Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on the safe use of various 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

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Abstract

The company Peroxychem Spain S.L.U. has requested an assessment of the safe use of three aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as processing aids. 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is included as a stabiliser.

The use proposed for the processing aids is the bacterial disinfection of water used for washing citrus fruit and peppers on their arrival at the processing plants. As the water used for washing is disinfected, it can be used in consecutive washes of the fruit and vegetables through a recirculation system, maintaining the washing water in acceptable condition and reducing water consumption. The quantity used depends on the solution used, and is less than 0.1 % in the three solutions, whether washing citrus fruits or peppers.

In 2013 and 2016, the Scientific Committee conducted assessments of similar products. Considering the worst-case scenario for the presence of residue and the consumption of citrus fruit and peppers in Europe, a Tolerable Daily Intake (TDI) has been estimated for the possible residue together with a consumer risk assessment, by calculating the Margin of Safety (MOS).

The Scientific Committee concludes that, based on the information provided by the applicant and considering the composition and conditions of use proposed, the use of the solutions does not involve a health risk for the consumer.

Key words

Citrus fruit, peppers, processing aid, bacterial disinfection.

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1. Introduction

The company, PeroxyChem Spain S.L.U., located in La Zaida (Zaragoza, Spain), has requested a safety assessment on the use of three aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as processing aids in the bacterial disinfection of water used for washing citrus fruits and peppers on their arrival at the processing plants. 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is also included as a stabiliser.

The three aqueous solutions, called VigorOx 5 F&V, VigorOx 15 F&V and VigorOx 10/15 F&V, differ in the concentrations of their active components and of the stabiliser, obtaining in all cases the same final concentration of peracetic acid in the washing solution (45 ppm). The different formats respond to commercial requirements, to adjust the composition to customer transport and storage regulations.

These are aqueous solutions with similar active components to another solution previously assessed by the Scientific Committee of the AECOSAN (2013). In addition, one of the solutions (VigorOx 15 F&V) has the same concentration, with respect to its active components, as another solution assessed in 2016 (AECOSAN, 2016).

As regards the authorised uses of the components in human food, hydrogen peroxide is authorised in Spain as a decontaminant in water intended for human consumption; acetic acid is a food additive (E 260) and peracetic acid is authorised as a food additive or processing aid in countries including Canada and Australia. With respect to the stabiliser (HEDP), this is authorised in Spain as a substance for the treatment of water intended for human consumption.

In response to the request, the Executive Council of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has asked the Section of Food Safety and Nutrition of the Scientific Committee for a safety assessment of the use of the aforementioned aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid, as processing aids in the bacterial disinfection of water used for washing citrus fruits and peppers on their arrival at the processing plants, considering the "Guidelines indicating the necessary documentation for the assessment of processing aids intended for use in human food" (AECOSAN, 2010).

As it is not possible to dismiss the presence of detectable residues in the final product after the use of these aqueous solutions, in accordance with the criteria established in the aforementioned Guidelines, the processing aid is classified as in a situation 4: substance authorised in human food for which the ADI (Acceptable Daily Intake) has not been established and the use of which may result in the technically unavoidable presence of residues.

In line with this situation, the applicant for the product presents information relating to the following aspects:

- Administrative data and general overview.
- Physicochemical properties.
- Technological function.
- Analysis of residues: analytical method and validation of the method.
- Studies and data on safety (Level A).
- Study on consumption and evaluation of the expected level of consumer intake.

2. Administrative data and general introduction

2.1 Commercial name and composition

The products proposed as processing aids, which have the commercial denominations VigorOx 5 F&V, VigorOx 15 F&V and VigorOx 15/10 F&V, are aqueous solutions of hydrogen peroxide and acetic acid which are maintained in chemical equilibrium with peracetic acid and water. To maintain this equilibrium, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is used as a stabiliser, to prevent the metal ions from catalysing the decomposition of the peracetic acid and hydrogen peroxide.

2.2 Intended use of the substance

As a processing aid in the bacterial disinfection of the water used for washing citrus fruits and peppers on their arrival at the processing plants.

