

Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the safe use of three aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as processing aids for the bacterial disinfection of citrus fruit and pepper washing water at processing plants

Reference number: AESAN-2020-002

Report approved by the Scientific Committee in its plenary session on 4 March 2020

Working group

Jordi Mañes Vinuesa (Coordinator), Carlos Manuel Franco Abuín, Elena González Fandos, Carmen Rubio Armendáriz and Ricardo López Rodríguez (AESAN)

Scientific Committee

Carlos Alonso Calleja Universidad de León	Rosa María Giner Pons Universitat de València	Sonia Marín Sillué Universitat de Lleida	Magdalena Rafecas Martínez Universitat de Barcelona
Montaña Cámara Hurtado Universidad Complutense de Madrid	Elena González Fandos Universidad de La Rioja	José Alfredo Martínez Hernández Universidad de Navarra	David Rodríguez Lázaro Universidad de Burgos
Álvaro Daschner Hospital de La Princesa de Madrid	María José González Muñoz Universidad de Alcalá de Henares	Francisco José Morales Navas Consejo Superior de Investigaciones Científicas	Carmen Rubio Armendáriz Universidad de La Laguna
Pablo Fernández Escámez Universidad Politécnica de Cartagena	Esther López García Universidad Autónoma de Madrid	Victoria Moreno Arribas Consejo Superior de Investigaciones Científicas	María José Ruiz Leal Universitat de València
Carlos Manuel Franco Abuín Universidade de Santiago de Compostela	Jordi Mañes Vinuesa Universitat de València	María del Puy Portillo Baquedano Universidad del País Vasco	Pau Talens Oliag Universitat Politècnica de València

Technical Secretary

Vicente Calderón Pascual

Abstract

The company Peroxychem Spain S.L.U. has requested a safety assessment of the use of three aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as processing aids. 1-Hydroxy ethylidene-1,1-diphosphonic acid (HEDP) was used as a stabiliser.

The proposed use is the antibacterial treatment of water used to wash citrus fruits and peppers in processing plants. When this water is disinfected, it can be reused for the consecutive washing of fruits and vegetables through a recirculating system, maintaining it in appropriate conditions and thus reducing water usage.

These are the same aqueous solutions previously assessed by the AESAN Scientific Committee in 2018, however an increased dosage has been requested here so that the concentration of peracetic acid in washing solutions is increased from the previously assessed 45 ppm to 200 ppm. The

requested dosages, both for washing citrus fruits and peppers, are 356 ml/100 l of water in the case of VigorOx 5 F&V, and 116 ml/100 l of water for VigorOx 15 F&V and VigorOx 15/10 F&V.

Considering the most adverse scenario of the presence of residues in citrus fruits and peppers and the consumption of these citrus fruits and peppers in Europe, an estimated daily intake (EDI) of these residues as well as a consumer risk assessment by calculating the margin of safety (MOS) have been made.

The Scientific Committee concludes that, based on the information provided by the applicant and taking into account the proposed composition and conditions of use, the usage of the aqueous solutions as processing aids does not involve a health risk for the consumer.

Key words

Citrus fruit, peppers, processing aid, bacterial disinfection.

Suggested citation

AESAN Scientific Committee. (Working group) Mañes, J., Franco, C.M., González, E., Rubio, C. and López, R. Informe del Comité Científico de la Agencia Española de Seguridad Alimentaria y Nutrición (AESAN) en relación a la seguridad del uso de tres soluciones acuosas de peróxido de hidrógeno, ácido acético y ácido peracético como coadyuvantes tecnológicos para la desinfección bacteriana del agua de lavado de cítricos y pimientos en las plantas de procesado. *Revista del Comité Científico de la AESAN*, 2020, 31, pp: 33-48.

1. Introduction

The company PeroxyChem Spain S.L.U., located in La Zaida (Zaragoza), has requested an assessment of the safety of the use of three aqueous hydrogen peroxide solutions as processing aids in the process of bacterial disinfection of water used for washing citrus fruits and peppers upon arrival at the processing plant. They also include 1-Hydroxyethane 1,1-diphosphonic acid (HEDP).

The three aqueous solutions, designated VigorOx 5 F&V, VigorOx 15 F&V and VigorOx 10/15 F&V are differentiated in the concentrations of their active components and the stabilizer, obtaining, in all cases, the same final concentration of peracetic acid in the washing solution (200 ppm). The different presentations respond to commercial reasons, to adjust the composition to the transport and storage standards of customers.

