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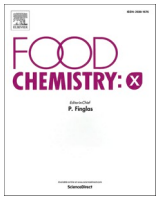

Acidic electrolyzed water: Food additive or sanitizer?

Dear Dr. Paul Finglas,

The term "food additive" has been used to describe "acidic electrolyzed water" in a lot of publications, especially in food and health fields (Table 1). It is important to indicate that in literature, various reports make unsubstantiated claims about the classification of "electrolyzed water" as a "food additive". Some sources state that certain countries, including Japan, Korea, and the USA, consider "electrolyzed water" a "food additive" (Q. Chen et al., 2023a; Ding et al., 2019; Liao et al., 2020; Zhang et al., 2024). However, other reports indicate that these same countries designate "electrolyzed water" as a "sanitizer" or "disinfectant" (Lee et al., 2014).

It appears that some authors mistakenly use the terms "food additive" and "sterilizer" interchangeably in describing "electrolyzed water". This confusion may stem from the varying definitions of the term "food additive" between Japan, where the industrial use of "electrolyzed water" originated, and other countries and international organizations. This Letter to the Editor aims to explore the reasons and the origin of this confusion.

To explore this issue, a literature search was conducted using three main database platforms: Web of Science, Science Direct, and Scopus (Table 1). Various combinations of terms related to "electrolyzed water" were utilized in this search, including "acidic", "electrolyzed", "water", "food", "additive", "sanitizer", "disinfectant", "oxidizing", "slightly", and "electro-activated". These terms were used both individually and in combinations, as shown in Table 1.

Due to the extensive number of references found in the literature by combining the terms "electrolyzed water" with "sanitizer" or "disinfectant," which totaled hundreds or even thousands, I decided to focus on those related to "food additive" and "acidic electrolyzed water" from the ScienceDirect database. However, I also included some additional references pertaining to the use of "electrolyzed water" with "sanitizer", "disinfectant", and those related to both "food additive" and "disinfectant/sanitizer" as seen in Table 2.

It is important to note that the term "food additive" used in conjunction with "acidified electrolyzed water" appears less frequently than the terms "sanitizer" or "disinfectant". For instance, in the ScienceDirect database, the usage counts for these terms are as follows: 319 for "food additive", 1257 for "sanitizer", and 1173 for "disinfectant" (Table 1).

Another point mentioned in Table 2 is that although some papers claim that "electrolyzed water" has been approved as a "food additive" in Japan, Korea, and the USA, the literature review indicates that only Japan has adopted this designation, as this will be discussed further below.

Before addressing whether "acidic electrolyzed water" is considered a "food additive" or "sanitizer", especially in Japan, it's important to understand how Japanese food agencies define food additives.

The Food Safety Standards and Evaluation Division of the Consumer Affairs Agency in Japan (https://www.caa.go.jp/en/policy/standards_evaluation/food_additives_en) mentions that "*the Ministry of Health, Labour and Welfare (MHLW) enacted the Food Sanitation Act (FSA) as the first comprehensive Act for food safety/hygiene, and introduced a positive list system for food additives*". After that, the Food Sanitation Act (FSA), in the first Chapter, defines "food additive" as:

"*Food additives:*

(1) *Substances used in or on food in the process of manufacturing food, or*
(2) *Substances used for the purpose of processing or preserving food.*

Consequently, "food additive" includes both substances remaining in the final products, such as food colors and preservatives, and substances not remaining in the final products, such as microorganism control agents and filtration aids.".

The FSA clearly states that "*the scope of food additives it refers to is different from that defined by the Codex Alimentarius Commission (CAC)*". It continues to clarify that "*The substances given below, which are not defined by the CAC as food additives, are all categorized as food additives in Japan.*

(1) *Processing aids,* like infiltration-supporting agents*
(2) *Vitamins, minerals, and amino acids*
(3) *Flavoring agents*

** Processing aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product (CAC, Procedural Manual, "Section I : Definitions for the purpose of the Codex Alimentarius")*".

FSA categorizes food additives based on their roles and effects (Bureau of Public Health, Tokyo Metropolitan Government; https://www.hokeniryo.metro.tokyo.lg.jp/shokuhin/eng/shokuten/shokuten2.html) as follows:

A. ***Food Sanitation Act categories***

(1) *Designated food additives*

Designated additives are substances that the Minister of Health, Labour and Welfare considers unlikely to harm human health, based on Article 10 of the FSA.

Notice: ONLY SUBSTANCES LISTED BELOW are allowed to use for food additives such as coloring, preservative, sterilizing, and manufacturing agents in Japan (excluding Natural flavoring agents and ordinary foods used as food

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Table 1
Results of search on ScienceDirect, ScienceDirect, and Scopus for "electrolyzed water".

