Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the safe use of an aqueous solution of dioxygen chloride (chlorine dioxide) as a processing aid for the bacterial disinfection of water for washing tomatoes in processing plants

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Working group

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Abstract

The company Servicios Técnicos de Canarias S.L.U. has requested an assessment of the safety of using an aqueous solution of dioxygen chloride (chlorine dioxide) (0.75 %) as a processing aid, with commercial designation AGRI DIS. The proposed use is the antibacterial treatment of water used for washing tomatoes in processing plants.

The dose of the processing aid to be used will be 0.04 %, such that the final concentration of chlorine dioxide in the washing solution is 3 ppm.

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Considering the most adverse scenario of the presence of residues in tomatoes and their consumption in Europe, an Estimated Daily Intake (EDI) of the possible residues as well as a consumer risk assessment have been made.

It is the conclusion of the Scientific Committee that, based on the information provided by the applicant and taking into account the proposed composition and conditions of use, the use of the aqueous solution of chlorine dioxide as a processing aid does not pose risks to consumer health.

Key words

Tomato, processing aid, bacterial disinfection, dioxygen chloride, chlorine dioxide, risk assessment.

Suggested citation

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1. Introducción

The company Servicios Técnicos de Canarias S.L.U., located in Las Palmas, Gran Canaria, has requested a safety assessment of the use of an aqueous solution of dioxygen chloride (cited as chlorine dioxide in this report) (0.75 %), with commercial designation AGRI DIS, as a processing aid for the bacterial disinfection of water used for washing tomatoes upon arrival at the processing plant.

In light of said request, the Management Board of the Spanish Agency for Food Safety and Nutrition (AESAN), has requested the Scientific Committee to assess the safety of using the aforementioned aqueous solution as a processing aid for the bacterial disinfection of water used for washing tomatoes upon arrival at processing plants, bearing in mind the "Guidelines on precise documentation required for evaluation of processing aids that are intended for use in human food" (AESAN, 2010).

The authorised uses of chlorine dioxide in human food include its use as an antimicrobial agent, processing aid or additive in some countries.

Likewise, a Tolerable Daily Intake (TDI), expressed as chlorine, of 0.03 mg/kg b.w. has also been established for chlorine dioxide (CMA, 1997) (IPCS, 2000) (EFSA, 2005). Given that we cannot discard the presence of residues in the final product after the use of this aqueous solution, the processing aid is classified under Situation 2 (AESAN, 2010). In light of this situation, the product applicant submits information relating to the following aspects:

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

2. General presentation and physicochemical characteristics

2.1 Detailed composition and formulation

The product proposed as a processing aid, with trade name AGRI DIS, is an aqueous solution of pure and stable chlorine dioxide (99.9 %) with a concentration of 0.75 %. Table 1 lists its composition.

Table 1. Composition of the processing aid

Component	Formula	CAS No.	Molecular weight (g/mol)	Concentration (%)
Chlorine dioxide	ClO_2	10049-04-4	67.45	0.75
Water	H_2O	7732-18-5	18.05	99.25

2.2 Product specifications

Table 2 displays the results of the analysis of three batches of the processing aid AGRI DIS.

Tabla 2. Declared concentrations and results of the analysis

Component	Concentration	Assay certificates		
Chlorine dioxide	0.75 %	0.77 %	0.75 %	0.77 %
Chlorites	-	13.5 mg/l	40 mg/l	10 mg/l

2.2.1 Product stability

The applicant has submitted a certificate on the stability of the aqueous solution of chlorine dioxide (AGRI DIS) for 30 days.