2.3 Authorised uses in human food

The main situations in which use in human food is authorised include:

- Hydrogen peroxide. Authorised in Spain as decontaminant of water intended for human consumption (Royal Decree 140/2003) (BOE, 2003).
- Acetic acid. Food additive (E 260) authorised by Regulation (EC) No 1333/2008 (EU, 2008), with a specific maximum dose of *quantum satis*.
- Peracetic acid. Authorised in human food (as a food additive or processing aid) in countries such as Canada or Australia. Several solutions containing peracetic acid are also authorised in human food (France and the United States).
- 1-hydroxyethylidene-1,1-diphosophonic acid (HEDP). Authorised in Spain for treating water intended for human consumption, and in France as a processing aid in sugar. In addition, it is authorised in the United States (for the washing process or as an aid when peeling fruit and vegetables) and in Australia (processing aid in water and as a chelating agent in disinfectants used with meat, fruit and vegetables).

Table 1. List of authorised uses and assessments

Substance	Authorised use/assessment	Country/ Reference
Hydrogen peroxide	Regulation (EC) 853/2004 establishes a hydrogen peroxide residue of 10 ppm for gelatine and collagen	European Union (EU, 2004)
	Its use is authorised for decontaminating water intended for human consumption	Spain (BOE, 2003)
	Favourable toxicological assessment as a processing aid in the processing of blood derivatives and cephalopods	Spain (AECOSAN, 2011)
	Its use is authorised as a processing aid in casings	France (Arrèté, 2006)
	Authorised for use in the production of beer as a clarifying agent (maximum quantity 135 mg/kg), in whey for the maintenance of pH (100 mg/kg) and with oat hulls as a bleaching agent (GMP)	Canada (DJC, 2018)
	Classified as GRAS (Generally Recognized As Safe) (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 %), dehydrated eggs, stomachs, legs of beef, herrings, wine, tea, wine vinegar and emulsifiers (1.25 %)	United States (FDA, 2018a)
	The additive that is a mixture of peracetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and HEDP is authorised as a disinfectant for carcasses, parts, casings and organs with a maximum peroxyacid concentration of 220 mg/kg for peracetic acid, and 75 mg/kg of hydrogen peroxide (110 mg/kg in poultry carcasses)	United States (FDA, 2018b)
	Its use is authorised as a processing aid (bleaching agent) in foods, establishing a maximum residue of 5 mg/kg	Australia (ANZFSC, 2018)
Acetic acid	Authorised as a food additive (E 260) according to Regulation (EC) No 1333/2008 with a specific maximum dose of *quantum satis*	European Union (EU, 2008)
Peracetic acid	Authorized for use as a processing agent of peracetic acid in solution with hydrogen peroxide and acetic acid, with egg shells intended for the manufacture of îlle flotant (solution at 2.5 % with 4.5 % of peracetic); with peas and green beans intended for sterilisation (500 mg/l of peracetic acid); in starch, corn starch and derivatives (1 kg/tonne); ready-to-eat raw salads (4th range); with blanched spinach intended for freezing (75 mg/l of peracetic) and with wheat before grinding (3 l of solution of 15 % peracetic and 23 % hydrogen peroxide per tonne of wheat)	France (Arrèté, 2006)
	Authorised for the process of washing or help in peeling fruits and vegetables that are not raw, unprocessed materials without exceeding 80 mg/kg in the washing water	United States (FDA, 2018c)

Table 1. List of authorised uses and assessments

Substance	Authorised use/assessment	Country/ Reference
Peracetic acid	The additive that is a mixture of peracetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and HEDP is authorised as a disinfectant for carcasses, parts, casings and organs with a maximum peroxyacid concentration of 220 mg/kg for peracetic acid	United States (FDA, 2018b)
	Included in the 'Effective Food Contact Substance (FCS) Notifications' database, essentially forming part of aqueous solutions with acetic acid, hydrogen peroxide and HEDP	United States (FDA, 2018d)
	Authorised as a food additive (starch modifying agent)	Canada (DJC, 2018)
	Authorised as a processing aid as a bleaching agent for washing and peeling, and as a catalyst with a maximum permitted level of 0.7 mg/kg	Australia (ANZFSC, 2018)
1-hydroxyethane-1,1-diphosophonic acid (HEDP)	Authorised for use as a substance for decontaminating water intended for human consumption (the product must not be present in the water above the detection limit of the best available analysis technique)	Spain (BOE, 2003)
	Its use is authorised as a processing aid for sugar	France (Arrèté, 2006)
	Authorised for the process of washing or help in peeling fruits and vegetables that are not raw, unprocessed materials without exceeding 4.8 mg/kg in the washing water	United States (FDA, 2018c)
	The additive that is a mixture of peracetic acid, octanoic acid, acetic acid, hydrogen peroxide and HEDP is authorised as a disinfectant for poultry carcasses, parts, casings and organs with a maximum peroxyacid concentration of 220 mg/kg for peracetic acid, 110 mg/kg for hydrogen peroxide and 13 mg/kg for HEDP	United States (FDA, 2018b)
	Included in the 'Effective Food Contact Substance (FCS) Notifications database' essentially forming part of aqueous solutions with acetic acid and hydrogen peroxide	United States (FDA, 2018d)
	Authorised as a processing aid in water and as a chelating agent in disinfectants used with meat, fruit and vegetables	Australia (ANZFSC, 2018)

