March 29, 2013

Japanese Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki Chiyoda-ku
Tokyo, 100-8916 Japan

RE: Proposed Limits on Isopropanol Residue in Foods

To whom it may concern,

The International Food Additives Council (IFAC) is an international association representing companies
that produce high quality substances used worldwide as food additives and food ingredients. IFAC
strives to promote science-based regulation worldwide.

We are responding to information we have received from the U.S. Embassy in Tokyo regarding a
proposal by the Japanese Ministry of Health, Labour and Welfare (MHLW) to limit residual levels of
isopropanol (IPA) in foods at 10 milligrams per kilogram (mg/kg) when IPA is used as an extraction
solvent. IFAC believes this proposed limit on the use of IPA as an extraction solvent could prohibit
the use of some food additives that are currently approved and used in foods in Japan without scientific
justification or providing any benefit to health and safety.

For example, sodium carboxymethyl cellulose (NaCMC), a commonly and safely used food additive, may
contain residual levels of IPA in excess of 10 mg/kg. NaCMC, which is also known as cellulose gum, is
an abundant and natural polysaccharide found in all plants. IPA is used to extract NaCMC from the
cellulose found in plants and will be present in food grade NaCMC and final food products that use
NaCMC to achieve specific technical functions. Once extracted, NaCMC is a water-soluble gum primarily
used in foods as a stabilizer and thickener, but may also be used as a bulking agent, emulsifier, firming
agent, gelling agent, glazing agent, and/or humectant according to the Codex Alimentarius General
Standard for Food Additives (GSFA). NaCMC is typically found in instant beverages, where it provides
texture; baked goods, where it prevents staling; and ice-cream, where it prevents the formation of ice-
crystals that can be formed from frequent freezing and re-thawing. When NaCMC is used in foods at its
typical use level of two percent, the residual levels of IPA found in NaCMC are likely to exceed the
proposed 10 mg/kg limit for IPA in the finished food.

Over its more than 50 years of safe use in food, NaCMC has been widely studied by panels of
toxicological experts in the European Food Safety Agency (EFSA), the Joint FAO/WHO Expert
Committee on Food Additives (JECFA) and many other organizations. Through these reviews of
NaCMC, no health or safety concerns have been identified with the use of NaCMC in food that contain
residual levels of IPA in excess of 10 mg/kg. Furthermore, the additive is an approved food additive in
Europe (E466), in the Codex Alimentarius (INS 466), and in the US (a Generally Recognized as Safe –
GRAS – substance by the FDA under 21 CFR 182.1745), as well as in numerous other countries. In
addition, purity criteria for NaCMC (which do not contain tests for IPA) are published in international
compendia such as Japan’s Specifications and Standards for Food Additives (JSSFA), the U.S. Food
Chemicals Codex (FCC), the EU Directive 231/2012, and FAO – JECFA monographs.

In all of the regulations and purity criteria mentioned above, there are no restrictions on use level of
NaCMC in food products, nor are any restrictions imposed on the presence of residual solvents such as
IPA used in the production of NaCMC. This indicates that the presence of residual solvents like IPA
typically found in NaCMC at very low levels do not contribute to any adverse health effects or present any
safety concerns. Furthermore, NaCMC is typically used at low levels in finished foods to achieve specific technological functions. Thus, trace levels of residual solvents like IPA that could be detected in final food products that contain NaCMC would again pose no health or safety concern.

Therefore, IFAC believes the MHLW proposal to limit the presence of IPA in foods at 10 mg/kg has the potential to prohibit technologically necessary and widely used food additives like NaCMC without scientific justification or any benefit to health and safety. Given the range of products that rely on NaCMC for technologically necessary functions, the 10 mg/kg limit has the potential to result in finished food products being removed from the Japanese market, negatively impacting Japanese consumers with no scientific basis or benefit to health and safety.

We thank you for the opportunity to provide comment.

Sincerely,

Haley Curtis Stevens, Ph.D.
Executive Director