TSCA Section 5(a)(3) Determination for Microbial Commercial Activity Notice (MCAN) J-18-0004 to 0009

Number: J-18-0004 to 0009
TSCA Section 5(a)(3) Determination: The microorganisms are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:
Generic: Biofuel-producing modified microorganisms, with chromosomally-borne modifications

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended use(s) (generic): Production of biofuel
Known conditions of use: 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 microorganisms are 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 Hazard[2]: 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 microorganism. EPA estimated the human health hazard of these microorganisms based on data for the recipient parental strain as well as the genetic modifications. There is low concern for human health hazard for the microorganisms based on the recipient strain not being a

[1] Under 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 chemical substance 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 Administrator expects the MCAN microorganism to be manufactured, processed, distributed, used, or disposed of. The identification of "reasonably foreseen" conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new microorganism outside the United States, evidence that the MCAN microorganism is sufficiently likely to be used for the same purposes as existing microorganisms that are similar, 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 analogous microorganisms), 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.

human pathogen and the introduced genetic material encoding common enzymes found in many microorganisms.

Environmental Hazard[3]: 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 these microorganisms based on data for the recipient parental strain as well as information on the genetic modifications. There is low concern for environmental hazard for the microorganisms based on the recipient strain not being an animal or plant pathogen and the introduced genetic material encoding for common enzymes found in many microorganisms.

_

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. However, in this case EPA did not estimate the exposure because EPA determined that the microorganism presents both low human health hazard and low environmental hazard. Due to low hazard, EPA believes that these microorganisms would be not likely to present an unreasonable risk even if exposures were high. Therefore, EPA concludes that the new microorganisms are not likely to present unreasonable risk under the conditions of use.

Potentially Exposed or Susceptible Subpopulation(s): Workers are potentially exposed. Given the low hazard of these microorganisms, EPA finds that these microorganisms are not likely to present unreasonable risk to workers. Risks to the general population were not assessed due to low hazard. No consumer use was identified, so risks to consumers were not assessed.

9/6/18
Date:

/s/
Jeffery T. Morris, Director
Office of Pollution Prevention and Toxics

[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.