**9 March 2023**

**DRAFT ROYAL DECREE ON PROCESSING AIDS USED IN FOOD PROCESSING AND PRODUCTION PROCESSES**

Together with food additives, enzymes and flavourings, processing aids constitute a group of substances identified as technological ingredients, the use of which is essential for the production and processing of foodstuffs.

Unlike food additives, enzymes and flavourings, which have their corresponding legislative acts, there is no harmonised regulation in the European Union for processing aids, except for a few exceptions such as extraction solvents, caseins and caseinates, among others. The only reference in European Union legislation is found in Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, which defines processing aids but expressly excludes them from its scope of application. Therefore, the legislation that, in each case, exists in the Member States of the European Union is applicable, which is why the principle of mutual recognition between Member States is of particular importance.

In Spain, there are numerous sectoral rules (technical and health regulations or quality standards) that regulate the use of processing aids. Many of these have been in force for more than 35 years, and have undergone profound changes as a result of the need to update them or due to the application of European Union regulations on hygiene, food additives, materials in contact with food, etc. which regulate aspects contained therein.

The purpose of this Royal Decree is to group into a single regulation the processing aids which are, at the time of publication, authorised in a dispersed manner in several national regulations, in order to facilitate their consideration and application by economic operators and control authorities in the development of their corresponding activities, and thus to provide them with greater legal certainty.

In addition, it was considered appropriate to eliminate those processing aids that have become obsolete, and to lay down provisions relating to their specifications and labelling in order to ensure their safety, correct identification and use.

For the incorporation of processing aids that were not authorised as such in national regulations, the autonomous body Spanish Agency for Food Safety and Nutrition (AESAN OA) initiated a procedure in which interested parties were invited to submit their applications. These applications were evaluated in order to verify compliance with the requirements laid down for the processing aids in their definition, and thus decide whether or not to include them in the list contained in Annex I of this Royal Decree.

Regarding processing aids used in foodstuffs of animal origin, this Royal Decree only covers those used in the production or processing of edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations, cephalopods, bones, tripe, natural casings and blood products, as these have a regulatory basis or a report of the AESAN OA Scientific Committee establishing that the use of the processing aid under specific conditions does not pose a risk to the health of the consumer.

However, since not all food categories have been included in Part A of Annex I, as not all sectors have rules governing the use of processing aids or currently have a report of the AESAN OA Scientific Committee establishing that their use under specific conditions does not pose a risk to the health of the consumer, this does not prevent the use of processing aids in these categories provided that their use can be demonstrated to be safe, i.e that the operator can reliably guarantee that the processing aids used are safe, as well as the food placed on the market, in compliance with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Likewise, due to the particularity of the product, the processing aids used in the process of producing edible oils, as regulated by Royal Decree 640/2015 of 10 July 2015 approving the list of processing aids authorised for the production of edible vegetable oils and their identity and purity criteria, and amending Royal Decree 308/1983 of 25 January 1983 approving technical and health regulations for edible vegetable oils, are not included in the scope of this Royal Decree.

In addition, it was considered appropriate to include in Annex I of this Royal Decree the processing aids used in particular situations, which did not have a regulatory basis but did have a safety assessment, thus facilitating their use on the basis of appropriate conditions in such a way as to ensure food safety and proper marketing.

This would be the case for processing aids used for the production of fruit and vegetables, whose conditions require, in many cases, washing to remove soil, dirt, dust, etc. before distribution. Given that water is a scarce commodity that needs to be optimised, its recirculation for repeated use during the washing of fruit and vegetables is a justified practice. In such cases, it may be necessary to use detergents and/or disinfectants, which would act as aids, in order to maintain the hygienic quality of the water in accordance with the regulations in force. In these cases, once the process of washing the fruit and vegetables has been completed and after the time required for the aids used to exert their intended effect, it is essential to take the necessary measures to ensure that they are removed from the fruit and vegetables.

In any event, the use of processing aids shall be subject to demonstration of compliance with the requirements laid down in the relevant definition in Regulation (EC) No 1333/2008 on food additives, and the criterion of safe use laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

It is also appropriate to clarify the legal status of these disinfectants used in the treatment of wash water, so that their use does not conflict with other applicable legislation. In this regard, it is appropriate to distinguish these disinfectants from those used on food contact surfaces, which are considered to be biocidal products and are therefore regulated by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, Article 2 of which explicitly excludes biocidal products used as processing aids.

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC applies to products intended, inter alia, to protect plants or plant products against all harmful organisms or to prevent the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene.

Therefore, the effects that substances with disinfecting properties may have on the surface of fruit and vegetables shall not be covered by this Royal Decree. Such substances could not be used in mixtures with plant protection products intended for use in post-harvest treatments, since, in such a case, they would contribute to improving effectiveness and would require authorisation as an ‘adjuvant’ in the Official Register of Plant Protection Products and Material of the Ministry of Agriculture, Fisheries and Food, in accordance with the provisions of Regulation (EC) No 1107/2009.

For the inclusion of new processing aids in the list in Annex I of this Royal Decree, a report of the AESAN OA Scientific Committee reflecting the absence of risk to the consumer shall be required. Given the importance of processing aids in the process of food production, which can have a major effect on the sector and a high impact on final quality, they must also receive a favourable opinion from the Ministry of Agriculture, Fisheries and Food.