Word/term combinations used in search	Number of results (references)		
	Web of Science	ScienceDirect	Scopus
Words			
"Electrolyzed", "Water", "Food", "Additive"	30	973	1419
"Acidic", "Electrolyzed", "Water", "Food", "Additive"	7	931	761
"Acidic", "Electrolyzed", "Water", "Sanitizer"	113	847	1641
"Acidic", "Electrolyzed", "Water", "Disinfectant"	126	906	1628
"Electrolyzed", "Water", "Sanitizer"	278	869	2356
"Electrolyzed", "Water", "Disinfectant"	296	945	2579
Terms			
"Electrolyzed Water", "Food Additive"	0	169	609
"Acidic Electrolyzed Water", "Food Additive"	0	84	339
"Electrolyzed Acidic Water", "Food Additive"	1	4	22
"Electrolyzed Oxidizing Water", "Food Additive"	1	0	303
"Slightly Acidic Electrolyzed Water", "Food Additive"	0	46	176
"Slightly Acidic Electro-Activated Water", "Food Additive"	0	13	0
"Electrolyzed Water", "Sanitizer"	278	698	2126
"Electrolyzed Water", "Disinfectant"	226	634	2115
"Slightly Acidic Electrolyzed Water", "Sanitizer"	34	183	866
"Slightly Acidic Electrolyzed Water", "Disinfectant"	51	187	750
"Acidic Electrolyzed Water", "Sanitizer"	87	376	1488
"Acidic Electrolyzed Water", "Disinfectant"	102	352	1403

additives).

(2) *Existing food additives*

Other than the designated additives, certain substances are permitted for use and distribution in Japan, as an exception, without the designation system provided by the FSA because they are widely used in Japan and have a long history of human consumption.

(3) *Natural flavoring agents*

Additives used for adding flavors, such as apples and green tea, and those obtainable from animals or plants like milk, which are generally used in small amounts and which have exhibited no adverse effects on health through many years of people eating them, are approved for use.

(4) *General food and drink additives.*

Articles that have generally been served for human consumption and that are used as additives

B. ***Categories by use***

Additives are categorized by their roles and effects as follows:

(1) *Items necessary for the production and processing of food*

These items are required for the production and processing of certain foods, including enzymes, filter aids, oil eluents, anti-foaming agents, and acidic and alkali processing aids.
Examples:

- *Coagulants for solidifying tofu.*
- *Kansui alkaline water used in the process making ramen noodles from wheat.*
- *Activated charcoal used when filtering beer, etc.*

(2) *Items used to improve food taste and appearance*

These items are added to improve food flavor and appearance to create attractive, high-quality food.
Examples:

- *Colorings, color fixatives, and bleaching agents to improve food color*
- *Flavoring agents to add fragrance*
- *Sweeteners and seasonings to improve food taste*
- *Emulsifiers and thickening agents to improve food texture.*

(3) *Items for improving food preservation and preventing food poisoning*

These items are used to prevent decomposition due to food oxidation or deterioration and microorganism propagation, as well as to improve food preservation.
Examples:

- *Preservatives*
- *Antioxidants*
- *Disinfectants and anti-mold agents*

(4) *Items which fortify food nutrition*

These items are used for fortifying and enhancing the existing nutritional content of food and for adding nutrients required by human beings.
Examples:

- *Vitamins*
- *Minerals*
- *Amino acids*

From the previous definition of Food Additives by FSA in Japan, we can derive the following notes:

I. The Japan Food Safety Standards and Evaluation Division's food additive list includes "hypochlorous acid water" under No. 177 but not "acidic electrolyzed water" (https://www.ffcr.or.jp/en/tenka/list-of-designated-additives/list-of-designated-additives.html).
II. Sterilizing agents, disinfectants, anti-mold agents, and acidic and alkali processing aids are considered food additives.

Regarding the Ministry of Health, Labor and Welfare's designation of

Table 2
Examples of the usage of the term "Electrolyzed Water" in the literature.