These are the same aqueous solutions previously assessed by the AESAN Scientific Committee in 2018, and for which an increased dosage has been requested so that the concentration of peracetic acid in washing solutions is increased from the previously assessed 45 ppm to 200 ppm. Furthermore, unlike the assessment carried out in 2018, the washing solutions will not be renewed on a daily basis.

In terms of authorised uses of components in human food, hydrogen peroxide is authorised in France as a processing aid in tripe; acetic acid is and food additive authorised in the European Union (E 260) and peracetic acid is authorised as an additive or processing aid in countries such as Canada and Australia. With regard to the stabilizer, HEDP is authorised as a processing aid or additive as part of solutions for the disinfection of meat, fruit and vegetables in Australia and the United States.

In light of said request, the Management Board of the Spanish Agency for Food Safety and Nutrition (AESAN), has requested the Scientific Committee to assess the safety of the use of those aqueous hydrogen peroxide solutions, acetic acid and peracetic acid as processing aids in the process of bacterial disinfection of water used in the washing of citrus fruits and peppers upon arrival at processing plants, bearing in mind the "Guidelines on precise documentation required for evaluation of processing aids that are intended for use in human food" (AESAN, 2010).

Following the criteria established in the previous assessment in 2018, given that the presence of residues in the final products (citrus and peppers) after the use of these aqueous solutions, the processing aid is classified within situation 4: substance authorised in human food whose ADI (acceptable daily intake) is not established and whose use can lead to the presence of technically inevitable residues. In light of this situation, the applicant for use of the product must submit information relating to the following aspects:

- Administrative data and general presentation.
- Physicochemical characteristics.
- Technological function.
- Residue studies: analytical method and validation method.
- Studies and data on safety: Level A.
- Study of consumption and evaluation of anticipated intake levels by the consumer.

2. General presentation and physiochemical characteristics

2.1 Detailed composition and formulation

The products proposed as processing aids, with commercial designations VigorOx 5 F&V, VigorOx 15/10 and VigorOx 15/10 F&V, are aqueous hydrogen peroxide and acetic acid solutions that are maintained in chemical equilibrium with peracetic acid and water. To maintain this equilibrium, the aforementioned stabilizer 1-Hydroxyethane-1,1-diphosphonic acid (HEDP) is used for the purpose of preventing the metallic ions from catalysing the decomposition of the peracetic acid and hydrogen peroxide. It consists of the same three solutions already assessed by the Scientific Committee in 2018 (AESAN, 2018).

The three aqueous solutions are differentiated in the concentrations of their active components (hydrogen peroxide, acetic acid and peracetic acid) and the stabilizer (HEDP), obtaining the same final concentration of peracetic acid (200 ppm) in the washing solutions (Table 1).

Table 1. Composition of processing aids

Component	Function	CAS No.	Concentrations (%)		
			VigorOx 5 F&V	VigorOx 15 F&V	VigorOx 15/10 F&V
Hydrogen peroxide	Active substance	7722-84-1	25	23	10
Acetic acid	Active substance	64-19-7	8	16	36
Peracetic acid	Active substance	79-21-0	5	15	15
1-Hydroxyethane-1,1-diphosphonic acid (HEDP)	Stabilizer	2809-21-4	0.5	0.6	0.6

With regard to pH, it is indicated that it is <1 at 20 °C.

2.2 Product specifications

Tables 2, 3 and 4 show the specifications and results of the analysis of four lots of processing aids.

Table 2. Specifications and analysis results for VigorOx 5 F&V

Component	Specifications (% p/p)	Analysis certificates (% p/p)			
		L16000P	L16005R	L16014R	L16020R
Hydrogen peroxide	25 ± 2	25.4	25.6	25.3	25.6
Acetic acid	8 ± 2	8.4	7.6	7.7	7.9
Peracetic acid	4.5-5	5	5	4.8	4.6
1-Hydroxyethane-1,1-diphosphonic acid (HEDP)	0.5	-	-	-	-

Table 3. Analytical results and specifications of VigorOx 15 F&V

Component	Specifications (% p/p)	Analysis certificates (% p/p)			
		L17425B	L17804B	L17818B	L17838B
Hydrogen peroxide	23 ± 2	24.7	24.5	24.8	23.9
Acetic acid	16 ± 2	16.3	16	16.3	15.5
Peracetic acid	15 ± 1	14.8	15.2	14.8	15.8
1-Hydroxyethane-1,1-diphosphonic acid (HEDP)	0.6	-	-	-	-

