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

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Abstract

The company AgroFresh Fruit Protection S.A. has requested a safety assessment of the use of two aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as a technological aid. 1-hydroxyethylene-1,1-diphosphonic acid (HEDP) is included as stabilizer.

The proposed use is the bacterial disinfection of the washing water of plums, cherries and pears in the processing plants.

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These aqueous solutions have the same composition and manufacturer as those previously evaluated by the Scientific Committee for the bacterial disinfection of washing water of citrus and peppers, and of apples and peaches. With regard to the doses of use, it is indicated that, given the reactivity of the active substances with the organic matter from the dirt on fruits, an initial addition of 0.1 % of FreshStart Disinfect 25-15 or 0.3 % of FreshStart Disinfect 25-5 will be required. In both cases, the final concentration of peracetic acid in the washing solution shall be 150 ppm. After this initial dosing of 150 ppm peracetic acid, maintenance dosages (0.033 % FreshStart Disinfect 25-15 or 0.1 % FreshStart Disinfect 25-5) will be applied to maintain a concentration of 50 ppm peracetic acid in the washing solution.

Considering the most unfavourable scenario of presence of residues in plums, cherries and pears and their consumption, an Estimated Daily Intake (EDI) of possible residues has been carried out, as well as an assessment of the risk they may pose to the consumer by calculating the Margin of Safety (MOS).

The Scientific Committee concludes that, on the basis of the information provided by the applicant, and taking into account the proposed composition and conditions of use, the use of aqueous solutions as processing aids does not pose health risk to consumers.

Key words

Plums, cherries, pears, processing aid, bacterial disinfection.

Suggested citation

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1. Introduction

AgroFresh Fruit Protection S.A., a company located in Paterna (Valencia), has requested an evaluation of the safe use of two aqueous solutions of hydrogen peroxide, acetic acid and peracetic acid as technological aids in the bacterial disinfection process of the water used for washing plums, cherries and pears upon their arrival at the processing plants. They also include 1-hydroxyethylene-1,1-diphosphonic acid (HEDP) as a stabiliser.

The two aqueous solutions, FreshStart Disinfect 25-15 and FreshStart Disinfect 25-5, differ in the concentrations of their active components and of the stabiliser, the final concentration of peracetic acid in the washing solution (150 ppm) remaining the same in all cases. The different presentations respond to commercial reasons, in order to adjust the composition to transport and storage standards of the customers.

These aqueous solutions have the same composition, dose of use and manufacturer as those previously evaluated by the Scientific Committee for the bacterial disinfection of washing waters of citrus and peppers (AESAN, 2018, 2020) and apples and peaches (AESAN, 2021).

As to authorised uses in human food, it should be noted that both the individual components of the processing aid and the solutions of hydrogen peroxide, acetic acid and peracetic acid are authorised for different uses in several countries.

Given the "Guidelines for the documentation needed for the assessment of processing aids intended to be used in human food" (AESAN, 2010), and since the presence of residues in the final products (plums, cherries and pears) cannot be ruled out 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 may lead to the presence of technically unavoidable residues. Based on this situation, the applicant submits information relating to the following aspects:

- Administrative data and general outline.
- Physicochemical characteristics.
- Technological function.
- Residue studies: analytical method and method validation.
- Studies and data relating to safety.
- Consumption study and evaluation of the expected level of consumer intake.

2. General presentation and physicochemical characteristics

2.1 Composition and detailed formulation

The products proposed as processing aids, with trade names FreshStart Disinfect 25-15 and FreshStart Disinfect 25-5, are aqueous solutions of peroxyacetic acid, hydrogen peroxide, acetic acid and 1-hydroxyethylene-1,1-diphosphonic acid (HEDP) as a stabiliser. The two compositions seek to maintain the chemical equilibrium of the ingredients.

The two aqueous solutions differ in the concentrations of their active components (hydrogen peroxide, acetic acid and peracetic acid) and the stabiliser (HEDP), the final concentration of peracetic acid in the washing solution (150 ppm) remains the same in all cases (Table 1).

Table 1. Composition of processing aids				
Substance	**Role**	**CAS No.**	**Concentrations (%)**	
			FreshStart Disinfect 25-15	**FreshStart Disinfect 25-5**
Peracetic acid	Active substance	79-21-0	15	5
Hydrogen peroxide	Active substance	7722-84-1	25	25
Acetic acid	Active substance	64-19-7	16	8
1-Hydroxyethylene-1,1-diphosphonic acid (HEDP)	Stabiliser	2809-21-4	0.6	0.5

The pH of the 100 % solution is <1 at a temperature of 20°C.