This Royal Decree complies with the principles of good regulation referred to in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, which are the principles of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

Thus, in relation to the principles of necessity and effectiveness, the Royal Decree meets an objective of general interest.

General Law 14/1986 of 25 April 1986 on Health established the obligation of public health administrations to focus their actions primarily on the promotion of health and the prevention of diseases. The aforementioned law provides that activities and products which, directly or indirectly, may have negative consequences for health are subject to control by the public health administrations.

Law 17/2011 of 5 July 2011 on food safety and nutrition aims to recognise and effectively protect the right to food safety, understood as the right to know the potential risks that may be associated with a food and/or any of its components; the right to know the impact of emerging risks on food safety and for the competent administrations to ensure the greatest possible protection against such risks. The recognition of this right results in the establishment of food safety standards, as a fundamental aspect of public health, in order to ensure a high level of protection of human health in relation to food. In addition, the specific purposes of this Royal Decree include the establishment of instruments that contribute to generating a high level of food and feed safety and the contribution to the prevention of risks to human health arising from food consumption.

Furthermore, the envisaged regulation is considered to be proportionate in the fulfilment of this purpose, without affecting in any way the rights and duties of citizens. It contributes to greater legal certainty for economic operators, providing them with a framework for action to use processing aids when producing or processing foodstuffs.

As regards the principle of transparency, the text underwent the procedures of prior public consultation and hearing and public information, giving all interested parties the opportunity to submit any comments deemed appropriate. Finally, in relation to the principle of efficiency, the Royal Decree does not entail more administrative burdens than strictly necessary, avoiding unnecessary or ancillary administrative burdens.

In the process of drafting this Royal Decree, the mandatory prior public consultation procedure was carried out in accordance with Article 26(2) of Law 50/1997 of 27 November 1997. Furthermore, the Autonomous Communities, the Autonomous Cities of Ceuta and Melilla, the affected sectors and associations of consumers and users were also consulted, and the Interministerial Commission for Food Management issued a report.

This Royal Decree also underwent the procedure provided for in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, as well as the provisions of Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and of rules on information society services, which transposes this Directive into Spanish law.

This Royal Decree is issued under the provisions of Article 149(1)(16) of the Constitution, which grants the State exclusive competence in matters of the bases and general coordination of health.

By virtue thereof, at the proposal of the Minister of Consumer Affairs and the Minister of Agriculture, Fisheries and Food, [...] the Council of State and after deliberation of the Council of Ministers at its meeting on [...]

THE FOLLOWING IS DECREED:

**Article 1.** *Purpose and scope of application.*

1. The purpose of this Royal Decree is to lay down the basic rules relating to the use of processing aids, compiling in a single regulation those which are, at the time of publication, authorised in a dispersed manner in several national regulations.

The purpose of this Royal Decree is also to lay down the identity and purity criteria which apply to said processing aids, their conditions of use and the information that must appear on their labelling.

1. This Royal Decree applies to the processing aids listed in Part B of Annex I used in the processes for producing and processing the foodstuffs identified in Part A of Annex I, whether used by food businesses, by mass caterers or in the domestic sphere, without prejudice to other regulations that may apply to the conditions for their use or labelling.
2. This Royal Decree shall apply without prejudice to other regulations that may be in force on processing aids, such as Royal Decree 1101/2011 of 22 July 2011 approving the positive list of extraction solvents which may be used in the manufacture of food products and their ingredients, Royal Decree 600/2016 of 2 December 2016 approving the general quality standards for edible caseins and caseinates, Royal Decree 640/2015 of 10 July 2015 approving the list of processing aids authorised for the production of edible vegetable oils and their identity and purity criteria, and amending Royal Decree 308/1983 of 25 January 1983 approving technical and health regulations for edible vegetable oils, or Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

**Article 2.** *Definitions*.

For the purposes of this Royal Decree, the following definitions apply:

1. ‘Processing aid’ shall mean any substance which:

(i) is not consumed as a food by itself;

(ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product.

1. Food business: as defined in Article 3(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
2. Mass caterers: as defined in Article 2(2)(d) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
3. Domestic sphere: the private sphere in the framework of a household in which no commercial operation or activity is carried out in the food sector.

**Article 3.** *Conditions of use.*

1. The processing aids identified in Part B of Annex I of this Royal Decree may be used in the foodstuffs or the production processes of the foodstuffs listed in Part A of Annex I and must do so in accordance with the identity and purity criteria set out in Annex II, such that they must be manufactured in such a way that, under normal or foreseeable conditions of use, they do not transfer any components to foodstuffs that may pose a risk to human health.

Processing aids shall be used in such a way that the quantity used shall be limited to the minimum dose necessary to obtain the desired effect.

The fact that a processing aid is listed in Annex I of this Royal Decree shall not exempt the economic operator using it from the obligation to demonstrate that its use complies with the requirements described for processing aids in the definition, where the competent authority so requires.

1. By way of derogation from Section 1, processing aids which are legally placed on the market in other Member States of the European Union may also be used, with the same restrictions and limitations as those existing there and for the same purpose, in accordance with the principle of mutual recognition. This is without prejudice to the responsibility of food business operators based on the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002.