Table 4. Specifications and analysis results for VigorOx 15/10 F&V

Component	Specifications (% p/p)	Analysis certificates (% p/p)			
		L16006N	L16003N	L16004N	L16005N
Hydrogen peroxide	10 ± 2	10.3	10.3	10.2	10.2
Acetic acid	36 ± 2	35.9	36.5	36	35.8
Peracetic acid	15 ± 1	15.8	15.1	15.7	15.9
1-Hydroxyethane-1,1-diphosphonic acid (HEDP)	0.6	-	-	-	-

The applicant has not provided data on compliance with the HEDP specifications.

2.2.1 Product stability

The applicant provides a study on the evolution of the peracetic acid concentration through a model based on calorimetric analysis and two stability studies conducted with composition solutions similar to Vigorox 5 F&V and Vigorox 15 F&V.

Based on the results obtained, the applicant indicates that the stability is 1 year for VigorOx 5 F&V and 9 months in the case of VigorOx 15 F&V and VigorOx 15/10 F&V.

2.2.2 Reactivity

The reactions that take place in water are decomposition of the compounds with peroxide groups to give rise to acetic acid and water (EFSA, 2005, 2014, 2016).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) indicates that, in contact with food, the active ingredients in these kinds of disinfectant solutions (with hydrogen peroxide, peracetic acid, octanoic acid, peroxyoctanoic acid and HEDP) decompose rapidly in non-toxic substances and that the quantities of acetic acid and octanoic acid that may remain as a result of decomposition of peracetic acid and peroxyoctanoic do not constitute a safety concern. It also states that hydrogen peroxide decomposes rapidly in contact with foods, obtaining water and oxygen (JECFA, 2004, 2005).

Furthermore, the use of these types of solutions do not appear to negatively affect the nutrient content (Vitamin C and β-carotene) present in fruit and vegetables based on the results of the study

conducted by the JECFA (2006) using washing solutions with 80 ppm of peracetic acid and 50 ppm of hydrogen peroxide for 5 minutes.

2.3 Authorised use in human food

Table 5 contains examples of authorised uses and assessments of these substances.

Table 5. Examples of authorised uses and assessments		
Substances	Authorised use/assessment	Country/Reference
Hydrogen peroxide	Regulation (EC) No. 853/2004 establishes a limit of 10 ppm hydrogen peroxide residue for gelatin and collagen	European Union (EU, 2004)
	Favourable toxicological assessment as processing aid in the processing of blood derivatives and cephalopods	Spain (AESAN, 2011)
	Authorised for use as t processing aid in tripe	France (Arrêté, 2006)
	Authorised for use in production of beer as a clarifying agent (maximum quantity 135 mg/kg) in buttermilk to discolour and maintain pH (100 mg/kg) and oat hulls as a bleaching agent (GMP)	Canada (DJC, 2020)
	Generally recognised as safe (GRAS) (21 CFR 184.1366), used in milk (0.05 %), whey (0.04 %), whey cheese coloured with annatto (0.05 %), starch (0.15 %), corn syrup (0.15 %), emulsifiers (1.25 %), dehydrated eggs, stomachs, beef trotters, herring, wine, tea and wine vinegar	United States (FDA, 2020a)
	Authorised in combination with acetic acid for the process of washing or peeling fruit and vegetables that are not unprocessed raw material and not exceeding 59 mg/kg in the washing solution	United States (FDA, 2020b)
	Authorised for use as processing aid (bleaching agent, washing and peeling, pH stabilizer and inhibitor) in several foods (5 mg/kg)	Australia (ANZFSC, 2020)
Acetic acid	Authorised as food additive (E 260) in accordance with Regulation (EC) No. 1333/2008, with maximum specific dose as <i>quantum satis</i>	European Union (EU, 2008)
Peracetic acid	Authorised for use as processing aid of peracetic acid in solution with hydrogen peroxide and acetic acid, in egg shells destined for manufacture of <i>ille flotant</i> (solution at 2.5 % with 4.5 % of peracetic); in peas and green beans for sterilization (500 mg/l of peracetic acid); in starch, potato starch and derivatives (1 kg/tonne); in raw ready-to-eat salads (4th range); blanched spinach for freezing (75 mg/l pf peracetic) and wheat prior to milling (3 l of a solution based on 15 % peracetic and 23 % hydrogen peroxide per tonne of wheat)	France (Arrêté, 2006)
	Authorised, in combination with acetic acid for the process of washing or peeling fruit and vegetable that are not unprocessed raw material and not exceeding 80 mg/kg in the washed solution	United States (FDA, 2020b)
	Authorised as a food additive (starch modifying agent)	Canada (DJC, 2020)
	Authorised as processing aid as bleaching agent, for washing and peeling and as a catalyst with maximum permitted level of 0.7 mg/kg	Australia (ANZFSC, 2020)