2.2 Product Specifications

Tables 2 and 3 include the specifications and the results of the analyses of several batches of the processing aids.

Table 2. FreshStart Disinfect 25-15 Specifications and Analytical Results				
Substance	**Specifications (% w/w)**	**Certificates of analysis (% w/w)**		
Peracetic acid	15 ± 1.0	15.3	15.9	15.2
Hydrogen peroxide	25 ± 2.0	24.8	24.7	24.6
Acetic acid	16 ± 2.0	15.4	15.7	14.8
1-Hydroxyethylene-1,1-diphosphonic acid (HEDP)	0.6	-	-	-

Table 3. FreshStart Disinfect 25-5 Specifications and Analytical Results				
Substance	**Specifications (% w/w)**	**Certificates of analysis (% w/w)**		
Peracetic acid	4.5-5	4.8	4.8	4.9
Hydrogen peroxide	25 ± 2.0	25.8	25.4	25.7
Acetic acid	8 ± 2.0	7.6	7.6	7.6
1-Hydroxyethylene-1,1-diphosphonic acid (HEDP)	0.5	-	-	-

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 concentration of peracetic acid by using a model based on the calorimetric analysis of solutions of similar composition.

From the results obtained, the applicant indicates that the stability is 9 months for FreshStart Disinfect 25-15 and 1 year for FreshStart Disinfect 25-5.

2.2.2 Reactivity

As already indicated in previous evaluations of solutions of similar composition, the reactions that occur in water are the decomposition of the compounds with peroxide groups to form acetic acid and water (EFSA, 2005, 2014).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) indicates that, in contact with food, the active ingredients of this type of disinfectant solutions (with hydrogen peroxide, peracetic acid, octanoic acid, peroxioctanoic acid and HEDP) are rapidly decomposed into non-toxic substances, and that the amounts of acetic and octanoic acid that may remain as a result of the decomposition of peracetic acid and peroxioctanoic acid do not pose a safety risk. It also points out that hydrogen peroxide rapidly decomposes in contact with food, producing water and oxygen (JECFA, 2004, 2005).

Likewise, the use of this type of solutions does not seem to negatively affect the content of nutrients (vitamin C and β-carotene) present in fruits, based on the results of a study carried out by JECFA (2006) using washing solutions for 5 minutes with 80 ppm of peracetic acid and 50 ppm of hydrogen peroxide.

2.3 Authorised uses in human food

As already indicated, these aqueous solutions have the same composition and manufacturer as those previously evaluated by the Scientific Committee for the bacterial disinfection of the washing waters of citrus and peppers (AESAN, 2018, 2020) and apples and peaches (AESAN, 2021). Examples of other authorised and assessed uses for these substances are included in Table 4.

Table 4. Examples of authorised uses and assessments

Substance	Authorised use/evaluation	Country/Reference
Hydrogen peroxide	Regulation (EC) No. 853/2004 establishes a 10 ppm hydrogen peroxide residue limit for gelatine and collagen	European Union (EU, 2004)
	Favourable toxicological evaluation as processing aid in the processing of blood products and cephalopods	Spain (AESAN, 2011)
	Authorised for use in the production of beer as a clarifying agent (135 mg/kg maximum), in buttermilk to discolour and maintain pH (100 mg/kg) and in oat hulls as a bleaching agent (GMP)	Canada (DJC, 2022)
	Recognised as GRAS (Generally Recognised as Safe) (21 CFR 184.1366), used in milk (0.05 %), whey (0.04 %), whey cheese annatto coloured (0.05 %), starch (0.15 %), corn syrup (0.15 %), emulsifiers (1.25 %), dehydrated eggs, stomachs, beef trotters, herrings, wine, tea, and wine vinegar	United States (ECFR, 2022a)
	Authorised in combination with acetic acid, for the washing or peeling process of fruit and vegetables that are not unprocessed raw materials, not exceeding 59 mg/kg in the washing solution	United States (ECFR, 2022b)
	Authorised for use as a processing aid (bleaching, washing and peeling agent, pH stabiliser and inhibitor) in various foods and water (5 mg/kg)	Australia (ANZFSC, 2022)