In order to demonstrate compliance with the provisions of the above Section, food industry operators shall have the appropriate supporting documentation available. Such documentation shall be made available to the competent authorities upon request.

1. Where a substance is authorised as a food additive, it may also be used as a processing aid, even if it is not included in the list of substances identified in Part B of Annex I of this Royal Decree, provided that compliance with the requirements in the definition of processing aids can be demonstrated.
2. In the food categories which do not fall within the scope of this Royal Decree because they do not have rules governing the use of processing aids or do not currently have a report of the AESAN Scientific Committee establishing that their use under specific conditions does not pose a risk to the health of the consumer, and that therefore, they have not been included in Part A of Annex I, there is no impediment to the use of such aids, provided that their use can be demonstrated to be safe, i.e that the operator can reliably guarantee that the processing aids used are safe, as well as the food placed on the market, in compliance with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

**Article 4.** *Labelling of processing aids.*

Without prejudice to the particulars provided for in other legislation which may be applicable, the following information shall appear on the packaging or container in which the processing aids are placed on the market:

1. A name enabling the identification of the substance (or substances) acting as a processing aid with a clear reference to the name of the substance as set out in Annex I.
2. The words ‘for food’, or ‘restricted use in food’, or a more specific reference to its intended use in food.
3. The words ‘not intended for sale to the final consumer’, where applicable.
4. Where the processing aid consists of more than one substance, a list of all components in decreasing weight order according to their percentage of the total weight.
5. Where appropriate, information on the presence in the processing aid of any of the substances included in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers.
6. Date of minimum durability or expiry date.
7. If necessary, the specific storage and preservation conditions.
8. The instructions for use enabling the processing aid to be used properly and safely, including, where appropriate, information on the quantitative limitation in foodstuffs that has been established to comply with the definition of a processing aid.
9. Information on the effect that the processing aid has on the food in question.
10. The name or business name and address of the manufacturer, packager or vendor of the processing aid.
11. The net quantity.
12. An indication enabling the lot or batch to be identified.

However, the information required under Subsections d), h) and j) may appear on the accompanying documents where ‘not intended for sale to the final consumer’ is clearly indicated on the container of the product.

Where processing aids are supplied in tanks, all information may appear on the accompanying documents presented at the time of delivery.

The above labelling requirements shall be without prejudice to more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or applying to the transport of such substances and preparations, in particular those of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

**Article 5.** *Conditions for companies engaged in manufacturing, packaging or distributing processing aids.*

In accordance with Royal Decree 191/2011 of 18 February 2011 on the General Health Register of Food and Food Businesses, companies engaged in any of the activities of manufacturing, packaging or distributing processing aids must be registered in the General Health Register of Food and Food Businesses, for which the heads of the companies must contact the competent health authorities of the Autonomous Community in which they are located.

Companies engaged in manufacturing, packaging or distributing processing aids shall be subject to the requirements described in the regulations of the Food Hygiene Package developed by the European Union which may apply to them, and in particular Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

**Single Additional Provision.***Mutual recognition clause.*

The requirements expressed in this Royal Decree shall not apply to foodstuffs legally manufactured or placed on the market in the other Member States of the European Union, nor to products originating in the countries of the European Free Trade Association (EFTA), Contracting Parties to the Agreement on the European Economic Area (EEA), and States that have a customs association agreement with the European Union.

**Single Repealing Provision.***Repeal of regulations.*

All rules of equal or lower rank are repealed if they oppose the provisions of this Royal Decree, and in particular the following:

1. Article 7(7) of Royal Decree 1798/2010 of 30 December 2010 regulating the exploitation and marketing of natural mineral waters and spring waters packaged for human consumption.
2. Article 6(4) of Royal Decree 1799/2010 of 30 December 2010 regulating the process of preparation and marketing of prepared waters packaged for human consumption.
3. Resolution of 2 December 1982 (rectified) of the Under-Secretariat for Health approving the positive list of additives and processing aids for use in the production of beer.
4. Article 6(5) and (6) and Article 8(6), (7) and (11) of Royal Decree 72/2017 of 10 February 2017 approving the quality standard for the different categories of natural cider and cider.
5. Article 3(12) of Royal Decree 650/2011 of 9 May 2011 approving technical and health regulations on soft drinks.
6. Article 6(4) of Royal Decree 1338/1988 of 28 October 1988 approving technical and health regulations for the production and sale of horchata de chufa.
7. Article 4(1), (2), (5) and (8) of Royal Decree 661/2012 of 13 April 2012 establishing the quality standard for the production and marketing of vinegars.
8. Section 5 and Annex of Royal Decree 1052/2003 of 1 August 2003 approving technical and health regulations on certain sugars intended for human consumption.
9. Article 11 of Royal Decree 380/1984 of 25 January 1984 approving technical and health regulations for the production and sale of syrups.
10. Article 28(5)(b), (5)(c) and (5)(d) of Royal Decree 1011/1981 of 10 April 1981 approving technical and health regulations for the production, circulation and trade of edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations.
11. Article 12 of Royal Decree 308/2019 of 26 April 2019 approving the quality standard for bread.
12. Resolution of 1 August 1979 of the State Secretariat for Health approving the positive list of additives authorised for use in the production of confectionery, cakes, pastries, desserts and biscuits.
13. Resolution of 28 September 1983 of the Under-Secretariat approving the positive list of additives and processing aids for use in the production of table olives.
14. Annex I, Part B(3)(d) to (l) of Royal Decree 781/2013 of 11 October 2013 establishing rules on the production, composition, labelling, presentation and advertising of fruit juices and similar products intended for human consumption.
15. Resolution of 21 April 1983 of the Under-Secretariat approving the positive list of additives and processing aids for use in the production of fruit juices and other vegetable juices and their derivatives.
16. Article 2 of Royal Decree 1044/87 of 31 July 1987 regulating the production of grape juice in line with Community legislation.
17. Resolution of 18 October 1982 of the Under-Secretariat for Health approving the positive list of additives authorised for use in the production of compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols.
18. Resolution of 26 February 1981 of the State Secretariat for Health approving the organisation of positive lists of additives authorised for use in various foodstuffs intended for human consumption.
19. Resolution of the State Secretariat for Health approving the positive list of additives authorised for use in the production of canned and semi-preserved vegetables (‘BOE’ No 249 of 17 October 1979).
20. Annex 1(2) of the Order of 21 November 1984 approving quality standards for canned vegetables.
21. Royal Decree 846/2011 of 17 June 2011 establishing conditions to be met by raw materials based on recycled polymeric materials for use in materials and articles intended to come into contact with food.

