# Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the safe use of an aqueous solution of hydrogen peroxide, acetic acid and peracetic acid (23/17/15) as a processing aid for the bacterial disinfection of the washing water used for cut carrots and lettuces, peeled garlic, sweet potatoes, persimmons, mangoes and avocados in processing plants

**Reference number: AESAN-2019-006**

**Report approved by the Scientific Committee in its plenary session on 26 November 2019**

**Working group**

**Jordi Mañes Vinuesa (Coordinator), Elena González Fandos, Carmen Rubio Armendáriz, Ricardo López Rodríguez (AESAN)**





## Abstract

The company Productos Citrosol S.A. has requested a safety assessment on the use of an aqueous solution containing hydrogen peroxide (23 %), acetic acid (17 %) and peracetic acid (15 %) as a processing aid. As stabilisers, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (<0.2 %) and dipicolinic acid (DPA) (≤0.01 %) are included in the solution.

The proposed use of the processing aid is the bacterial disinfection of the washing water used for cut carrots and lettuces, peeled garlic, sweet potatoes, persimmons, mangoes and avocados in processing plants. By disinfecting the washing water, it can be employed for the consecutive washing of fruits and vegetables through a recirculation system, keeping the water in suitable conditions and reducing water consumption. The dosages requested are 0.07 % for cut carrots

*Translated from the original published in the journal: Revista del Comité Científico de la AESAN, 30, pp: 29-48*

and lettuces, 0.13 % for peeled garlic, 0.27 % for sweet potatoes and avocados, and 0.20 % for persimmons and mangoes.

Considering the worst-case scenario for the presence of residues and the consumption of lettuces, carrots, garlic, sweet potatoes, persimmons, mangoes and avocados in Europe, a daily intake 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 taking into account the proposed composition and conditions of use, the use of the processing aid does not involve a health risk for the consumer.



## Key words

Lettuces, carrots, garlic, sweet potatoes, persimmons, mangoes, avocados, processing aid, bacterial disinfection.

## 1. Introduction

The company Productos Citrosol S.A., located in Potríes (Valencia), has requested a safety assessment on the use of an aqueous solution of hydrogen peroxide (23 %), acetic acid (17 %) and peracetic acid (15 %) as a processing aid in the bacterial disinfection of water used for washing cut carrots and lettuces, peeled garlic, sweet potatoes, persimmons, mangoes and avocados on their arrival at the processing plants. The processing aid, manufactured by the company Solvay Chemicals International S.A. (Brussels, Belgium), is made from two active compounds: hydrogen peroxide and acetic acid in aqueous solution, resulting in the formation of a third active compound, peracetic acid, by means of chemical equilibrium. To maintain this equilibrium, the stabilisers 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (<0.2 %) and dipicolinic acid (DPA) (≤0.01 %) are used. This is the same aqueous solution as that previously assessed by the Scientific Committee of the AESAN in 2016 for use on citrus fruit and tomatoes (AESAN, 2016), and has a similar composition to another solution previously assessed in 2013 (AESAN, 2013).

In response to the application, the Management Board of the Spanish Agency for Food Safety and Nutrition (AESAN) has asked the Scientific Committee for a safety assessment of the use of said aqueous solution as a processing aid, considering the "Guidelines of the relevant documentation for the assessment of processing aids intended for use in human food" (AESAN, 2010).

As regards to the authorised uses of the components in human food, hydrogen peroxide is authorised in France as a processing aid in casings; acetic acid is a food additive authorised in the European Union (E 260) and peracetic acid is authorised as an additive or processing aid in countries including Canada and Australia. With regard to the stabilisers, HEDP is authorised as a processing aid or additive forming part of solutions for the disinfection of meat, vegetables and fruit in Australia and the United States, and DPA is found in a traditional Japanese fermented food.

As it is not possible to dismiss the presence of residues in the final products (fruit and vegetables) 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 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: A Level.
- 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 product proposed as a processing aid with the commercial designation Citrocide Plus is an aqueous solution of hydrogen peroxide (23 %) and acetic acid (17 %) that maintains a chemical equilibrium with peracetic acid (15 %) and water. To maintain this equilibrium, two additional stabilizers are used (1-Hydroxyethane-1,1-diphosphonic acid (HEDP) (<0.2 %) and dipicolinic acid (DPA) (≤0.01 %)).

## 2.2 Intended use of the substance

Processing aid in the bacterial disinfection process of water used for washing cut lettuce and carrots, peeled garlic, sweet potatoes, persimmons, mangoes and avocados at processing plants.

## 2.3 Authorised uses in human food

Table 1 contains examples of authorised uses and assessments of these substances.



