



## RESOLUTION OIV-SECSAN 627-2018

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

*WARNING: this resolution repeals the following resolution:*

*- OIV-SECSAN 357-2011*

*WARNING: this resolution amends the following resolution:*

*- OIV-OENO 362-2011*

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,

CONSIDERING of the works of the « Food Safety » expert group and the resolution OIV-SECSAN 357-2011 adopted in 2011,

CONSIDERING the Strategic Plan 2015-2019 of the OIV and action linked to assessment on food safety linked to new viticultural and oenological treatments, and other innovative processes and practices,

CONSIDERING 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,

CONSIDERING the work of Joint FAO/WHO Expert Committee on Food Additives (JECFA) or national food safety authorities in particular on the assessment of food additives,

CONSIDERING the need to develop a useful procedure in order to help in the assessment on food safety related to a new oenological practice,

CONSIDERING the definition of contaminant of the Codex Alimentarius,

CONSIDERING the resolution OIV-OENO 362-2011 regarding the prevention or minimisation of contaminants as published in the OIV Code of oenological practices,

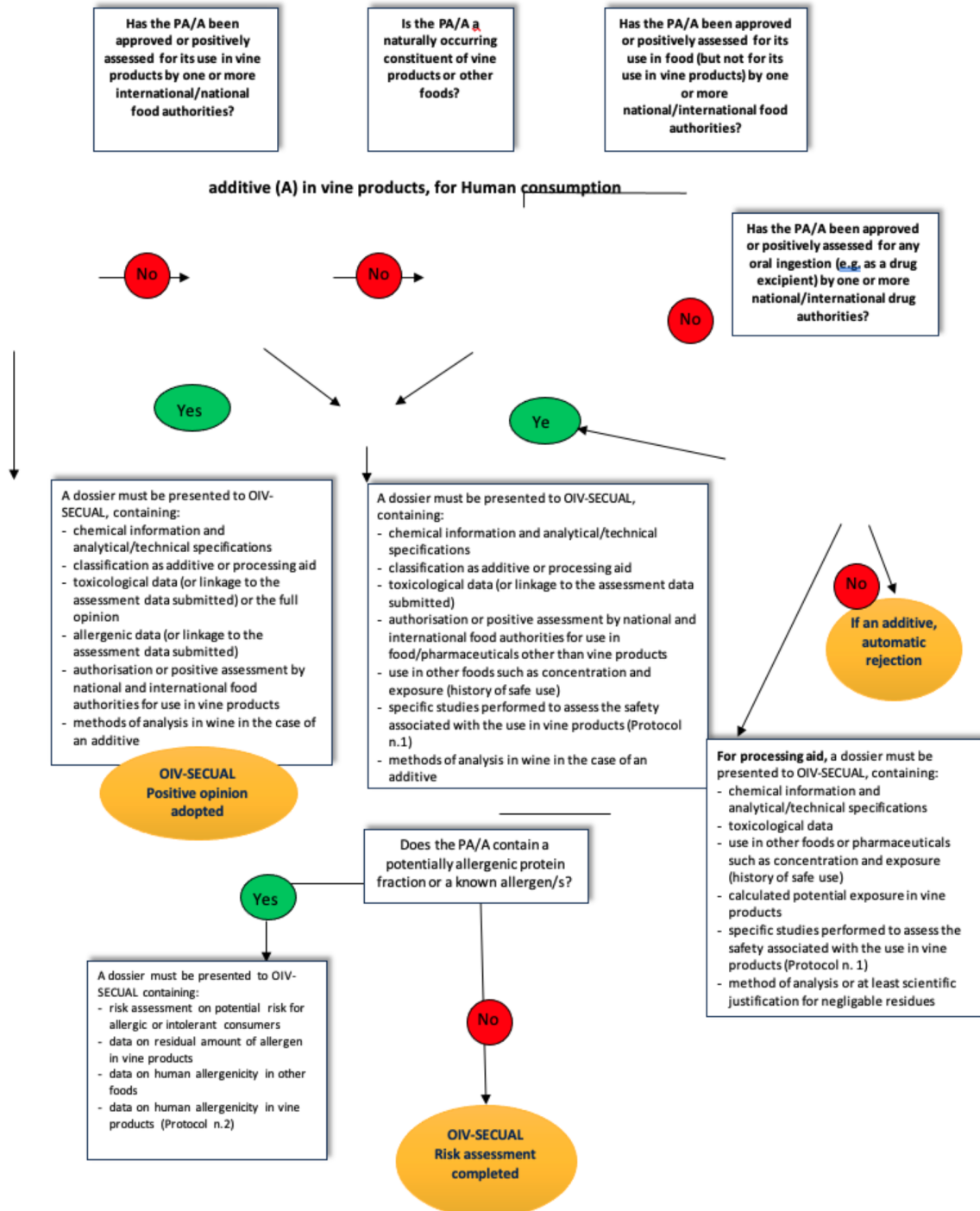
DECIDES, to replace the resolution OIV-SECSAN 357-2011, in particular the decision tree, as follows during the procedure for adoption of an oenological practice related to processing aids or additives.