**First Final Provision.** *Title of competence.*

This Royal Decree is issued under the provisions of Article 149(1)(13) and (16) of the Constitution, which grants the State exclusive competence in matters of the bases and general coordination of health***.***

**Second Final Provision.** *Development powers.*

1. The heads of the Ministry of Consumer Affairs and the Ministry of Agriculture, Fisheries and Food are authorised to issue, within the scope of their competences, the provisions necessary for updating and amending Annexes I and II of this Royal Decree in order to adapt it to scientific and technical knowledge, and to the European Union regulations adopted, where appropriate, on the subject.
2. Processing aids not listed in Annex I, and which are not covered by Article 3(2) and (3) of this Royal Decree, shall, in order to be approved and included in said Annex I, be subject to a risk assessment by the Scientific Committee of the Spanish Agency for Food Safety and Nutrition establishing the safety of the intended use, following a favourable report from the Directorate-General for the Food Industry at the Ministry of Agriculture, Fisheries and Food.

**Third Final Provision.***Entry into force*

This Royal Decree shall enter into force on the day following its publication in the Official State Gazette.

ANNEX I

**Part A. List of Foodstuffs**

The following table sets out the list of foodstuffs included in the scope of application of this Royal Decree, together with a reference, if available, to the legislation defining them:

|  | **Foodstuffs** | **Definition** |
| --- | --- | --- |
| 1. | Table olives | Royal Decree 679/2016 of 16 December 2016 establishing the quality standard for table olives. |
| 2. | Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Royal Decree 164/2014 of 14 March 2014 laying down additional rules for the production, description, presentation and labelling of certain spirit drinks. |
| 3. | Natural mineral waters and spring waters | Royal Decree 1798/2010 of 30 December 2010 regulating the exploitation and marketing of natural mineral waters and spring waters packaged for human consumption. |
| 4. | Prepared waters | Royal Decree 1799/2010 of 30 December 2010 regulating the process of preparation and marketing of prepared waters packaged for human consumption. |
| 5. | Sugars | Royal Decree 1052/2003 of 1 August 2003 approving technical and health regulations on certain sugars intended for human consumption. |
| 6. | Sugars - other sugars | Royal Decree 1261/1987 of 11 September 1987 approving technical and health regulations for the production, storage, transport and marketing of sugars intended for human consumption. |
| 7. | Soft drinks | Royal Decree 650/2011 of 9 May 2011 approving technical and health regulations on soft drinks. |
| 8. | Cephalopods | Marine invertebrates belonging to the taxonomic class *Cephalopoda* placed on the market in Spain for human consumption. |
| 9. | Beers | Royal Decree 678/2016 of 16 December 2016 approving the quality standard for beer and malt beverages. |
| 10. | Canned vegetables | Royal Decree 2420/1978 of 2 June 1978 approving technical and health regulations for the production and sale of canned vegetables. |
| 11. | Fresh and frozen fruit and vegetables | Decree 2484/1967 of 21 September 1967 approving the text of the Spanish Food Code. |
| 12. | Edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations | Royal Decree 1011/1981 of 10 April 1981 approving technical and health regulations for the production, circulation and trade of edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations. |
| 13. | Blood products | Whole blood, red blood cells and plasma. |
| 14. | Horchata de chufa | Royal Decree 1338/1988 of 28 October 1988 approving technical and health regulations for the production and sale of horchata de chufa. |
| 15. | Bovine bones, tripe and natural casings | Bones of bovine animals intended for human consumption in Spain.  Royal Decree 474/2014 of 13 June 2014 approving the quality standard for meat derivatives.  Order of 29 October 1986 approving the quality standard for natural casings for the internal market. |
| 16. | Syrups | Royal Decree 380/1984 of 25 January 1984 approving technical and health regulations for the production and sale of syrups. |
| 17. | Bread and speciality breads | Royal Decree 308/2019 of 26 April 2019 approving the quality standard for bread. |
| 18. | Confectionery, cakes, pastries, desserts and biscuits | Royal Decree 496/2010 of 30 April 2010 approving the quality standard for confectionery, cakes, pastries and desserts.  Royal Decree 1124/1982 of 30 April 1982 approving technical and health regulations for the production, manufacture, circulation and trade of biscuits. |
| 19 | Cheese | Royal Decree 1113/2006 of 29 September 2006 approving quality standards for cheeses and processed cheeses. |
| 20. | Ciders and other apple-derived beverages | Royal Decree 72/2017 of 10 February 2017 approving the quality standard for the different categories of natural cider and cider. |
| 21. | Vinegars | Royal Decree 661/2012 of 13 April 2012 establishing the quality standard for the production and marketing of vinegars. |
| 22. | Fruit juices and similar products | Royal Decree 781/2013 of 11 October 2013 establishing rules on the production, composition, labelling, presentation and advertising of fruit juices and similar products intended for human consumption. |
| 23. | Grape juice | Royal Decree 1044/1987 of 31 July 1987 regulating the production of grape juice. |
| 24. | Other vegetable juices and their derivatives | Royal Decree 667/1983 of 2 March 1983 approving technical and health regulations for the production and sale of fruit juices and other vegetable juices and their derivatives. |

