

Memorando de decisión ambiental para la notificación de contacto con alimentos No. 1811

Fecha: 5 de octubre de 2017

Para: Jessica Urbelis, Ph.D., División de Notificaciones de Contacto con Alimentos, HFS-275

A través de: Mariellen Pfeil, Líder del Equipo Ambiental Interino, Oficina de Seguridad de Aditivos Alimentarios, HFS 255

De: Biólogo, Equipo Ambiental, División de Biotecnología y Revisión de Avisos GRAS, HFS-255

Asunto: Hallazgo de ningún impacto significativo para la notificación de contacto con alimentos (FCN) 1811 para el ácido hipocloroso (número de registro CAS 7790-92-3).

Notificador: IET, Inc., DBA Ecolox

Se adjunta el Resultado de No Impacto Significativo (FONSI) para FCN 1811 para el uso de ácido hipocloroso, ClO₂, (número de registro CAS 7790-92-3), donde el cloro libre disponible (FAC) no excederá de 60 ppm, como agente antimicrobiano en solución acuosa en la producción y preparación de carnes y aves enteras o cortadas; carnes y aves procesadas y preformadas; pescados y mariscos; frutas y vegetales; y huevos con cáscara.

Después de que esta notificación entre en vigencia, las copias de este FONSI y la evaluación ambiental del notificador (EA), con fecha del 22 de agosto de 2017, pueden ponerse a disposición del público. Publicaremos transcripciones digitales del FONSI y el EA en el sitio web público de la agencia.

Háganos saber si hay algún cambio en la identidad o el uso de la sustancia en contacto con los alimentos.

Leah D. Proffitt

Adjunto: Hallazgo de ningún impacto significativo

NO SE ENCUENTRA IMPACTO SIGNIFICATIVO

A food-contact notification (FCN No. 1811), submitted by IET, Inc., DBA Ecolox, to provide for the safe use of hypochlorous acid, ClO₂, (CAS Reg. No. 7790-92-3), where free available chlorine (FAC) will not exceed 60 ppm, as an antimicrobial agent in an aqueous solution in the production and preparation of whole or cut meat and poultry; processed and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment, dated August 22, 2017. The EA is incorporated by reference in this Finding of No Significant Impact, and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms, and will be used in food processing facilities throughout the United States, as well as in open water, on-board fish processing. Waste water from the proposed uses will be either discharged ultimately to a publicly-owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment. In the case of on-board fish processing, effluent will be released directly to the open ocean. The proposed uses are as follows:

1. in process water or ice which comes into contact with food as a spray, wash, rinse, dip, chiller water, and scalding water for whole or cut meat and poultry, including carcasses, parts, trim, and organs;
2. in process water, ice, or brine used for washing, rinsing, or cooling of processed and pre-formed meat and poultry products as defined in 21 CFR 170.3(n)(29) and 21 CFR 170.3(n)(34), respectively;
3. in process water or ice for washing, rinsing or cooling fruits, vegetables, whole or cut fish and seafood; and
4. in process water for washing or rinsing shell eggs.

Shortly after entering the treatment facility, the FCS is expected to decay to an environmental introduction concentration (EIC) of 4×10^{-27} ppm. This EIC is also assumed to apply to all major breakdown products, including hypochlorite (OCL)-, chlorite (ClO₂), and chlorate (ClO₃). This EIC of 4×10^{-27} ppm is well below the lowest endpoint of 17 µg/L (Chlorine (FAC), *Daphnia magna*, LC₅₀). Ultimately, the FCS and its breakdown products will be reduced to chloride. The worst-case effective environmental concentration.

(EEC)^[1] for chloride is expected to be 6 ppm^[2], which is far below the endpoint for the most sensitive species (735 ppm, *Cladoceron sp.*, EC₅₀). Any chloramines formed are projected to decay to an EIC of 1×10^{-10} ppm, which is 11 orders of magnitude lower than the lowest ecotoxicity

endpoint of 0.016 mg/L (*Daphnia magna*, LC50).

Organohalogenes (AOX) such as trihalomethanes (THM), trichloroacetic acid (TAA), and other haloacetic acids HAA), are expected to form as disinfection byproducts. Overall AOX formation comprises 1.5% of total active chlorine, or 900 ppb based on the FAC concentration of 60 ppm. The percentage of each AOX species formed from the FCS is reflected below. These are considered to be EICs.

THM: 9.6% total AOX, or $0.096 \times 900 \text{ ppb} = 86.4 \text{ ppb}$ (EEC = 8.64 ppb)

TAA: 3.5% total AOX, or $0.035 \times 900 \text{ ppb} = 31.4 \text{ ppb}$ (EEC = 3.14 ppb)

HAA: 4.0% total AOX, or $0.040 \times 900 \text{ ppb} = 36.0 \text{ ppb}$ (EEC = 3.60 ppb)

The highest EEC (8.64 ppb) is much lower than EC50 of 0.24 ppm for the most sensitive species (aquatic plants; bromoform).

Use of the FCS as an antimicrobial agent in food processing is not expected to result in a net increase in the use of energy and resources, since the raw material used to produce the FCS are already in common use in other chemical and industrial processes.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS as an antimicrobial agent in the production and preparation of whole or cut meat and poultry; processed and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Preparado por _____ Fecha: firmado digitalmente 10-05-2017

Leah D. Proffitt

Bióloga

Oficina de Seguridad de Aditivos Alimentarios

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Administración de Alimentos y Medicamentos

Aprobado por _____ Fecha: firmado digitalmente 10-05-2017

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Administración de alimentos y medicamentos

[1] $CEE = EIC \div \text{factor de dilución de 10}$

[2] Concentración de FAC \div factor de dilución de 10 veces al verterse en aguas superficiales