

# Citizen Petition

4 April 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 stipulate to use “mcg” as the abbreviation for the unit “micrograms” to use the official symbol  $\mu\text{g}$  for the unit of measure.

For cases relating to drugs and dosages where handwriting may be involved, the petitioner requests that the international standard of writing the word “micrograms” in full or even using “ug” as an unofficial abbreviation of the unit “micrograms” be recommended.

## B. Statement of Grounds

All units in the International System of Units (SI), also known as the modern metric system, use symbols and not abbreviations. Abbreviations, in fact, are disallowed in the SI when referencing any units. It is, therefore, incorrect to write SI measurements with ad-hoc and invented symbols and abbreviations as is done in the case of the unit “micrograms”. This is corroborated by every international and national standard and guidance, such as the SI Brochure itself,<sup>1</sup> IEEE/ASTM SI 10-2016,<sup>2</sup> NIST Special Publication 330<sup>3</sup>, and even the government’s own Government Publishing Office Style Manual.<sup>4</sup>

Historically, the status quo might have arisen due to a tangential issue where handwritten prescription notes by doctors were being misinterpreted. I.e., the symbol  $\mu\text{g}$  (one millionth of a gram), when poorly handwritten, resembles the SI symbol Mg for the unit “megagram” (one million grams, which is equivalent to 1 000 kilograms or 1 tonne). Due to its implausibility as a dosage for a drug, the symbol would be contextually misinterpreted as the SI symbol mg for the unit “milligram” (one thousandth of a gram). As such, the difference in amounts between the original intended dosage and the contextual misinterpretation is three orders of magnitude (1 000 times), as there are 1 000 micrograms in 1 milligram. To remedy this large disparity which was leading to medical errors and subsequent overdosing, The Joint Commission and the Institute for Safe Medication Practices (ISMP) collaborated and released a report recommending, among other things, that the microgram be abbreviated as “mcg” rather than symbolized as  $\mu\text{g}$ .<sup>5</sup>

While the original intentions of this were virtuous, it has led to unforeseen unintended consequences. Firstly regarding the original problem itself, the internationally standard solution to this problem is the

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<sup>1</sup> [\*SI Brochure: The International System of Units \(SI\)\*](#). 9th ed., International Bureau of Weights and Measures (BIPM), 2019, p. 149.

<sup>2</sup> [\*IEEE/ASTM SI 10-2016 \(Revision of IEEE/ASTM SI 10-2010\): American National Standard for Metric Practice\*](#). IEEE, 2016.

<sup>3</sup> Newell, David B., and Eite Tiesinga. [\*NIST Special Publication 330: The International System of Units \(SI\)\*](#). 2019th ed., National Institute of Standards and Technology, 2019, p. 32.

<sup>4</sup> [\*Style Manual\*](#). US Government Publishing Office (GPO), 2016, p. 237.

<sup>5</sup> [\*ISMP’s List of Error-Prone Abbreviations, Symbols, and Dose Designations\*](#). Institute of Safe Medication Practices, 2017.

recommendation to write the word “micrograms” in full such that there’s absolutely no confusion. In the case where brevity is preferred or even necessary due to space constraints, the unofficial abbreviation “ug” is recommended because it resembles the official symbol  $\mu\text{g}$  while avoiding the aforementioned handwriting problem. The issue with abbreviating it as “mcg” is that it can easily be confused with mg (milligram) when one is glossing over written measurements, which results in the original problem to begin with! This is especially true of cases where the measurements are printed rather than written, as the issues of poor handwriting do not arise in those situations and further reinforce the pattern of an “m” at the beginning of the unit symbol being interpreted as the prefix milli- in the SI.

This leads to the second issue: the FDA seems to have taken this recommendation, which only applies to the medical and drug fields, and applied it to all fields within the purview of the FDA. Since Nutrition Facts and Supplement Facts labels are not strictly drug- or medical-field-related, and since the labels are virtually always printed, the aforementioned problem is compounded. In addition, it also leads to another problem in that it legitimizes what is an incorrect SI symbol for the microgram. As the number of people exposed to Nutrition Facts and Supplement Facts labels are far larger (practically every US resident) than those who are exposed to the drug labels originating in the medical field, the general population starts to believe that the official symbol for the microgram is indeed “mcg” rather than  $\mu\text{g}$ . This results in higher costs in terms of education (in having to teach people the proper SI symbols and have them “unlearn” the incorrect ones they might have encountered in daily life) and lack of standardization (in terms of trade friction, lack of unified communication among and within businesses, etc.).

Furthermore, it leads to yet another issue: one of incompatibility among government bodies’ recommendations and publications. For example, the FDA seems to uniformly recommend and even require that labels use “mcg” as the abbreviation for the microgram, but the US Department of Agriculture (USDA) uses the official SI symbol  $\mu\text{g}$  in its Food and Nutrient Database for Dietary Studies (FNDDS; formerly known as the National Nutrient Database) which many look to for nutritional guidance. Similarly, many (if not every) other government bodies seem to use or recommend the official symbol  $\mu\text{g}$  as the symbol for the microgram (e.g., NIST and the GPO). This inconsistency among governmental bodies surely leads to confusion among the general population who might otherwise expect consistency from “the government” as a whole.

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.

## 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 Chandra*

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