**Table 1.** Examples of authorised uses and assessments

| Substances | Authorised use/assessment | Country/ Reference |
|---|---|---|
| **Hydrogen peroxide** | Regulation (EC) No. 853/2004 establishes a limit for hydrogen peroxide residue of 10 ppm for gelatine 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 processing aid in tripe | France (Arrèté, 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, 2019) |
| | 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 Sates (FDA, 2019a) |
| | 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 59 mg/kg in the washed solution | United Sates (FDA, 2019b) |
| | Authorised for use as processing aid (bleaching agent, washing and peeling, pH stabilizer and inhibitor) in several foods (5 mg/kg) | Australia (ANZFSC, 2019) |
| **Acetic acid** | Authorised as food additive (E 260) in accordance with Regulation (EC) No. 1333/2008, with maximum specific dose as *quantum satis* | European Union (EU, 2008) |
| **Peracetic acid** | Authorised for use as technological adjuvant of peracetic acid in solution with hydrogen peroxide and acetic acid, in egg shells destined for manufacture of *île flotant* (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 (Arrèté, 2006) |

**Table 1.** Examples of authorised uses and assessments

| **Substances** | **Authorised use/assessment** | **Country/ Reference** |
|---|---|---|
| **Peracetic acid** | 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, 2019b) |
| | Authorised as a food additive (starch modifying agent) | Canada (DJC, 2019) |
| | 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, 2019) |
| **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, 2019b) |
| | 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, 2019c) |
| | Toxicological assessment favourable 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) |
| **Dipicolinic acid (DPA)** | Included in the database of Effective Food Contact Substance (FCS) Notifications comprised primarily of aqueous solutions together with acetic acid, peracetic acid, hydrogen peroxide and HEDP | United States (FDA, 2019d) |
| | Present in the spores of the bacteria *Bacillus subtilis* and found in great quantities in a traditional Japanese fermented food known as *natto*[1], a food which consists of fermented soy seeds | Japan (Ohsugi et al., 2005) |

[1]The average daily intake of dipicolinic acid (DPA) of the Japanese population from the food *natto* is 0.6-4 mg (Ohsugi and Sumi, 2011).

## 2.4 Acceptable Daily Intake

No ADI has been established for hydrogen peroxide, peracetic acid, DPA and HEDP as individual components (EFSA, 2019a) (JECFA, 2019a). With regard to acetic acid, it is authorised as a food additive (E 260) with a maximum specific dose as *quantum satis* (EU, 2008).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a non-specified ADI for antimicrobial solutions which may include hydrogen peroxide, acetic acid and peracetic acid, also including HEDP as a stabilizer (JECFA, 2019b). JECFA also considers that in the conditions of use for these solutions, the quantities of residue in treated foods do not pose a great concern from a food safety perspective (JECFA, 2004, 2005).

## 3. Physiochemical properties

### 3.1 Composition and detailed formulation

The product proposed as a processing aid is an aqueous solution of hydrogen peroxide (23 %) and acetic acid (17 %) that maintains a chemical equilibrium with peracetic acid (15 %) and water. As indicated in the application, together with active compounds, the product contains two stablizers: 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (<0.2 %) and dipicolinic acid (DPA) (≤0.01 %). Table 2 shows the composition of the processing aid.

**Table 2.** Composition of processing aid Citrocide Plus

| Component | Function | CAS No. | Molecular weight (g/mol) |
|---|---|---|---|
| Hydrogen peroxide | Active substance | 7722-84-1 | 34 |
| Acetic acid | Active substance | 64-19-7 | 60.1 |
| Peracetic acid | Active substance | 79-21-0 | 76.1 |
| 1-Hydroxyethane-1,1-diphosphonic acid (HEDP) | Stabilizer | 2809-21-4 | 205.02 |
| Dipicolinic acid (DPA) | Stabilizer | 499-83-2 | 167.12 |
| pH <1.5 | | | |

### 3.2 Product specifications

Table 3 shows the specifications and results of the analysis of four batches of the processing aid assessed.

**Table 3.** Specifications and results of analysis of four batches of Citrocide Plus

| Component | Specifications (% p/p) | Analysis certificates (% p/p) | | | |
|---|---|---|---|---|---|
| Hydrogen peroxide | 21-24 | 22.5 | 22.3 | 22.5 | 22.5 |
| Acetic acid | - | - | - | - | |
| Peracetic acid | 14.5-15.5 | 15 | 15.1 | 14.9 | 14.9 |
| 1-Hydroxyethane-1,1-diphosphonic acid (HEDP) | <0.2% | 0.164 | 0.172 | 0.179 | 0.155 |
| Dipicolinic acid (DPA) | <0.01% | 0.0034 | 0.0018 | 0.0097 | 0.0116 |

#### 3.2.1 Product Stability

The applicant employs the same formula assessed in 2016, for which data were provided with the aim of demonstrating its stability at room temperature, with the loss of concentration of peracetic acid approximately 1 % p/p per year (AESAN, 2016).