2.4 Acceptable Daily Intakes

An ADI has not been established by the JECFA (Joint FAO/WHO Expert Committee on Food Additives) for hydrogen peroxide, peracetic acid and HEDP as individual components (JECFA, 2018a, b, c).

A non-specific ADI has been established for antimicrobial peroxyacid solutions including hydrogen peroxide, acetic acid and peracetic acid, with HEDP as a stabiliser (JECFA, 2018d). JECFA considers the quantities of residues in treated foods not to be any cause for concern in terms of food safety in the intended conditions of use (JECFA, 2004, 2005).

3. Physicochemical properties

3.1 Composition and detailed formulation

The products proposed as processing aids are solutions of hydrogen peroxide and acetic acid in chemical equilibrium with peracetic acid and water.

1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is also included as a stabiliser.

The three aqueous solutions differ in the concentrations of their active components (hydrogen peroxide, acetic acid and peracetic acid) and of the stabiliser (HEDP), obtaining in all cases the same final concentration of peracetic acid (45 ppm) in the washing solution (Table 2).

Table 2. Composition of the 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-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	Stabiliser	2809-21-4	0.5	0.6	0.6

The pH is given as <1 to 20 ºC.

3.2 Product specifications

Tables 3, 4 and 5 list the specifications and the test results for four batches of the proposed processing aids.

Table 3. Specifications and test results for VigorOx 5 F&V

Component	Specifications (% p/p)	Certificate of analysis (% 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-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	0.5	–	–	–	–

Table 4. Specifications and test results for VigorOx 15 F&V

Component	Specifications (% p/p)	Certificate of analysis (% 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-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	0.6	–	–	–	–

Table 5. Specifications and test results for VigorOx 15/10 F&V

Component	Specifications (% p/p)	Certificate of analysis (% p/p)			
		L17425B	L17804B	L17818B	L17838B
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-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	0.6	–	–	–	–

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

3.2.1 Product stability

The applicant has provided a study on the evolution of the peracetic acid concentration with a model based on the calorimetric study and two stability tests performed with solutions with a composition 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.

3.2.2 Reactivity

The reactions that take place in the water are those involving the decomposition of the compounds with peroxide groups to form acetic acid and water (EFSA, 2005):

$$H_2O_2 + 2H^+ + 2e^- \longrightarrow 2\,H_2O$$
$$CH_3COOOH + 2H^+ + 2e^- \longrightarrow CH_3COOH + H_2O$$

The reactions that occur in the contact environment are as follows (JECFA, 2004):

$$H_2O_2 \longrightarrow H_2O + \tfrac{1}{2}\, O_2$$
$$CH_3COOOH + H_2O \longrightarrow CH_3COOH + H_2O_2$$
$$CH_3COOOH \longrightarrow CH_3COOH + \tfrac{1}{2}\, O_2$$

JECFA, upon assessing disinfectant solutions containing hydrogen peroxide, peracetic acid, octanoic acid, peroxyoctanoic acid and HEDP, indicates that, in contact with foods, the active ingredients decompose rapidly into non-toxic substances and that the quantities of acetic and octanoic acid that may remain as a result of the decomposition of peracetic acid and peroxyoctanoic acid do not pose a safety concern. It is also noted that hydrogen peroxide decomposes rapidly in contact with foods, giving water and oxygen (JECFA, 2004, 2005).

Furthermore, the use of this kind of solution does not seem to negatively affect the nutrient content (vitamin C and β-carotene) present in fruits and vegetables (JECFA, 2006).

4. Technological function

4.1 Alleged technological use

The applicant indicates that the alleged technological use is as a bacterial disinfectant of the water used for washing citrus fruit and peppers on their arrival at the processing plants.

