

**TSCA Section 5(a)(3)(C) Determination for Microbial Commercial Activity Notice
(MCAN) J-23-0002**

Number: J-23-0002

TSCA Section 5(a)(3) Determination: The microorganism is not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic: Microorganism stably transformed to express a recombinant protein

Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended use(s) (generic): Manufacture for use in the manufacture of a recombinant protein consistent with the manufacturing, processing, use, distribution, and disposal information described in the MCAN.

Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found none.

Reasonably foreseen conditions of use(s): Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and found none.

Summary: The microorganism is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard associated with the recipient microorganism and introduced genetic material. The recipient microorganism is not pathogenic to humans or animals and has an extensive history of safe use. The introduced genetic modifications pose low concern for health and environmental hazard and do not include antibiotic resistance markers.

Human Health Hazard²: Human health hazard is relevant to whether a new microorganism is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (e.g., pathogenicity/toxicity) of the microorganism and the extent of exposure to the

¹Under TSCA § 3(4), the term “conditions of use” means “the circumstances, as determined by the Administrator, under which a chemical substance (including an intergeneric microorganism) is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” In general, EPA considers the intended conditions of use of a new microorganism to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from MCAN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the MCAN microorganism may be manufactured, processed, distributed, used, or disposed of. EPA expects that the identification of “reasonably foreseen” conditions of use will be made on a fact-specific, case-by-case basis. EPA will apply its professional judgment and experience when considering factors such as evidence of current use of the MCAN microorganism outside the United States, information about known or intended uses of microorganisms that are structurally analogous to the MCAN microorganism, and conditions of use identified in an initial MCAN submission that the submitter omits in a revised MCAN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA MCAN databases (containing use information on analogue chemicals), other U.S. government public sources, and Internet searches.

² A microorganism is considered to have low human health hazard if it is not known to be a frank human pathogen that causes disease in healthy adults, and/or animal studies have demonstrated a lack of pathogenicity or toxicity; a microorganism is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies. In the absence of animal data on a microorganism, EPA may use other data or information obtained through literature searches.

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microorganism. EPA estimated the human health hazard of this microorganism based on data for the recipient strain as well as the genetic modifications. There is low concern for human health hazard for the microorganism based on the recipient strain not being a human pathogen and because the introduced genetic material encoding proteins is not expected to increase the potential for adverse human health effects.

Environmental Hazard³: Environmental hazard is relevant to whether a new microorganism is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (e.g., pathogenicity/toxicity) of the microorganism and the extent of exposure to the microorganism. EPA estimated the environmental hazard of this microorganism based on data for the recipient strain as well as information on the genetic modifications. There is low concern for environmental hazard for the microorganism based on the recipient strain not being an animal or plant pathogen and because the introduced genetic material encoding proteins is not expected to increase the potential for adverse effects on animals or plants.

Exposure and Risk Characterization: The exposure to a new microorganism is potentially relevant to whether a new microorganism is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (e.g., pathogenicity/toxicity) of the microorganism and the nature and extent of exposure to the substance.

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a potentially exposed or susceptible subpopulation on the basis of greater exposure potential compared to the general population who do not use specific products.

EPA estimated occupational and environmental exposures to the new microorganism. No consumer use was identified, so exposures to consumers were not assessed. Due to low hazard, EPA believes that this microorganism would be not likely to present an unreasonable risk even if exposures were high. Therefore, EPA concludes that the new microorganism is not likely to present unreasonable risk under the conditions of use.

12/29/2022
Date:

/s/

Madison H. Le, Director
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

³ A microorganism is considered to be of low ecological hazard if it is not known to be an animal or plant pathogen, and the genetic modifications do not impart pathogenic or toxigenic traits, and the introduced genetic material does not provide a selective growth advantage in outcompeting indigenous microbial communities in the environment.