Table 5. Examples of authorised uses and assessments

Substances	Authorised use/assessment	Country/Reference
1-Hydroxyethane-1,1-diphosphonic acid (HEDP)	Authorised together with peracetic acid for the process of washing or peeling fruit and vegetable that are not unprocessed raw material and not exceeding 4.8 mg/kg in the washed solution	United States (FDA, 2020b)
	Mixed peracetic acid additive authorised, acetic acid, hydrogen peroxide, peroxyoctanoic acid and HEDP as disinfectant for poultry carcasses, parts, tripe and organs with a maximum concentration of peroxyacids of 220 mg/kg as peracetic acid, 110 mg/kg of hydrogen peroxide and 13 mg/kg of HEDP	United States (FDA, 2020c)
	Favourable toxicological assessment for acetic acid solutions, peracetic acid, hydrogen peroxide and HEDP (may also include octanoic and peroxyoctanoic acid) for use in poultry carcasses and meat	(EFSA, 2014)
	Authorised for use as a processing aid in water and as a chelating agent in disinfectants for meat, fruit and vegetables	Australia (ANZFSC, 2019)

2.4 Admissible Daily Intake

No ADI has been established for hydrogen peroxide, peracetic acid and HEDP as an individual components (EFSA, 2020a) (JECFA, 2020a). With regard to acetic acid, it is authorised as a food additive (E 260) with a maximum specific dose as *quantum satis* (EU, 2008).

JECFA has established non-specified ADI for antimicrobial solutions which may include hydrogen peroxide, acetic acid and peracetic acid, also including HEDP as a stabilizer (JECFA, 2020b). JECFA also considers that in the conditions of use for these solutions, the quantities of residues in treated foods are not in any way concerning from a food safety perspective (JECFA, 2004, 2005).

3. Technological function

3.1 Technological use claimed

The applicant claims that the technological use is that of bacterial disinfectant of water used for washing citrus fruits and peppers in processing plants.

3.2 Level of use requested

The requested dosages, both for citrus fruits and peppers, are 356 ml/100 l of water in the case of VigorOx 5 F&V, and 116 ml/100 l of water for VigorOx 15 F&V and VigorOx 15/10 F&V. In all cases, the final concentration of peracetic acid in the washing solutions shall be 200 ppm.

The washing solutions shall be reused for days or weeks and it will be left to circulate for at least 90 seconds before washing citrus fruits and peppers, with the contact time of 90 seconds. After washing, a final rinsing of the fruit and vegetables shall be performed using drinking water.

3.3 Justification of use, interest and efficiency

As indicated in the report of the Scientific Committee of 2018, the first post-harvest processing performed on vegetable products is washing, which may take the form of immersion in a drum or

using a drenching or showering of pallets system. In both methods the maintenance of the washing solution is fundamental as it is recirculated, which means that residues from the chemical treatment applied to the crops previously; dirt from harvesting and spores and pathogenic organisms deposited on vegetable material are passed to the solution. This leads to the accumulation of contamination, increasing considerably on each recirculation. To prevent the washing solution from becoming a vector of infection due to cross-contamination, it must be ensured that the microbiological quality is retained, using disinfectant products for that purpose while ensuring that the degradation products and residue of the antimicrobial agent used do not constitute a risk to the health of the consumer or to the environment (AESAN, 2018).

Unlike the assessment carried out in 2018, on this occasion an increase in the dosage used of the processing aids is requested so that the peracetic acid concentration in the washing solutions is 200 ppm, compared to the 45 ppm assessed previously. According to the applicant, the reason for this increase in the dosage used is that the continued input of organic material (dirt) to the washing solution causes continued degradation of the peracetic acid, necessitating continued addition of 200 ppm of peracetic acid, depending on the level of dirt, to maintain the minimum effective concentration of 45 ppm.