Description of EW	Country concerned	Identified sentence	Reference
Food additive	Japan, Korea, USA	"*EW (Electrolyzed Water) is also generally recognized as safe (GRAS) and already regarded as a legitimate food additive in the US, Japan, and Korea (Xuan et al., 2017).*"	(Ding et al., 2019)
	Japan	"*In Japan, EW is designated as a food additive in June 2002, and EW includes AEW and SAEW in the current ingredient standard. In addition, as the same sterilization agent of halogen type, sodium hypochlorite is designated in the year 1955, and advanced sarashmeal powder is designated as food additive in 1931 (Japan Food Safety Commission 2006).*". "*As early as 2002, EW has been designated as a food additive by the Ministry of Health, Labour and Welfare of Japan (Official Gazette No. 3378 MHLW Notification No. 212; MHLW 2002).*".	
	Japan	*"Japan's Ministry of Health, Labor and Welfare have approved Acid Electrolyzed Water (AEW) in 2002 as a food additive."*.	(Mostafidi et al., 2020)
	Japan	"*In 2002, it (AEW) was recognized as a food additive by Japan. At present, the use of AEW on fruits and vegetables has been officially approved by China, Japan, and USA*".	(Sun et al., 2022)
	Japan	"*Electrolyzed oxidizing water, a novel antimicrobial agent and permitted food additive in Japan, is produced by electrolysis of a diluted salt (NaCl) solution in a cell containing the anode and cathode electrodes that are separated by a membrane.*"	(Sikin et al., 2013)
	Japan, Korea, USA	"*Slightly acidic electrolyzed water has been approved as a food additive in the United States, Japan, and Korea*".	(Lee et al., 2014)
	Japan, Korea, USA	"*SAEW is a legal food additive in the United States, Korea, and Japan*".	(Zhang et al., 2024)
	Japan	"*SAEW has been approved as a food additive by the Japanese Ministry of Health, Labour and Welfare*".	(Okanda et al., 2019)
	Nd	*"Slightly acid electrolyzed water (SAEW) is a novel antimicrobial agent and has been widely approved as a legal food additive"*.	(He et al., 2023)
	Japan, Korea, USA	"*SAEW has been approved as a food additive in the US, Japan, and Korea*".	(Liao et al., 2020)
	Nd*	*"the primary objective of this study was to evaluate the effect of neutral EO water as a permanently administered water additive on water quality and performance of broiler chickens"*.	(Bügener et al., 2014)
	Japan	"*Electrolyzed acidic water has been approved as a food additive in Japan*".	(Koike & Suzuki, 2015)
	Japan	"*In 2002, it was recognized as a food additive (fungicide) by the Ministry of Health, Labor and Welfare of Japan, and it has been applied to the disinfection of food-processing utensils as well as fruits and vegetables*".	(Zhao et al., 2024)
	Japan, Korea, USA	"*In addition, as a food additive, SAEW has been applied in the U.S., Japan and Korea*".	(Kong et al., 2022)
	Nd	"*Slightly acidic electrolyzed water and sodium benzoate are recognized as safe food additives*".	(Chen, Tyagi, Vijayalakshmi, et al., 2022)
	Japan	"*Accordingly, the Japanese Ministry of Health, Labor, and Welfare has permitted EW as a food additive to inactivate pathogenic bacteria in various foods and on food processing surfaces*".	
	Japan	"*Since 2002 electrolyzed oxidizing (EOW) water has been an approved food additive in Japan as it reduces microbiological pollutants, particularly in vegetables*".	(Tyagi et al., 2022)
	Japan, USA	*"SAEW was identified as the legally permitted food additives of antibacterial agent that can be directly used on foods in Japan and America*".	(S. Wang et al., 2018)
	Japan	*"SAEW also has the advantage of having been a legal food additive in Japan since 2002 because of its biological safety and disinfection efficacy*".	(L. Li et al., 2018)
	Japan, USA	"*SAEW has been certified as a food additive by Japan Ministry of Health, Labour and Welfare (MHLW) and United States Food and Drug Administration (FDA)*".	(Y.-X. Chen et al., 2020)
	Japan	*"Acidic electrolyzed water that was first authorized as food additive and allowed to be used directly to food in Japan by the Japanese Ministry of Health, Labor and Welfare in 2002, has been applauded as a potential and an emerging non-thermal food sanitizer effective against a number of food pathogens"*.	(Issa-Zacharia et al., 2011)
	Japan, Korea, USA	*"Slightly acidic electrolyzed water (SAEW) is considered as a novel nonthermal sterilizing agent and it is already regarded as a legitimate food additive in US, Japan, and Korea*".	(Xuan et al., 2017)
	Japan, Korea, USA	*"In recent years, an increasing number of publications have indicated that SAEW can be used in the fresh produce industry. It has been approved as a food additive in the United States, Japan, and Korea"*.	(Chen, Tyagi, Chelliah, et al., 2022)
	Japan	"*Slightly AEW has been an authorized food additive in Japan since 2002 because of its proven biological safety and effectiveness as a bactericide even at low available chlorine concentrations (ACC) of 10–30 mg/L and pH 5.0–6.5*".	(Liu et al., 2013)
	Japan	"*Japan's Ministry of Health, Labor and Welfare have approved Acid Electrolyzed Water (AEW) in 2002 as a food additive*". *"As a pioneer in application of EW, Japan has conducted decades of fruitful research in development of functional EW and officially approved EW as a food additive as early as 2002*".	(Mostafidi et al., 2020) (H. Wang et al., 2022)
	Japan	"*In 2002, EOW was approved as an indirect food additive in Japan*".	(Lu et al., 2010)
	Japan	"*Slightly acidic hypochlorous water (SAHW) which is similar to slightly acidic electrolyzed water (SlAEW) has been an authorized food additive in Japan since 2002*".	(Soli et al., 2010)
	Japan	*"Electrolyzed oxidizing water, a novel antimicrobial agent and permitted food additive in Japan"*.	(Sikin et al., 2013)
	Japan	"*In 2002, Japan had officially approved EO water as a food additive*".	(Huang et al., 2008)
	Japan	*"Slightly acidic electro-activated water has been permitted as a food additive in Japan since 2002 because it has been proven as a biologically safe and effective bactericide"*.	(Liato et al., 2015)
Sanitizer/Disinfectant	US, Japan, and Korea	"*There are diverse opinions and regulations across different countries on the applications of EW as a sanitizing agent.*".	(Ding et al., 2019)
	Nd	"*As a result, SAEW has effective antimicrobial properties that inhibit bacterial growth, thereby prolonging the shelf life of fish*"	
	Nd	"*Sanitizers such as iodophors, chlorine and chlorine derivatives, hydrogen peroxide, and quaternary ammonium compounds have been used. Additionally, in recent years there has been growing interest in new applications for the bactericidal activity of slightly acidic electrolyzed water (SAEW) in the food industry*".	(Jeon et al., 2018)

