Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) in relation to the use of an antimicrobial aqueous solution containing hydrogen peroxide, acetic acid and peroxyacetic acid as a processing aid on citrus fruits and peppers, and their wash water

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Abstract

The company Productos Citrosol S.A. located in Potríes (Valencia), has requested a safety assessment on the use of an antimicrobial aqueous solution containing hydrogen peroxide (23 %), acetic acid (10 %) and peroxyacetic acid (5 %) as a processing aid on citrus fruits and peppers when entering processing plants, as well as the wash water. The dose requested is 0.6 % and all components (active substances and stabilizers) of the proposed processing aid are allowed or present in human food, and none of them has an ADI value.

The intended use is disinfectant for citrus fruits and peppers when entering processing plants in order to minimise contamination and recontamination during this first step of the processing chain. The disinfection of wash water allows its reuse in consecutive washings of fruits and vegetables through a recirculating water system, keeping wash water in adequate conditions and reducing water consumption.

These types of formulations have been evaluated by different international organizations showing that, in contact with food, active ingredients rapidly break down to non-toxic products and the remaining quantity of acetic acid occurring by decomposition of the peroxyacetic acid would pose no safety concern. They also state that hydrogen peroxide rapidly breaks down to water and oxygen in contact with food. Additionally, the use of these solutions does not seem to have an adverse effect on the nutritional content (vitamin C and β-carotene) of fruits and vegetables. Adverse effects on the protein and lipid content of the solution-treated food were not detected.

The applicant has analyzed residues in the treatment wash water and in the liquids used to rinse off the fruits after the treatment with the processing aid as an indirect measure of the residues that may remain on the fruits. Using these data, and considering the worst case-scenario and the consumption of citrus fruits and peppers according to the National Survey of Dietary Intake (ENIDE), an Estimated

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Daily Intake (EDI) of fruits treated with the processing aid, has been calculated, as well as an evaluation of the potential risk to the consumers by calculating the "Margin of Safety" (MOS). The Scientific Committee concludes that, based on the information submitted by the applicant, and on the proposed dose and conditions, the use of the processing aid evaluated does not pose a risk to the health of consumers.

Key words

Citrus fruits, peppers, processing aid, bacteriological disinfection.

Introduction

The company Productos Citrosol S.A., located in Potríes (Valencia), has applied for a safety assessment on the use of an aqueous solution of hydrogen peroxide (23 %), acetic acid (10 %) and peracetic acid (5 %) as a processing aid in the bacterial disinfection of citrus fruits and peppers when they reach processing plants, as well as washing water. The processing aid, manufactured by the company Solvay (Brussels, Belgium) is composed of two active compounds: hydrogen peroxide and acetic acid in an aqueous solution, which form a third active compound, peracetic acid, by chemical equilibrium. Two stabilisers are also included to maintain this equilibrium.

To respond to this application, the Executive Director of the Spanish Agency for Food Safety and Nutrition (AESAN) asked the Scientific Committee to assess the safety of using the aforementioned aqueous solution of hydrogen peroxide, acetic acid and peracetic acid as a processing aid in the bacterial disinfection of citrus fruits and peppers and the washing water used in this process, taking into account the "Guidelines indicating the necessary documentation for the assessment of processing aids intended for use in human food" (AESAN, 2010).

As concerns hydrogen peroxide, it is authorised in Spain for the bleaching of natural tripes and there has been no acceptable daily intake (ADI) released by JECFA (Joint FAO/WHO Expert Committee on Food Additives) (JECFA, 2004a). Acetic acid is a food additive (E260) authorised in the European Union and peracetic acid (PAA) is authorised in human food (as a food additive or processing aid) in countries such as Canada and Australia. It also lacks an established ADI (JECFA, 2004a).

There is also no established ADI for the stabilisers included in the formula. The company has requested that the nature of the stabilising substances be kept confidential. For this reason they are not named in this version of the report which is made public, although they have been assessed by the Scientific Committee in its full report.

As we cannot discount the possibility of detectable residues being present in the end product (citrus fruits and peppers) after employing this aqueous solution, in accordance with the standards set out in the aforementioned Guidelines, the processing aid is classified as Situation 4: substance authorised in human food whose ADI is not established and whose use can lead to the presence of residues that are technically unavoidable. In line with this situation, the applicant for the product presents information relating to the following aspects:

- Administrative data and general outline.
- Physicochemical characteristics.
- 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.