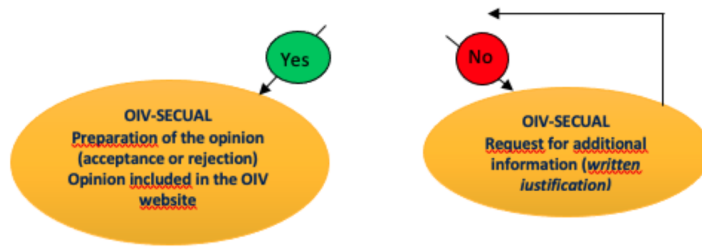
DECIDES, to adopt the definition of a contaminant included in the present draft



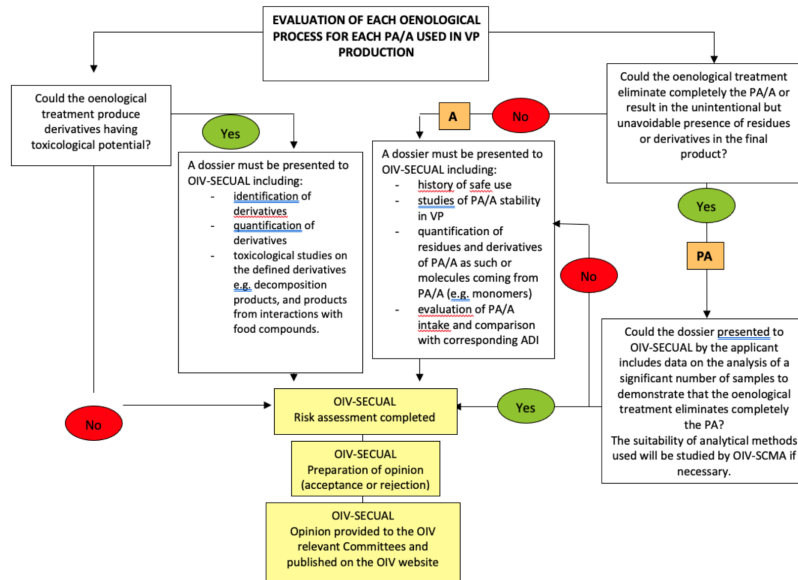
resolution mentioned below, and to replace the definition of a contaminant mentioned in the resolution OIV-OENO 362-2011 with this new definition as well as in the relevant OIV documents where this is necessary.

**Decision tree for toxicological evaluation by OIV-SECUAL about the use of a processing aid (PA) or**

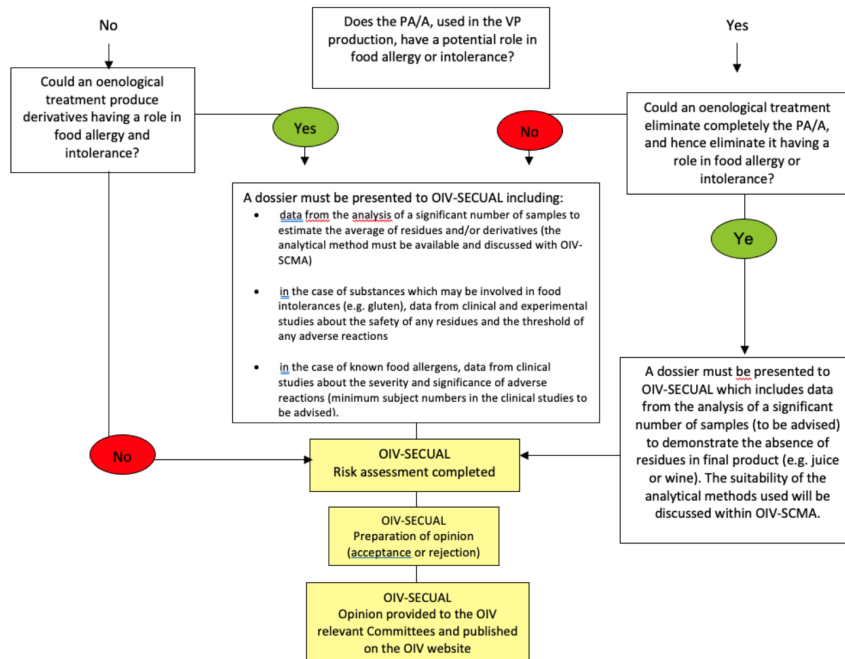




PROTOCOL 1 – EVALUATION OF SAFETY OF A PA/A APPROVED FOR FOOD OR FOR ORAL USE, OR A NATURALLY OCCURRING CONSTITUENT OF VINE PRODUCTS OR OTHER FOODS, BUT NOT APPROVED FOR VINE PRODUCTS. EVALUATION OF A SAFETY OF PA NEITHER APPROVED FOR FOOD NOR FOR ORAL USE