**Part B. List of Processing Aids**

In addition to those set out in the table below, nitrogen gas1 can be used as a processing aid during food processing, in order to avoid oxidation, and always in stages prior to packaging. If used for this purpose in packaging, it must be labelled in accordance with Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

| **Food** | **Name of processing aid** | **Category** | **Conditions of Use/Function** | **Maximum residual quantity** |
| --- | --- | --- | --- | --- |
| Table olives | Hydrochloric acid1 | Neutralising | For the neutralisation of residual alkaline solution / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Table olives | Cultures of lactic micro-organisms | Fermentation starters | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Table olives | Manganese gluconate | Catalyst in the darkening process | Dosage strictly necessary to achieve the desired effect | Technically unavoidable (GMP) |
| Table olives | Sodium hydroxide1 | Conditioning | For the preparation of alkaline solution for the removal of the bitter principle in commercial types and preparations where required / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Table olives | Manganese lactate | Catalyst in the darkening process | Dosage strictly necessary to achieve the desired effect | Technically unavoidable (GMP) |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Albumin | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Bentonite | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Activated carbon1 | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Casein2 | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Cellulose | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Amorphous silicon dioxide1 | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Enzymes | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Edible gelatin | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Tannins | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols | Infusorial earth | Filtration and clarification | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural mineral waters, spring waters and prepared waters packaged for human consumption | Nitrogen1 | Packaging gas | Maintaining adequate pressure in the container to ensure its stability / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Paraffin oil | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Vaseline oil | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Edible vegetable oils | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Hydrochloric acid1 | Product for the chemical purification of diffusion juice and refining of sugar | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Sulphuric acid1 | Product for the chemical purification of diffusion juice and refining of sugar | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Activated carbon1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Sodium carbonate1 | Product for the chemical purification of diffusion juice and refining of sugar | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Powdered cellulose1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Microcrystalline cellulose1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Disodium cyanodithioimidocarbonate | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes. | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 2.5 mg/kg cane or beet | Technically unavoidable |
| Sugars | Quaternary ammonium compounds | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 10 mg/kg cane or beet | Technically unavoidable |
| Sugars | Carbon dioxide1 | Neutralising | Lime neutraliser for the purification of sugar diffusion juice / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Silicon dioxide (Silica gel)1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Disodium ethylenebisdithiocarbamate | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 3 mg/kg cane or beet | Technically unavoidable |
| Sugars | Ethylenediamine | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 2 mg/kg cane or beet | Technically unavoidable |
| Sugars | Calcium hydroxide1 | Product for the chemical purification of diffusion juice and refining of sugar | Chemical purification of the juice by precipitation of a part of the dissolved and dispersed non-glycoside substances / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Sodium hydroxide1 | Product for the chemical purification of diffusion juice and refining of sugar | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Mixture of natural β-acids from hop extract | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 3 mg/kg cane or beet | <0.01 mg/kg sugar |
| Sugars | Sorbitan monostearate1 | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Potassium N-methyldithiocarbamate | Products for the control of micro-organisms in sugar milling, extraction and diffusion processes | For the control of micro-organisms in sugar milling, extraction and diffusion processes. Maximum use level: 3.5 mg/kg cane or beet | Technically unavoidable |
| Sugars | Glyceryl oleate1 | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Polyethylene glycol oleate | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Sodium polyacrylate | Antifouling | 5 ppm in syrup | Technically unavoidable |
| Sugars | Polyethylene glycol1 | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Polymers of acrylic and methacrylic acids, their sodium salts, esters, amides and N-methyl-amides, and homo- and copolymers thereof | Flocculating | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Polypropylene glycol1 | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Sodium salt of polyaspartic acid (CAS No 181828-06-8), in 40 % aqueous solution | Antifouling | To prevent the formation of calcium and magnesium phosphate deposits at the maximum dose of 5 ppm sodium salt of polyaspartic acid on beet or cane | <2 mg/kg sugar |
| Sugars | Sodium potassium aluminium silicate | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Calcium sulphate1 | Product for the chemical purification of diffusion juice and refining of sugar | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Egg albumin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Bentonite | Filtering-bleaching-clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Kaolin | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Activated carbon1 | Bleaching | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Silicon dioxide (Silica gel)1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Edible gelatin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in Syrups | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Edible vegetable oils | Anti-foaming | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Hydrochloric acid1 | Products for starch hydrolysis and pH regulation in mixtures and syrups | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Sulphuric acid1 | Products for starch hydrolysis and pH regulation in mixtures and syrups | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Alpha-amylase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Beta-amylase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Sodium bisulphite or metabisulphite1 | Products for starch hydrolysis and pH regulation in mixtures and syrups | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Activated carbon1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Sodium carbonate1 | Products for starch hydrolysis and pH regulation in mixtures and syrups | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Malt extracts3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Glucoamylase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Washed wood flour | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Ammonium hydroxide1 | Products for starch hydrolysis and pH regulation in mixtures and syrups | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Isomerase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Pullulanase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Anion-exchange resins | Syrup deioniser | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Cation-exchange resins | Syrup deioniser | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Sodium potassium aluminium silicate | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Sugars - Only permitted in ‘other sugars’ | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Invert sugars | Hydrochloric acid1 | Hydrolysis agent | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Invert sugars | Sulphuric acid1 | Hydrolysis agent | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Invert sugars | Invertase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Invert sugars | Resins | Others for the production of invert sugars | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Bentonite | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Kaolin | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Activated carbon1 | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Cellulose | Filtering | Filtering agent for basic syrups or preparations | Technically unavoidable |