3.3.1 Efficacy studies

No additional studies have been published on the efficacy of the processing aid as the objective of increasing the dosage used is to maintain at all times the minimum effective concentration of 45 ppm of peracetic acid already assessed in the previous report of the Scientific Committee (AESAN, 2018).

In relation to this, the results of a trial carried out by an independent laboratory were provided, containing the microbiological parameters established in Royal Decree 140/2003 establishing the health criteria of water quality for human consumption (*Escherichia coli*, Enterococo and *Clostridium perfringens*) (BOE, 2003). The count of mesophilic aerobes was also included.

The trial was conducted with VigorOx 15/10 F&V, as it is the processing aid with the same final concentration of peracetic acid (45 ppm) in the washing solutions and the lowest concentration of hydrogen peroxide (30 ppm). The results obtained showed reductions equal to or in excess of 4 logarithmic units of the seed materials of *Escherichia coli*, *Enterococcus fecalis* and *Clostridium perfringens* (100 % of the seed material added) after submerging the contaminated displays in the washing solution (45 ppm of peracetic acid) for 90 seconds. In the case of mesophilic aerobes, the reduction varied between 0.15 and 1.10 logarithmic units.

In addition, the results of two other studies on the efficiency of these aqueous solutions in synthetic hard waters were presented.

3.4 Description of the process

3.4.1 Forms of incorporating the processing aid

The incorporation of processing aid in the process takes place during the washing of citrus fruits and peppers upon arrival at the processing plants, using both the drum and drencher washing systems in both cases.

In the case of the drencher, or pallet shower, the incorporation of the processing aid into the water used for the preparation of the washing solution is done using a programmable automatic dispenser with the objective of guaranteeing the appropriate dosage, ensuring that after each wash the quantity of processing aid necessary for maintaining the peracetic acid concentration (200 ppm) in the washing solution is replaced. In addition, ad hoc controls of the concentration are conducted using reactive strips.

The incorporation of the processing aid into the water used for the preparation of the washing solution in drums (and recodification) is also carried out using a programmable automatic dispenser.

The washing solution shall be reused for days or weeks with the washing solutions renewed upon any change in the initial treatment with different active materials.

3.4.2 Identification of phases of elimination of the processing aid

In the case of active substances, it is expected that their presence in fruit and vegetable is negligible given that these substances decompose rapidly, giving rise to acetic acid, water and oxygen.

As the applicant indicates, both the hydrogen peroxide and the peracetic acid in the solution are unstable, especially in the presence of oxidable organic material. The hydrogen peroxide disassociates in water and oxygen and peracetic acid decomposes in acetic acid.

The applicant also states that both the citrus fruits and peppers are subjected to final rinsing with drinking water for the purpose of removing any potential residue of water-soluble substances.

It is also pointed out that in the assessment carried out in 2018, no residues of peracetic acid were detected after the final rinsing of citrus fruits and peppers with drinking water.

Similar to the previous assessment, the results of new trials of peracetic acid and HEDP residues carried out with citrus fruits and peppers are presented.

4. Residue studies

It must be stressed that these types of solutions have undergone evaluation both on the part of JECFA and EFSA (European Food Safety Authority). JECFA has carried out an evaluation of the antimicrobial solutions of peroxyacids that contain HEDP (<1 %), hydrogen peroxide (4-12 %), acetic acid (40-50 %) and octanoic acid (3-10 %) in equilibrium with peracetic acid (12-15 %) and peroxyoctanoic acid (1-4 %). JECFA considers that the small quantities of these peroxyacids in the foodstuffs at the time of consumption do not present a safety problem (JECFA, 2005).

For its part, the EFSA (2005) has evaluated the use in poultry carcasses of a peroxyacid-based solution, comprised of peracetic acid (<15 %), peroxyoctanoic acid (<2 %), hydrogen peroxide (<10 %), acetic acid, octanoic acid and 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (<1 %), concluding that in the conditions of use described, they pose no safety concern. The EFSA reached similar conclusions with respect to the safety of possible residues in a previous study (EFSA, 2014), where it also evaluated the use, in poultry carcasses and meat, of solutions comprised of peracetic acid (12-20 %), hydrogen peroxide (6-10 %), acetic acid (35-45 %) and HEDP (0.1-<1 %). One of the solutions also contains octanoic acid (3.2%) and peroxyoctanoic acid (1.4 %). The concentration of use of peracetic acid varied according to the type of application, between 230 and 2000 ppm.

