Use of population-weighted Estimated Average Requirements as a basis for Daily Values on food labels[1–3]

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ABSTRACT
In both Canada and the United States, nutrition labeling is now mandatory for most packaged foods. The labeling is intended to help consumers select foods that can contribute to a healthful diet, but current label values are based on outdated notions of nutrient requirements. The Committee on Use of Dietary Reference Intakes in Nutrition Labeling has recommended that the reference values used for nutrition labeling be based on a population-weighted Estimated Average Requirement (EAR) for any nutrient for which requirements have been estimated. This value approximates the median of the distribution of nutrient requirements for individuals who are members of the target population for food labels. It provides the most scientifically valid, single point of comparison for an appraisal of the probable contribution of a specific food to the overall nutrient needs of individuals in the target population. In contrast, a reference value based on a population coverage approach would understate the nutrient contribution of the food item relative to the requirements of the vast majority of individuals in the target population and thus offer misinformation rather than positive guidance to the consumer. *Am J Clin Nutr* 2006;83(suppl):1217S–22S.

KEY WORDS Daily Values, food labels, nutrition labeling, Estimated Average Requirement

INTRODUCTION

Although the effectiveness of food labeling as a health strategy is questionable, controversies abound over what should and should not be said on food labels (1). In both Canada and the United States, nutrition labeling is now mandatory for most packaged foods. The nutrient content of a food is declared on a per serving basis in a Nutrition Facts box. For consumers, the presentation of Nutrition Facts is intended to facilitate comparisons of the nutrient content of different food products and provide information about the relative contributions of a food to an overall health-promoting diet (2–5). Nutrient content is expressed as a percent of a Daily Value (DV), but the reference values currently in use are based for the most part on recommended nutrient intakes derived in the United States from the 1968 Recommended Dietary Allowances (RDAs) and in Canada from the 1983 Recommended Nutrient Intakes (RNIs).

The recent publication of the Dietary Reference Intakes, which includes both revised estimates of nutrient requirements and estimates of tolerable upper intake levels (6–10), has highlighted the need for an examination of the ways in which current science should be applied to inform food regulations and dietary guidance systems. Recognizing the need to revise food labeling, the Institute of Medicine convened the Committee on Use of Dietary Reference Intakes in Nutrition Labeling in 2002 to develop guiding principles for setting reference values for nutrients on the food label (11).

This article begins with an explication of the scientific basis for the Committee's recommendation that the reference values used for nutrition labeling be based on population-weighted Estimated Average Requirements (EARs) or population-weighted Adequate Intakes (AIs). The rationale for this approach is then examined in contrast with the conventional application of the RDAs as a basis for DVs. It is argued that use of a population coverage approach to set the DVs results in consumer misinformation on the food label. Finally, potential implications of using population-weighted EARs on food labels are explored.

UNBIASED ESTIMATES OF NUTRIENT NEEDS: THE BASIS FOR DAILY VALUES

Central to any exercise to set reference values for nutrition labeling is the question of what purpose these values serve. Any nutrient standard would suffice as a basis for product comparison, but the task becomes much more complex if the reference values are to enable consumers to appraise the nutrient contribution of individual food products in relation to their overall nutrient needs.

Our best estimates of individuals' nutrient needs are the estimated nutrient requirements of similar persons. The derivation of the requirement estimates presented in the Dietary Reference Intakes incorporates both an understanding of intake levels necessary to prevent nutrient deficiencies and, where the current science permits, intake levels conducive to the reduction in risk of chronic degenerative diseases. By definition, there is no demonstrable health benefit to nutrient intake levels in excess of requirements. Thus, overall nutrient needs can be represented by nutrient requirement estimates where these have been defined in the Dietary Reference Intakes.

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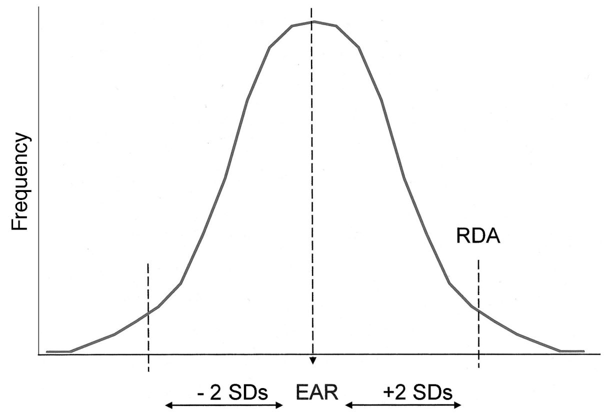

FIGURE 1. Distribution of nutrient requirements for a single life-stage and sex group. EAR, Estimated Average Requirement; RDA, Recommended Dietary Allowance.