Administrative data and general outline

1. Commercial name and composition

The product proposed as a processing aid, which has the commercial denomination Citrocide PC, is an aqueous solution of hydrogen peroxide and acetic acid which maintains chemical equilibrium with peracetic acid and water. Two stabilisers are also included to maintain this equilibrium.

2. Intended use of the substance

Processing aid in the process of bacterial disinfection of citrus fruits and peppers when they arrive at the processing plant and in bacterial disinfection of washing water used in said process.

3. Authorised use in human food

Among the main situations in which use in human food is authorised are:

- Hydrogen peroxide. Authorised in Spain, up to a maximum dose of 5 000 mg/kg, for bleaching natural tripes (BOE, 1986) and decontaminating water intended for human consumption (BOE, 2003).
- Acetic acid. Food additive (E260) authorised by Regulation (EC) No 1333/2008 (EU, 2008b), with a specific maximum dose of *quantum satis.*
- Peracetic acid. Authorised in human food (as a food additive or processing aid) in various countries such as Canada or Australia. Solutions containing peracetic acid are also authorised in human food (France and the United States of America).
- Both of the stabilisers used are authorised or present in human food.

In addition to the above, Table 1 presents other authorised uses.

Table 1. Authorised uses

Substance	Authorised use	Country/Reference
Hydrogen peroxide	Regulation (EC) No 853/2004 establishes a hydrogen peroxide residue level of 10 mg/kg for finished gelatines (those obtained from bones, hides and skins of farmed ruminants, pig skins and poultry skins).	European Union (EU, 2004)
	Its use is permitted for producing gelatine from products of animal origin.	European Union (EU, 2008a)
	Its use is authorised in bleaching of natural tripes (maximum dose 5 000 mg/kg).	Spain (BOE, 1986)
	Its use is authorised as a substance 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 (AESAN, 2011)
	Its use is authorised as a processing aid for tripes.	France (Arrêté du Ministère de l'Economie, des Finances et de l'Industrie, 2006)
	Favourable toxicological assessment as a processing aid in the manufacture of whey for baby milks.	France (AFSSA, 2005a, 2007)
	Favourable toxicological evaluation in solution with peracetic acid and acetic acid for the microbiological decontamination of flour.	France (AFSSA, 2006, 2010)
	Classified as GRAS (Generally Recognised As Safe) (21 CFR 184.1366) by the FDA (Food and Drug Administration) authorising its use in milk (0.05 %), whey (0.04 %), whey cheese coloured with annatto (0.05 %), starch (0.15 %), corn syrup (0.15 %) and emulsifiers (1.25 %).	United States of America (FDA, 2011a)
	Authorised for treating chicken organs and carcasses (21 CFR 173.370).	United States of America (FDA, 2012a)
	Its use is authorised as a processing aid (bleaching agent) in foods, for which a maximum residue level of 5 mg/kg is laid down.	Australia (ANZFSC, 2011)
Acetic acid	Authorised as a food additive (E260) by Regulation (EC) No 1333/2008, with a specific maximum dose of *quantum satis*.	European Union (EU, 2008b)
Peracetic acid	Its use is authorised as a processing aid for paracetic acid in a solution with hydrogen peroxide and acetic acid for cleaning eggshells intended to manufacture *île flottante*.	France (Arrêté du Ministère de l'Economie, des Finances et de l'Industrie, 2006)
	Favourable toxicological assessment of a solution of peracetic acid (15 %), hydrogen peroxide (23 %) and two stabilisers[1] as a processing aid for the decontamination of flour in wheat milling.	France (AFSSA, 2006, 2010)
	Favourable toxicological assessment of a solution of peracetic acid (approximately 10 %), hydrogen peroxide (approximately 5 %) and acetic acid (approximately 10 %) for washing ready-to-eat salads.	France (AFSSA, 2005b)

Table 1. Authorised uses

Substance	Authorised use	Country/Reference
	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 of America (FDA, 2012b)
	The additive that is a mixture of peracetic acid, octanoic acid, acetic acid, hydrogen peroxide and HEDP is authorised as a disinfectant for meat carcasses, parts, trim and organs with a maximum peroxyacid concentration of 220 mg/kg for peracetic acid and 75 mg/kg for hydrogen peroxide.	United States of America (FDA, 2012a)
	Included in the Effective Premarket Notification database of substances in contact with food.	United States of America (FDA , 2011b)
	Authorised as a food additive (starch modifying agent).	Canada (DJC, 2012)
	Authorised as a processing aid as a bleaching agent for washing and peeling, and as a catalyst with a maximum level permitted of 0.7 mg/kg.	Australia (ANZFSC, 2011)

[1]The manufacturer indicates that the product assessed by AFSSA has the same components (active substances and stabilisers) as the product proposed but in different concentrations.