#### 3.2.2 Reactivity

As indicated in the 2016 report, the reactions that take place in water are decomposition of the compounds with peroxide groups producing acetic acid and water (EFSA, 2005, 2014) (AESAN, 2016).

JECFA, when evaluating disinfectant solutions that contain hydrogen peroxide, peracetic acid, octanoic acid, peroxyoctanoic acid and HEDP indicate that, in contact with foods, the active ingredients decompose rapidly in non-toxic substances and the quantities of acetic and octanoic acid that may remain as a result of the decomposition of peracetic acid and the peroxyoctanoic, do not constitute a safety concern. It also states that hydrogen peroxide decomposes rapidly in contact with food, obtaining water and oxygen (JECFA, 2004, 2005).

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

## 4. Technological function

### 4.1 Technological use claimed

The applicant claims that the technological use is as bacterial disinfectant of water used for washing cut lettuce and carrots, peeled garlic, sweet potatoes, persimmons, mangoes and avocados. The washing of fruit and vegetables takes place on arrival at processing plants with the aim of minimising contaminations or recontaminations during this phase of the process. It also allows for the reduction of water consumption at packing plants and prevents the emission of waste with a strong chemical contaminant load.

Other advantages indicated by the applicant, in addition to efficiency, are that it does not alter the quality and nutritional value of food treated and presents a very low phytotoxicity level.

### 4.2 Target foods or food group

Water used for washing cut lettuce and carrots, peeled garlic, sweet potatoes, persimmons, mangoes and avocados.

### 4.3 Level of use requested

According to the applicant, the dosages of processing aid to be used are those presented in table 4.

**Table 4.** Use dosage of Citrocide Plus and concentrations of components in the washing solutions

| **Product** | **Use dosage (% V/V)** | **Concentrations in washing solutions (mg/l)** | | | |
|---|---|---|---|---|---|
| | | **Peracetic acid** | **Hydrogen peroxide** | **HEDP** | **DPA** |
| Cut lettuce | 0.07 | 100 | 153 | 1.33 | 0.07 |
| Cut carrots | 0.07 | 100 | 153 | 1.33 | 0.07 |
| Peeled garlic | 0.13 | 200 | 306 | 2.67 | 0.14 |
| Sweet potatoes | 0.27 | 400 | 612 | 5.32 | 0.28 |
| Persimmons | 0.20 | 300 | 459 | 4 | 0.21 |
| Mangoes | 0.20 | 300 | 459 | 4 | 0.21 |
| Avocados | 0.27 | 400 | 612 | 5.32 | 0.28 |

The maximum contact time of fruit and vegetables with washing solutions shall be 1 minute and these solutions shall be replaced daily. After washing, a final rinsing of the fruit and vegetables shall be performed using potable water.

## 4.4 Justification of use, interest and efficiency

As indicated in the reports of the Scientific Committee of 2013 and 2016 (AESAN, 2013, 2016), the first post-harvest treatment carried out with vegetable products is washing. The maintenance of the washing solution is fundamental as it recirculates, with residues from the chemical treatment applied to the crops previously, dirt from the harvest and spores and pathogenic organisms deposited on vegetable material passing to the solution. This leads to the accumulation of contamination increasing considerably on each recirculation. To prevent the washing solution from being converted into a vector of infection due to cross-contamination, it must be ensured that the microbiological quality is retained, using disinfectant products for that purpose provided that it is guaranteed that degradation products and residue of the antimicrobial agent used do not constitute a risk to the health of the consumer or the environment.

According to the indications of the applicant, in the case of minimally processed fruit and vegetables, this problem becomes even more relevant as some of these products are marketed as ready-to-eat which implies that the final consumer does not need to carry out any washing of the product in their home. At industrial level, if the washing process is completed exclusively using potable water from the network, this water will become contaminated quickly, reaching levels of microbiological contamination that would constitute a risk to the consumer. For this reason, the water must be continually replaced to reduce this risk, which would involve increased water consumption and a significant environmental impact.

The applicant highlights, as an advantage over the chlorine-based disinfectants commonly used in the sector (sodium hypochlorite and, to a lesser extent, chlorine dioxide or calcium hypochlorite), the absence of evidence in relation to the formation of potentially harmful derivatives like trihalomethanes (Monarca et al., 2002). In this regard, results of a trial carried out with minimally processed vegetables washed with different dosages of Citrocide Plus (250, 375 and 500 ppm of peracetic acid) showed that the use of the technological adjuvant did not increase the concentration of trihalomethanes present in the water used.