4.2 Target foods or food group

Water used for washing citrus fruit and peppers.

4.3 Level of use requested

The applicant states that the dose of the processing aids to be used for citrus fruits and peppers is 80 ml/100 l washing solution in the case of VigorOx 5 F&V and 26 ml/100 l washing solution for VigorOx 15 F&V and VigorOx 15/10 F&V. In all cases the final concentration of peracetic acid in the washing solution is 45 ppm.

The washing solution is renewed every day and is allowed to circulate for at least 90 seconds before washing the citrus fruit and peppers, with a contact time of 90 seconds. After washing, the citrus fruit and peppers are rinsed with drinking water.

4.4 Justification for use, interest and effectiveness

As stated in the Scientific Committee Report 2013, the first post-harvest treatment undertaken on vegetable products is washing, which can take place either by immersion in a water tank or using a system known as drencher or pallet shower.

In both methods, proper maintenance of the washing solution is fundamental, because this is recirculated, sending the remains of the chemical treatments previously applied to cultivation, some of the dirt from the harvest, and pathogenic microorganisms and spores deposited in the vegetable matter to the solution.

This situation causes the accumulation of contamination to increase considerably with each recirculation.

To prevent the washing solution from becoming a channel through which infection is spread by cross-contamination, it must be ensured that its microbiological quality is maintained. For this, disinfecting products can be used, always making sure that the degradation products and residues from the antimicrobial agent used do not pose a risk to the health of the consumer or the environment (AECOSAN, 2013).

As regards the effectiveness of the technological processing aid proposed, it is alleged that they are oxidants from the group of broad spectrum bactericides, and are efficient in a wide range of temperatures and pH<8.

They are easily biodegradable, breaking down into oxygen, water and acetic acid.

It is also stated that peracetic acid is the most efficient active ingredient, having a similar effect to other bactericides used as oxidising agents.

The bactericidal activity of peracetic acid may be derived from the oxidisation of proteins and, in particular, of the sulfhydryl bonds (Kitis, 2004).

4.4.1 Studies on effectiveness

In order to establish a minimum dose of use necessary to ensure an effective disinfection in all the requested uses, the applicant has submitted the results of a test conducted by an independent laboratory which considers the microbiological parameters established in Royal Decree 140/2003, laying down the health criteria for the quality of water intended for human consumption (*Escherichia coli*, *Enterococcus* and *Clostridium perfringens*) (BOE, 2003). The aerobic mesophilic count is also included.

The test was conducted using VigorOx 15/10 F&V, as this is the processing aid which, at the same final concentration of peracetic acid (45 ppm) in the washing solutions, has the lowest concentration of hydrogen peroxide (30 ppm). To prepare the washing solution, 26 ml of VigorOx 15/10 F&V were added to every 100 l of sterile distilled water.

Several batches of contaminated and uncontaminated samples of mandarins and peppers were analysed (to confirm the initial microbial load). In the case of the contaminated samples, strains of *Escherichia coli*, *Enterococcus faecalis* and *Clostridium perfringens* at a concentration of 10^4 CFU/ml were inoculated in the samples. The washing solutions used in the test were also analysed.

The results obtained show reductions equal to or higher than 4 log units of the added inocula of *Escherichia coli*, *Enterococcus faecalis* and *Clostridium perfringens* (100 % of the added inocula) after immersing the contaminated samples in the washing solution (45 ppm of peracetic acid) for 90 seconds. The aerobic mesophilic count was reduced by between 0.15 and 1.10 log units.

In addition, the results of two studies on the effectiveness of these aqueous solutions are presented:

- The first study assesses the effectiveness of VigorOx 15 (0.26 ml/l) used in solutions with synthetic hard water (prepared in accordance with the AOAC) to which vegetable juice (1 %) and suspensions of *Escherichia coli* O157:H7, *Salmonella enterica* and *Listeria monocytogenes* were added. The results of the study, carried out in conditions of good laboratory practices (40 CFR Part 160) (EPA, 2011), reveal reductions of more than 99.9 % after 90 seconds of exposure at 25 ± 1 ºC.

- In the second study, the effectiveness of VigorOx 15 F&V was assessed at different concentrations (0.16 ml/l and 0.20 ml/l, equivalent to 25 and 30 ppm of peracetic acid) in solutions with synthetic hard water (prepared in accordance with the AOAC) to which vegetable juice was added (1 %) and inocula of *Escherichia coli* O157:H7 and *Listeria monocytogenes (*1-10 x 10^6 CFU/ml). The concentrations of VigorOx 15 F&V used are lower than the requested concentration (0.26 ml/l).

