World Health Organization

WHO PERFORMANCE, QUALITY & SAFETY

# WHO PQS
# Immunization Cold Chain
# Manufacturer Consultation

## - 2020 –

November 3
*Geneva, Switzerland*

## Executive summary

On Tuesday 3rd November 2020, the WHO Performance, Quality and Safety (PQS) Team conducted its annual technical consultation with manufacturers of PQS-prequalified immunization products and devices from the E003 (Refrigerators and freezers) and E006 (Temperature Monitoring Devices) equipment categories. The meeting took place virtually by teleconference in lieu of a face-to-face meeting due to the Covid-19 pandemic. A link to previous consultation reports can be found here: 2018 consultation https://www.technet-21.org/en/library/main/4926; 2019 consultation https://www.technet-21.org/en/library/main/6730 . Over 60 participants joined the teleconference, including industry representatives alongside non-industry members and partners of the WHO PQS Working Group (see *Annex 1*).

The purpose of the 2020 consultation was to present general PQS progress updates plus next steps on the following prevailing themes discussed during the 2019 PQS consultation:

1. WHO PQS Electronic Monitoring System Specifications,
2. WHO PQS E003 Target Product Profiles,
3. Gavi Cold Chain Equipment Optimization Platform Update,
4. WHO PQS PMM & Sentinel Surveillance Pilots.

In light of the Covid-19 pandemic, a new topic was added to last year's themes.

5. WHO PQS Ultra-Low Temperature Specifications

**The *2020 WHO PQS Manufacturer Teleconference* continued the trend of building efficiently on the highly successful first step collaboration of 2018, via remote conferencing. It was once again a core element ensuring manufacturers remain up to date and integral to the PQS standards development processes.**

Background to WHO PQS manufacturer engagement

The WHO PQS mission is to lead the and setting of performance, quality and safety standards for immunization equipment and devices, such that country programmes, procurement agents and product end users can be assured of the adequate and appropriate characteristics of WHO prequalified products. Central to this mission is the development and improvement of product specifications, product verification protocols and description of future desired product features (`target product profiles`). Manufacturers expressed a desire to have earlier and more substantive involvement in the PQS standard-setting process[1], and the 2018 consultation served as a forum to improve engagement with manufacturers, gather inputs on PQS standards and to signal new directions for TPPs. This (third) consultation was another important step in the ongoing work to drive greater engagement between WHO PQS and manufacturers.

[1] This insight was collected via a summer-2017 McKinsey Management Review of the WHO PQS initiative and during the October 2017 TechNet-21 conference.

## Consultation sessions

The general progress update and the five topical sessions were each composed of a presenter-led introduction to the issues provided by a member of the WHO PQS Working Group, along with a description of the 2019 action points, progress and key updates. In many cases, a direct question related to the topic was put to manufacturers via MentiMeter[2] in order to gather their input and/or feedback on future action items. Participants were also invited to submit any additional questions or comments via MentiMeter; facilitating the anonymously participation of manufacturers almongst their industry peers.

Annexes to this document include:

Link to the thematic presentations (pdf) – *Annex 2*

A list of manufacturers' responses to MentiMeter questions - *Annex 3a*.

Mentimeter participant evaluation responses – *Annex 3b*

[2] A software programme accessible to participants via their laptop or smartphone that allows anonymous questions or suggestions to be submitted to the session presenter in real time. It also enables voting/polling of participants on specific questions posed by the presenters.

# I. PQS PROGRESS REPORT & UPDATES

## 1. WHO PQS Electronic Monitoring System Specifications

*In this session Mr. Steve DeSandis, Independent Expert, introduced the purpose of each new EMS standard and the requirements they will specify, and explained that having received industry feedback by the end of November, the next step will include workshopping key technical elements and revising specifications by Q1 2021. Mr. DeSandis also described the revised system architecture -the "Connected Cold Chain" – with the aid of a diagram (see presentation) and described new data logging requirements, USB-A/C power transfer and revisions of required vs optional parameters. Lastly, Mr. DeSandis described the next steps, to be approached in iterations with industry towards finalization, concerning: data standards verification protocol to be completed by Q1 2021; EMS & machine to machine interface also for Q1 2021; and new category E00X storage and transport TPPs/ specifications.*

### Discussion

- Mr. DeSandis noted that, in the feedback received to date on the draft new standards, there is a diverse spread of challenges noted.
- He also described how PQS aims to catalyse workshopping activities around technical elements by inviting all those that provide feedback to be part of these technical working groups.
- Lastly, the session leads requested feedback on the 'next steps' of the process to create the EMS specifications – how can PQS move quickly on these standards? The following input was received:
    - Standardization is key. How about the costs of communication?
    - Do we prefer wireless connection to export data from refrigerator to the equipment monitoring system?
    - We have to do a major redesign from the current solution.
    - How to test? Third party or visual presentation?
    - Uniform data standards need to be established as soon as possible.
    - We need to discuss EMS openly as there is too much complexity in the proposed systems.
    - Soonest to get finalized how the test of integrated EMS is supposed to be carried out and by whom?
    - Waiting time for tests can be long. We need more qualified labs.