Other uses of the same product authorised in Spain are as a pesticide (bactericide-fungicide) for use in the food industry (contact disinfection of surfaces and equipment and air disinfection) and for environmental use (contact and air disinfection). The applicant indicates that the active substances are included in Regulation (EC) No 1451/2007 (EU, 2007) (Annex I lists the existing unauthorised biocidal substances). This notification indicates that during a period of transition they can be used whilst these uses are assessed.

4. Acceptable Daily Intakes

None of the components of the product has an established ADI.

It is also pointed out that this type of formula has been assessed by several international bodies. Thus, for antimicrobial peroxyacid solutions such as hydrogen peroxide, acetic acid and peracetic acid, including hydroxyethylene diphosphonic acid as a stabiliser, JECFA (2004a) considers the quantities of residues in treated foods not to be any cause for concern in terms of health safety at the moment of their consumption in the intended conditions of use.

Physicochemical characteristics

1. Composition and detailed formula

The product proposed as a processing aid is an aqueous solution of hydrogen peroxide and acetic acid in chemical equilibrium with peracetic acid and water. As set out in the application, together with the active compounds, the product contains two chelating-type stabilisers in chemical equilibrium below 0.5 %. Table 2 shows the detailed formulation of the processing aid.

Table 2. Composition of the processing aid

Component	Function	CAS No	Molecular weight	Product specifications (% w/w)	Analysis certificates
Hydrogen peroxide	Active substance	7722-84-1	34 g/mol	21-24 %	25.61±0.10 (% w/w)
Acetic acid	Active substance	64-19-7	60.1 g/mol	7-9 %	–
Peracetic acid	Active substance	79-21-0	76.1 g/mol	4.5-5.4 %	5.03±0.15 (% w/w)
	pH			1	–

2. Product specifications

Table 2 presents the specifications of the product and the results of the analyses of three batches of the proposed processing aid (mean ± standard deviation).

Product stability

The stability of the preparation is 12 months according to the study conducted by the manufacturer over 24 months at room temperature using a product with a different commercial name but, as explained by the applicant, with identical composition to that proposed as a processing aid.

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):

$H_2O_2 + 2H^+ + 2e^- \rightarrow 2\ H_2O$

$CH_3COOOH + 2H^+ + 2e^- \rightarrow CH_3COOH + H_2O$

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

$H_2O_2 \rightarrow H_2O + ½\ O_2$

$CH_3COOOH + H_2O \rightarrow CH_3COOH + H_2O_2$

$CH_3COOOH \rightarrow CH_3COOH + ½\ O_2$

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

Furthermore, the use of this kind of solution does not seem to negatively affect the nutrient content (vitamin C and ß-carotene) present in fruit and vegetables as indicated by JECFA (2006). Similarly, EFSA (2005), in assessing the use of peroxyacids to treat chicken carcasses, concludes that there were no

perceived effects on proteins and lipids in the products treated. Bearing in mind the low proportion of proteins and lipids (<1 %) in the products to which the treatment is to be administered (citrus fruits and peppers), no significant effects are expected in this sense.

Technological function

1. Alleged technological use

The applicant relates that the alleged technological use is as a bacterial disinfectant of citrus fruits and peppers as well as washing waters. Citrus fruits and peppers are washed when they arrive at processing plants in order to minimise contamination or recontamination during this first phase of the process. This also enables the disinfection of the water used for washing, as this water is used in the consecutive washing of the fruits and vegetables through a recirculation system which makes it necessary to use a disinfectant to keep the washing water in suitable conditions.

It also enables water consumption to be reduced by recycling and reusing it, avoiding waste emission with a high chemical pollution levels on aquifers in particular, unlike other disinfection methods used frequently in the sector (for example: trihalomethanes formed after the water chlorination process). According to what is stated, water consumption in citrus fruits under drench treatment is approximately 2 000 l/day to wash 100 tons of fruit and 4 000 l/day for every 100 tons of peppers in the post-harvest wash.