The results show reductions of 98.4 % for *Listeria monocytogenes* after 2 minutes of exposure to the solution with 30 ppm of peracetic acid (0.20 ml/l of VigorOx 15 F&V) and 99.99 % after 3 minutes exposure to the solution with 25 ppm of peracetic acid (0.16 ml/l of VigorOx 15 F&V).

In the case of *Escherichia coli* O157:H7, the reduction was 100 % after 2 minutes of exposure to the solution with 30 ppm of peracetic acid (0.20 ml/l of VigorOx 15 F&V).

The applicant also highlights the assessment made by the FSNAZ (Food Standards Australia New Zealand) on the effectiveness of an aqueous solution (hydrogen peroxide, acetic acid, peracetic acid, octanoic acid, peroxyoctanoic acid and HEDP) in the reduction of aerobic bacteria, coliforms, moulds and yeasts on the surface of celery, potatoes, cabbage, blueberries and strawberries.

The concentration of peroxyacids in the washing solutions was 40 ppm.

The studies were conducted by comparing the bacterial load before and after washing with the aqueous solution and showed the effectiveness with statistical significance in comparison to washing with water and other disinfectants (chlorinated), also indicating its higher level of effectiveness with respect to other solutions without octanoic acid (FSANZ, 2005).

4.5 Description of the process

4.5.1 Ways of inserting the processing aid

The inclusion of the processing aid in the procedure takes place during the washing of the citrus fruit and peppers on their arrival at the processing centres, in both cases using either the water tanks or the drencher as the washing system.

In the case of the drencher, or pallet shower, an automatic programmable dispenser is used to add the processing aid to the washing water in order to ensure the correct dose. In this way, after each wash the processing aid is replaced in the amount necessary to maintain the concentration of peracetic acid (45 ppm) in the washing solution. In addition, the peracetic acid concentration is measured at intervals using test strips.

Automatic programmable dispensers are also used to add the processing aid to the washing water in the tanks (and to maintain its concentration).

4.5.2 Identifying the processing aid elimination phases

According to the applicant, both the hydrogen peroxide and the peracetic acid in solution are unstable, especially in the presence of oxidisable organic matter.

The hydrogen peroxide separates into water and oxygen, and the peracetic acid decomposes into acetic acid.

The applicant also confirmed that both the citrus fruit and peppers undergo a final wash with potable water in order to remove any possible residues of water-soluble substances from the surface.

Regarding peracetic acid, the 2013 report from the AECOSAN, on a formula with the same components but in different proportions, stated that the peracetic acid concentration was observed to remain or decrease slightly in the citrus fruit and pepper washing solutions due to the continuous dosage that compensated for its degradation.

In addition, it was confirmed that the HEDP not only did not build up but degraded with successive treatments (AECOSAN, 2013).

In this respect, the results of peracetic acid and HEDP residue tests conducted on citrus fruit and peppers are presented.

5. Analysis of residues

As indicated in the 2013 report (AECOSAN, 2013), several studies have analysed the disinfecting properties of these systems together with their toxicological properties. JECFA has assessed the antimicrobial solutions of peroxyacids containning 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 believes that the small quantities of residues from these peroxyacids in foods when consumed do not pose a safety concern (JECFA, 2005).

These kinds of solutions have also been assessed by the European Food Safety Authority (EFSA). The EFSA assessed the use in poultry carcasses of a solution a based on peroxyacids composed of peracetic acid (<15 %), peroxyoctanoic acid (<2 %), hydrogen peroxide (<10 %), acetic acid, octanoic acid and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (<1 %). Total peroxyacid content, expressed as peracetic acid, is 220 mg/l and the maximum concentrations of hydrogen peroxide and HEDP are 110 and 13 mg/l, respectively. In the assessment in question, aspects such as the possible toxicological risks of reaction products (for example semicarbazide) were taken into account, and it was concluded that in the conditions of use described they pose no safety concern (EFSA, 2005).

EFSA reached similar conclusions with respect to the safety of the possible residues in a later study (EFSA, 2014), in which they also assessed the use in poultry carcasses and meat of solutions composed 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 in-use concentration of peracetic acid varies, depending on the application type, between 230 and 2 000 ppm.