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



## NOTES TO TOXICOLOGICAL PROTOCOLS

### DEFINITIONS

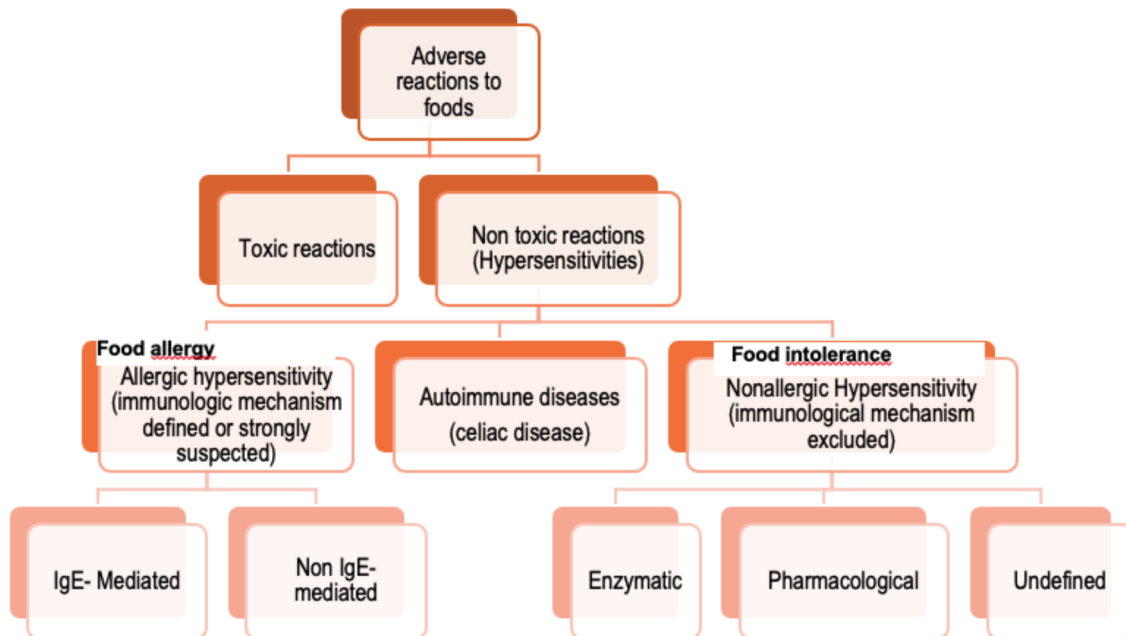
### CONTAMINANT

“Any substance not intentionally added to food or feed for food-producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter”.

### FOOD ALLERGY AND INTOLERANCE

The European Academy of Allergy and Clinical Immunology (EAACI) and the European Food Safety Authority (EFSA) have presented two position papers on the

nomenclature of adverse reactions to food (1, 3). 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-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. Celiac disease has been recently classified as an autoimmune disease, being immune-mediated but with a pathogenesis different from food allergy (3).

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 intolerance, phenylketonuria, etc) or

pharmacological actions of compounds or other pharmacologically active substances added to the food or naturally present in it (caffeine, theobromine, 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, Bousquet J, Bruijnzeel-Koomen C, Dreborg S, Haahtela T, Kowalski ML, Mygind N, Ring J, van Cauwenberge P, van Hage-Hamsten, M., Wuthrich B. A revised nomenclature for allergy. An EAACI position statement from the EAACI nomenclature task force. *Allergy* 2001; 56:813-824.
3. EFSA 2014. Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes. *EFSA Journal* 2014;12(11):3894.

## ABBREVIATIONS

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

## COMMENTS TO THE DECISION TREE

1. Decision tree is used only for additives and processing aids which are being evaluated for their technological justification by the relevant OIV group of experts and for which the enological practices are already included in the work programme according the OIV procedure mentioned in the OIV internal rules.
2. OIV-SECUAL prepares opinions on the safety of all compounds used in VP but the decision tree (DT) can be applied only to additives and processing aids (for example, microorganisms could be evaluated differently).
3. The request of opinion on a specific PA/A 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.

4. Toxicological data must relate to the substance as well as potential decomposition products and products resulting from interaction with food compounds.
5. These indications are critical to assess:
  - Possible interactions between PA/A and VP (natural or other added compounds) with the production of new substances for which toxicological risk must be evaluated when necessary;
  - Possible interactions responsible for the reduction of natural potentially healthy VP compounds (antioxidants, etc.); and
  - The residues of PA/A when the safety of allergic and intolerant subjects must be ensured.
6. Specific analytical method/methods capable to detect PA/A in suitable amount must be available and presented in the dossier. The relevance of the method must be discussed within the OIV-SCMA taking into account the recommendation of the "Food safety" expert group.
7. Additives never approved or positively assessed for their use in food or for any oral ingestion (e.g. as a drug excipient) will not be considered by the Food Safety experts' group.

## COMMENTS TO THE PROTOCOL 1

1. The absence of residues means undetectable.
2. Methods with a suitable detection and quantification limits must be set up and approved.
3. The analytical limits must ensure the protection of consumers, permitting a comparison between PA/A intake and the corresponding ADI (Acceptable Daily Intake).
4. If PA/A 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 the VP can contribute to increased intakes above the ADI.





## COMMENTS TO THE PROTOCOL 2

1. The absence of residues means undetectable.
2. 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 for allergic subjects the safety of the analytical limits established.