Other advantages cited by the applicant, in addition to its efficiency and the fact that it does not alter the organoleptic properties of the vegetable products treated, are its low phytotoxicity and the ability to apply it together with fungicides. As highlighted by the applicant, there is a very limited number of disinfectants that comply with all the necessary criteria (disinfection of the treatment liquid, safety for consumption of the fruit and vegetable products treated, elimination of the possibility of reinfection or infection from cross-contamination, absence of risk to consumer health from degradation and/or waste products, the possibility to combine with plant protection products, no effect on organoleptic properties). Combinations of peracetic acid and hydrogen peroxide are almost the only that are effective.

2. Target foods or food group

The target foods or groups of foods are citrus fruits and peppers.

3. Level of use required

According to the applicant, on the basis of the trials performed, the dose of the processing aid to be used shall be 0.6 % for citrus fruits and peppers.

4. Justification of use, interest and effectiveness

In accordance with various studies (FAO/WHO, 2009) (EFSA, 2013), the main pathogenic microorganisms linked to diseases that affect human beings as a result of the consumption of fresh, non-animal products, among which fruit and vegetables, are *E. coli*, *Salmonella* spp., *Shigella* spp., *Listeria monocytogenes*, *Cryptosporidium* spp., *Cyclospora* spp. and *Clostridium botulinum*. These

sources also cite several enteric viruses as pathogens (Norovirus or the hepatitis A virus). There has also been a perceived increase in health alerts linked to contamination from microorganisms that are pathogenic for human health in foods of non-animal origin (EFSA, 2013). The *E. coli* VTEC O104 outbreak discovered in 2011 in Europe in sprouts, which affected 3 800 people and caused 53 deaths, is an example of how foods of non-animal origin –even those not widely consumed– can have a significant impact on public health (EFSA, 2013). In fresh fruit and vegetables the largest proportion of contamination from microorganisms pathogenic for human health are due ultimately to factors existing before harvest. Potential sources of contamination at different stages of cultivation can be: irrigation water, fertilisers and manure, contaminated instruments, poor hygiene of field workers, etc. Furthermore, even in fruits and vegetables consumed with minimal post-harvest handling/processing, there is a higher risk of microbiological contamination from cross-contamination in phases subsequent to harvesting, which increases the risk to human health. Processes such as washing and packing are very common practices in the majority of fruits and vegetables intended to be consumed fresh. These processes are crucial aspects when it comes to microbiological contamination.

The processes of post-harvest washing with drinkable water can succeed in eliminating only some of the microorganisms present on the surface of the fruit; they do not act as disinfecting treatment. The post-harvest washing stage is crucial. These processes require the use of large quantities of water, making it essential to recycle water to save resources and minimise the environmental impact of this practice. In fruit and vegetable washing systems with water recirculation, if the water is not disinfected properly, it acts as a means of transferring microorganisms, leading to cross-contamination of the fruit washed.

In the fruit and vegetable sector, 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 which enables the fruits or vegetables to be wet to the perfect level. In both methods, proper maintenance of the washing liquid or water is fundamental, because this is recirculated through the fruit pallet by pallet, which sends both the remains of the chemical treatments previously applied to cultivation and some of the dirt from the harvest (leaves, branches, earth, etc.) and from the fruit itself, as well as pathogenic microorganisms and spores deposited in vegetable matter. This situation causes the accumulation of contamination to increase considerably with each recirculation, making the device a source of dissemination of microorganisms which can affect the safety of the products. To avoid the washing water 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 degradation products and residues from the antimicrobial agent used do not pose a risk to the health of the consumer or the environment, that they do not alter the organoleptic properties of the fruit or vegetable (Gil et al., 2009) (Kyanko et al., 2010) and that they can be combined with plant protection products without degrading them. To show that the plant protection products used in the case of citrus fruits jointly with the proposed product do not degrade, the company provides studies assessing the stability of post-harvest fungicides used in the presence of peracetic acid and the product in citrus fruits (1.1 % w/v).

As regards the effectiveness of the processing aid proposed, it is stated that the behaviour of these hydrogen peroxide, acetic acid and peracetic acid solutions is similar to that of chlorogenic acids. In

other words, this kind of solutions has high oxidising power but, unlike chlorogenic acids, their action is less corrosive, they have a wider range of action, they are effective in the presence of organic material and hard water and the products they generate when they react are oxygen, water and acetic acid. Another major advantage when compared with chlorination (the most frequently used disinfection method in the sector) is the elimination of the hazard posed by the formation of trihalomethanes and chlorine vapours, as the oxidation reaction of the organic material resulting from the action of the peracetic acid generates oxygen and acetic acid, substances which are not toxic (Vero et al., 2004) (Gil et al., 2009).