(*continued on next page*)

Table 2 (*continued*)

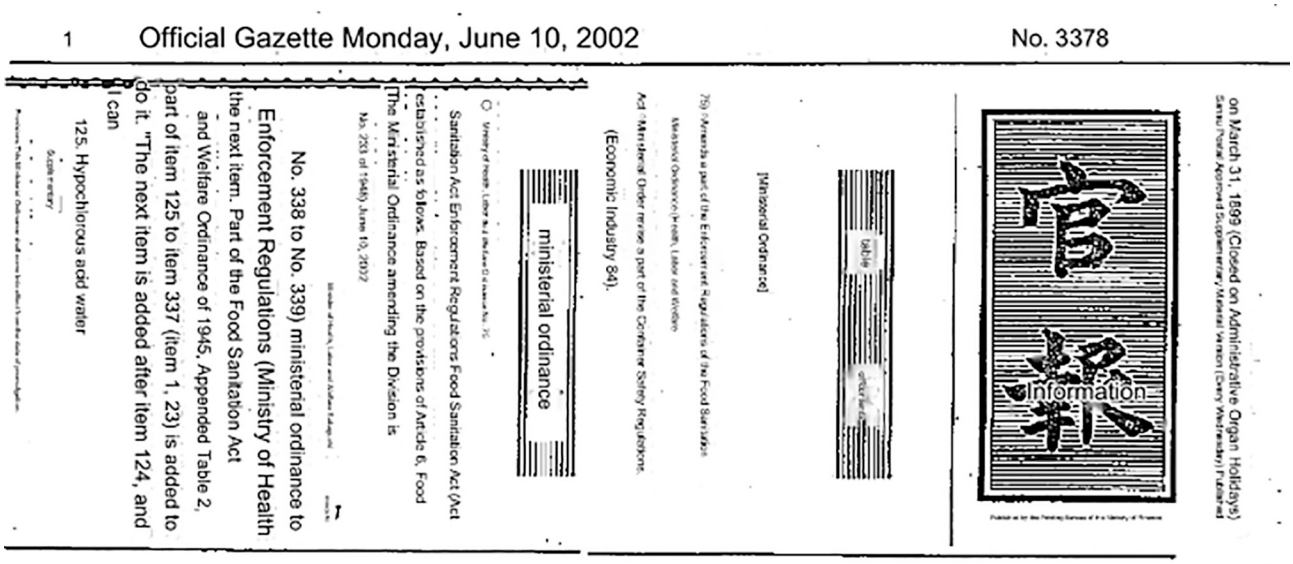
Description of EW	Country concerned	Identified sentence	Reference
	Japan, Korea, USA	*"The application of electrolyzed water to fresh produce has been officially approved by the governmental food safety agencies in Japan, Republic of Korea, and the USA, with a limit of 200 ppm of available chlorine (HClO)."*.	(Lee et al., 2014)
	Japan	*"Slightly acid electrolyzed water was approved as a permitted food additive by the Ministry of Health, Labor, and Welfare of Japan"*.	(Gao et al., 2022)
	Nd	"*Slightly acidic electrolyzed water (SAEW) has been used as a disinfectant in food industry*".	(Lan et al., 2022)
	Nd	"*Electrolyzed water (EW) has been regarded as a new sanitizer*". "*SAEW is a promising nonthermal food sanitizer*".	(Rahman et al., 2016)
	Nd	"*Slightly acidic electrolyzed water (SAEW) has been used as novel sanitizer for fresh produce decontamination*".	(Seo et al., 2019)
	Nd	"*EW is an effective wash water sanitizer and has a good control activity on disease development*".	(Fallanaj et al., 2013)
	Nd	"*Slightly acidic electrolyzed water (SAEW) has been employed as a non-thermal disinfect technique for fresh products*".	(Shao et al., 2023)
	Nd	"*Ozone and electrolyzed water are two broad-spectrum effective and environmental friendly sanitizing agents*".	(Morata et al., 2017)
	Nd	"*SAHW has been applied in food processing plants' cleaning and sanitizing procedures*".	(Nguyen Trang et al., 2023)
		"*Several sanitizers have been evaluated to inactivate foodborne pathogens on produce including chlorine, ozonated water, electrolyzed water*"	(Park et al., 2018)
	Nd	"*SAEW is known to be an effective disinfectant with strong antibacterial activity against various microorganisms*"	(F. Li et al., 2022)
	Nd	"*Among the alternatives to sodium hypochlorite, electrolyzed water (EW) has recently become a popular sanitizer in the food chain*".	(Feliziani et al., 2016)
	Nd	"*EW has been considered as a new type of disinfectant (electrolyzed water (EW) contains HOCl) and cleaning agent (EW contains NaOH) in recent year*".	(Chiu et al., 2023)
	Nd	"*It has been regarded as a novel disinfectant or sanitizer (if containing HOCl) and cleaner (if containing NaOH)*".	(Sahoo et al., 2021)
	Nd	"*Recently the use of EOW as a sanitizing agent for fresh produce has received lot of attention for microbial load reduction purposes*".	(Joshi et al., 2013)
	Nd	"*It has become clear that electrolyzed water is one of the promising sanitizers for future, which can provide pesticide- and drug-free food products*".	(Shiroodi & Ovissipour, 2018)
	Nd	"*Slightly acidic electrolyzed water (SAEW) is well recognized as an alternative sanitizer*".	(Fallik & Ilic, 2022)
	Nd	"*EW is a promising sanitizer in the fresh produce industry*".	(Q. Wang & Salvi, 2023)
		"*Electrolyzed water (EW) has been recently considered as a potential non-thermal food sanitizer*".	(Khan et al., 2017)