2.2.2 Reactivity

The main products of the reaction, resulting from the use of chlorine dioxide in water, are chlorite, chlorate and chloride ions (IPCS, 2000) (WHO, 2017). The following are examples of the reactions that take place (EFSA, 2005):

- reduction of chlorine dioxide in water to generate chlorite ions:
  $ClO_2 + e^- \rightarrow ClO_2^-$
- reduction of chlorite ion to chloride ion:
  $ClO_2^- + 4H^+ + 4e^- \rightarrow Cl^- + 2\ H_2O$
- decomposition of chlorine dioxide into chlorite and chlorate ions in an alkaline medium and with the absence of oxidisable substances:
  $2ClO_2 + H_2O \rightarrow ClO_2^- + ClO_3^- + 2H^+$

Regarding reactivity with the contact environment, it is indicated that chlorine dioxide does not react with oxidisable material to form trihalomethanes nor does it lead to the formation of chloramines (EPA, 1999) (IPCS, 2000) (Bello Aragón, 2015). Likewise, some authors highlight its capacity to destroy phenols, which cause bad odour and taste in drinking water; oxidise iron and manganese, enhancing their elimination; oxidise nitrites and sulphides to nitrates and sulphates, respectively, and the absence of reactivity to bromides to form bromates or other by-products of bromine (EPA, 1999) (Bello Aragón, 2015).

2.3 Authorised uses in human food

Table 3 contains examples of authorised uses of chlorine dioxide.

Table 3. Examples of authorised uses

Substance	Authorised uses	Country/Reference
Chlorine dioxide	Authorised as antimicrobial agent for use in water for processing birds and in water for washing fruits and vegetables (3 ppm of residual chlorine dioxide). Processing fruits and vegetables with chlorine dioxide must be followed by rinsing with drinking water or scalding, cooking or canning	United States (CFR, 2021)
	Authorised as antimicrobial agent for use in water for processing poultry meat (3 ppm of residual chlorine dioxide)	Chile (MSC, 2017)
	Authorised as processing aid for use in water (1 ppm available chlorine); and as bleaching, washing and peeling agent of foods (1 ppm available chlorine)	Australia (ANZFSC, 2021)
	Authorised as additive (dough whitening, maturing and conditioning agent) for use in flour	Canada (FDR, 2021)
	Authorised as substance used to disinfect drinking water (0.4 mg/l)	Germany (Umweltbundesamt, 2020)

Additionally, the applicant informs that notification has been made of the market launch of this product as biocide for the disinfection and sanitisation of drinking water in accordance with the second transitional provision of Royal Decree 1054/2002 (BOE, 2002).

2.4 Acceptable Daily Intakes

A Tolerable Daily Intake (TDI) has been established for chlorine dioxide, expressed as chlorine, of 0.03 mg/kg b.w. based on a No Observed Adverse Effect Level (NOAEL) of 2.9 mg/kg b.w./day derived from the effect of chlorite on neural development observed in rats (CMA, 1997) (IPCS, 2000) (EFSA, 2005).

3. Technological function

3.1 Claimed technological use

The applicant claims that the technological use is the bacterial disinfecting of water used for washing tomatoes in processing plants.

3.2 Requested level of use

As indicated by the applicant, the dose of the processing aid (AGRI DIS) to be used will be 0.04 %, such that the final concentration of chlorine dioxide in the washing solution is 3 ppm. The tomatoes shall be in contact with the washing solution for a period of 1 minute.

3.3 Justification of use, interest and efficacy

The first post-harvest processing of plant products is washing, and it is essential to maintain the hygienic conditions of the washing solution as it is recirculated, thus dirt from the harvesting passes into the solution, in addition to microorganisms deposited on the plant material. This may lead to increased accumulation of contamination in each recirculation. To prevent the washing solution from becoming a vector for the spread of microorganisms due to cross-contamination, it must be ensured that its microbiological quality is retained by using disinfectant products, provided it is guaranteed that the products of the degradation and residues do not pose a risk to consumer health or to the environment (AESAN, 2016).

As an advantage over other chlorine-based disinfectants used in this sector, the applicant highlights the absence of derivatives such as trihalomethanes or chloramines (EPA, 1999) (IPCS, 2000) (Bello Aragón, 2015). Likewise, chlorine dioxide possesses a wider range of action against pH than chlorine, as it is not pH-dependent.

3.3.1 Efficacy trials

The results of a trial conducted by an independent laboratory have been provided, which include the microbiological parameters established in Royal Decree 140/2003 that establishes the health criteria of water quality for human consumption (BOE, 2003). The analysis procedures used are those of the standard ISO9308-1:2014 for *Escherichia coli*, UNE EN ISO 14189: 2019 for Enterococcus and UNE EN ISO 78192: 2001 for *Clostridium perfringens*.