Setting label reference values that enable individuals to appraise the nutrient contribution of particular food products to their overall nutrient needs is complicated by the fact that individuals differ in their requirements for nutrients. Dietary Reference Intakes are presented for 22 different sex and life-stage groups because of evidence that each group has a unique set of nutrient needs. Furthermore, within each group, variability exists in nutrient requirements among individuals. The distributions of requirements within particular sex and life-stage groups have been estimated for iron (9), protein (10), and vitamin A (9), but for most nutrients, data on the variability in requirements between individuals within specific sex and life-stage groups are lacking. In these cases, it has been assumed that the distribution of requirements is normal, with an assumed 10% CV within each group (6–9).

Despite differences in nutrient requirements within and among sex and life-stage groups in the population, it is impractical to present multiple sets of reference values on a food label. The labels are simply too small to accommodate very much information. Thus, for each nutrient on the food label, it is necessary to identify the single value that best represents the nutrient requirements of the population. The target population for nutrition labeling can be thought of as all those who might consume the foods to be labeled. In keeping with past practices in the United States, the Committee recommended that the target population be defined as individuals 4 y of age and older, excluding pregnant and lactating women. The exclusion of younger children reflects the assumption that their eating patterns typically differ from those of older children and adults. The exclusion of pregnant and lactating women reflects the recognition that their requirements differ markedly from those of the general population. [Specific guiding principles are presented for nutrition labeling of foods targeted to infants, toddlers, pregnant women, and lactating women (11).] When these exclusions are taken into account, the target population for nutrition labeling comprises 13 distinct sex and life-stage groups.

Although the true requirement for any one individual is unknown, it can be assumed to lie within the distribution of requirements for the sex and life-stage group to which he or she belongs (**Figure 1**). However, we have no way of knowing where the requirement of any randomly selected individual lies within the distribution of requirements for the group. Given this uncertainty, the best estimate of an individual's requirement is the midpoint of the distribution of requirements for the particular sex and life-stage group to which he or she belongs. When intake levels are greater than the EAR, the likelihood that intake exceeds the individual's needs increases. Conversely, at intake levels below the EAR, the likelihood that intake is below actual needs increases. It follows that the EAR provides the most logical, and most scientifically valid, single point of comparison for an appraisal of the probable contribution of a specific food to the overall nutrient needs of an individual.

This logic can be extended to identify the single value that best represents the nutrient requirements of all individuals in the target population for nutrition labeling. The distribution of requirements for this population can be computed if both the distribution of requirements for each sex and life-stage group and the proportions of each group in the total population are known. One method of computation for this distribution, called a mixture of the requirement distributions for the 13 subpopulations, is presented in the Committee's report (11). A simulated distribution of requirements for vitamin A for a population aged 4 y and older (excluding pregnant and lactating women) that is based on US Census population projections for 2005 is shown in **Figure 2**. The median of the distribution of vitamin A requirements constitutes the best estimate of the vitamin A requirement for any randomly selected individual in this population, and thus it is the best single point of comparison for appraising the contribution of any food item to the overall nutrient needs of individuals within this population. For this reason, the Committee on Use of Dietary Reference Intakes in Nutrition Labeling proposes that the median of the distribution of requirements for the population be used as the basis for DVs on food labels. This median is termed the *population-weighted EAR*, which reflects the fact that it is approximated by the weighted average of the EARs for the 13 sex and life-stage groups that make up the target population for labeling.

As illustrated by the spread of the simulated distribution in Figure 2, considerable variation in vitamin A requirements exists within the population. This variation is a function of the fact that EARs for vitamin A range from 275 μg retinol activity equivalents (RAE) for girls and boys aged 4–8 y to 630 μg RAE for 14–18-y-old males (9). It also reflects the 20% CV in vitamin A requirements for individual sex and life-stage groups (9). Despite this variation, the median provides a reasonable approximation of the actual nutrient requirements of most individuals in the target population. The actual vitamin A requirements of 54% of the population lie within 20% of the median; 72% have requirements within 30% of the median.