| Soft drinks | Dimethyl polysiloxane1 | Anti-foaming | Facilitates the manufacturing process of soft drinks / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Carbon dioxide1 | Packaging gas | Maintaining adequate pressure in the container to ensure its stability / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Silicon dioxide (Silica gel)1 | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Nitrogen1 | Packaging gas | Maintaining adequate pressure in the container to ensure its stability / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Sodium aluminium silicate1 | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Diatomaceous or infusorial earth | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Soft drinks | Zeolite | Filtering | Filtering agent for basic syrups or preparations / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Cephalopods | Hydrogen peroxide | Bacteriostatic | Concentration of use: 0.05 %; Contact time: 24 hours. | Technically unavoidable |
| Beer | Albumin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Alginate1 | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Activated carbon1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Cellulose | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Carbon dioxide1 | Propellant gas | Propellant gas for dispensing draught beer or other large formats / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Silicon dioxide (Silica gel)1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Aqueous emulsion of fats, waxes and hard resins extracted from hops (CAS No 8060-28-4, EINECS No 232-504-3) | Anti-foaming | Maximum use level of 100 g emulsion/hl (i.e. < 8 g hop extract/hl) | Technically unavoidable |
| Beer | Nitrogen1 | Propellant gas | Propellant gas for dispensing draught beer or other large formats / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Perlite | Clarifying/Filtering | At the dosage strictly necessary to obtain the desired effect. 5 to 100 g per hectolitre of beer, in the first pre-coat. | Technically unavoidable residual content, after filtration through a filter with a porosity of 1.6 µm. |
| Beer | Polyamides | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Insoluble polyvinylpyrrolidone1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Amylolytic enzyme preparations3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Proteolytic enzyme preparations3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Beer | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Canned vegetables | Hydrochloric acid1 | Other | Chemical peeling / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Canned vegetables | Sodium hydroxide1 | Other | Chemical peeling / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit and vegetables | Chlorine dioxide | Wash water treatment agent | Food subjected to the washing solution shall be rinsed and dried to minimise the presence of residues | Trihalomethanes (THMs) <100 µg/l (in wash water - bromodichloromethane, bromoform, chloroform and dibromochloromethane); Organochlorines formed as a result of water chlorination <200 ppm (in wash water); Chlorate <700 µg/l (in wash water); In addition, the food in question must comply with the maximum residue level for chlorate laid down in Regulation (EC) No 396/2005. |
| Fresh fruit and vegetables | Sodium hypochlorite | Wash water treatment agent | Subsequent rinsing with water for human consumption is mandatory to remove the remains of chlorinated water. Concentration of free chlorine in wash water: maximum 80 ppm | Trihalomethanes (THMs) <100 µg/l (in wash water - bromodichloromethane, bromoform, chloroform and dibromochloromethane); Organochlorines formed as a result of water chlorination <200 ppm (in wash water); Chlorate <700 µg/l (in wash water); In addition, the food in question must comply with the maximum residue level for chlorate laid down in Regulation (EC) No 396/2005. |
| Fresh fruit and vegetables | Sodium lauryl ether sulphate | Agent for increasing the ability to remove dirt from fresh fruits and vegetables | Food subjected to the washing solution shall be rinsed with water for human consumption to minimise the presence of residues | Technically unavoidable |
| Fresh fruit and vegetables | Hydrogen peroxide / peracetic acid / acetic acid | Wash water treatment agent | Food subjected to the washing solution shall be rinsed with water for human consumption to minimise the presence of residues | The product shall be used in accordance with good manufacturing practice to ensure that it complies with the definition of processing aids and that no residues of active substances or stabilisers, or their derivatives, remain in the food in question in concentrations which may pose a risk to the health of consumers and/or may have a technological effect on the final product. |
| Fresh fruit and vegetables | Aqueous solution of phosphoric acid and propylene glycol | PH stabilisation of plant-based food treatment solutions to promote the antimicrobial activity of chlorine. The intended pH will range from 5.5-6.5 | Food subjected to the washing solution shall be rinsed and dried to minimise the presence of residues | Non-detectable residues of propylene glycol; Phosphate residues that may be detected shall not exceed those that would be detected without the addition of the aid. |
| Fresh and frozen fruit and vegetables | Chlorine gas | Wash water treatment agent | Subsequent rinsing with water for human consumption is mandatory to remove the remains of chlorinated water. Concentration of free chlorine in wash water: maximum 80 ppm | Trihalomethanes (THMs) <100 µg/l (in wash water - bromodichloromethane, bromoform, chloroform and dibromochloromethane); Organochlorines formed as a result of water chlorination <200 ppm (in wash water); Chlorate <700 µg/l (in wash water); In addition, the food in question must comply with the maximum residue level for chlorate laid down in Regulation (EC) No 396/2005. |
| Fresh and frozen fruit and vegetables | Sodium hypochlorite | Wash water treatment agent | Subsequent rinsing with water for human consumption is mandatory to remove the remains of chlorinated water. Concentration of free chlorine in wash water: maximum 80 ppm; | Trihalomethanes (THMs) <100 µg/l (in wash water - bromodichloromethane, bromoform, chloroform and dibromochloromethane); Organochlorines formed as a result of water chlorination <200 ppm (in wash water); Chlorate <700 µg/l (in wash water); In addition, the food in question must comply with the maximum residue level for chlorate laid down in Regulation (EC) No 396/2005. |
| Edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations | Activated carbon1 | Bleaching | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations | Alkaline aqueous solutions and/or the use of authorised organic solvents and/or products by vacuum stripping with water vapour or an inert gas, or high vacuum distillation. | Neutralising | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations | Salts, acids or alkalis authorised in accordance with Regulation (EC) No 1333/2008 on food additives. | Demucilagination | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations | Bleaching earth. | Bleaching | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Red blood cells | Hydrogen peroxide | Bleaching | Concentration of use: 0.75 % | Technically unavoidable |
| Horchata | 1 % active chlorine solutions | Surface disinfection of chufas | The tubers must be washed in the disinfectant solution with mechanical agitation for at least 30 minutes This should be followed by effective washing to remove germicidal residues. | Technically unavoidable |