**Decision points from this session:**
The standards are planned for publication and adoption for Q1 2021

*Action points from this session:*

- *PQS to kick-off the workshopping of the key technical elements with a separate imminent communication.*
- *PQS Working Group to finalize revisions of the standards by Q1 of 2021.*

## 2. WHO PQS Progress Updates

*Mr. Isaac Gobina provided a review of action points and key updates on the following current workstreams:*

- *CCE data standards: Improving data interoperability & use – the current version of these standards will be reviewed by a working group of industry representatives to finalize technical elements, and the PQS Working Group to finalize them thereafter.*
- *Humidity control TPP for ILRs & SDDs – all previous action points are completed with the TPP having been published in August 2020. The timeline for PQS inclusion is January 2023.*
- *Energy harvesting control: Test options & user guidance – field trials are ongoing (slightly delayed by COVID-19) and a FAQ sheet and other guidance has been produced. Engagement with users is ongoing to comprehensively understand use-cases.*
- *Retroactive PQS requirements & CCE grandfathering – actions are on track and the grandfathering period has been changed from 2 to 3 years. PQS will indicate which changes are exempt from the grandfathering clause where relevant.*
- *Quality management systems (QMS) inspections – PQS inspection delayed due to conflicting priorities and expected to resume in Q2 2021, where after the QMS inspections SOP can be published.*
- *Process for prequalifying products and devices – delayed due to conflicting priorities and expected to resume in Q1 2021, where after PQS will continue to monitor laboratory testing requirements' impact on application timelines & identify opportunities to improve guidance to manufacturers in the generic field protocol.*
- *WHO PQS Strategy 2019-2023 – the new strategy brochure has been shared in spring 2020. PQS will continue to update manufacturers on progress made towards PQS Strategy goals and targets.*
- *WHO PQS accreditation of new testing laboratories - PQS has accredited two new testing laboratories over the past 12 months and three additional laboratories are currently being reviewed for accreditation. Results to be shared at the 2021 consultation.*

### Discussion

- Mr. Gobina noted that humidity control was a 'burning issue' in the first face-to-face. He requested that those who have reviewed the TPP online and do not consider the timeline to be feasible to kindly explain why (not) in more detail.
- He notes that the current set of TPPs in development will be the first to test the grandfather clause.
- Concerning PQS accreditation of new testing laboratories, Mr. Gobina noted that efforts will be made to develop the testing protocols for each category during 2021.

**Decision points from this session:**
None.

*Action points from this session:*

- *CCE data standards. current version will be taken to a working group including industry to finalize key technical elements.*
- *Humidity Control TPP was published in August 2020 - timeline for PQS inclusion: January 2023.*
- *EHC – field trials data collection to be completed in November 2020 & EHC FAQ sheet to be published on PATH website.*
- *Retroactivity & grandfathering: period changed from 2 to 3 years, PQS will indicate and inform which specification changes will be retroactive, and which changes will be exempt from the grandfathering clause.*
- *QMS inspections: scheduled to resume in 2021 Q2.*
- *Prequalification process: scheduled to commence in 2021 Q1.*
- *WHO PQS Strategy: progress updates will be provided to manufacturers ongoing.*
- *PQS accreditation of new laboratories: 2 laboratories accredited during 2020, 3 laboratories currently under review for prequalification.*

## 3. WHO PQS E003 Target Product Profiles

*Mr. Pat Lennon updated the conference on the progress made in developing the ILR and SDD target product profiles. Notably, that refrigerator improvement ideas have been collected from stakeholders and a resulting list prioritized by regional experts. The TPPs will be available during November for review via industry consultation. Mr. Lennon then discussed reports of failed voltage stabilizers and the risk that they pose in terms of equipment damage. Lastly Mr. Lennon detailed a list of five upcoming TPPs concerning: extra solar power; reliable voltage stabilizers; vaccine baskets and racks; humidity and condensation control; drain plugs; compartment access; wheels and brakes.*

### Discussion

- Mr. Lennon stressed that these TPPs are essential in order for immunization programmes to receive the technologies, and therefore health outcomes, required.
- An attendee asked when performance standards and test protocols for humidity control are likely to be available.
    - In 4 months (March-April 2021). The TPP is already published and we will modify E3 specifications and include TPPs in Jan 2023.