As indicated in the 2018 report (AESAN, 2018), the processing aid subject to assessment was classified within situation 4: substance authorised in human food with no established ADI and use of which can lead to the presence of residues technically inevitable in accordance with "Guidelines on precise documentation required for evaluation of processing aids that are intended for use in human food" (AESAN, 2010). Consequently, the applicant must present information on studies of residues (analytical method and validation method).

In this regard, the applicant presents the results of two studies carried out by an independent laboratory to determine the residues of peracetic acid and HEDP. The trial was conducted with VigorOx 5 F&V, as it is the processing aid with the same final concentration as peracetic acid (200 ppm) as the washing solutions and the lowest concentration of HEDP (20 ppm).

Duplicate samples were taken of the washing solution for oranges and peppers, corresponding to three phases of the process:

- Pre-treatment solution: sample taken once the processing aid was added and prior to commencing the processing of oranges and peppers.
- Post-treatment solution: sample taken after washing of oranges and peppers via drenching.
- Post-rinsing water: sample taken after final rinsing of oranges and peppers with drinking water.

The analyses of peracetic acid were carried out through nuclear magnetic resonance (^1NMR) with detection and measurement limits of 8 mg/l and 25 mg/l, respectively (Table 6).

Samples	Pre-treatment solution	Post-treatment solution	Post-rinsing water
Peppers	193	<8	<8
	184	<8	<8
Oranges	151	<8	<8
	146	<8	<8

The peracetic acid residues present in the post-rinsing water were below the detection limit. However, it is observed that the initial concentration of peracetic acid in the pre-treatment solutions is lower than that initially forecast (200 ppm), particularly in the case of oranges.

In relation to the presence of HEDP residues, the analyses were carried out via Nuclear Magnetic Resonance (^{31}NMR) with detection and measurement limits of 1.5 mg/l and 4 mg/l, respectively.

No residues of HEDP were detected after final rinsing with drinking water (post-rinsing water). Nevertheless, it is noted that HEDP was not detected in the initial (pre-treatment) solutions either, prior to commencing the washing of oranges and peppers, where the concentration should be 20 ppm. The applicant indicates that this may be due to the degradation of HEDP in contact with peracetic acid and acetic acid. In this regard, it must be pointed out that in other evaluations of similar solutions carried out by the Scientific Committee, HEDP was detected and measured.

Given that it is considered that the HEDP analysis results presented are not adequate, as it was not detected in the pre-treatment solutions, a theoretical estimate was made for the maximum quantities of HEDP in citrus fruits and peppers, considering the worst case scenario, that is assuming that the post-treatment solution contains the same concentration of HEDP as the pre-treatment solution (20 ppm) (with no degradation, evaporation, etc.) and the rinsing water applied subsequently does not eliminate the HEDP that could remain on the surface of the citrus fruits and peppers.

This situation is an overestimation of the possible residues, for the calculation of which it is considered that the post-treatment solution retained on the surface of the oranges and peppers is 0.007 l solution/kg and 0.018 l solution/kg, respectively. Assuming a concentration of HEDP of 20 ppm in the post-treatment solution and the use of 0.018 l solution/kg for peppers and 0.007 l solution/kg for oranges, the estimated HEDP residues would be 0.36 mg HEDP/kg for peppers and 0.14 mg HEDP/kg for oranges. The same quantity of solution used for oranges (0.007 l solution/kg) will be applied to all citrus fruits and, therefore, the expected residues are the same (0.14 mg HEDP/kg for citrus fruits).

5. Study and data relating to the innocuousness of HEDP

Given that there is no ADI established for HEDP, the risk assessment is based on the determination of the margin of safety (MOS), considering that where the MOS is >100 there is no risk to the consumer. The MOS is calculated taking into account the no observed adverse effect level (NOAEL) and the estimated daily intake (EDI).

In the case of HEDP, several studies have been carried out on the toxicity establishing different NOAELs (EFSA, 2014). Following the same criteria as EFSA, for the calculation of the MOS, a NOAEL of 50 mg/kg b.w./day will be used, as established based on studies conducted on rats and rabbits.