It also indicates that the mixtures of peracetic acid/hydrogen peroxide are a type of disinfectant that presents one of the broadest spectres of activity, highly efficient in various ranges of pH and working temperatures, with the presence of organic material not being a limiting factor in said activity. By replacing the washing water daily, the possibility of accumulating residue of the processing aid components that are not degraded on the vegetable products undergoing washing is minimized.

### 4.4.1 Efficacy studies

The applicant provides the results of trials carried out on a pilot scale to establish the dosage of processing aid necessary to maintain the washing waters recirculating in adequate microbiological conditions for all the uses requested:

- In the case of lettuce and carrots, a trial was conducted in which they were inoculated with *Escherichia coli* O157:H7 (4.42-4.54 log UFC/ml) and subsequently washed for 45 seconds with washing solutions prepared with different dosages of the processing aid (250, 375 and

500 ppm of peracetic acid). The counts of *Escherichia coli* were inferior to the detection limit (1 UFC/ml) in all washing solutions analysed. Petri et al. (2015) also obtained counts of *Escherichia coli* O157:H7 below the detection level (1 UFC/ml) in washing solutions, in a trial in which the washing water for lettuce and carrots was inoculated with 9 log UFC/ml and subsequent washing was carried out with a processing aid solution (100 ppm of peracetic acid).

- For peeled garlic, baseline samples of the washing solutions were taken (freshly prepared solution) and after 1 or 2 hours of use for washing in the drum. The immersion time of peeled garlic was 1 minute and the washing solution was prepared by adding Citrocide Plus to 0.13 % (200 ppm of peracetic acid). The counts of total mesophilic bacteria, enterobacteriaceae, moulds and lactic bacteria were below the detection limit in all the washing solutions analysed.
- In the case of sweet potatoes, immersion for 1 minute in the two washing solutions prepared with Citrocide Plus at 0.20 % (300 ppm of peracetic acid) and at 0.27 % (400 ppm of peracetic acid). Baseline samples were taken (freshly prepared solution) and after successive washing of 10 pallets. The counts of total mesophilic bacteria, enterobacteriaceae, moulds and yeast were below the detection limit for the washing solution prepared with Citrocide Plus at 0.27 %.
- For persimmons, a simulation was carried out in dynamic solution until 32 washing cycles were completed with two washing solutions prepared with Citrocide Plus at 0.13 % (200 ppm peracetic acid) and 0.20 % (300 ppm of peracetic acid), respectively. In the case of samples of solution prepared with Citrocide Plus at 0.20 %, the counts of total mesophilic bacteria were, in all cases, below the detection limit. For mangoes, a semi-industrial pilot trial was carried out, in which a growing dosage of Citrocide Plus was added until an accumulated concentration of 400 ppm of peracetic acid was reached. The counts of total mesophilic bacteria, enterobacteriaceae, moulds and yeast were below the detection limit for the washing solution prepared with Citrocide Plus at 0.20 % and 0.27 %.
- In the case of avocados, the results of a study carried out with a processing aid (used at 0.8 %, 400 ppm of peracetic acid) with the same components as the processing aid under study although to a lesser concentration. Baseline samples of the washing solutions were taken (freshly prepared solution) and after 1, 2, 3 and 4.5 hours of use for washing in the drum. The counts of total mesophilic bacteria, total coliforms, faecal coliforms and *Escherichia coli* were, in all cases, below the detection limit.
- In addition, 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). To carry out the trial, Citrocide Plus at 0.07 and 0.27 % was added to the water samples, obtaining, in all cases, counts below the detection limit (1 UFC/ml) from the first 30 seconds of contact.

With respect to phytotoxicity, the applicant presents the results of the trials carried out with some of the products in which the phytotoxicity thresholds are established.

## 4.5 Description of the process

### 4.5.1 Forms of incorporating processing aid

The incorporation of processing aid takes place during the washing of vegetable products on arrival at processing plants. In the case of lettuce, carrots and peeled garlic the washing system is used, consisting of a drum varying in size where the vegetables are first cut (or not, depending on the size) to be washed, subsequently proceeding with the final rinsing process with potable water through a system of pressure showers. The maximum time in the drum is 1 minute. Then, vegetables are spun to eliminate the highest possible quantity of water before packaging.

The washing of other vegetable products (avocados, sweet potatoes, persimmons and mangoes) can be carried out using immersion in the drum or pressure showers or jets over brushes, turning the fruit on a conveyor belt that feeds the fruit through a moving brush washer. In both cases, the maximum time for contact with the washing solution is 1 minute and after washing takes place with a final rinsing with potable water through showers.

The addition of the processing aid to the washing water in the drums or showers takes place using programmable automatic dispensers, using waves to measure the peracetic acid concentration and to maintain it at a constant level. These washing solutions are replaced in full daily.