**Decision points from this session:**
None.

*Action points from this session:*

- *TPPs are currently being drafted and should be available before end of November.*
- *PQS Working Group to organize an industry consultation in order to gain manufacturer feedback and inputs.*

## 4. WHO PQS PMM & Sentinel Surveillance Pilots

*Mr. Paul Mallins reminded the conference of the imperative for product feedback in order to help strengthen current specifications, address performance issues and empower PQS to foster product improvements and innovations. It is also a requirement of the PQS annual review. Mr Mallins went on to describe the progress of the PMM workstream, active since 2018, notably that the pilot study remains in roll-out, that pilots launched in 4 countries in 2019/2020, including a surveillance officer engaged for 15 months, all supported by the Gates foundation, in collaboration with PATH, IRD and SELF, and in Close collaboration with national EPI program & local partners. Mr. Mallins provided greater detail on the current activities and updates of PMM, as well as an overview of the newly-developed performance indicators, the PMM taxonomy and the use of PMM tags to classify CCE failures.*

### Discussion

- Mr. Mallins stated that if the pilot outcome is successful the aim would be integrated into PMM into standard EPI practice.
- An attendee asked whether any data (possibly anonymized) be broadly be available from the surveillance programs.
    - Data is owned by each country and countries are sharing with WHO. The aspiration is to be able to share anonymized data in other ways to as wide a group as possible. There is a plan to have independent review of the pilot and publish a report that includes data as far as possible.

**Decision points from this session:**
None.

*Action points from this session:*

- *PMM taxonomy will be circulated in the coming weeks and industry feedback is very welcome. All stakeholders will be requested to use the taxonomy to describe performance issues. It will be include into the 2021 annual review.*

## 5. WHO PQS Ultra-Low Temperature Specifications

*Mr. Simon Leach began an update on the new ultra-low temperature freezer specification and verification protocol, noting its importance for the Ebola vaccine and potentially for Covid-19 along with other new vaccines. He also provided answers to some questions already posed by industry members. Mr. Steve MCarney took the relay on this topic, describing the challenges, solutions and power assumptions for powering ULT freezers in logistically difficult environments with unreliable electricity and significant electricity consumption requirements. He outlined key aspects of the draft ULT POW specification, including requirements for a UPS 8-hour backup and two sources of continuous electricity. Lastly, he described that the equipment needs to movable over short distances by 2 people for transport between stationary cold chain points, short term storage and mass outreach sessions. Other key usability requirements include maintaining vaccines at -80°C and holding at least 5L of vaccines. Mr. Isaac Gobina concluded the topic with the current status of the specification development process: notably the details of the drafting process and scoping to ensure feasibility and understand risks.*

### Discussion

- Mr. Leach thanked everybody who has provided feedback on the ULT specification and VP, noting that it is essential and very welcome.
- Mr. McCarney noted that COVID-19 vaccines will represent a critical load.
- The session leads asked the attendees what issues they foresee with offering/bundling an uninterruptible power supply (UPS) with your ULT freezer offerings. Responses were:
    - PQS specifications for the UPS, like voltage stabilizers.
    - It's a challenge to the life of UPS.
    - The high consumption of ULT freezers.
    - No big issues, could be arranged, only obstacle could be linked to the delivery times of suitable UPS.
    - ULTs require a lot and stabilized power. AVS today for ILRs are unreliable and it will be difficult for manufacturers of ULTs to as well take care of UPS.
    - Knowing the energy consumption, of the ULT with sufficient accuracy.
- The following questions were received from attendees during the discussion:
    - Is there likely to be a need for -20C vaccine storage?
        - -20°C vaccine storage already exists so no need of new specifications for this. It is unclear if there is a need for this for vaccines outside of COVID-19 (currently is only OPV requires this). For some PCM there may be a need to prepare the vaccines before they go into ultra-low freezing transport or storage.
    - Is there any update on forthcoming PQS requirements for temperature monitoring or loggers? Both shipment and storage?
        - Once specifications for the freezer and portable carriers are published, PQS will contact MFC of TMDs - end January 2021.
    - What plans do you have for writing a specification of ULT data loggers?
        - To be developed once the main ULT specifications have been published.
    - Are there already specifications for the storage of vaccines from the manufacturers? Pfizer COVID-19 vaccine storage temperature for example is -75 C?

- Mr. Diesburg replied: it still seems that there are many possibilities being considered and a specific "specification" even on a single vaccine candidate tend to include a lot of safety-factor so it is hard to understand how solid the nominal numbers we all hear quoted really are. Between -60C and -80C seems likely still.
- Mr. Gobina: regarding power requirements this will be a support to UNICEF procurement, for countries where power supply is a challenge these specifications will help this agency to identify the component to the continuous power supply system - so freezer manufacturers are not obliged to provide it.

