1

1. The absence of residues means undetectable
2. A methods with a suitable detection and quantification limits must be set up and approved
3. The limits must ensure the protection of consumers, permitting a comparison between WPA intake and corresponding ADI (Acceptable Daily Intake)

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4. If WPA is widely used in food industry, an estimation of the average WPA intake with the diet in different countries should be performed. In fact it is necessary to evaluate if VP can contribute to increase intakes above ADI.

Comments to the Protocol 2

1. The absence of residues means undetectable
2. A methods with a suitable detection and quantification limits must be set up and approved
3. The analytical limits must ensure the protection of allergic and/or intolerant consumers.
4. To reach this aim, some clinical studies must evaluate the safety for allergic subjects of the analytical limit established
5. For intolerant subjects (such those suffering from celiac disease), analytical limits must permit the respect of safety level (20-100 ppm for gluten)

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[1] The definition of food additive is given in the CODEX Alimentarius published in the 19th edition of the procedure manual

[2] The definition of processing aid is given in the CODEX Alimentarius published in the 19th edition of the procedure manual

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