6. Study of consumption and assessment of anticipated intake level of HEDP by the consumer

To obtain the estimate for exposure, the data for the European Union Member State with the highest consumption of citrus fruits and peppers (mean and 95th percentile consumers only) for, both for adults and toddlers (ages 1 to 3), was used in accordance with the EFSA's Comprehensive European Food Consumption Database (2020b) (Data updated as of February 2020). As additional criteria, only the data corresponding to a number of consumers ≥ 10 were used. In the case of adults, the highest consumption of peppers (Latvia) is 0.57 and 1.32 g/kg b.w./day for the mean and the 95th percentile, respectively. For citrus fruits, the highest consumption (resulting from the sum of oranges, mandarins, lemons, grapefruits, orange juice, lemon juice and grapefruit juice in Germany) was 10.83 and 29.32 g/kg b.w./day for the mean and the 95th percentile, respectively. Considering the estimated HEDP residues (0.14 mg/kg in citrus fruits and 0.36 mg/kg for peppers) the estimated daily intake (EDI) is obtained. The margin of safety (MOS) (Tables 7 and 8) is calculated based on the estimated daily intake and NOAEL (50 mg HEDP/kg b.w./day).

Table 7. Estimated exposure to HEDP in adults and calculation of MOS

Product	Adults			
	Consumption (g/kg b.w./day)	EDI (mg HEDP/kg b.w./day)	MOS	
Peppers	Mean	0.57	0.000205	243 665
	P95	1.32	0.000475	105 219
Citrus fruits	Mean	10.83	0.001516	32 977
	P95	29.32	0.004105	12 181

In the case of toddlers (aged 1-3), the highest consumption of peppers (Latvia) is 0.86 and 2.83 g/kg b.w./day for the mean and the 95th percentile, respectively. For citrus fruits, the highest consumption (resulting from the sum of oranges, mandarins, lemons, grapefruits, orange juice, lemon juice and grapefruit juice) was Slovenia, with 18.27 and 43.69 g/kg b.w./day for the mean and the 95th percentile, respectively.

Table 8. Estimated exposure to HEDP in toddlers and calculation of MOS

Product	Toddlers			
	Consumption (g/kg b.w./day)	EDI (mg HEDP/kg b.w./day)	MOS	
Peppers	Mean	0.86	0.000310	161 499
	P95	2.83	0.001019	49 077
Citrus fruits	Mean	18.27	0.002558	19 548
	P95	43.69	0.006117	8174

The high values obtained for the MOS (>>100) in all cases would indicate that there is no risk to the consumer.

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the request for use of these aqueous solutions as processing aids in the process of bacterial disinfection of water used for the washing of citrus fruits and peppers upon arrival at processing plants, concludes that, based on the information provided by the applicant and taking into consideration the composition and conditions of use proposed, the use of the processing aids is not a health concern for the consumer.

The conclusions of this report refer exclusively to the solutions subject to assessment as processing aids under the conditions of use proposed and their current composition, both in terms of their active components and their stabilizers and cannot be extrapolated to any formulations or conditions other than those assessed herein. One must bear in mind that the kg of fruit processed, the climate conditions or dirt can influence the concentrations of the components of processing aids in the washing solutions and therefore, can influence the final residues.

This assessment does not constitute an authorisation for use nor does it affect any uses other than use as a processing aid in the process of bacterial disinfection of water used for the washing of citrus fruits and peppers upon arrival at processing plants. This use involves a final rinsing with drinking water, subsequent to the application of washing water with processing aid, so that any possible residues on the citrus fruits and peppers are eliminated.

The products, thus processed, must comply with all applicable food safety legislation and, once they are on the market, the operator must ensure the absence of undesirable contaminants, residues or microorganisms or ensure that their presence remains under the established maximum limits.