As indicated in section 1, the processing aid is classified in situation 4: substance authorised in human food for which the ADI has not been established and the use of which may result in the technically unavoidable presence of residues in accordance with the "Guidelines indicating the necessary documentation for the assessment of processing aids intended for use in human food" (AESAN, 2010). As a consequence, the applicant must present information on studies on residues (analytical method and validation of the method).

In relation to the possible presence of residues of peracetic acid and HEDP in products treated with the processing aid, the applicant has submitted the results of two tests conducted by inde-

pendent laboratories. The tests were conducted with VigorOx 5 F&V, as the processing aid which in the same final concentration of peracetic acid (45 ppm) in the washing solutions has the highest concentration of HEDP (4.5 ppm).

Samples of the orange and pepper washing solutions were taken, in drencher, corresponding to the three stages of the process:

- Pre-treatment solution: taken at the start of the day, after adding the processing aid and before starting the treatment of the oranges and peppers.
- Post-treatment solution: sample taken after 1 day washing oranges and peppers.
- Post-rinsing water: sample taken after final rinse with drinking water of the oranges and peppers.

The peracetic acid tests were conducted using HPLC-UV with a limit of quantification of 0.5 mg/l (Table 6). The method used is based on that described by Pinkernell et al. (1997).

Table 6. Peracetic acid content in washing solutions and post-rinsing water

Samples			Peracetic acid content (ppm)
Washing of oranges	Pre-treatment solution	CF1R1/2	33.7
		CF1R2/2	33.5
	Post-treatment solution	CF2R1/2	1.4
		CF2R2/2	1.7
	Post-rinsing water	CF3R1/2	n.d.[1]
		CF3R2/2	n.d.
Washing of peppers	Pre-treatment solution	P1R1/2	36.1
		P1R2/2	37.1
	Post-treatment solution	P2R1/2	21.9
		P2R2/2	23.1
	Post-rinsing water	P3R1/2	n.d.
		P3R2/2	n.d.

[1] n.d.: not detected. Limit of quantification: 0.5 mg/l.

No traces of peracetic acid were detected after the final rinse with drinking water. However, it is observed that the initial concentration of peracetic acid in the pretreatment solutions is lower than that initially expected (33.7 compared to 45 ppm). According to the applicant, this may be due to the degradation of the peracetic acid, given the length of time elapsed between the taking of the samples and the performance of the tests. In addition, significant differences were observed between the peracetic acid content in the post-treatment solutions of oranges and peppers.

With regard to the possible presence of HEDP residues, the tests were carried out using Nuclear Magnetic Resonance (NMR) with a limit of quantification of 0.2 mg/l (Table 7).

Table 7. HEDP content in washing solutions and post-rinsing water

Samples			HEDP content (mg/l)
Washing of oranges	Pre-treatment solution	CF1R1/2	<0.2
	Post-treatment solution	CF2R1/2	<0.2
	Post-rinsing water	CF3R1/2	<0.2
Washing of peppers	Pre-treatment solution	P1R1/2	<0.2
	Post-treatment solution	P2R1/2	<0.2
	Post-rinsing water	P3R1/2	<0.2

No HEDP residue was detected after the final rinse with drinking water. In any case, no HEDP had been detected in the pre-treatment solutions. As for the peracetic acid, the applicant stated that this may be due to the degradation of the peracetic acid, given the length of time elapsed between the taking of the samples and the performance of the tests.

In the case of the HEDP, as the results of the tests presented are considered unsuitable as no HEDP was found in the pre-treatment solutions, a similar strategy to that used in the 2013 report (AECOSAN, 2013) has been followed. A theoretical estimation was made of the maximum quantities of HEDP residues on peppers and oranges, assuming that the post-rinsing water contained the same initial quantity of HEDP (4.5 ppm) (without degradation, evaporation, etc.), implying an overestimation of the possible residues, and that 0.018 l water/kg were used to rinse the peppers and 0.007 l water/kg to rinse the oranges.

Assuming an HEDP concentration in post-rinsing water of 4.5 ppm and the use of 0.018 l water/kg peppers and 0.007 l water/kg oranges, the estimated HEDP residues would be 0.081 mg HEDP/kg peppers and 0.032 mg HEDP/kg oranges. The same quantity of rinsing water will be applied to all the citrus fruit as used for the oranges (0.007 l water/kg oranges) and, therefore, the expected residues will be equal (0.032 mg HEDP/kg citrus fruit).

