Citizen Petition

14 May 2020

The undersigned ("petitioner") submits this petition under 21 USC §343(q) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §10.30 to request the Commissioner of Food and Drugs to amend 21 CFR.

A. Action Requested

The petitioner requests the Commissioner to amend all parts of 21 CFR which mention and stipulate to use the "calorie" as the unit of food energy to use the official SI unit of energy, the joule (specifically, the kilojoule for food energy). Consequently, the petitioner requests that the Nutrition Facts and Supplement Facts labels be redesigned to have the "Calories" field changed to "Energy" with the measurement written as "<n> kJ", where "<n>" is the number of kilojoules contained in the food or supplement item.

For cases of backwards compatibility, the petitioner requests that the food energy mentioned on the Nutrition Facts and Supplement Facts labels could be allowed to optionally include "calories" written below the kilojoules measurement as "<n> kcal", where "<n>" is the number of "calories" contained in the food item.

B. Statement of Grounds

The International System of Units (SI), also known as the modern metric system, was created in order to standardize the plethora of units prevalent before its existence, both in terms of old measures but also pre-SI metric measures. The calorie (cal), also called the gram calorie or small calorie, was one such pre-SI metric measure that was used at the time. Given that the energy it represents is small and is, therefore, not sufficient to adequately express food energy, a prefix was added to it, giving the unit kilocalorie (kcal). This pre-SI metric measure became popular and has since been used widely to express food energy around the world. There were two problems with this, however.

First, the name "kilocalorie" was at some point standardized as a unit unto itself, creating a new unit called the kilogram calorie, large calorie, or food calorie, which then started being referred to simply as the "calorie". This created much confusion and ambiguity every time it was invoked. The ambiguity was especially stark, as the calorie and the kilocalorie ("calorie") were different by a factor of 1000!

Second, the calorie (and thus the kilocalorie) were deprecated when the SI was standardized, and a universal measure for energy was created, namely the joule (J). Given that the SI is used by virtually every country in the world, almost all countries had moved onto using the newly created joule (and its multiples) for various uses, including food energy. In the case of food energy, the prefix "kilo-" (for 1000) is used to quantify the amount of energy appropriately, giving the kilojoule (kJ).

Furthermore, the fact that FDA guidelines require the use of the term "calorie" to refer to the kilocalorie, which can be represented with the abbreviation "Cal" (as opposed to the calorie whose symbol is "cal") only exacerbated the problems further. Given these problems, it is clear why it is not advisable to continue using this archaic and deprecated unit. In fact, this recommendation is corroborated by every

international and national standard and guidance, such as the SI Brochure itself,¹ and even the federal government's own NIST Special Publication 1038.²

Eschewing this archaic unit not only has benefits of avoiding ambiguities and complying with SI and NIST recommendations, but economic benefits as well. The European Union (EU) and the United Kingdom (UK) are both large trading partners of the United States (US). Seeing as both the EU and the UK have long ago adopted and mandated the kilojoule as the primary unit of energy on food labels, it is clear that any US exporter of food had to comply with those regulations in addition to and/or in place of domestic regulations in order to legally export food products to those countries/territories. However, updating FDA regulations to include the kilojoule as the primary unit of energy would largely place domestic food regulations in line with those of the EU and the UK, considerably reducing the burden on domestic food producers.

Adopting this change also has second order benefits, such as those in education and the costs associated with it. The SI is currently taught in every school, primarily as part of a science curriculum. Since the calorie nor the kilocalorie are a part of the SI, and as the number of people exposed to Nutrition Facts and Supplement Facts labels is quite large (practically every US resident), every student would need to be educated on what a calorie is as well. This results in higher education costs and unnecessary complexity for students who are already burdened with learning two sets of measures (US customary and SI) rather than just the one international standard: namely, the SI.

Recognizing that there would be a transition period necessary for those who are already accustomed to the current measure of kilocalories ("calories"), the petitioner requests that listing the kilocalories be made optional below the kilojoules in the Nutrition Facts or Supplement Facts label. As such, producers who receive feedback from their customers that kilocalories be included can include them as needed, and those who are more forward-looking can do away with listing them altogether. This would result in the least amount of disruption from a consumer perspective, while still having the regulations be up-to-date with the rest of the world.

Hence, the petitioner implores the Commissioner to ameliorate this situation by following international standards and guidance and amending the relevant regulations as outlined previously.

C. Environmental Impact

The petitioner claims a categorical exemption from an environmental impact assessment under 21 CFR §25.30 and 21 CFR §25.32.

D.Economic Impact

The petitioner will provide an economic impact assessment if the Commissioner deems it necessary for this petition and requires one.

¹ <u>SI Brochure: The International System of Units (SI)</u>. 9th ed., International Bureau of Weights and Measures (BIPM), 2019, pp. 160–161.

² Butcher, Kenneth et al. <u>NIST Special Publication 1038: The International System of Units (SI) – Conversion Factors for General Use</u>. National Institute of Standards and Technology, 2006, p. 4.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Hopefully,

Varun Chandro
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