### 4.5.2 Identification of phases of elimination of processing aid

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

With respect to stabilizers, in a form evaluated in 2013 with the same components but in different proportions, it was verified that HEDP not only accumulated but that, unlike DPA, it rapidly disintegrated with successive treatments. Moreover, it indicated that peracetic acid remained or diminished slightly in final treatment solutions for peppers and citrus fruits using continuous dosage, compensating for its degradation (AESAN, 2013).

DPA is accumulated in the washing solution using successive cycles. In this case, the washing solution is renewed daily and therefore it is expected that the level of dipicolinic acid residue in these matrices stay below the detection level in the evaluation carried out for citrus and tomatoes (AESAN, 2016).

Moreover, the applicant affirms that both the fruit and vegetables are subject to a final rinse with potable water before proceeding with commercialisation, preventing the possible presence of peracetic acid residue or the stabilizers in these foods. In addition, in the case of carrots and lettuce, after final rinsing with potable water are they undergo mechanical spinning for the purpose of eliminating the highest possible quantity of surface water.

## 5. Residue studies

As indicated in the 2016 report (AESAN, 2016), these types of solutions have undergone evaluation both on the part of JECFA and EFSA (European Food Safety Authority). In this study, 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 balance with peracetic acid (12-15 %) and peracetic 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 concern (JECFA, 2005).

On their side, EFSA (2005) assessed 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), concluding that in the conditions of use described, they pose no safety concern. EFSA reached similar conclusions with respect to the safety of possible residues in a previous study (EFSA, 2014), where it also assessed 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 could vary according to the type of application, between 230 and 2000 ppm.

With regard to the processing aid subject to assessment, as indicated before, is classified within a 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 of the relevant documentation for the assessment of processing aids 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 a study carried out for the determination peracetic acid residue, HEDP and DPA in the washing solutions for fruit and vegetables subject to the application. The study was carried out by the applicant in a pilot plant using a simulation in which organic material, suspended solids and a microbial load were used, with the aim of simulating the closest conditions to reality.

Samples of the washing solution for fruit and vegetables corresponding to three phases of the process were taken:

- Pre-treatment solution (cycle 0): sample taken once the processing aid is added to the washing water in the dosage requested for each fruit and vegetables and prior to commencing the washing process.
- Post-treatment solution (cycle 10): sample taken after 10 simulated washing cycles with contact time of the solution with fruit and vegetables of 1 minute.
- Post-rinsing water: sample taken after final rinsing with distilled water in the fruit and vegetable previously drained for 10 seconds.

The analyses of peracetic acid were carried out using an amperometric analyser (Table 5). With regard to HEDP and DPA, the analysis was conducted by an external laboratory contracted by the industry requesting the report via LC-MS/MS, with detection limits and quantification of 0.01 μg/l and 0.1 μg/l for HEDP (Table 6), and of 0.25 μg/l and 1 μg/l in the case of DPA (Table 7).

| **Table 5.** Contents of peracetic acid (ppm) in the washing solutions and post-rinsing water | | | |
|---|---|---|---|
| **Samples** | **Pre-treatment solution** | **Post-treatment solution** | **Post-rinsing water** |
| Cut lettuce | 102 | 104 | n.d. |
| Cut carrots | 107 | 104 | n.d. |
| Peeled garlic | 202 | 201 | n.d. |
| Whole sweet potatoes | 407 | 400 | n.d. |
| Whole avocado | 408 | 406 | n.d. |
| Whole mango | 304 | 300 | n.d. |
| Whole persimmon | 308 | 290 | n.d. |

n.d.: not detected. Detection limit: 1 ppm.

| **Table 6.** Contents of peracetic acid HEDP (mg/l) in the washing solutions and post-rinsing water | | | |
|---|---|---|---|
| **Samples** | **Pre-treatment solution** | **Post-treatment solution** | **Post-rinsing water** |
| Cut lettuce | 1.1191 | 2.6757 | 1.7176 |
| Cut carrots | 0.6122 | 1.7022 | 0.9177 |
| Peeled garlic | 1.3357 | 2.8356 | 1.3442 |
| Whole sweet potatoes | 4.5543 | 11.6080 | 0.2887 |
| Whole avocado | 5.3349 | 8.5232 | 2.2730 |
| Whole mango | 3.6371 | 6.8793 | 1.2105 |
| Whole persimmon | 3.7477 | 3.5599 | 1.3174 |

| **Table 7.** Contents of DPA (mg/l) in the washing solutions and post-rinsing water | | | |
|---|---|---|---|
| **Samples** | **Pre-treatment solution** | **Post-treatment solution** | **Post-rinsing water** |
| Cut lettuce | 0.0720 | 0.1322 | 0.0760 |
| Cut carrots | 0.0687 | 0.1322 | 0.0834 |
| Peeled garlic | 0.1129 | 0.1799 | 0.0864 |
| Whole sweet potatoes | 0.2356 | 0.5581 | 0.0965 |
| Whole avocado | 0.3145 | 0.4665 | 0.1148 |
| Whole mango | 0.3060 | 0.5933 | 0.1393 |
| Whole persimmon | 0.3582 | 0.5707 | 0.1561 |

Unlike other studies (AESAN, 2013) carried out in the pilot plant with conditions for real use, this was carried out at a pilot plant through a simulation, HEDP does not degrade.

