March 15, 2024

United States Environmental Protection Agency

1200 Pennsylvania Ave, N.W.

Washington, D.C. 20460

Submitted via: labgraderefrigeration@energystar.gov

Re: EPA Energy Star Product Specifications for Laboratory Grade Refrigerators and Freezers, Eligibility Criteria Draft 2, Version 2.0

To whom it may concern,

This letter summarizes the concerns and comments from PHC Corporation of North America (PHCNA) regarding the listing and published test criteria for the EPA Energy Star Product Specifications for Laboratory Grade Refrigerators and Freezers, Eligibility Criteria Draft 2, Version 2.0

PHC Corporation is a global leader in providing products for the scientific community with 2300 employees operating in 125 countries around the world. Our mission is to contribute to the wellbeing of society through our diligent efforts by creating new value propositions for all people who wish for better health.

With respect to the Energy Star Lab Grade Program, PHCNA has been a participant and stakeholder in the Energy Star committee since our first meetings were in 2009. We have been instrumental in helping to drive the standard through to its final form in place today. We are excited to see that the standard now provides customers with peer-reviewed data under controlled conditions rather than manufacturer's claims for which they are able to make informed decisions. PHCNA recognizes that the Energy Star program goals are to provide customers with unbiased information related to not only energy performance on products listed under the Energy Star program but also provides customers with critical information related to the performance of the equipment. Temperature uniformity and recovery is especially important with respect to lab-grade products because contents stored at very specific temperatures these units create are often very expensive, or irreplaceable; they require uniform temperatures and rapid recovery to set temperature following door openings. Upon examination. it appears the current listings for some lab products on the Energy Star website may include confusing information. Additionally, these listings do not include critical information that customers often must consider in making purchase decisions on selecting the most energy-efficient products without compromising performance.

Comments on Listing Ultra-low Freezers based on cubic feet.

As a manufacturer of ultra-low freezers, high performance refrigerators and freezers that currently lead for the lowest energy in some categories we are wondering why the current listing on the Energy Star lists ultra-low freezer products by energy per cubic foot. This decision by Energy Star is puzzling because no other Energy Star product category is set forth in this manner. We request that energy listings for ultra-low freezers be listed based on the specific product's overall MDEC performance. Customers cannot

purchase ultra-low freezers on a per cubic foot basis. They purchase a complete freezer. The current method of listing energy performance per cubic foot without listing the actual energy performance of the complete unit is often confusing to customers and misrepresents the totality of the freezer energy performance.

Comments on publishing data at both -70C and -80C for Ultra-low Freezers

Since the product listings first appeared on the EPA Energy Star website, educated customers familiar with the Energy Star process, and those that have reviewed the final standards, have begun to request more specific information contained in the data submitted by the licensed testing agencies to the EPA. As you are aware, many customers prefer to store products at various setpoint temperatures including -70°C and -80°C. Higher temperature settings on ultra-low temperature freezers can allow for greater energy-saving opportunities for those customers who accept warmer temperatures as part of their protocol. Furthermore, the data set required that we submit steady-state energy consumption (no door openings) as well as energy consumption with door openings that simulate real-world operating conditions. As an original corporate committee member, PHCNA encouraged and supported this additional metric within the standards to provide more realistic data as part of the final energy equation. This data is represented in the final Equation 1 for MDEC energy consumption as E1 and E2, where:

E1 = Total energy consumption during the test at -70°C

E2 = Total energy consumption during the test at -80°C

Since these data points are *required* as part of the Energy Star submission, we request that these numbers also be published on the Energy Star site for specific products along with the appropriate definition. This allows customers to make informed decisions based on their usage patterns as they make product selections with energy savings as but one very important factor in the process.

For the same reasons listed above, customers have also requested average interior temperature measurements at both -70°C and -80°C setpoint temperatures. This information is also submitted by the licensed testing agencies to the EPA as part of the Energy Star qualification process and is represented as T1 and T2 where:

T1 = Overall average of all recorded internal temperature measurements over the course of the test at -70°C test condition.

T2 = Overall average of all recorded internal temperature measurements over the course of the test at -80°C test condition.

This information provides more thorough information on freezer performance since it includes a composite of steady-state energy consumption as well as deviation from door openings at both -80°C and -70°C setpoint temperatures.

Peak Variance

In Draft 1 of Version 2.0, there is a question posed by Energy Star as to whether peak variation should be eliminated. We believe that this question arises due to how the peak variation is applied during testing. The current definition in the Energy Star Product Specifications for laboratory grade Refrigerators and

Freezers Eligibility Criteria Version 1.1 defines *Peak Temperature Variance* as "The difference between the maximum and minimum temperatures measured across all temperature measurement devices (TMD) over the course of a given measurement period". The lack of a clear definition of the given measurement period forces the testing agencies to consider all test conditions, including door openings. In our opinion, this information does not reflect accurate performance as it only addresses a worst-case scenario condition which typically occurs when a freezer door is opened, and room air enters the freezer. Frankly, it is more of an observation than a performance metric. These products are not typically used in an empty state.

When you consider the fact that the temperature difference between room air and the interior temperature of an ultra-low freezer can be more than 100°C during testing. When tested for Energy Star qualification, freezers are essentially empty during the testing period. Peak temperature variance which includes door openings has the ability to disqualify otherwise suitable products in the high-performance category, especially for freezers. This becomes even more problematic for freezers that have maximum low setpoints below -20°C as naturally, there will be more warm-up on door openings. The lower maximum setpoint temperature that these units operate at could easily cause the peak temperature to pass beyond the 10°C performance criteria set for high-performance freezers. Under these conditions, the current Energy Star standard biases the testing procedure to favor freezers that have a warmer set limit, while potentially eliminating freezers that have very good performance other than the temperature rise that occurs during the door opening section of the test. The result being that manufacturers are forced to consider these products as general purpose, which may explain, in part, why there is less participation in the general-purpose category.