**Decision points from this session:**
None.

*Action points from this session:*

- *For passive transport & storage at ULT discussions are ongoing regarding previous similar efforts (specifically Ebola vaccine trials) and any needs for additional R&D.*

## 6. Gavi Cold Chain Equipment Optimization Platform Update

*Ms. Karuna Luthra provided a comprehensive update on the Gavi CCEOP Programme, commencing with a reminder that the CCEOP addresses critical gaps in the cold chain. Ms. Luthra displayed data regarding the good quality of "Service Bundling" to date, and the current improvement in healthy market development following corrective action by the alliance and responsiveness by the Industry. She noted that more than 100 unique products have been prequalified, less than half of which are in demand however. Turning to the Gavi 5.0 strategy, Ms. Luthra described the mission as 'leaving no one behind with immunization', and laid out key elements of the strategic action plan until 2025. She concluded this section with Gavi policy updates and platform eligibility criteria. Lastly, Ms. Luthra presented the background and need for the Intelligent Maintenance and Planning Tool (IMPT), an overview of its purpose and use and the development timeline.*

### Discussion

- The session lead asked attendees whether, if we adopted a different approach, what would be an idea alternative approach for ILRs/SDD sizing options / volume categories? Responses were:
  - <100L, 100L-200L >200L (proposed twice)
  - Why categories if so few models procured? / What is the driver for having categories?

**Decision points from this session:**
None.

*Action points from this session:*

- *IMPT V1 finalized per demo feedback in December 2020, in January 2021 the IMPT trainings begin and during the course of 2021 the IMPT V2 and onboarding of new countries will begin.*

# ANNEXES

## Annex 1a: List of manufacturers invited to the meeting (not participants)

**Manufacturers that were invited to the meeting, in alphabetical order:**

B-Medical Systems
Berlinger & Co AG
Beyond Wireless
Dulas
Elpro
Haier Biomedical
Ikas
Log Tag Recorders
Modum
New Horizons
Nexleaf
Rueger
Solar System Services
Sundanzer
Surechill
Vestfrost Solutions

## Annex 1b: List WHO PQS and partner organization participants

**Representatives of the WHO PQS Working Group & other non-industry invitees were:**

Isaac Gobina – WHO PQS
Paul Mallins – WHO PQS
Pat Lennon – PATH
Joanie Robertson - PATH
Matt Morio - PATH
Denise Habimana – PATH
Steven Diesberg – PATH
Edda Magnus - PATH
Thierry - UNICEF Supply Division
Teshome Yemamu Copois – UNICEF Supply Division
Michelle Seidel – UNICEF Programme Division
Steve McCarney – Sunny Day, LLC
Steve DeSandis – Independent Expert
Omileye Toyobo – Clinton Health Access Initiative (CHAI)
Karuna Luthra – Gavi, the Vaccine Alliance
Simon Leach – Independent Expert
Kelly Hamblin – Bill & Melinda Gates Foundation
Gemma Huckerby – Consultant to WHO PQS