| Horchata de chufa (powder) | Maltodextrins | Other | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Horchata de chufa (powder) | Amylolytic enzymes3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bovine bones, tripe and natural casings | Hydrogen peroxide | Whitening | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Edible oils | Release agent | For baking moulds, sheets and machinery / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Amylase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Beeswax1 | Release agent | For baking moulds, sheets and machinery / Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Glycosidases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Pentosanases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Bread and speciality breads | Proteases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Plasma | Hydrogen peroxide | Bleaching | Concentration of use: 0.1 % for 30 minutes | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Edible oils | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Thermo-oxidised edible oils | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Amylase3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Natural amino acids | Other | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Magnesium carbonate1 | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Natural waxes of plant and animal origin | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Magnesium, calcium and aluminium stearate dimethyl polysiloxane (silicone) | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Polyglycerol esters of fatty acids of edible oils dimerised by heat | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Polyglycerol esters of transesterified castor fatty acids | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Glycosidases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Edible fats | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Invertases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Pharmaceutical grade liquid paraffin | Release agent | Dosage strictly necessary to achieve the desired effect / Maximum 3 % in the release emulsion | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Pentosanases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Confectionery, cakes, pastries, desserts and biscuits | Proteases3 | Enzyme | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Cheese made from pasteurised milk | Calcium chloride | Standardising curd formation while maintaining stable coagulation capacity of milk | Necessary quantity (0.01-0.02 %) equivalent to the soluble calcium content lost during pasteurisation (in the case of lactic fermentation cheeses the necessary quantity may be lower than for enzymatic fermentation, since the pH during production also makes it easier for caseins to coagulate) | Technically unavoidable |
| Whole blood | Hydrogen peroxide | Bleaching | Concentration of use: 0.75 % | Technically unavoidable |
| Cider - Only permitted in cider must | Pectolytic enzyme preparations3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Bentonite | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Activated carbon1 | Filtering agent | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Casein2 | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Egg white / Egg albumin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Ammonium phosphate | Fermentation starter | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Calcium phosphate1 | Fermentation starter | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Edible gelatin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Skimmed milk | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Natural cider | Lebrija and Pozaldez earth | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Phytic acid and iron-removing salts | Iron removing | Dosage strictly necessary to achieve the desired effect and subject to prior authorisation by the competent body of the Autonomous Community in which the industrial installation is located | Technically unavoidable |
| Vinegar | Albumin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Activated carbon1 | Clarifying-Bleaching | Dosage strictly necessary to achieve the desired effect provided that no foreign substances are left in the vinegars. | Technically unavoidable |
| Vinegar | Chemically inert filter aids and precipitating agents5 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Dimethyl polysiloxane1 | Anti-foaming | Facilitates the vinegar production process. Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Ammonium phosphate | To promote the multiplication of acetic acid bacteria | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Edible gelatin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Nitrogen1 | Gas | Agent to maintain adequate pressure in the container and ensure its stability | Technically unavoidable |
| Vinegar | Insoluble polyvinylpyrrolidone1 | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Vegetable proteins of plant origin from wheat, peas or potatoes | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Inorganic substances such as phosphates and ammonium salts | To promote the multiplication of acetic acid bacteria | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Organic substances, in particular liquid starch, glucose, malt preparations | To promote the multiplication of acetic acid bacteria | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Vinegar | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Amylase3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Bentonite | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Vegetable carbon=Activated carbon1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Chemically inert adsorption aids used to reduce the limonoid and naringin content of citrus juice without significantly affecting the contents of limonoid glycosides, acids or sugars (including oligosaccharides) or the mineral content4 | Other | To reduce the limonoid and naringin content of citrus juice without significantly affecting the contents of limonoid glycosides, acids or sugars (including oligosaccharides) or the mineral content / Dosage strictly necessary to achieve the desired effect. | Technically unavoidable |
| Fruit juices and similar products | Chemically inert filter aids and precipitating agents (including perlite, washed diatomite, cellulose, insoluble polyamide, polyvinylpolypyrrolidone, polystyrene)4 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Silicon dioxide (Silica gel)1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Edible gelatin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Nitrogen1 | Agent to maintain adequate pressure in the container and ensure its stability. | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Pectinases3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Perlite / expanded perlite | Filtration | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Proteases3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Vegetable proteins of plant origin from wheat, peas or potatoes | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Fruit juices and similar products | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Amylase3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Bentonite | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Kaolin | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Carbons=Activated carbon1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Silicon dioxide (Silica gel)1 | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Pectinases3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Proteases3 | Enzymes | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Tannins | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Other vegetable juices and their derivatives | Diatomaceous or infusorial earth | Filtering | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Grape juice | Partial deacidification by means of neutral potassium tartrate or calcium carbonate, the latter may contain small amounts of double calcium salt of D-tartaric and L-malic acids | Deacidifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Grape juice and Other vegetable juices and their derivatives | Casein2 | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Grape juice and Other vegetable juices and their derivatives | Egg white / Albumin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |
| Grape juice and Other vegetable juices and their derivatives | Edible gelatin | Clarifying | Dosage strictly necessary to achieve the desired effect | Technically unavoidable |