Through the lab grade standard development, since it began in 2009, as we recall, the intent of the peak variance requirement was to align with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In ICH Harmonized Tripartite Guideline, Stability Testing of New Drug Substances and Products Q1A(R2), dated 6 February 2003, Section 2.1.7.3 Drug substances intended for storage in a freezer, long-term storage conditions are defined as -20°C +/-5C, this is consistent with the 10°C peak temperature variance that was written in the Energy Star Lab Grade Standard Version 1.1. To further support this, the ICH Guideline in Section 2.1.7.2 defines long-term storage of drug substances in refrigerators as 5°C, +/- 3°C, which is also consistent with how the High Performance grade is defined for refrigerators in the Lab Grade Refrigerator Standard with a peak variation of no greater than 6°C.

Therefore, we believe that peak variation listings and qualification requirements remain as part of the Version 2.0 Standard, but the definition of Peak Variance be defined as "The difference between the maximum and minimum temperatures measured across all temperature measurement devices (TMD) over the course of the *steady state* portion of the test". Changing the definition would allow for more insightful information related to peak variance to be available to consumers if displayed in the Qualified Product List with the products, while not penalizing products that would otherwise meet the high-performance standard. Keeping in mind that the goal is to provide lower energy consumption while maintaining high performance while providing useful information for long-term steady state operation.

While the proposal by the EPA set out in lines 206 through 209 in the Draft 2 of Version 2.0 would address the disparity caused by units with operating temperatures below -20°C by testing all units at the -20°C set

temperature, it still does not address the main concern that many end-users have about peak variance during steady state operation at the temperature the units were designed to reach.

Clarification of test Data Listed on the Energy Star Website:

Since the Energy Star Standard for Lab grade Products was first introduced, more and more freezers have been launched that have set temperature capable of controlling at temperatures below -20°C. Although the Test Methodology for the current Energy Star Standard version 1.1 under 6.1 B) 2) states that products are to be set to the lowest temperature they are capable of operating, there is no indication on the Energy Star website that indicates what temperature high performance freezers were set to during testing. While the proposal by the EPA set out in lines 206 through 209 in the Draft 2 of Version 2.0 does seek to address this issue by listing the set points that tested units are capable of being operated at are reported, it does not address whether these units meet the high performance criteria at the lowest operating set temperature. The result would be that it not provide end users with useful comparative data related to energy consumption for a specific application that require temperatures colder than -20°C. It stands to reason that units that operate at colder temperatures will consume more energy. Redefining Peak Variance to consider steady state operation without temperature rise during door openings would address these concerns and provide more meaningful data to end-users.

Reference to NSF/ANSI 456

High-Performance refrigerators and freezers are often used to store not just vaccines, but other biologics as well. Given that the original Lab Grade Version 1.1 standard took into account the needs of the pharmaceutical standards, we feel it is important to continue to take the needs of the pharmaceutical industry that typically follow ICH standards where steady-state peak variance is important in their high performance product decisions. Although NSF/ANSI 456 – 2021a is also an appropriate standard, it is narrow in scope as it deals specifically with vaccine storage and does not take into account the storage requirements of all biologics. For the reasons listed previously, changing the definition and test requirements for peak variance would address a broader range of useful information to consumers. However, your proposal of separating NSF approved units to be encompassed in a separate definition would also address this issue.

Definition of High Performance Refrigerator

Draft 2 of Version 2.0 made a change to narrow the definition of high performance refrigerators to have a maximum peak variation in temperature no greater than 4°C. This definition translates to a maximum peak variation of +/- 2°C from set point temperature. Draft version 1 stated that the peak variation in temperature be no greater than 6°C. (+/-3°C from set temperature), which is consistent to what the definition has been since the start of the Energy Star Lab Grade Standard. As an original stakeholder in the Standard when it began development in 2009, we recall that the reason for the 6°C peak variation was to harmonize with the intent of the peak variance requirement was to align with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as well as WHO and other world standards for pharmaceutical storage where storage temperatures are defined as +/- 3°C, consistent with a peak variation 6°C. Even when you consider, the NSF 456-2021a standard which was developed later, the peak variation of temperature storage requirements for refrigerators is 2°C to 8°C, which is also consistent with a peak variation of 6°C.

Changing the standard to narrow the peak variation of temperature to 4°C is needlessly over prescriptive and will do nothing but eliminate many products from the Energy Star standard which would otherwise meet or exceed the long standing definition of what constitutes a high performance refrigerator.

In summary, PHCNA requests:

- The title page for products listings state the MDEC for each ultra-low freezer product listed on Energy Star, similar to how Laboratory Grade Refrigerators and Freezers are listed.
- Additional inclusion of E1, E2, T1 and T2 data on the customer facing Energy Star web pages with appropriate definitions to allow customers to make informed decisions.
- List ultra-low freezers as total MDEC energy consumption of the product, rather than a per cubic foot basis
- A change in definition and the test criteria of Peak Variance to allow freezers with lower operating temperatures, but acceptable energy performance to meet the high performance standard to remove testing bias.
- Maintain the definition of high performance refrigerators to be those with a peak variation in temperature be no greater than 6°C.

By creating a more robust standard with adjustments based on lessons learned, the industry can provide product innovations to reduce overall energy consumption while not sacrificing performance by making these important considerations visible to consumers. Consumers can also make informed decisions based on a peer reviewed standard, rather than manufacturer claims. At PHCNA, we have worked diligently over the last 14 years to help create this standard. We look forward to its continued success as an Energy Star partner.

Sincerely,

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