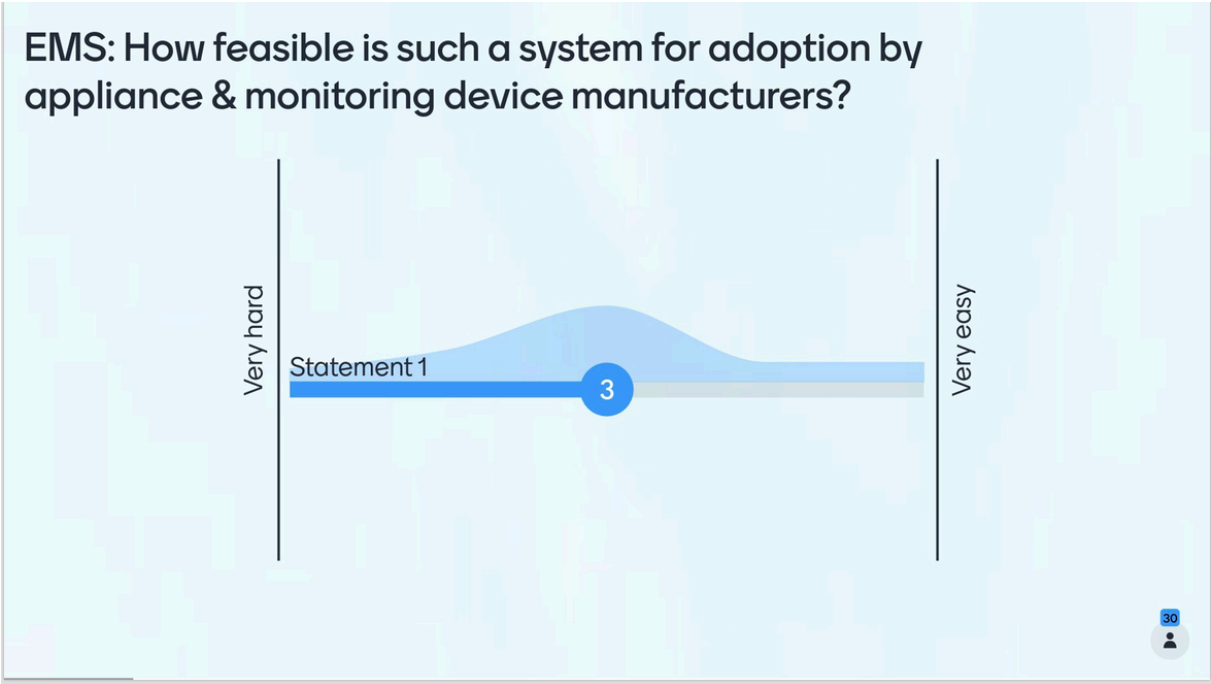
## Annex 2: Meeting presentations

The presentation given for each of the five technical themes and the progress update can be accessed here:
https://drive.google.com/drive/folders/1RgTiP0rBMlapbzdNcoUH3FouC1aA9kdA?usp=sharing

## Annex 3a: MentiMeter manufacturer responses to PQS (closed) questions

Note: PQS presenters' responses to questions posed by participants are discussed in the respective sections of the main body of this report, as are participants feedback on open-ended questions.

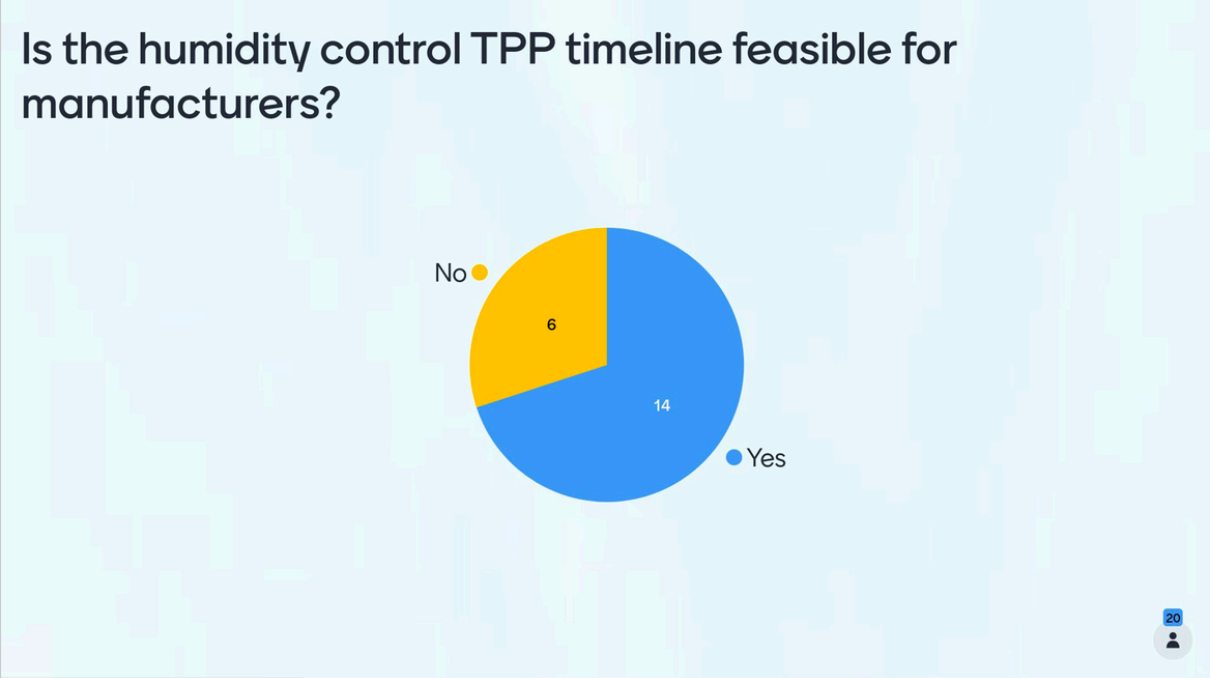
## I. WHO PQS Electronic Monitoring System Specifications