To conduct the trial, water samples from the washing plants were inoculated (in triplicate) with *Escherichia coli*, *Enterococcus faecalis* and *Clostridium perfringens*, the inoculum concentrations used being 10^7 to 2 x 10^8 cfu/ml. Tomatoes were added to these inoculated water samples in order to simulate the process generally performed in the plant. Next, the processing aid AGRI DIS was added until a concentration of 3 ppm was obtained in the washing water with the tomatoes, and it was left to act for 1 minute. Counts were made on the different samples of washing water both before washing the tomatoes (T0) and after 1 minute of applying the processing aid (T1); in the latter, all results obtained were lower than the quantification limit (1 cfu/100 ml) (Table 4).

Table 4. Results of the efficacy trial

Microbiological parameter	Counts	
	T0	T1
E. coli	8 x 10^4 cfu/100 ml	<1 cfu/100 ml
	2 x 10^5 cfu/100 ml	<1 cfu/100 ml
	6 x 10^4 cfu/100 ml	<1 cfu/100 ml
C. perfringens	5 x 10^3 cfu/100 ml	<1 cfu/100 ml
	3 x 10^4 cfu/100 ml	<1 cfu/100 ml
	8 x 10^3 cfu/100 ml	<1 cfu/100 ml
E. faecalis	1 x 10^5 cfu/100 ml	<1 cfu/100 ml
	9 x 10^4 cfu/100 ml	<1 cfu/100 ml
	2 x 10^5 cfu/100 ml	<1 cfu/100 ml

3.4 Description of the process

3.4.1 Forms of incorporating the processing aid

The processing aid AGRI DIS is included at the washing stage of the tomatoes upon their arrival at the processing plants, using shower/spraying or immersion as the washing system. For this, the processing aid is added to the recirculating circuit of the washing solution by means of an automatic dosing system. An amperometric system is used to keep the concentration of chlorine dioxide in the washing solution at 3 ppm. The contact time of the washing solution with the tomatoes is 1 minute.

3.4.2 Identification of the stages of elimination of the processing aid

As indicated by the applicant, once the tomatoes are washed, no additional process is required to eliminate the chlorine dioxide, as it is spontaneously eliminated by evaporation and/or photosensitivity.

Likewise, several Organisations have highlighted the high reactivity of chlorine dioxide in water, rapidly transforming mainly into chlorite ions, and in chlorate and chloride ions, also highlighting the rapid reduction of the remaining chlorine dioxide to chlorite and chloride after ingestion (IPCS, 2000) (EFSA, 2005) (WHO, 2017). In this regard, Directive (EU) 2020/2184, on the quality of water intended for human consumption, establishes certain parametric values for chlorate and chlorite of 0.25 mg/l, indicating that the applied value shall be 0.7 mg/l when a disinfection method that generates chlorate is used, particularly chlorine dioxide, to disinfect water intended for human consumption, although a transition period has been established, until 2026, with regard to the compulsory need to monitor these values (EU, 2020a).

In relation to the possible presence of these by-products of the reaction in tomatoes processed with the aqueous solution of chlorine dioxide, the applicant presents the results of a study on chlorate residues.

4. Residue studies

The results of a study on the presence of chlorate residue in tomatoes, conducted by the Centre of Edafology and Applied Biology of Segura (CEBAS) of the Higher Council for Scientific Research (CSIC) at a washing plant, are given. For the study, the washing solution was prepared by using a dosing pump to add the processing aid to the recirculation tank, which contained dirty water from washing the boxes.

Next, approximately 600 kg of tomatoes were added to the washer and the washing solution was sprayed on them by means of a sprinkler system. The initial concentration of chlorine dioxide in the washing solution was 2.9 mg/l, the average concentration during the washing process being 2.7 ± 0.3 mg/l. As indicated by the applicant, the decrease in the concentration may be due to factors such as the loss of chlorine dioxide when spraying tomatoes, loss due to contact with surfaces, or the presence of oxidisable substances in the washing solution.