References

- AESAN (2010). Agencia Española de Seguridad Alimentaria y Nutrición. Líneas Directrices de la documentación precisa para la evaluación de coadyuvantes tecnológicos que se pretenden emplear en la alimentación. *Revista del Comité Científico de la AESAN*, 12, pp: 79-93.
- AESAN (2011). Agencia Española de Seguridad Alimentaria y Nutrición. Informe del Comité Científico de la Agencia Española de Seguridad Alimentaria y Nutrición (AESAN) en relación al uso del peróxido de hidrógeno como coadyuvante tecnológico en el procesado de hemoderivados y cefalópodos. *Revista del Comité Científico de la AESAN*, 15, pp: 11-32.
- AESAN (2018). Agencia Española de Seguridad Alimentaria y Nutrición. Informe del Comité Científico de la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN) en relación a la seguridad del uso de varias soluciones acuosas de peróxido de hidrógeno, ácido acético y ácido peracético como coadyuvantes tecnológicos para la desinfección bacteriana del agua de lavado de cítricos y pimientos en las plantas de procesado. *Revista del Comité Científico de la AESAN*, 27, pp: 41-60.
- ANZFSC (2020). Australia New Zealand Food Standards Code. Standard 1.3.3 Processing aids. Available at: <https://www.legislation.gov.au/Details/F2016C00196> [accessed: 20-02-20].
- Arrêté (2006). Arrêté du 19 de octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires. Ministère de l'Économie, des Finances et de l'Industrie. Journal Officiel de la République Française de 2 de diciembre de 2006. Available at: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000020667468&dateTexte=20200220> [accessed: 20-02-20].
- BOE (2003). Real Decreto 140/2003, de 7 de febrero, por el que se establecen los criterios sanitarios de la calidad del agua de consumo humano. BOE 45 de 21 de febrero de 2003, pp: 7228-7245.
- DJC (2020). Department of Justice Canada. Food and Drug Regulations. Food Additives that may be used as Starch Modifying Agents. Available at: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/FullText.html [accessed: 20-02-20].
- EFSA (2005). European Food Safety Authority. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to treatment of poultry carcasses with chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids. *EFSA Journal*, 297, pp: 1-27.
- EFSA (2014). European Food Safety Authority. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. *EFSA Journal*, 12 (3): 3599.
- EFSA (2020a). European Food Safety Authority. Chemical hazards data – OpenFoodTox. Available at: <https://www.efsa.europa.eu/en/data/chemical-hazards-data> [accessed: 20-02-20].
- EFSA (2020b). European Food Safety Authority. Comprehensive European Food Consumption Database. Available at: <http://www.efsa.europa.eu/en/food-consumption/comprehensive-database> [accessed: 6-02-20].
- EU (2004). Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs. OJ L 139 of 30 April 2004, pp: 55-205.

- EU (2008). Regulation (EC) No. 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354 of 31 December 2008, pp: 16-33.
- FDA (2020a). Food and Drug Administration. Direct Food Substances Affirmed as Generally Recognized as Safe. §184.1366 Hydrogen peroxide. Available at: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=3922fd7a-c44288a0e9e699cc3607b353&rgn=div8&view=text&node=21:3.0.1.1.14.2.1.102&idno=21> [accessed: 20-02-20].
- FDA (2020b). Food and Drug Administration. CFR-Code of Federal Regulations. Title 21-Food and Drugs, Sec. 173.315. Chemicals used in washing or to assist in the peeling of fruits and vegetables. Available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=9e43c8243ba638d9049d069fcc658ec5&mc=true&node=pt21.3.173&rgn=div5#se21.3.173_1315 [accessed: 20-02-20].
- FDA (2020c). Food and Drug Administration. CFR-Code of Federal Regulations. Title 21-Food and Drugs, Sec. 173.370 Peroxyacids. Available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=9e43c8243ba638d9049d069fcc658ec5&mc=true&node=pt21.3.173&rgn=div5#se21.3.173_1315 [accessed: 20-02-20].
- JECFA (2004). Joint FAO/OMS de Expert Committee on Food Additives. Chemical and Technical Assessment. Hydrogen peroxide, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) as components of antimicrobial washing solution. Available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/technical-assessments/en/> [accessed: 12-11-19].
- JECFA (2005). Joint FAO/OMS de Expert Committee on Food Additives. Evaluation of certain food additives: sixty-third report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report series 928. Geneva. pp: 8-17.
- JECFA (2006). Joint FAO/OMS de Expert Committee on Food Additives. Safety evaluation of certain food additives. Prepared by the sixty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives. WHO Food Additives Series: 54.
- JECFA (2020a). Joint FAO/OMS de Expert Committee on Food Additives. Evaluations of the JECFA. Available at: <http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx> [accessed: 20-02-20].
- JECFA (2020b). Joint FAO/OMS de Expert Committee on Food Additives. Evaluations of the JECFA. Peroxyacid antimicrobial solutions. Available at: <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=4909> [accessed: 20-02-20].