Table 4. Examples of authorised uses and assessments

Substance	Authorised use/evaluation	Country/Reference
Acetic acid	Authorised as a food additive (E 260) under Regulation (EC) No. 1333/2008 with maximum specific dose as *quantum satis*	European Union (EU, 2008)
Peracetic acid	Authorised as a processing aid for peracetic acid in solution with hydrogen peroxide and acetic acid, in egg shells intended for the manufacture of *îlle flotant* (2.5 % solution with 4.5 % peracetic acid); in peas and green beans intended for sterilisation (500 mg/l peracetic acid); in starch and derivatives (1 kg/tonne); in ready-to-eat raw salads (4th range); in blanched spinach, aromatic herbs and unbleached leeks intended for freezing (75 mg/l peracetic acid); in wheat before milling (3 l of a 15 % peracetic acid and 23 % hydrogen peroxide solution per tonne of wheat) and dehydrated legumes (500 mg/l peracetic acid)	France (Arrêté, 2006)
	Authorised for the washing or peeling of fruit and vegetables that are not unprocessed raw materials and not exceeding 80 mg/kg in the washing solution	United States (ECFR, 2022b)
	Authorised as a food additive (starch modifying agent)	Canada (DJC, 2022)
	Authorised as a processing aid as a bleaching, washing and peeling agent in food, and as a catalyst with a maximum permitted level of 0.7 mg/kg	Australia (ANZFSC, 2022)
1-Hydroxyethylene-1,1-diphosphonic acid (HEDP)	Favourable toxicological assessment of solutions of acetic acid, peracetic acid, hydrogen peroxide and HEDP (which may also include octanoic acid and peroxioctanoic acid) for use in poultry and meat carcasses	(EFSA, 2014)
	Authorised together with peracetic acid for the washing or peeling aid process of fruits and vegetables that are not unprocessed raw materials and not exceeding 4.8 mg/kg in the washing solution	United States (ECFR, 2022b)
	An additive mixture of peracetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and HEDP is authorised as a disinfectant of poultry carcasses, parts, casings and organs with a maximum peroxyacid concentration of 220 mg/kg as peracetic acid, 110 mg/kg hydrogen peroxide and 13 mg/kg of HEDP	United States (ECFR, 2022c)
	Authorised as a processing aid in water and as a chelating agent in meat, fruit and vegetable disinfectants, and as a processing aid in water	Australia (ANZFSC, 2022)

2.4 Acceptable daily intakes

No ADI has been established for hydrogen peroxide, peracetic acid and HEDP as individual components (EFSA, 2022a) (JECFA, 2022a). Acetic acid is authorised as a food additive (E 260) with a maximum specific dose as *quantum satis* (EU, 2008).

JECFA has established a non-specified ADI for peroxyacid antimicrobial solutions including hydrogen peroxide, acetic acid, and peracetic acid, further including HEDP as a stabiliser (JECFA, 2022b). JECFA also considers that, under the intended conditions of use of these solutions, the amounts of residues in the treated food do not pose any food safety concern (JECFA, 2004, 2005).

3. Technological function

3.1 Alleged technological use

The applicant claims that the technological use is as a bacterial disinfectant of the washing waters for plums, cherries and pears.

3.2 Requested level of use

As indicated by the applicant, given the reactivity of the active substances with the organic matter present in the dirt covering the fruits, an initial addition of 0.1 % FreshStart Disinfect 25-15 or 0.3 % FreshStart Disinfect 25-5 will be required. In both cases, the final concentration of peracetic acid in the washing solution shall be 150 ppm. After this initial dosage of 150 ppm peracetic acid, maintenance dosages (0.033 % FreshStart Disinfect 25-15 or 0.1 % FreshStart Disinfect 25-5) shall be given in order to maintain a concentration of 50 ppm peracetic acid in the washing solution.

The washing solution shall be reused and, in the case of washing by immersion (drums), it will be allowed to circulate at least 45 seconds before washing the plums, cherries and pears, with a contact time of 90 seconds. With regard to the spray washing, the average amount of dilution used for the treatment is 150 ml solution/kg of fruit. After washing, the plums, cherries and pears will be rinsed with potable water.

3.3 Justification of use, interest and effectiveness

As indicated in the evaluation of similar products, washing is the first post-harvest treatment performed on plant products. It is therefore essential to maintain the hygiene of the washing solution, as dirt from the harvesting and microorganisms deposited on plant material pass into the solution. This situation causes the accumulation of contamination, which increases with each recirculation. To prevent the washing solution from becoming a vector of propagation of microorganisms 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 pose a risk to the health of the consumer or to the environment (AESAN, 2021).