6. Studies and data on HEDP safety

As indicated above, no ADI has been established for HEDP.

To assess the risk, one alternative involves the use of the Margin of Safety (MOS), considering that when the MOS is >100 there is no risk to the consumer. The MOS is calculated considering the NOAEL (No Observed Adverse Effect Level) and the Estimated Daily Intake (EDI).

In the case of HEDP, a number of studies were conducted on its toxicity, establishing different NOAELs (EFSA, 2014). Using the same criteria as the EFSA, for the calculation of the MOS a NOAEL of 50 mg/kg b.w./day is used, established based on studies on rats and rabbits.

7. Study on consumption and assessment of the expected level of consumer intake of HEDP

To estimate the level of exposure, data have been taken from the European Union country with the highest consumption of citric fruit and peppers (mean and 95th percentile), both for adults and children aged from 1 to 3 years old (toddlers), in accordance with the Comprehensive European Food Consumption Database of the EFSA (2018). As an additional criterion, only the data corresponding to a number of consumers ≥ 10 has been considered. In Spain, the consumer data used was collected in ENALIA 1 (National Dietary Survey on the Child and Adolescent Population) and ENALIA 2 (National Food Survey on the Adult, Elderly and Pregnant women Populations), both conducted by AECOSAN (2018).

In the case of adults, the highest consumption of peppers (data from Austria) is 58.18 and 124.7 g/day for the mean and 95th percentile, respectively. For citrus fruit, the highest consumptions (the result of the sum of the consumption of oranges, mandarins, lemons, orange juice, lemon juice and grapefruit juice in Germany) are 809 and 2 365.40 g/day for the mean and 95th percentile, respectively. Considering the estimated results of HEDP (0.032 mg /kg in citrus fruit and 0.081 mg/kg in peppers) and a body weight in adults of 70 kg (EFSA, 2012), the Estimated Daily Intake (EDI) is obtained. Based on the estimated intake and the NOAEL (50 mg HEDP/kg b.w./day) the Margin of Safety is calculated (MOS) (Table 8).

Table 8. Estimation of exposure in adults and calculation of the MOS

		Adults		
		Intake (g/day)	**EDI (mg HEDP/kg b.w./day)**	**MOS**
Peppers	Mean	58.18	0.00007	**714 285**
	P95	124.7	0.00014	**357 142**
Citrus fruits	Mean	809	0.00037	**135 135**
	P95	2 365.4	0.00108	**46 296**

With respect to children (1-3 years), the estimations and the calculation of the MOS are made in a similar manner as that used for the adults, considering the highest consumptions of peppers (data from Germany) and citrus fruit (data from Spain) and a body weight of 12 kg (EFSA, 2012) (Table 9).

Table 9. Estimation of exposure in children (1-3 years old) and calculation of the MOS

		Children (1-3 years)		
		Intake (g/day)	**EDI (mg HEDP/kg b.w./day)**	**MOS**
Peppers	Mean	7.12	0.00005	**1 000 000**
	P95	28.33	0.00019	**263 157**
Citrus fruits	Mean	370.97	0.00099	**50 505**
	P95	733.01	0.00195	**25 641**

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

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the application file for use of these aqueous solutions as processing aids in the process of bacterial disinfection of the water used for washing citrus fruit and peppers on their arrival at the processing plants, concludes that, based on the information provided by the applicant and considering the composition and proposed conditions of use, the use of the processing aid is not a health concern for the consumer.

The conclusions of this report refer exclusively to the solutions under assessment as a processing aid under the conditions of use proposed and with the current composition, both as regards its active components and its stabilisers. They cannot be extrapolated to other formulae or conditions other than those assessed. It should be remembered that the kg of fruit treated, the climatic conditions and the dirt may affect the concentrations of the components of the processing aid in the treatment mixes and therefore in the possible residues.

This assessment does not imply an authorisation for use, nor does it affect uses other than as a processing aid in the process of bacterial disinfection of the water used for washing citrus fruit and peppers on their arrival at the processing plants. This use implies a final rinse with drinking water, immediately after the application of the washing water containing the processing aid, in order to eliminate the possible residues from the fruit.

Products processed in this way must comply with all applicable food legislation and, once on the market, the food business operator must ensure the absence of contaminants, residues or undesirable micro-organisms, or their presence below the maximum established limits.

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