Studies on effectiveness

The company provides trials to assess the effectiveness of the product in controlling microbial contamination present on the surface of peppers and citrus fruits as well as the contamination that accumulates in washing water after the recirculation that takes place in post-harvest washes. Specifically, the following trials have been conducted:

1. Peppers

Four pilot-scale trials and one laboratory trial were conducted.

2. Citrus fruits

As in the previous case, the applicant company conducted several trials to test the bacteriological quality (total aerobic bacteria) resulting from the use of the product proposed as a processing aid. Specifically, three pilot-scale trials and one laboratory trial were carried out using clementine mandarins and *Navel-late* oranges.

3. Other trials

In addition, the applicant company has provided the results of a trial conducted in an independent laboratory. To test the effectiveness of the processing aid, samples of peppers, citrus fruits and water were inoculated with ATCC strains of *Escherichia coli*, *Enterococcus faecalis* and *Clostridium perfringens*. In the case of citrus fruits and peppers, the fruits were subsequently submerged in a suspension of water and the product at 0.5 % and 0.6 %, the samples were left to dry and the subsequent count was taken. In the case of the water, the sample was inoculated and the product was added to it at 0.5 % and 0.6 %, then the count was taken. The recovery percentage following inoculation was also observed by analysing control samples (with no disinfecting treatment).

To determine aerobic bacteria, the PCA culture medium was used (incubated at 30 ºC for 72 hours). For *Clostridium perfringens* the culture medium used was Perfringens Agar BASE incubated to 37 ºC for 48 hours.

In the case of citrus fruits and peppers at the proposed usage dose (0.6 %) <10 CFU/g are recuperated and in the case of water recuperation is lower than 1 CFU/g.

Interpretation and discussion of the results of the studies on effectiveness

In the recirculation systems of drinkable water without treatment used for pre-washing peppers or drencher washing of citrus fruits, a large total number of bacteria were found, such as coliforms and *E. coli* at some points during the washing process. This contamination can pass to the surface of the fruit during processing.

To avoid this potential cross-contamination, bearing in mind the results obtained in the pilot trials presented, in order to be able to guarantee the control of microbiological contamination in washing water used for peppers and citrus fruits, a 0.60 % usage dose of processing aid has been established. The dose must be kept constant throughout the washing process and it is observed that after continuous washing (with recirculation) of 40 and 60 tons of peppers and citrus fruits respectively, the microbiological quality of the water is preserved. To this end, studies have been presented that set out the microbiological parameters stipulated in Royal Decree 140/2003 (BOE, 2003), which lays down the public health standards for the quality of water intended for human consumption *(E. coli, Enterococcus, Clostridium perfringens)* and in the conditions studied 100 % effectiveness was observed.

At the proposed usage dose, both in peppers and in citrus fruits, effectiveness in industrial trials has been above 97 %.

The applicant states that no phytotoxic effect has been detected for pepper, nor in the different varieties of citrus fruits, which were washed at the stipulated usage dose of 0.6 % processing aid. They also affirm that no alterations in the organoleptic quality of the peppers were found at any of the doses trialled. In some types of citrus fruit damages by phytotoxicity were observed on the skin at processing aid doses above 0.6 %.

5. Description of the process

Ways of adding the technological processing aid

In the application presented, the procedure for applying the processing aid is described in detail. Inclusion of the processing aid proposed for the process takes place during washing treatment of the fruit and vegetable products when they reach processing plants. For this, the treatment water is added using a programmable automatic dosage system with the aim of guaranteeing at all times that the added dose is the right one. At the same time, devices for measuring the concentration of peracetic acid are added to the tanks. These enable them to be regulated such that the acid maintains a consistent concentration. The washing system used varies according to the product being treated. Peppers are treated in tanks while oranges are treated using the drencher system.

Identifying the processing aid elimination phases

As instructed by the applicant, the active substances are decomposed into acetic acid, water and oxygen, with no residues remaining on the surface of the fruit and vegetable products once they have undergone the process of rinsing with potable water.

Taking the above into account, when talking about reactivity, the active components (peracetic acid and hydrogen peroxide), upon contact with the foods, would decompose rapidly into acetic acid, oxygen and water, and the quantities of acetic acid that might remain as a result of decomposition of the peracetic acid do not pose a safety concern (JECFA, 2004a).