3.3.1 Efficacy trials

The applicant provides four efficacy trials conducted on plums, cherries and pears, taking into account the microbiological parameters established in Royal Decree 140/2003, which establishes the sanitary criteria for the quality of water for human consumption (*Escherichia coli*, *Enterococcus* and *Clostridium perfringens*) (BOE, 2003). To carry out the tests, the replacement dose of the FreshStart Disinfect 25-15 was used, as it was the processing aid that, at the same final concentration of peracetic acid (50 ppm) in the washing solutions, had the lowest concentration of hydrogen peroxide. In addition, various application techniques were used, emulating both immersion and spray application.

The results obtained showed reductions of 100 % of the added inoculums (at levels of 10^4 cfu/ml) of *Escherichia coli, Enterococcus faecalis* and *Clostridium perfringens* in the washing solutions af-

ter dipping plums, cherries or pears for 90 seconds (7 ml solution/kg of fruit) or after spraying plums (150 ml of solution/kg of fruit).

3.4 Description of the process

3.4.1 Forms of incorporation of the processing aid

The incorporation of the processing aid takes place during the washing of plums, cherries and pears upon arrival at the processing plants, using the dip in a raft or the spray as washing systems. To this end, the processing aid is added by an automatic dispenser with an initial dose that ensures a 150 ppm concentration of peracetic acid in the washing solution and subsequent replenishment of the amount necessary to maintain a concentration of 50 ppm of peracetic acid. Additional controls of the concentration of peracetic acid are eventually performed using a spectrometer or test strips.

The contact time of the washing solution for plums, cherries and pears is 90 seconds in the case of washing in drums while, for spraying, the average dilution is 150 ml solution/kg of fruit.

3.4.2 Identification of the phases of elimination of the processing aid

The presence of active substances in fruit is expected to be negligible since these substances decompose rapidly to acetic acid, water and oxygen.

As indicated by the applicant, both hydrogen peroxide and peracetic acid in solution are unstable, especially in the presence of oxidisable organic matter. Hydrogen peroxide decomposes into water and oxygen, and peracetic acid into acetic acid and water.

The applicant further claims that the fruit undergoes a final rinsing with potable water to remove possible residues of water-soluble substances from its surface.

Results of peracetic acid and HEDP residue tests carried out on plum, cherry and pear washing and rinsing solutions are presented here.

4. Residue studies

The results of two studies carried out by an independent laboratory to determine peracetic acid and HEDP residues are provided. The tests were carried out with FreshStart Disinfect 25-5, the processing aid that has the highest concentration of HEDP (15 ppm) at the same final concentration of peracetic acid (150 ppm) in the washing solutions.

Samples of plum, cherry and pear washing solutions were taken for three stages of the process:

- Pre-treatment solution: sampling after addition of the processing aid and before starting the treatment.
- Post-treatment solution: sampling after washing by immersion.
- Post-rinsing water: sampling after final rinsing with potable water.

Peracetic acid analyses were performed by nuclear magnetic resonance imaging (^{1}HRNM) with detection and quantification limits of 2 mg/l and 4 mg/l, respectively (Table 5).

Table 5. Peracetic acid content (mg/l) in washing solutions and post-rinsing water

Samples	Pre-treatment solution	Post-treatment solution	Water post-rinsing
Plums	143.51	131.62	<2
	141.89	132.38	<2
Cherries	134.28	93.35	<2
	133.84	93.69	<2
Pears	133.88	132.91	<2
	134.12	132.69	<2

Peracetic acid residues present in the post-rinsing water were below the limit of detection, corroborating the rapid decomposition of the peracetic acid.

Regarding HEDP analyses, they were also carried out by nuclear magnetic resonance imaging (^{1}HRNM) with the same detection and quantification limits as in the case of peracetic acid (2 mg/l and 4 mg/l, respectively) (Table 5).

Table 6. HEDP acid content (mg/l) in washing solutions and post-rinsing water

Samples	Pre-treatment solution	Post-treatment solution	Water post-rinsing
Plums	12.26	11.16	<2
	13.34	10.44	<2
Cherries	12.67	12.05	<2
	11.59	11.03	<2
Pears	11.66	8.88	<2
	12.94	10.32	<2

HEDP residues present in the post-rinsing water are below the limit of detection (2 mg/l).

5. Studies and data on the safety of HEDP

Since no ADI is established for HEDP, the risk assessment is based on the determination of the Margin of Safety (MOS), considering that when MOS > 100, there is no risk to the consumer. MOS is calculated considering NOAEL (No Observable Adverse Effect Level) and EDI (Estimated Daily Intake).