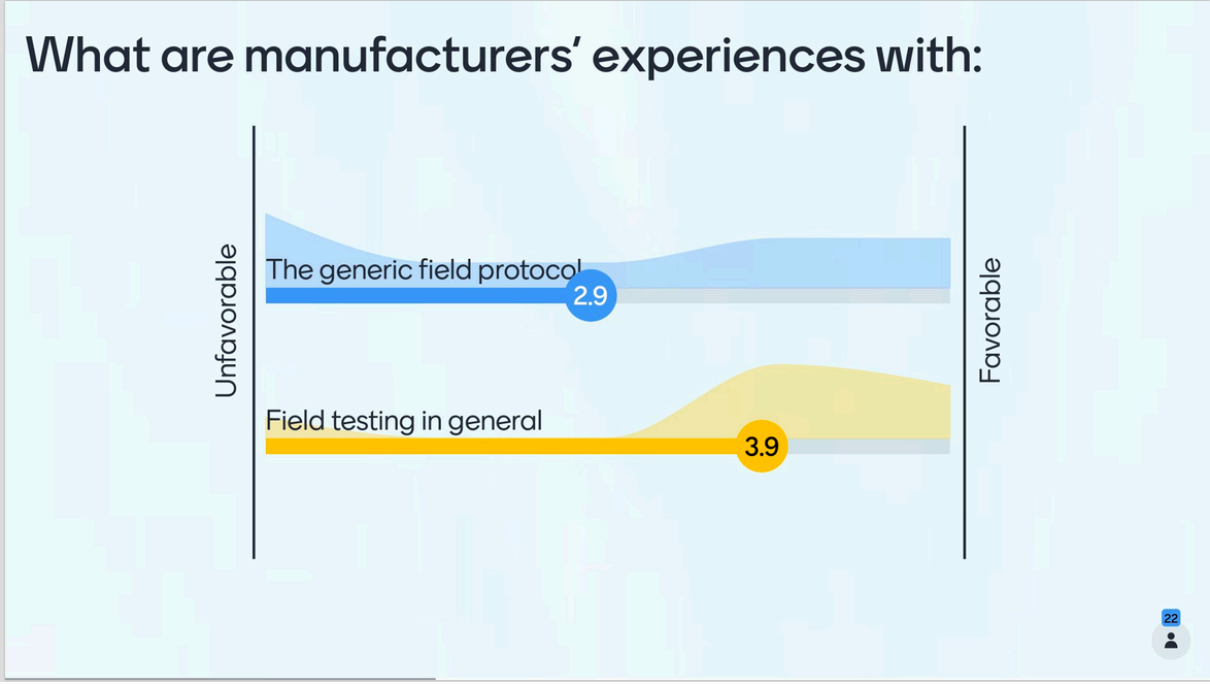



## II. WHO PQS Progress Updates

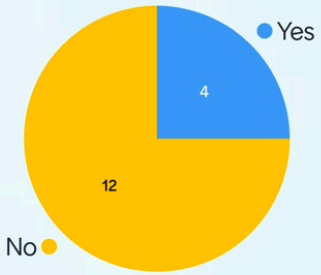
None.

## III. WHO PQS E003 Target Product Profiles



## Have you had experience with the field testing protocol?

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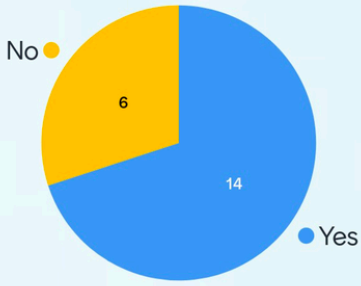
## Is the humidity control TPP timeline feasible for manufacturers?