The results of similar calculations for a fuller array of nutrients, on the basis of estimated distributions of nutrient requirements for the Canadian and US populations, are presented in **Table 1**. It is important to note that vitamin A represents the worst case scenario in this table. For 8 of the 17 nutrients listed, >80% of the population has a nutrient requirement within 20% of the population-weighted EAR. Thus, the population-weighted EAR is a highly relevant point of comparison for appraisals of the nutrient contribution of individual food items to overall nutrient needs for the vast majority of the population to whom these labels are intended to apply.

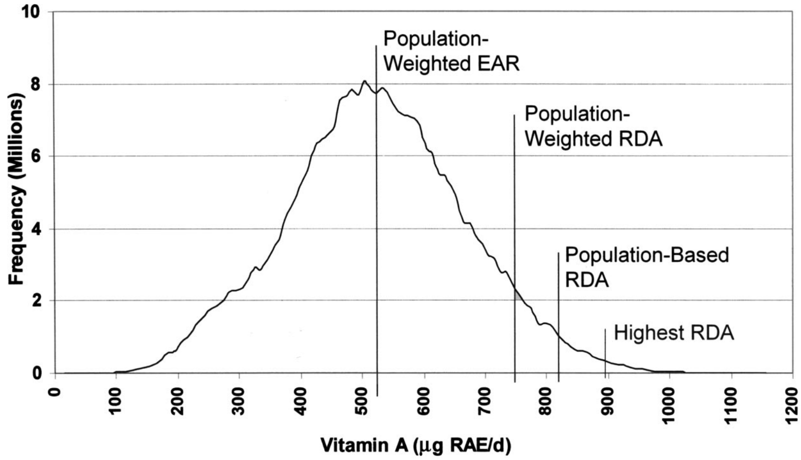

FIGURE 2. Simulated distribution of vitamin A requirements for the US population aged 4 y and older on the basis of population projections for 2005. The vertical lines indicate 4 possible bases for the Daily Value: the population-weighted Estimated Average Requirement (EAR; set at the median of the distribution), the population-weighted Recommended Dietary Allowance (RDA) for vitamin A, the population-based RDA (set at the 97.5th percentile of the distribution), and the highest RDA for vitamin A for any single life-stage and sex group in the target population. RAE, retinol activity equivalent.

SETTING REFERENCE VALUES IN THE ABSENCE OF REQUIREMENT ESTIMATES

For some nutrients, the scientific evidence on requirements was insufficient to define an EAR. In these cases, AIs have been established. These values are intended to represent average daily intakes that will maintain a defined nutritional state or criterion of adequacy in all members of a healthy population. However, AIs have been estimated in several different ways: some are based on median intakes of healthy populations, some on experimental evidence, and some on chronic disease associations (12). Thus, we cannot assume that AIs bear consistent properties of estimation or that they have a predictable relation to the EARs and RDAs for other nutrients.

If a reference value is sought for a nutrient without an EAR, the Committee recommends that a population-weighted AI be

TABLE 1

Illustrative calculations of populated-weighted Estimated Average Requirements (EARs) for persons aged 4 y and older with the use of 2005 US population figures and 2006 Canadian population figures[1]

	US population figures[2]			Canadian population figures[3]		
Nutrient	Population-weighted EAR	Percentage within ±20%[4]	Percentage within ±30%[5]	Population-weighted EAR	Percentage within ±20%[4]	Percentage within ±30%[5]
		%	%		%	%
Vitamin A (µg RAE)	529	54	72	533	55	73
Vitamin C (mg)	63	65	79	64	67	82
Vitamin E (mg α-tocopherol)	12	83	91	12	85	92
Thiamine (mg)	0.9	80	90	0.9	81	92
Riboflavin (mg)	1.0	73	88	1.0	75	90
Niacin (mg)	11	70	86	11	72	87
Vitamin B-6 (mg)	1.1	69	83	1.1	70	85
Folate (µg DFE)	314	84	92	315	86	93
Vitamin B-12 (µg)	2.0	83	91	2.0	85	92
Copper (µg)	684	84	92	686	86	93
Iodine (µg)	93	85	95	93	86	96
Iron (mg)	6.1	59	77	6.1	61	78
Magnesium (mg)	286	60	79	288	62	81
Molybdenum (µg)	33	84	92	33	85	93
Phosphorus (mg)	588	75	81	587	77	83
Selenium (µg)	44	84	92	44	86	93
Zinc (mg)	7.5	61	79	7.5	62	80