The estimation of the residue of the peracetic acid, HEDP and DPA present in the fruit and vegetables was conducted determining, by difference of weight, the water retained on each fruit and vegetable after the treatment with the solution and subsequently considering that all this water retained evaporates leaving residues of HEDP and DPA on the fruit and vegetables. To carry out the estimation residues of HEDP and DPA, measured concentrations are used in the post-treatment solutions given that, in some cases, the concentrations in the post-treatment solutions are inferior to those expected (Table 8). It is therefore considered a worse scenario before possible variations in the dosage of processing aid.

In the case of peracetic acid, it is not detected in the post-rinsing waters and, as would be expected, its decomposition in acetic acid and water (EFSA, 2014).

**Table 8.** Estimations of residues (mg/kg) of HEDP and DPA in fruit and vegetables

| Samples | HEDP | DPA |
|---|---|---|
| Cut lettuce | 0.1579 | 0.0078 |
| Cut carrots | 0.1958 | 0.0152 |
| Peeled garlic | 0.0539 | 0.0034 |
| Whole sweet potatoes | 0.0929 | 0.0045 |
| Whole avocado | 0.0511 | 0.0028 |
| Whole mango | 0.0069 | 0.0006 |
| Whole persimmon | 0.0142 | 0.0023 |



## 6. Study and data relating to safety of DPA and HEDP

As indicated, there is no ADI established for DPA and HEDP. Similar to the procedure followed in 2016 for this same processing aid (AESAN, 2016), the risk assessment is based on the determination of the margin of safety (MOS), considering when 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 this regard, EFSA (2009) assessed chromium and zinc picolinates as food supplements based on the calculation of the MOS, concluding that picolinates do not constitute a risk to the consumer. To do that, a NOAEL of 2100 mg/kg b.w./day was established for picolinic acid was established based on a study carried out on rats (NTP, 2008) (EFSA, 2009) and exposure due to the use of zinc picolinate (Zn) as the source of Zn was estimated at 1.57 mg picolinate/kg b.w./day. In the case of HEDP, a NOAEL of 50 mg/kg b.w./day was established based on the studies carried out using rats and rabbits (EFSA, 2014).

## 7. Study of consumption and evaluation of anticipated level of intake of DPA and HEDP by the consumer

To obtain the estimate for exposure, the European Union country with the highest consumption (mean and 95th percentile consumers only) for each product, both for adults and toddlers (aged 1 to 3), in accordance with the EFSA's Comprehensive European Food Consumption Database

(2019b) was selected. As additional criteria, data corresponding to a number of consumers <10 were not taken into account, except in cases where they were the only data available (persimmons in children). In the case of Spain, the consumption data was collected by ENALIA (*Encuesta Nacional de Alimentación en la población Infantil y Adolescente*) and ENALIA 2 (*Encuesta Nacional de Alimentación en población adulta, mayores y embarazadas*), both included in the Comprehensive European Food Consumption Database. In this regard, in the case of adults, higher consumption data were used for lettuce (Spanish data), carrots (Netherlands), garlic (Romania), sweet potatoes (France), avocados (Belgium), mangoes (Portugal) and persimmons (Estonia) (Tables 9-10); and in the case of toddlers (aged 1-3), the highest consumption levels were: lettuce (Holland), carrots (Finland), garlic (Estonia), sweet potatoes (Portugal), avocados (United Kingdom) mangoes (United Kingdom) and persimmons (Estonia) (Tables 11-12).

To obtain the estimated daily ingestion (EDI), estimated residues of DPA and HEDP were considered for each product (Table 8). The margins of safety (MOS) (Tables 9-12) are calculated based on the estimated daily intake and NOAELs (2100 mg DAP/kg b.w./day and 50 mg HEDP/kg b.w./day).