	Nd	"*There are two types of electrolyzed water with sanitizing properties: acidic electrolyzed water or electrolyzed oxidizing water (AEW) and neutral electrolyzed water (NEW)*".	(Ramos et al., 2013)
	Japan, USA	"*Electrolyzed oxidizing water is a novel antimicrobial method, originally developed in Japan and gaining importance in USA. EO water is being considered favorably over other disinfectants such as chlorine and chlorine based compounds, acids and salts for treating fresh produce and food contact surfaces*".	(Mukhopadhyay & Ramaswamy, 2012)
Both food additive and sanitizer	Japan	"*Strongly acidic water and weakly acidic water are produced by electrolysis of sodium chloride- and hydrochloride-contained water, respectively*". "*Both types of EOW are permitted as food additives by the Japanese Ministry of Health, Labour, and Welfare*".	(Komachiya et al., 2014)
	Japan	"*In 2002, Japan had officially approved EO water as a food additive*". "*Electrolyzed water has been tested and used as a disinfectant in the food industry and other applications*".	(Huang et al., 2008)
	Korea, Japan, USA	"*As it is known that SAEW (Slightly Acidic Hypochlorous Water) has been approved as a food additive in Korea, Japan, and the US*".	(Q. Chen et al., 2023b)
	Japan	"*Slightly acidic electrolyzed water (SAEW), a disinfectant solution with a lower available chlorine concentration (ACC) than sodium hypochlorite solution, has a comparable disinfectant effect and is used as a food additive in Japan.*".	(Shimamura et al., 2024)
	Japan	"*Japan's Ministry of Health, Labor, and Welfare designated SAEW as a food additive sanitizer in 2002*"	(Kurahashi et al., 2021)
	Japan	"*Electrolyzed water (EW) is the sanitizer created by adding small amounts of NaCl to the washing water subjected to electrolysis.*". "*The use of acidic EW as a food additive has been approved in Japan since 2002*".	(Gil et al., 2015)
	Japan	"*Electrolyzed water (pH 2.7 or 6.5, 20 to 60 ppm available chlorine) and ozonated water (1 to 10 ppm ozone) are disinfectants approved as food additives by Ministry of Health, Labor, and Welfare of Japan*"	(Izumi, 2007)
	Japan, USA	"*Various Ministry have authorized the use of hypochlorous acid water on designated food additives. In 2017, the FDA also authorized hypochlorous acid (electrolytically generated on-site) for use on food contact surfaces*".	(Nyamende et al., 2023)
	Korea, Japan, USA	*"EW has been considered as an alternative to synthetic hazardous sanitizers and it is generally recognized as a safe (GRAS) food additive in Japan, the US, and Korea"*.	(Rathod et al., 2024)

Nd, Not defined. *, authors used the term "water additive". EW: Electrolyzed water; EOW: Electrolyzed oxidizing water; SAEW: Slightly acidic electrolyzed water; EO: Electrolyzed oxidizing; SAHW: Slightly acidic hypochlorous water; AEW: Acidified electrolyzed water.