After the washing was over, chlorate residues was analysed in 10 samples of washing solution and 12 samples of tomatoes via High Performance Liquid Chromatography attached to Mass Spectrometry (HPLC-MS).

In the case of washing solutions, the results showed an average chlorate concentration of 45.9 ± 0.5 mg/l. As indicated by the applicant, this high concentration may be the result, for example, of a prolonged staying period of the processing aid in the solution before washing. With regard to the tomato samples, it was assumed that chlorates would be present principally on the surface and not in the pulp. Therefore, the tomatoes were peeled and a 10 g sample of skin was analysed. The results of the analyses conducted on the samples of tomato skin revealed chlorate concentrations higher than 0.01 mg/kg in all cases, the maximum concentration being 0.04 mg/kg.

With reference to the regulatory framework, Regulation (EU) 2020/749 sets temporary Maximum Residue Levels (MRL) for chlorate in certain products, between 0.1 and 0.7 mg/kg, according to the ALARA principle (As Low As Reasonably Achievable), considering that these residues are not derived from the use of pesticides, but from the use of chlorine-based solutions in food processing and in the treatment of drinking water. This approach ensures that food business operators apply measures to prevent and reduce the chlorate levels in food as far as possible in order to protect public health, but also takes into account the need for microbiological safety of food. For tomatoes, the temporary MRL for chlorate is 0.1 mg/kg (EU, 2020b).

5. Studies and data relating to the innocuousness of chlorate

The presence of chlorate in foods and drinking water was subjected to assessment by the European Food Safety Authority (EFSA) in 2015. This assessment highlighted the use of chlorinated water in food processing and the disinfection of equipment as one of the main sources of chlorate in foods, and established a Tolerable Daily Intake (TDI) of 3 µg chlorate/kg b.w., a critical effect of chronic exposure to chlorate being the inhibition of iodine capture by the thyroid in adults. Likewise, for acute exposure, a reference dose (ARfD) of 36 µg chlorate/kg b.w. was established, with methaemoglobin formation identified as a critical effect (EFSA, 2015).

For all the population groups studied, drinking water was identified as the main contributor to both

chronic and acute exposure to chlorates, the average chlorate concentrations detected being 28 and 39 µg/l, considering the Lower Bound (LB) and Upper Bound (UB), respectively. In this regard, considering the LB of concentration, the contribution of drinking water to chlorate exposure was 25-58 % in infants, 12-48 % in toddlers aged 1 to 3, 0-38 % in children aged 3-9 and in adolescents, 6.2-48 % in adults, 8.1-35 % in the elderly and 5.5-39 % in the very elderly.

With regard to the total dietary exposure to chlorates and considering mean consumptions, the estimates of chronic exposure range between 0.5 µg chlorate/kg b.w./day in adolescents (considering the LB) and 4.1 µg chlorate/kg b.w./day in the case of children below the age of 1 (considering the UB), whereas for the 95th percentile, the highest exposure was in children under the age of 1 (6.6 µg chlorate/kg b.w./day, considering the UB). In the case of acute exposure, the estimates ranged between 1.0 µg chlorate/kg b.w./day (adolescents, UB) and 13 µg chlorate/kg b.w./day (children below the age of 1, UB) considering mean consumptions, whereas for the 95th percentile, the estimates ranged between 2.6 µg chlorate/kg b.w./day (adolescents) and 31 µg chlorate/kg b.w./day (children below the age of 1). Considering the consumption of individual foods (for the 95th percentile and the range of UB concentrations), the estimate of the highest acute exposure corresponded to drinking water (32 µg chlorate/kg b.w./day).

In the case of adolescents and adults, the estimates of chronic exposure (for the mean and the 95th percentile) were in all cases lower than the established TDI (3 µg chlorate/kg b.w./day), whereas the TDI was exceeded in the children's groups (below the age of 1 and between 1 and 3 years old) in all cases when considering elevated consumptions (95th percentile) and in some cases, when considering high levels of chlorates (UB). With regard to the estimates of acute exposure, the established ARfD was not exceeded in any case (EFSA, 2015).