[1] Adapted from Tables B-1 and B-2 in *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* (11). RAE, retinol activity equivalents; DFE, dietary folate equivalents.

[2] Population subgroup proportions were based on US Census Bureau middle series of the national population projections (Population Projections Program, 2000).

[3] Population subgroup proportions were based on Statistics Canada national population projections (Statistics Canada, 2003).

[4] Estimated proportion of the population with a requirement within 20% of the population-weighted EAR.

[5] Estimated proportion of the population with a requirement within 30% of the population-weighted EAR.

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TABLE 2
Illustrative calculations of populated-weighted Adequate Intakes (AIs) for persons aged 4 y and older with the use of 2005 US population figures[1]

Nutrient	Population-weighted AI[2]	Highest AI
Biotin (μg)	28	30
Calcium (mg)	1091	1300
Choline (mg)	460	550
Chromium (μg)	27	35
Fluoride (mg)	3	4
Linoleic acid (g)	13	17
α-Linoleic acid (g)	1.3	1.6
Manganese (mg)	2.0	2.3
Pantothenic acid (mg)	5	5
Vitamin D (μg)	7	15
Vitamin K (μg)	95	120

[1] Adapted from Table B-3 in *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* (11) and the *Summary Tables, Dietary Reference Intakes* (10).

[2] Population subgroup proportions were based on US Census Bureau middle series of the national population projections (Population Projections Program, 2000).

used.It is impossible to know how population-weighted AIs relate to the actual nutrient requirements of individuals in the target population, but a comparison of sample calculations for the US population with the highest AI for any one life-stage and sex group indicates the effect of population weighting on these estimates (**Table 2**). Inconsistency will exist between DVs based on AIs and those based on fully characterized nutrient requirement distributions, but this is unavoidable. As the science underpinning requirements for nutrients with AIs evolves and EARs are defined, it will be important to revise the DVs so that they are eventually all based on population-weighted EARs. Such revisions are imperative to provide consumers with a consistent standard against which to evaluate the nutrient contributions of foods.

AVOIDING CONSUMER MISINFORMATION: THE CASE AGAINST A POPULATION COVERAGE APPROACH

Conceptually, the proposed use of a population-weighted EAR or population-weighted AI as the basis for reference values on food labels marks a major departure from past practice. For most nutrients, the label reference values currently in use represent the highest recommended nutrient intake level (RDA or RNI) among all age and sex groups for whom the label was considered applicable, drawing on requirement estimates from 1968 in the case of the United States and 1983 in Canada. For most nutrients, this has meant basing labels on the intake levels recommended to meet the requirements for young males. For iron, women of child-bearing age have the highest recommended intake, so their RDA or RNI has been used as the basis for the DV. The logic in selecting the highest RDA or RNI was that a reference value set this high would encompass the nutrient requirements of all members of the population. Thus, if the DVs were used for planning individuals' diets, there would be no risk of an individual failing to satisfy his or her nutrient requirements.

Although the requirement estimates outlined in the Dietary Reference Intakes differ from previous estimates for most nutrients because of the changing science underpinning our notions of nutrient requirements, it could still be argued that a DV based on the concept of population coverage would be a more appropriate reference value for labels intended to guide food selection. The RDA is considered to be the most appropriate reference value for planning individuals' diets because, if the assumptions about the within-person variation in requirements are correct, the RDA will exceed the actual nutrient requirements of 97.5% of individuals in any one life-stage and sex group (12). (It is important to bear in mind that for almost all nutrients, the assumptions about variance in requirements used to derive the RDA from the EAR are untested and are not based on empirical evidence.) Following this logic, one might argue that the DV should be based on the highest RDA among the 13 life-stage and sex groups that make up the target population. Alternatively, working with a population distribution of requirements (eg, Figure 2), one could define a population-based RDA as the 97.5th percentile of this distribution (ie, the point encompassing 97.5% of the distribution). A third option would be to base the DV on a population-weighted average of the RDAs for the 13 sex and life-stage groups that make up the target population.