1 Specifications in accordance with those laid down in Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

2 In accordance with Royal Decree 600/2016 of 2 December 2016 approving the general quality standards for edible caseins and caseinates.

3 In accordance with Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes.

4 In accordance with Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

5 Chemically inert filter aids and precipitating agents including perlite, washed diatomite, cellulose, insoluble polyamide, polyvinylpyrrolidone, polystyrene, polypropylene, borosilicates, polyether sulfone and/or ceramics.

ANNEX II

**Criteria for the Identity and Purity of Processing Aids**

1. The substances used as processing aids as referred to in Annex I which are listed below must meet the following identity and purity criteria.

**Bentonite**:

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| Definition | Bentonite is a natural clay containing a high proportion of montmorillonite, a native hydrated aluminium silicate in which some aluminium and silicon atoms were naturally replaced by other atoms such as magnesium and iron. Calcium and sodium ions are trapped between the mineral layers. There are four common types of bentonite: natural sodium bentonite, natural calcium bentonite, sodium-activated bentonite and acid-activated bentonite |
| Einecs No  Chemical formula  Molecular mass | 215-108-5  (Al, Mg)8(Si4O10)4(OH)8·12H2O  819 |
| Content | Smectite: no less than 80 % |
| Description | Very fine, yellowish or greyish white powder. The structure of bentonite allows it to absorb water in its structure and on its external surface (swelling properties) |
| Identification:  A. Methylene blue test |  |
| B. X-ray diffraction | Characteristic peak values at 12.5/15 Å |
| C. IR absorption | Peak values at 428/470/530/1 110-1 020/3 750 — 3 400 cm-1 |
| Purity:  Loss on drying | Not more than 15.0 % (105 °C, 2 h) |
| Arsenic | No more than 2 mg/kg |
| Lead | No more than 20 mg/kg |

1. If the substances used as processing aids provided for in Annex I are not included in Section 1 of this Annex II but are included in Annex II of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, they shall comply with the identity and purity criteria adopted in Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
2. If the substances used as processing aids provided for in Annex I are not included in Section 1 of this Annex II or in Annex II of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008, the identity and purity criteria established by the European Pharmacopoeia or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) shall apply or, in the absence of such criteria, the following general purity criteria if appropriate by virtue of their characteristics:

|  |  |
| --- | --- |
| Lead | < 5 mg/kg |
| Arsenic | < 1 mg/kg |
| Mercury | < 1 mg/kg |
| Cadmium | < 1 mg/kg |