"hypochlorous acid water" as "acidic electrolyzed water" and the classification of the latter as a "food additive" as cited by many publications, including the present ones, after researching the source of this information, I found two documents (original documents are in Japanese) related to "acidic electrolyzed water" on the website of the Japan Electrolyzed Water Association (JEWA)(https://jewa.jp/saew/public/):

III. The "Official Gazette No. 3378, Ministry of Health, Labor and Welfare Notification No. 212" (Document 1 below shows the English translation).

IV. Main points of Acidic Electrolytic Water (hypochlorous acid water) designated as a food additive in the "Official Gazette No. 3378, Ministry of Health, Labor and Welfare Notification No. 212" (Document 2 below shows the English translation).



1 Official Gazette Monday, June 10, 2002 No. 3378

on March 31, 1899 (Closed on Administrative Organ Holidays)

Information

[Ministerial Ordinance]

(Economic Industry 84).

ministerial ordinance

No. 338 to No. 339) ministerial ordinance to Enforcement Regulations (Ministry of Health

the next item. Part of the Food Sanitation Act

and Welfare Ordinance of 1945, Appended Table 2,

part of item 125 to item 337 (item 1, 23) is added to

do it. "The next item is added after item 124, and

I can

125. Hypochlorous acid water

Monday, June 10, 2002 Official Gazette No. 3378

0.005mol/1 sodium thiosulfate solution Add freshly boiled and cooled water to the 0.1mol/1 sodium thiosulfate solution to dilute to 20 times the volume, and standardize the time of use according to the 0.1mol/1 sodium thiosulfate solution.

Add the following paragraph next to iron sesquioxide in the section of Part 2 Additives D Ingredient Standards/Storage Standards.

Hypochlorous acid water

Hypochlorous Acid Water

Definition This product is an aqueous solution containing hypochlorous acid as the main component, obtained by electrolyzing hydrochloric acid or salt water.

It is a liquid. This product is made by electrolyzing strongly acidic hypochlorous acid water (0.2% or less sodium chloride aqueous solution) in a diaphragm electrolytic cell (consisting of an anode and a cathode separated by a diaphragm). Water obtained from the anode side

A solution.) and slightly acidic hypochlorous acid water (2 to 6% hydrochloric acid) in a non-diaphragm electrolytic cell (composed of an anode and a cathode that are not separated by a diaphragm).).

Strongly acidic hypochlorous acid water This product contains 20~60mg/kg of available chlorine.

Slightly acidic hypochlorous acid water This product contains 10 to 30 mg/kg of available chlorine.

This product is a colorless liquid with no odor or a slight chlorine odor. condition

Confirmation test (1) When adding 1 ml of sodium hydroxide solution (1→2,500) and 0.2 ml of potassium iodide test solution to 5 ml of this product, the solution turns yellow. When adding another 0.5ml of starch test solution, the solution turns dark blue.

Ru.

(2) Add 0.1ml of potassium permanganate solution (1→300) to 5 dishes of this product, and add 1 dish of sulfuric acid (1→20) to this.

When added, the reddish-purple color of the liquid does not fade.

(3) A solution obtained by adding 10 ml of sodium hydroxide solution (1→5) to 50 ml of this product has a maximum absorption at a wavelength of 290 to 294 nm.

There is.

Purity test (1) Liquid Strongly acidic hypochlorous acid water pH2.7 or less

Slightly acidic hypochlorous acid water pH5.0~6.5

(2) Evaporation residue 0.25% or less,

Weigh 20:0 g of this product, evaporate it, dry it at 110℃ for 2 hours, and weigh the residue.

Assay method (1) Accurately weigh approximately 200g of strongly acidic hypochlorous acid water, add 2g of potassium iodide and acetic acid (1→4) Add 10ml, immediately stopper tightly and leave in a dark place for 15 minutes, then titrate liberated iodine with 0.01mol/1 sodium thiosulfate solution (indicator: starch test solution). Perform a separate blank test and make corrections.

0.01mol/1ml of sodium thiosulfate solution=0.35453mg Cl

(2) Slightly acidic hypochlorous acid water Weigh out approximately 200g of this product accurately, add 2g of potassium iodide and 10ml of acetic acid (1-4), immediately seal it tightly, and leave it in a dark place for 15 minutes to remove the liberated iodine. 0.005mol/ Sodium thiosulfate

(indicator starch test solution). Perform a separate blank test and make corrections.