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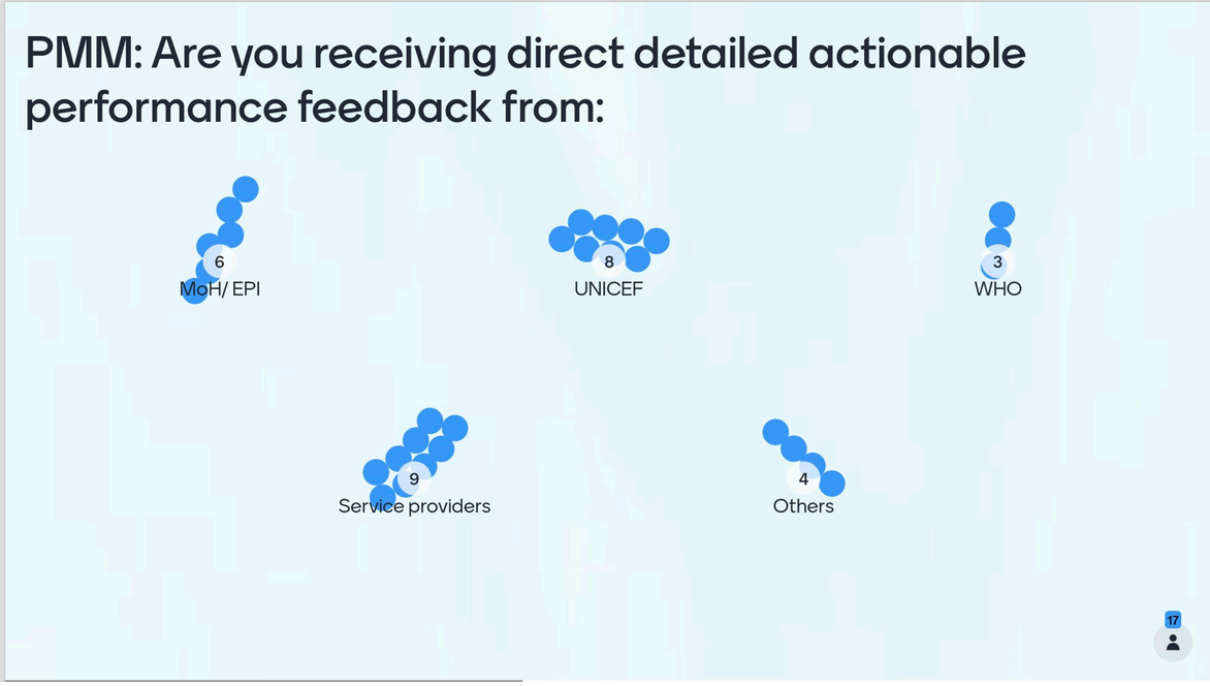
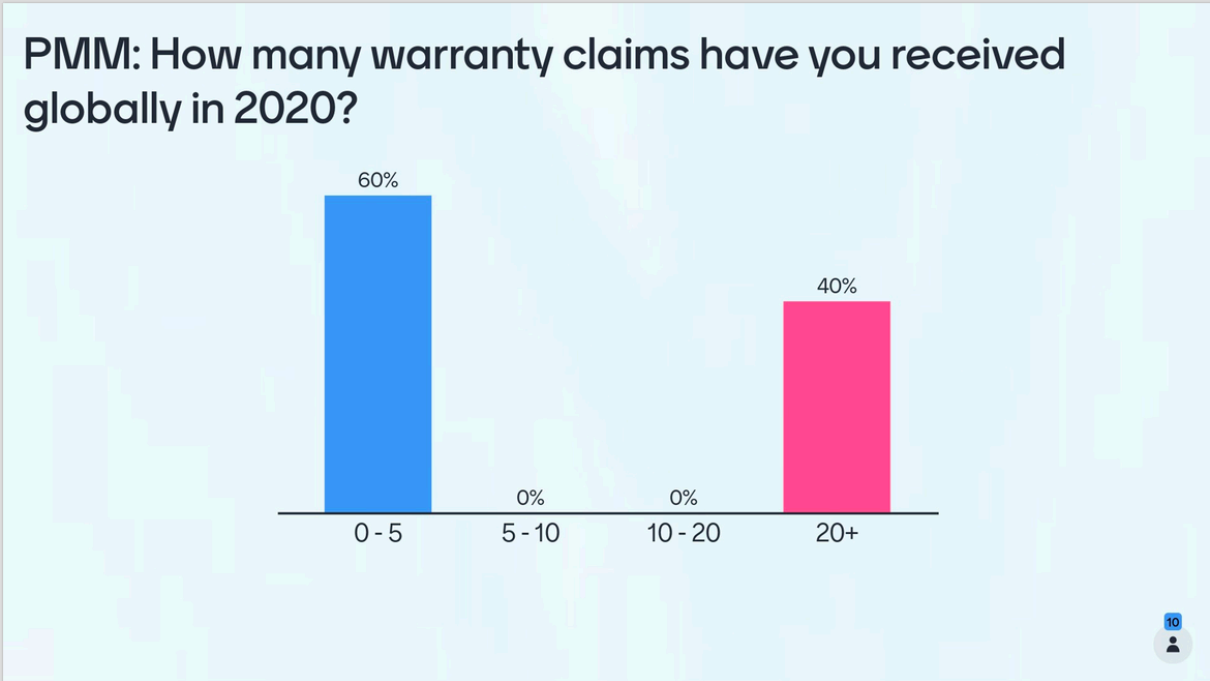
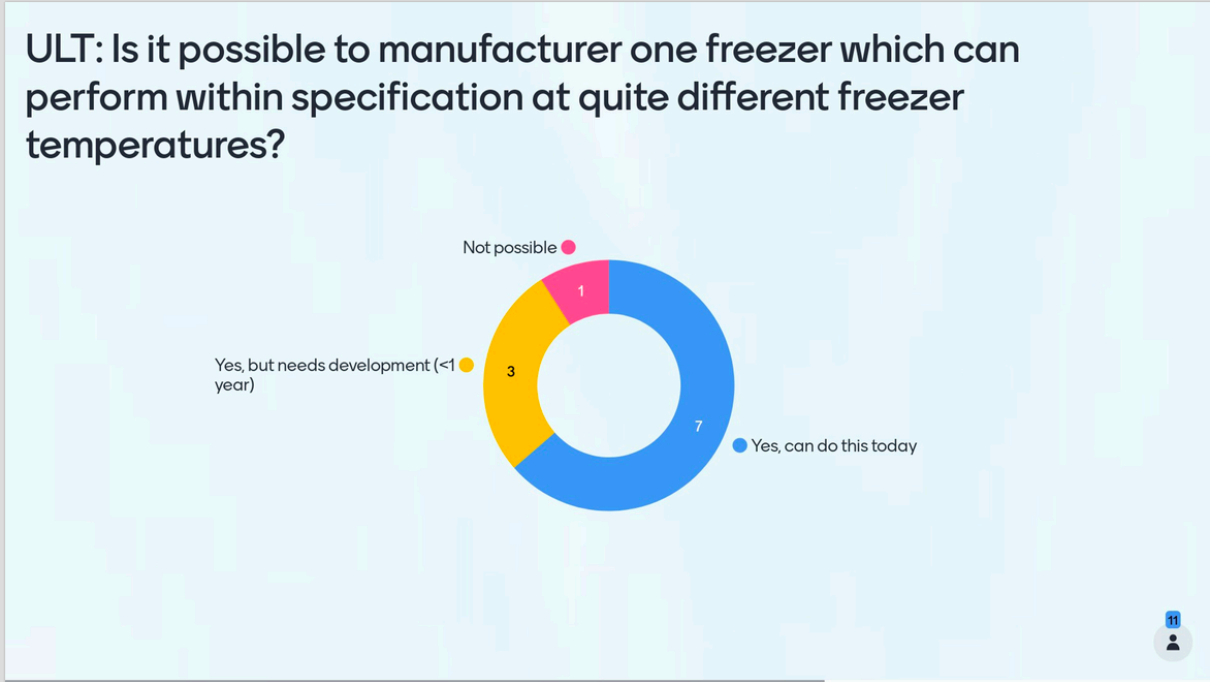
## IV. WHO PQS PMM & Sentinel Surveillance Pilots