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

6. Consumer studies and assessment of the anticipated level of HEDP intake by the consumer

To estimate exposure, the data of the European Union country with the highest chronic consumption (mean and 95th percentile of consumers only) of plums, cherries and pears, both for adults and for children aged 1 to 3 years (toddlers) and children under 1 year (infants), have been taken into account, according to the Comprehensive European Food Consumption Database of EFSA (2022b) (data updated as to May 2022):

- For adults, the highest consumption corresponds to: 1.42 and 4.49 g/kg b.w./day for the mean and the 95th percentile, respectively, for plums (data from Italy); 1.37 and 4.55 g/kg b.w./day for the mean and the 95th percentile, respectively, for cherries (data from the Czech Republic); and 1.80 and 4.87 g/kg b.w./day for the mean and the 95th percentile, respectively, for pears (data from Greece).
- For children aged 1 to 3 years, consumption is 5.21 and 11.37 g/kg b.w./day for the mean and the 95th percentile, respectively, for plums (data from Portugal); 5.45 and 11.06 g/kg b.w./day for the mean and the 95th percentile, respectively, for cherries (data from Slovenia); and 7.67 and 20.27 g/kg b.w./day for the mean and the 95th percentile, respectively, for pears (data from Estonia).
- Following the same criteria, for children under 1 year of age, consumption is 4.35 and 11.25 g/kg b.w./day for plums (data from Estonia); 3.82 and 9.61 g/kg b.w./day for cherries (data from Bulgaria); and 9.38 and 35.37 g/kg b.w./day for pears (data from Latvia).

In the case of HEDP residues, the immersion of fruit is considered to retain 0.007 l of post-treatment solution/kg while the spraying is 0.15 l/kg fruit. Considering a concentration of HEDP in the post-treatment solution of 2 ppm (limit of detection) and the use of 0.007 l solution/kg fruit per immersion and 0.15 l solution/kg fruit per spraying, the estimated residues of HEDP would be 0.014 mg HEDP/kg fruit and 0.3 mg HEDP/kg fruit, respectively.

Considering the highest consumption for each type of fruit and the estimated residues of HEDP (being the worst case 0.3 mg HEDP/kg fruit), the Estimated Daily Intake (EDI) is obtained. Based on the estimated intake and NOAEL (50 mg HEDP/kg b.w./day) the Margin of Safety (MOS) is calculated (Table 7).

Table 7. Estimation of HEDP exposure and calculation of MOS

Population	Fruit	Consumption (g/kg b.w./day)		EDI (mg HEDP/kg b.w./day	MOS
Adult	Plums	Mean	1.42	0.0004	125 000
		P95	4.49	0.0013	38 462
	Cherries	Mean	1.37	0.0004	125 000
		P95	4.55	0.0014	35 714
	Pears	Mean	1.80	0.0005	100 000
		P95	4.87	0.0015	33 333
Children (1-3 years)	Plums	Mean	5.21	0.0016	31 250
		P95	11.37	0.0034	14 706
	Cherries	Mean	5.45	0.0016	31 250
		P95	11.06	0.0033	15 152
	Pears	Mean	7.67	0.0023	21 739
		P95	20.27	0.0061	8197
Children (<1 year)	Plums	Mean	4.35	0.0013	38 462
		P95	11.25	0.0034	14 706
	Cherries	Mean	3.82	0.0011	45 455
		P95	9.61	0.0029	17 241
	Pears	Mean	9.38	0.0028	17 857
		P95	35.37	0.0106	4717

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the request for the use of the aqueous solutions with trade names FreshStart Disinfect 25-15 and FreshStart Disinfect 25-5 as processing aids in the process of bacterial disinfection of the water used for washing plums, cherries and pears upon arrival at the processing plants, concludes that, based on the information provided by the applicant and taking into account the proposed composition and conditions of use, the use of the processing aids does not pose a risk to the health of the consumer.

The conclusions of this report refer exclusively to the solutions subject to evaluation as a processing aid under the proposed conditions of use and with their current composition, both in terms of their active components and their stabilisers, and cannot be extrapolated to other formulations or conditions other than those evaluated including the joint use with other substances. It should be noted that the amount (kg) of fruit treated, the climatic conditions or dirt can influence the concentrations of the processing aid components in the washing solutions and, therefore, in their possible residues.

This evaluation does not imply authorisation for use or affect uses other than as an aid in the process of bacterial disinfection of the washing water of plums, cherries and pears upon arrival at the processing plants. This use involves a final rinse with drinking water, consecutive to the application of washing with the processing aid, to eliminate any possible residues in plums, cherries and pears.

The products thus processed must comply with all food laws applicable to them. Once on the market, the operator must ensure the absence of undesirable contaminants, residues or microorganisms, or ensure their presence remains below the maximum limits established.

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