0.005mol/1ml of sodium thiosulfate solution=0.17727mg Cl

Add the following item next to iron sesquioxide in the 2nd Additives Section F Usage Standards section.

Hypochlorous acid water

Hypochlorous acid water must be removed before the final food product is completed.

Then add the next stroke.

June 10, 2002: Part of the

and Welfare, Ka Sakaguchi

Ministry of Health, Labor and Welfare Notification No. 317

provisions of Article 7, Paragraph 1 of the Food Sanitation Act (Act No. 233 of 1945), food additives, etc. are prohibited by the Minister of Health, Labor

specifications and standards (Ministry of Health and Welfare Notification No. 370 of 1959) will be revised as follows. Based on the

Document 1: Official Gazette No. 3378, Ministry of Health, Labor and Welfare Ordinance No. 75, Notification No. 212 (English translated version of the Japanese original).

Document 2: Main points of acidic electrolytic water (hypochlorous acid water) designated as a food additive in the "Official Gazette No. 3378, Ministry of Health, Labor and Welfare Ordinance No. 75, Notification No. 212" (English translated version of the Japanese original).

Key points about acidic electrolyzed water (hypochlorous acid water) designated as a food additive

Official Gazette No. 3378 (June 10, 2002): Ministry of Health, Labor and Welfare Ordinance No. 75, Notification No. 212

1. Name: Hypochlorous Acid Water

2. Definition: An aqueous solution containing hypochlorous acid as its main component, obtained by electrolyzing hydrochloric acid or saline solution. There are strong acidic hypochlorous acid water and slightly acidic hypochlorous acid water.

Strong acidic hypochlorous acid water: Produced by electrolyzing 0.2% or less NaCl aqueous solution in a membrane-equipped electrolytic cell from the anode side. Slightly acidic hypochlorous acid water: Produced by electrolyzing 2-6% hydrochloric acid in a membrane-less electrolytic cell. *Both NaCl and hydrochloric acid should be diluted with potable water.

3. Specifications: See table below

4. Safety: Since there is no risk of harm to human health, there is no problem with designating it as a food additive. Report by the Chairman of the Pharmaceutical Affairs and Food Sanitation Council (Mitsuru Uchiyama) to the Minister of Health, Labor and Welfare (Tsutomu Sakaguchi) (Yakushoku-Shikaku No. 0327004, March 27, 2002)

5. Usage criteria:
1) Check the pH, available chlorine concentration, etc. before use.
2) Wash off any food stains with potable water before use.
3) After use, wash food thoroughly with potable water.
4) Ensure adequate ventilation when the generator is in operation (trace amounts of chlorine and hydrogen gas will be generated).
5) When using for the sanitation management of food preparation facilities, etc., follow the "Mass Cooking Facility Sanitation Management Manual (Notification No. 85 by the Director-General of the Public Health Bureau of the Ministry of Health and Welfare, March 24, 1997)" etc.

6. Generator
Electrodes: The electrode parts, such as platinum and titanium, must not dissolve.
others: Parts that come into contact with electrolytic water, such as electrolytic cells, water storage tanks, hoses, and pumps, must conform to the standards set forth in Section 3 of the Standards for Apparatus and Containers/Packaging (Ministry of Health and Welfare Notification No. 370, 1959).
Durability: It has been confirmed that its quality and performance are stable and that it can withstand long-term use. Furthermore, regular maintenance is carried out.
*use: Business operators who use hypochlorous acid water for their own consumption do not need an additive manufacturing license.

7. Others: Hypochlorous acid water itself is not in circulation.

	Strongly acidic hypochlorous acid water (strongly acidic electrolyzed water)	Slightly acidic hypochlorous acid water (slightly acidic electrolyzed water)
electrolyzed water	0.2% or less NaCl diaphragm	Dilute hydrochloric acid (2~6%)
electrolyzer	electrolytic cell	membraneless electrolytic cell
Electrolyzed liquid		
Effective chlorine concentration	20~60mg/kg	10~30mg/kg
pH	2.7 or less (2.2~2.7)*	5.0~6.5
Chemical species produced	HClO、H^+、ClO^-	None in particular
(molecular weight)	(52.47、1.01、51.45)	None in particular
Use	Disinfectant	Sterilizer
Approved Use*	for cleaning and disinfecting hands and endoscopes	None in particular

*Refer to "Electrolyzed Water Guide (2001)" published by the Functional Water Research Promotion Foundation.