As illustrated in Figure 2, the highest RDA, the population-based RDA, and the population-weighted RDA reside at various points along the upper tail of the distribution of requirements for vitamin A. The population-weighted mean of the RDAs for the 13 sex and life-stage groups included in the target population (757 μg RAE) is somewhat lower than the 97.5th percentile of the requirement distribution (822 μg RAE), and both fall below the highest RDA for any single sex and life-stage group (900 μg RAE for males aged 14 y and older). However, the vast majority of the target population has a requirement that is substantially lower than any of these values (**Table 3**). Only 30% of the population has a requirement that falls within 20% of the population-weighted RDA. An even smaller number, 19%, has a requirement within 20% of the 97.5th percentile of the distribution, and fewer than 10% could be expected to have vitamin A requirements within 20% of the highest RDA. As a tool for appraising the nutrient contribution of individual food items to one's overall nutrient needs, a DV based on any of these 3 values would be irrelevant to the vast majority of the target population.

To illustrate the implications of using a population-weighted EAR rather than the RDA as the label reference value, consider the simple example of 250 mL of low-fat (1%) milk with added vitamin A. Assume the milk contains 142 μg RAE. If the DV is based on the population-weighted EAR in Table 3, the milk will be labeled as having 27% DV. Because the milk provides ≥20% of the DV for this vitamin, it will qualify to bear the nutrient content claim, an "excellent source of vitamin A." Whereas 27% represents the milk's contribution relative to the population median requirement, it will provide between 21% and 38% of vitamin A requirements for 73% of the population. Thus, the DV and the nutrient content claim will provide a reasonable basis for appraising the contribution of the food to the nutrient needs of most individuals in the target population. If the DV is based on the population-weighted RDA (ie, the most conservative of the 3 population coverage approaches outlined in Table 3), the same serving of milk would be labeled as having 19% DV, an understatement of its contribution in relation to the vitamin A requirements of 93.5% of the population. Furthermore, the milk will qualify to be labeled as only a "good source" of vitamin A (the nutrient content claim permitted for a product containing 10–19% DV), but in fact it will be an excellent source of vitamin A

TABLE 3
Estimated proportions of the US population with vitamin A requirements above, below, and within ±20% of the Daily Value (DV) on the basis of different reference values[1]

Basis for DV	DV[2]	Percentage of population within ±20%[3]	Percentage of population with requirement < DV	Percentage of population with requirement > DV
	μg RAE	%	%	%
Population-weighted EAR	533	55	50	50
Highest RDA	900	10	> 99	< 1
Population-based RDA[4]	822	19	97.5	2.5
Population-weighted RDA	757	30	93.5	6.5

[1] RAE, retinol activity equivalents; EAR, Estimated Average Requirement; RDA, Recommended Dietary Allowance.
[2] Value derived for population requirements on the basis of US Census population projections for 2005. (Slight discrepancies between this table and the results presented in Table 1 reflect minor differences in the computational methods and the population projections used).
[3] Estimated proportion of the population with a requirement within 20% of the reference value.
[4] Defined as the 97.5th percentile of the distribution of requirements for the population.

for >90% of the population. Thus, basing the DV on a population coverage approach will provide misleading information about the contribution of the food to the overall nutrient needs of most members of the target population.

One might argue that setting the DV at a value in excess of the nutrient requirements of most members of the population would do no harm. If the label was in fact an effective tool for dietary planning, this would merely mean that individuals with lower requirements would have nutrient intakes in excess of their requirements. However, the promotion of nutrient intakes that far exceed individuals' requirements is irresponsible insofar as it can lead individuals to incur unnecessary food costs and possibly foster overconsumption. In some instances, excess nutrient intakes can also jeopardize individuals' health. For some nutrients, the highest RDA is at or near the lowest UL among the 13 groups to whom the label is intended to apply. A population-weighted RDA or 97.5th percentile of a population distribution of requirements could also be expected to approach the UL in these cases. Thus, use of the RDA concept to establish the DV could have deleterious consequences if this label value were used for dietary planning.