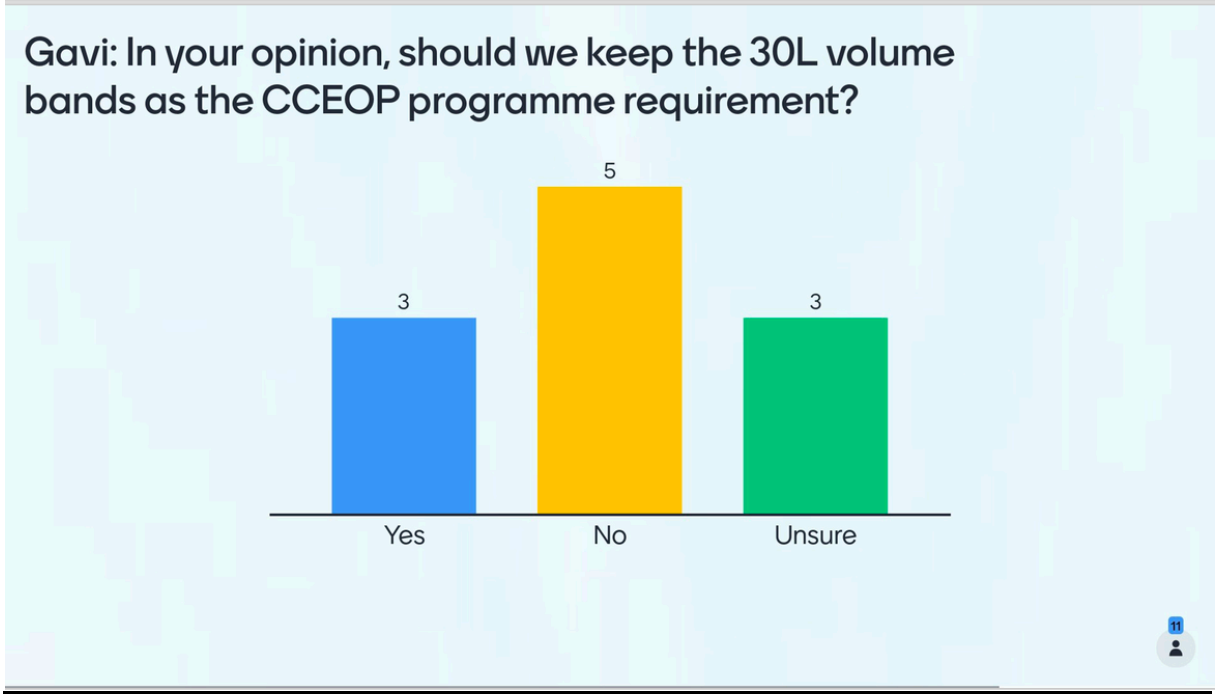


## V. WHO PQS Ultra-Low Temperature Specifications




## VI. Gavi Cold Chain Equipment Optimization Platform Update



## Annex 3b: Mentimeter participant evaluation responses