When examining the official gazette No. 3378 Ministry of Health, Labour and Welfare Ordinance No. 75, Notification No. 212 (Documents 1 and 2), we can note the following statements:

I. "***Hypochlorous acid water must be removed before the final food product is completed***".
II. In section **4. Safety**, we find this statement: "*Since there is no risk of harm to human health, **there is no problem with designating it as a food additive**. Report by the Chairman of the Pharmaceutical Affairs and Food Sanitation Council (Mitsuru Uchiyama) to the Minister of Health, Labor and Welfare (Tsutomu Sakaguchi). (Yakushoku-Shikaku No. 0327004, March 27, 2002).*".
III. *Strongly Acidic Hypochlorous Acid Water (Strongly Acidic Electrolyzed Water)* was described as a "**disinfectant**" for "*cleaning and disinfecting hands and endoscopes*", whereas *Slightly Acidic Hypochlorous Acid Water (Slightly Acidic Electrolyzed Water)* was described as a "**sterilizer**" (Document 2).

From the above-cited documents, we can note that the Ministry of Health, Labour and Welfare described "acidic electrolyzed water" as "sanitizer" and "disinfectant" in its Notification No. 212, and it says that "*there is no problem with designating it as a food additive*".

Definition of Food Additive by Different International Organizations:

Now, let's refer to the international definition of food additives (Berry Ottaway, 2003; Griffiths & Borzelleca, 2005):

- ***The Codex Alimentarius**: Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may reasonably be expected to result (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such food. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.*
- ***US Food and Drug Administration (FDA):** The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.*
- ***European Economic Community (EEC):** A food additive is any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods. 89/107/EEC.*
- ***World Health Organization (WHO):** Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities Codex Alimentarius, second edition (revised 1995), volume 1 A (General Requirements), p. 11.*

Electrolyzed Water Status in Some National and International Regulations:

Although the U.S. FDA Food Additive Status List (https://www.fda.gov/food/food-additives-petitions/food-additive-status-list) and the U. S. Code of Federal Regulations (21 CFR) part 178 "Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers" (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-178) include some sanitizers, they don't include "hypochlorous acid" nor "acidic electrolyzed water".

However, in addition to ingredients authorized and listed in 21 CFR, the FDA maintains separate inventories for premarket authorizations for food contact substances issued under the Food Contact Substance notification (FCN), where the "hypochlorous acid" (CAS Reg. No. 7790-92-3) is present in the U.S. FDA Food Contact Substance (FCS) list (https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&sort=Sort_FCS&order=DESC&startrow=1&type=basic&search=). However, "acidic electrolyzed water" is not included in this list. Moreover, it is important to note that the FDA designated "hypochlorous acid," like other items in the FCS list, a "food contact substance" and not a "food additive".

Additionally, both the Codex Alimentarius food additives list (https://www.fao.org/gsfaonline/additives/index.html) and the European Commission Food additives list (https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search) do not include "hypochlorous acid" or "acidic electrolyzed water".

On the other hand, in the USA, the National Organic Standards Board (NOSB) determined that "hypochlorous acid" generated from "electrolyzed water" is considered a "disinfectant" and "sanitizer" and meets the evaluation criteria for National List substances under the Organic Foods Production Act (OFPA)(Agricultural Marketing Service, 2018).

In contrast, in Canada, "electrolyzed water" did not meet the criteria for disinfectants in food premises, according to Health Canada (Gaulin et al., 2011).

In the European Union, "electrolyzed water" has been reported to be used only in drinking water, and its use in meat and fish products is not permitted (Stoica, 2018).

In other countries and areas, regulatory approval is still the biggest challenge for the adoption and extension of "electrolyzed water" in the food industry (Ding et al., 2019).

1. Conclusion

To conclude, considering the aforementioned international definition of food additives and that of Japan, we can draw the following conclusion:

The FSA in Japan clarifies that its definition of food additives differs from that of the Codex Alimentarius Commission (CAC). While international food agencies do not consider "acidic electrolyzed water" or "hypochlorous acid water" as food additives, the Japanese FSA does. While the Ministry of Health, Labour and Welfare in Japan designates "acidic electrolyzed water" (AEW) as a "food additive", it also describes AEW as a "sterilizer" and "disinfectant". It requires its removal before the final food product is completed. Therefore, both national and international food agencies, including Japan, require the exclusion of AEW from the final product and consider it as a "sterilizer" or "disinfectant".

The confusion surrounding the classification of "electrolyzed water" as a "food additive" or "sterilizer" arises from differing definitions of the term "food additive" between Japan, where the industrial use of "electrolyzed water" originated, and other countries and international organizations. Some of these entities designate "electrolyzed water" as a "sterilizer" or "disinfectant" rather than a "food additive".

Because the Japanese definition of food additive differs from that of other international food-related agencies, and Japan is the only country that designates "electrolyzed water" as a "food additive", using the term "food additive" in scientific publications to refer to "acidic electrolyzed

water" or "electrolyzed water" is not recommended. This can lead to confusion and mislead the reader.

CRediT authorship contribution statement

Duried Alwazeer: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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