In the foregoing discussion, I have repeatedly framed the application of DVs for planning individuals' diets in terms of "if." Planning individuals' diets is not the stated intent of nutrition labeling. Moreover, given the outdated nature of the recommended nutrient intakes on which current reference values are based, their use for dietary planning is surely ill-advised. Studies in Canada and the United States suggest that the label is used in making purchasing decisions (11), a function consistent with its original intent. However, literature is not available indicating that individuals use DVs on product labels to guide their dietary intakes over the day as a means of ensuring nutrient adequacy.

Despite this apparent lack of research, one might argue that, with appropriate consumer education, nutrition labels could indeed become a valuable tool for dietary planning. There are 2 problems with this proposition: *1*) Irrespective of how the DV is derived, the fact that only one set of reference values can appear on a food label means that the DV can never be a meaningful target for planning intakes for all individuals in the population aged 4 y and older. Just as this target population includes 13 different life-stage and sex groups, it encompasses several different sets of requirement estimates. No single value will be suitable for planning the diets of individuals in all 13 groups. *2*) Many foods are exempt from nutrition labeling. Fresh fruit and vegetables, fish, meat, cheese, and freshly baked goods do not typically bear nutrition labels, nor do prepared foods purchased in restaurants, fast-food outlets, cafeterias, and other commercial eating establishments (although nutrition information about specific food items may be available on request). Unless individuals' diets are made up exclusively of packaged foods, it is not feasible for them to plan their intakes by using DVs to ensure nutrient adequacy. Given the centrality of fresh fruit and vegetables to healthy eating practices, it would be inappropriate to encourage such consumption patterns. In sum, regardless of how the DVs are set, nutrition labels are not an appropriate tool for dietary planning for individuals.

IMPLICATIONS

The net result of basing reference values on a population-weighted EAR rather than on some point on the upper tail of the population requirement distribution will be an increase in the apparent contribution of individual food items to individuals' overall nutrient needs. Because nutrient content claims are presently linked to label reference values, the amount of a nutrient required for a food to be considered a good source or an excellent source will be lower unless the standards for these claims change. Insofar as the thresholds for nutrient content claims are lowered, there will be less difference in apparent nutrient value between foods with naturally occurring nutrients and those that have been fortified. This can only complement efforts to increase the consumption of whole foods, such as fruit and vegetables and whole grains.

The implementation of DVs based on population-weighted EARs also has implications for the voluntary addition of vitamins and minerals to foods by manufacturers. Insofar as manufacturers add vitamins and minerals to foods at levels that enable their products to qualify for nutrient content claims, changes to the current label reference values can be expected to alter fortification practices. Because there have been substantial changes in our estimation of requirements for many nutrients since the current DVs were developed, the effect of adopting DVs based on population-weighted EARs and AIs will vary by nutrient. For some nutrients, the DV will rise; for others it will fall; and for others the difference between the population-weighted EAR and the current DV will be negligible. In the absence of other regulatory changes, any substantial change in the DV will alter the level of nutrient addition required for a product to qualify for a nutrient content claim.

More research is needed to assess the effects of changes to label reference values on the usual nutrient intakes of particular population subgroups as this operates through their effect on voluntary fortification practices. Obviously, the nature of the effects will be nutrient specific, but there are some indications that such changes may be positive. For example, a recent examination of dietary intakes among subgroups in the United States eligible for the Women, Infants, and Children (WIC) program showed substantial proportions of low-income infants and children to have intakes of zinc and preformed vitamin A above the UL (13). How much of a public health problem this constitutes is debatable, but the report's authors attributed the high intakes to the consumption of fortified foods (breakfast cereals and milk). Unless the criteria for nutrient content claims are changed, lower DVs could be expected to result in a lower addition of vitamin A and zinc to these foods.

In conclusion, in recommending the population-weighted EAR approach for nutrition labeling, the Committee has put forward a scientifically valid method to translate our current understanding of human nutrient needs into relevant consumer information. The report represents an extremely important positive step in both encouraging sound nutritional guidance and discouraging unnecessary and potentially harmful excesses. It is a report that is directed to consumer health and safety, and it warrants adoption.

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