**Table 9**. Estimated exposure to DPA in adults and calculation of MOS

| **Product** | **Adults** | | | |
|---|---|---|---|---|
| | **Consumption (g/kg b.w./day)** | | **EDI (mg DPA/kg b.w./day)** | **MOS** |
| Lettuce | Mean | 0.69 | 0.00000538 | 390 189 521 |
| | P95 | 1.88 | 0.00001466 | 143 207 856 |
| Carrots | Mean | 0.66 | 0.00001003 | 209 330 144 |
| | P95 | 1.85 | 0.00002812 | 74 679 943 |
| Garlic | Mean | 0.05 | 0.00000017 | 12 352 941 176 |
| | P95 | 0.13 | 0.00000044 | 4 751 131 222 |
| Sweet potatoes | Mean | 0.87 | 0.00000392 | 536 398 467 |
| | P95 | 1.66 | 0.00000747 | 281 124 498 |
| Avocados | Mean | 0.75 | 0.00000210 | 1 000 000 000 |
| | P95 | 1.71 | 0.00000479 | 438 596 491 |
| Mangoes | Mean | 1.80 | 0.00000108 | 1 944 444 444 |
| | P95* | 3.80 | 0.00000228 | 921 052 632 |
| Persimmons | Mean | 1.36 | 0.00000313 | 671 355 499 |
| | P95 | 3.01 | 0.00000692 | 303 336 704 |

*Includes mango, mango juice and mango juice drink.

**Table 10**. 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 |
| Lettuce | Mean | 0.69 | 0.000109 | 458 922 |
| | P95 | 1.88 | 0.000297 | 168 434 |
| Carrots | Mean | 0.66 | 0.000129 | 386 913 |
| | P95 | 1.85 | 0.000362 | 138 034 |
| Garlic | Mean | 0.05 | 0.000003 | 18 552 876 |
| | P95 | 0.13 | 0.000007 | 7 135 721 |
| Sweet potatoes | Mean | 0.87 | 0.000081 | 618 636 |
| | P95 | 1.66 | 0.000154 | 324 225 |
| Avocados | Mean | 0.75 | 0.000038 | 1 304 631 |
| | P95 | 1.71 | 0.000087 | 572 207 |
| Mangoes | Mean | 1.80 | 0.000012 | 4 025 765 |
| | P95* | 3.80 | 0.000026 | 1 906 941 |
| Persimmons | Mean | 1.36 | 0.000019 | 2 589 064 |
| | P95 | 3.01 | 0.000043 | 1 169 810 |

*Includes mango, mango juice and mango juice drink.

**Table 11**. Estimated exposure to DPA in toddlers and calculation of MOS

| Product | Toddlers | | | |
|---|---|---|---|---|
| | Consumption (g/kg b.w./day) | | EDI (mg DPA/kg b.w./day) | MOS |
| Lettuce | Mean | 1.37 | 0.00001069 | 196 518 810 |
| | P95 | 2.75 | 0.00002145 | 97 902 098 |
| Carrots | Mean | 2.60 | 0.00003952 | 53 137 652 |
| | P95 | 6.58 | 0.00010002 | 20 996 641 |
| Garlic | Mean | 0.16 | 0.00000054 | 3 860 294 118 |
| | P95 | 0.38 | 0.00000129 | 1 625 386 997 |
| Sweet potatoes | Mean | 2.00 | 0.00000900 | 233 333 333 |
| | P95 | 4.43 | 0.00001994 | 105 342 363 |
| Avocados | Mean | 1.36 | 0.00000381 | 551 470 588 |
| | P95 | 3.91 | 0.00001095 | 191 815 857 |
| Mangoes | Mean | 5.26 | 0.00000316 | 665 399 240 |
| | P95* | 13.71 | 0.00000823 | 255 288 111 |
| Persimmons | Mean | 4.15 | 0.00000955 | 220 010 477 |
| | P95 | 6.81 | 0.00001566 | 134 073 932 |

*Includes mango, mango juice and mango juice drink.

**Table 12.** 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 |
| Lettuce | Mean | 1.37 | 0.000216 | 231 136 |
| | P95 | 2.75 | 0.000434 | 115 148 |
| Carrots | Mean | 2.60 | 0.000509 | 98 216 |
| | P95 | 6.58 | 0.001288 | 38 809 |
| Garlic | Mean | 0.16 | 0.000009 | 5 797 774 |
| | P95 | 0.38 | 0.000020 | 2 441 168 |
| Sweet potatoes | Mean | 2.00 | 0.000186 | 269 107 |
| | P95 | 4.43 | 0.000412 | 121 493 |
| Avocados | Mean | 1.36 | 0.000069 | 719 466 |
| | P95 | 3.91 | 0.000200 | 250 249 |
| Mangoes | Mean | 5.26 | 0.000036 | 1 377 638 |
| | P95* | 13.71 | 0.000095 | 528 547 |
| Persimmons | Mean | 4.15 | 0.000059 | 848 464 |
| | P95 | 6.81 | 0.000097 | 517 052 |

*Includes mango, mango juice and mango juice drink.