However, *a priori*, it cannot be discounted that residues from the stabilisers may be present, considering that the processing aid is added to the treatment water using a programmable automatic dosage system with the aim of guaranteeing that the concentration of the active ingredients remains constant at all times. Because, in principle, the stabilisers do not degrade, their concentration could keep increasing as the water is used in successive cycles.

Therefore the company was asked to conduct a study of the residues of the stabilisers in citrus fruits and peppers treated with the processing aid under assessment at 0.6 %, following the procedure set out in the application.

Analysis of residues

Several studies have analysed the disinfecting characteristics of these systems and their toxicological properties. JECFA carried out an assessment of the antimicrobial peroxyacid solutions which contain hydrogen peroxide (4-12 %), acetic acid (40-50 %), octanoic acid (3-10 %), hydroxyethylene diphosphonic acid (<1 %) in equilibrium with peracetic acid (12-15 %) and peroxyoctanoic acid (1-4 %). JECFA considers 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). EFSA (2005) assessed the use in poultry carcasses of a solution 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 (<1 %). Total peroxyacid content, expressed in peracetic acid, is 220 mg/l and the maximum concentration of hydrogen peroxide is 110 mg/l. 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.

As mentioned in Section 1, the processing aid is classed as a Situation 4: substance authorised in human food whose ADI is not established and whose use can lead to the presence of residues that are technically unavoidable, 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).

Bearing in mind the technical difficulties in determining residues of stabilisers in the fruits treated, the applicant analyses the residues in the fruit treatment and rinsing liquids after having undergone treatment as an indirect measurement of any residues remaining on the fruit.

1. Analysis of residues in treatment liquids

Treatment liquids were analysed with the processing aid being assessed at a dosage of 0.6 %, recently prepared, and liquids used at the end of treatment of peppers and citrus fruits under pilot conditions (after four days of continuous work for peppers and a month of continuous work for citrus fruits).

It is observed that in this way the peracetic acid is preserved or slightly reduced in end treatment liquids for peppers and citrus fruits respectively, because of the continuous dosage compensating for

their degradation, and the phosphate-type stabiliser disappears, the nitrogen-type stabiliser does not degrade and they accumulate in the end treatment liquid for citrus fruits and, to a lesser degree, that used for peppers.

2. Analysis of residues from the fruit rinsing liquid

Before being dried and prepared, the fruits treated with the processing aid undergo a phase of rinsing with running water, which makes it possible to reduce any residues from hydrosoluble substances on the surface of the fruit, such as the ingredients under consideration. The applicant performed an analysis after using the final treatment liquid and after the rinsing with running water in an industrial washer with the water drained from the fruit. Only residues of 0.11 mg/kg of the nitrogen stabiliser were detected in the drained pepper water. In addition, a theoretical estimate was made of the maximum quantities of residues in peppers, oranges and orange peel, assuming that the entire processing aid remained in the treated fruit (with no degradation, evaporation, etc.) and that 0.018 l water/kg fruit was used to rinse peppers and 0.007 l water/kg fruit to rinse oranges. According to this estimate, only residues from the nitrogen stabiliser would be found on oranges and peppers. In a less favourable scenario, in which rinsing did not eliminate any of the processing aid retained on the fruits, the quantities of residues from the nitrogen stabiliser could reach 0.0168 mg/kg for citrus fruits and 0.0079 mg/kg for peppers.

In accordance with the guidelines for processing aids (AESAN, 2010), the possible presence of residues indicates the need to assess their safety. After the Scientific Committee's assessment of the data on the safety of the nitrogen stabiliser and the study of consumption and assessment of the expected level of intake of this stabiliser on the part of the consumer, it is observed that, even in the worst scenario, extreme consumers of both fruits (percentile 97.5 %) and assuming that all residues found in the rinsing water remain on the surface of the fruit, the MOS (Margin of Safety) is very high and, as such, no risk is posed to the consumer.

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the application file for use of this technological processing aid in the process of bacterial disinfection of citrus fruits and peppers as well as washing waters, concludes that, based on the information provided by the applicant and the proposed dosage and conditions, there is no risk posed to consumer safety.

The conclusions of this report refer exclusively to the product under assessment as a processing aid under the conditions of use proposed and with its current composition, both as regards its active components and its stabilisers. They cannot be extrapolated to other formulas or conditions other than those assessed.

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