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

To obtain the estimate of chlorate exposure, the data on the EU Member State with the highest consumption (chronic) of tomatoes (mean and 95th percentile consumers only) for both for adults and toddlers (aged 12 to 35 months), and infants below the age of 1, was used in accordance with the Comprehensive European Food Consumption Database of EFSA (2021) (data updated as of May 2021).

In the case of infants below the age of 1, the highest consumption of tomatoes (from the sum of the consumption of tomatoes, tomato juice, and concentrated tomato paste in Cyprus) is 10.61 and 14.38 g/kg b.w./day for the mean and the 95th percentile, respectively. For toddlers aged 12-35 months, the highest consumption is 8.17 and 15.29 g/kg b.w./day for the mean and the 95th percentile (data from Bulgaria) respectively, while in the case of adults, the highest consumption (data from Germany) is 3.10 and 8.46 g/kg b.w./day for the mean and the 95th percentile, respectively.

With reference to the highest concentration of chlorate detected in the tomato skin (0.04 mg/kg) compared to the tomato as a whole, and considering that the skin is approximately 8.5 % of its weight (Barriger et al., 1999), we obtain a concentration of 0.0034 mg chlorate/kg of tomato.

The Estimated Daily Intake (EDI) of chlorates is calculated on the basis of this concentration (0.0034 mg/kg) and the consumption data (Table 5).

Table 5. Estimate of chronic chlorate exposure

Population	Consumption of tomatoes (g/kg b.w./day)		EDI chlorate (mg/kg b.w./day)	% TDI
Infants (<1 year)	Mean	10.61	0.00004	1.20
	P95	14.38	0.00005	1.63
Toddlers (12-35 months)	Mean	8.17	0.00003	0.93
	P95	15.29	0.00005	1.73
Adults	Mean	3.10	0.00001	0.35
	P95	8.46	0.00003	0.96

The EDI represents 1.2 and 1.63 % of the TDI established by the EFSA (3 µg chlorate/kg b.w.) for the mean and the 95th percentile respectively, in the case of infants below the age of 1; 0.93 and 1.73 % respectively in toddlers aged 12-35 months; and 0.35 and 0.96 % respectively in adults.

Likewise, as an ARfD for chlorate has been established, an estimate of acute exposure has also been made (Table 6), following the same criteria as in the case of chronic exposure.

Table 6. Estimate of acute chlorate exposure

Population	Consumption tomatoes (g/kg b.w.)		EI chlorate (mg/kg b.w.)	% ARfD
Infants (<1 year)	Mean	11.14	0.00004	0.11
	P95	26.44	0.00009	0.25
Toddlers (12-35 months)	Mean	14.18	0.00005	0.13
	P95	25.68	0.00009	0.24
Adults	Mean	5.31	0.00002	0.05
	P95	14.70	0.00005	0.14

In the case of infants under the age of 1, Estimated Intakes (EI) of 0.00004 and 0.00009 mg chlorate/kg b.w./day are obtained for the mean and the 95th percentile respectively, which entails 0.11 and 0.25 % of the ARfD (36 µg chlorate/kg b.w.). With regard to toddlers between 12 and 35 months of age, the EI is 0.13 % and 0.24 % respectively of the ARfD, while in adults, this percentage decreases to 0.05 and 0.14 % respectively.

Conclusions of the Scientific Committee

Having assessed the request for use of an aqueous solution of dioxygen chloride (chlorine dioxide), with commercial designation AGRI DIS, as a processing aid for the bacterial disinfection of water used to wash tomatoes upon arrival at processing plants, and based on the information provided by the applicant and taking into consideration the composition and conditions of use proposed, the Scientific Committee deems that the use of the processing aid does not imply any risk to consumer health.

The conclusions of this report refer exclusively to the solution that is subject to assessment as a processing aid under the proposed conditions of use and in its current composition, and cannot be extrapolated to any formulations or conditions other than those assessed herein. One must bear in mind that the kg of tomatoes processed, the climate conditions, or dirt may influence the concentrations of the processing aid's components in the washing solutions and therefore, may influence the final residues.

This assessment does not constitute an authorisation for use nor does it affect any uses other than the use as a processing aid for the bacterial disinfection of water used to wash tomatoes upon arrival at processing plants.

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

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