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

## Conclusions of the Scientific Committee

The Scientific Committee, having assessed the application for the assessment of the safe use of an aqueous solution of hydrogen peroxide (23 %), acetic acid (17 %), peracetic acid (15 %), 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (<0.2 %) and dipicolinic acid (DPA) (≤0.01 %) as a processing aid in the bacterial disinfection of water used for washing cut carrots and lettuces, peeled garlic, sweet potatoes, persimmons, mangoes and avocados at the processing plants, concludes that, based on the information provided by the applicant, and considering the composition and conditions of use proposed, the use of the processing aid is not a health concern for the consumer.

The conclusions of this report refer exclusively to the solution 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 and vegetables 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 the bacterial disinfection of the water used for washing cut carrots and lettuces, peeled garlic, sweet potatoes, persimmons, mangoes and avocados in processing plants. This use implies a final rinse with potable water, immediately after the application of the washing water containing the processing aid, in order to eliminate the possible residues from the fruit and vegetables.

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 microorganisms, or their presence below the maximum established 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 (2013). 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 de una solución acuosa de peróxido de hidrógeno, ácido acético y ácido peracético como coadyuvante tecnológico para la desinfección bacteriana de cítricos y pimientos y el agua de lavado de los mismos. *Revista del Comité Científico de la AESAN*, 18, pp: 53-69.

AESAN (2016). Agencia Española de Seguridad Alimentaria y Nutrición. Informe del Comité Científico de la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN) en relación al uso de una solución acuosa de peróxido de hidrógeno, ácido acético y ácido peracético (23/17/15) como coadyuvante tecnológico para la desinfección bacteriana de cítricos y tomates y el agua de lavado de los mismos. *Revista del Comité Científico de la AESAN*, 23, pp: 21-43.

ANZFSC (2019). Australia New Zealand Food Standars Code. Standard 1.3.3 Processing aids. Available at: https://www.legislation.gov.au/Details/F2016C00196 [accessed: 19-11-19].

Arrèté (2006). Arrèté du 19 de octubre 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=JORFTEXT000000271061&dateTexte=20160309 [accessed: 19-11-19].

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 (2019). 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: 19-11-19].

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 form the Commission related to treatment of poultry carcasses with chlorine dioxide, acidifed sodium chlorite, trisodium phosphate and peroxyacids. *EFSA Journal*, 297, pp: 1-27.

EFSA (2009). European Food Safety Authority. Scientific Opinion on chromium picolinate, zinc picolinate and zinc picolinate dehydrate added for nutritional purposes in food supplements. *EFSA Journal*, 1113, pp: 1-41.

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 (2019a). European Food Safety Authority. Chemical hazards data - OpenFoodTox. Available at: https://www.efsa.europa.eu/en/data/chemical-hazards-data [accessed: 12-11-19].

EFSA (2019b). European Food Safety Authority. Comprehensive European Food Consumption Database. Available at: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database [accessed: 12-11-19].

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 (2019a). 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=3922fd7ac44288a0e9e699cc3607b353&rgn=div8&view=text&node=21:3.0.1.1.14.2.1.102&idno=21 [accessed: 12-11-19].

FDA (2019b). 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: 12-11-19].

FDA (2019c). 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: 12-11-19].

FDA (2019d). Food and Drug Administration. Inventory of Effective Food Contact Substance (FCS) Notifications. Available at: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing [accessed: 12-11-19].

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 (2019a). 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: 12-11-19].

JECFA (2019b). 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: 12-11-19].

Monarca, S., Richardson, S.D., Feretti, D., Grottolo, M., Thruston, J.A.D., Zani, C., Navazio, G., Ragazzo, P., Zerbini, I. and Alberti, A. (2002). Mutagenicity and disinfection by-products in surface drinking water disinfected peracetic acid. *Environmental Toxicology and Chemistry*, 21 (2), pp: 309-318.

NTP (2008). National Toxicology Program. Toxicology and carcinogenesis studies of chromium picolinate monohydrate (CAS No. 27882-76-4) in F344/N rats and B6C3F1 mice (feed studies). Technical Report Series No. 556, NIH Publication No. 8-5897. National Institutes of Health, Public Health Service, US Department of Health and Human Services, Research Triangle Park (draft).

Ohsugi, T., Ikeda, S. and Sumi, H. (2005). Anti-platelet aggregation and anti-blood coagulation activities of dipicolinic acid, a sporal component of *Bacillus subtilis Natto*. *Food Science and Technology Research*, 3 (11), pp: 308-310.

Ohsugi, T. and Sumi, H. (2011). The effects of dipicolinic acid on the Thrombolytic activity of human cells. *Journal of Food Biochemistry*, 35, pp: 370-380.

Petri, E., Rodríguez, M. and García, S. (2015). Evaluation of Combined Disinfection Methods for Reducing *Escherichia Coli* O157:H7 Population on Fresh-Cut Vegetables. *International Journal of Environmental Research and Public Health*, 12, pp: 8678-8690.