



Quality assurance tools in milk-testing laboratories: The view of an instrument manufacturer

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The objective of this work is to provide an overview on a) the validation and certification of FOSS's milk analysers, b) working with FTIR technology/data and standardisation as part of quality assurance as well as c) quality assurance for new milk-testing parameters.

Summary

Besides extensive internal as well as field testing of milk analysers, FOSS seeks for thorough validation and certification of its instruments according to internationally accepted standards, like ISO 8196, performed by independent organisations. In terms of the Fossomatic™, legislation dictates that only certified milk analyser are approved for enumeration of somatic cell count in payment samples in the EU and the USA. Beyond that, additional national approvals might be required in some countries. In terms of the analysis of the composition of milk primarily approvals on national level are required so far. The newly available ICAR certification service for milk analysers, however, covers the validation of both somatic cell counter and milk component analyser. It is further thought to replace national approvals with the ICAR certification and thus contribute to the optimisation of the validation and certification process of milk analysers around the world. Besides fulfilling regulatory requirements, the validations and certifications can generally be used to demonstrate the performance of an instrument. Furthermore, the international ICAR validation would allow laboratories to implement new instruments by simply verifying them according to ISO 17025 using reference materials and proficiency tests.

Fourier Transform InfraRed (FTIR) spectrometry as applied on MilkoScan™ instruments is nowadays a commonly used technique for analysis of milk samples on fat, protein, and lactose and more recently other minor components such as urea, BHB, and acetone. Beyond that, the spectra data are more and more utilised to describe a dairy cow's health and welfare status and possibly other conditions as precisely as possible. In this context, the standardisation of spectra is of utmost importance to make data comparable and transferable. Furthermore, actual possibilities and limitations of FTIR technology need to be considered.

The implementation of new parameters on high-throughput milk analysers for laboratories often requires the availability of appropriate reference methods to allow confirmation of accuracy of results generated on the high-throughput instrument. In the example of ketosis screening, which is based on the prediction of BHB (and acetone) using MilkoScan™, an official reference method is not available.

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However, in Canada and France, quality assurance programmes based on wet-chemistry methods were developed and are used successfully since. In the example of the new differential somatic cell count (DSCC) parameter a reference method is lacking. But initial work on this subject has begun within the International Dairy Federation (IDF).

In conclusion, FOSS helps to allow quality assurance working with its milk analysers by obtaining different certifications, offering a standardisation concept for FTIR analysers, and supporting the development of analytical methods, reference materials, and proficiency testing programmes. Raw milk samples hold a wealth of valuable information that can help us to make significant improvements in the dairy milk supply (both milk quality and dairy herd management). Hence, the development of new parameters, associated quality assurance tools, and effective communication of data are clearly in the interest of and supported by FOSS.

Keywords: Daniel Schwarz, quality assurance, instrument certification, milk analysis.

Introduction

Laboratories providing analytical services need to be able to demonstrate to their customers that the results provided are precise, accurate, and equivalent. In this context, regulatory requirements need to be fulfilled and quality assurance procedures are key. According to ISO 9000 quality assurance is defined as "part of quality management focused on providing confidence that quality requirements will be fulfilled". Quality assurance is further described as the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention.

The objective of this work is to provide an overview on how FOSS supports milk-testing laboratories in terms of meeting regulatory requirements as well as establishing quality assurance procedures. Specifically, the paper provides information on a) the validation and certification of FOSS's milk analysers, b) working with FTIR technology/ data and standardisation as part of quality assurance as well as c) quality assurance for new milk-testing parameters.

International certifications of milk analysers

Various different international certifications/approvals of milk analysers are available. Briefly, the EU RL (European Union Reference Laboratory) certification in the EU as well as the NCIMS (National Conference on Interstate Milk Shipments) approval in the USA are required for Somatic Cell Count (SCC) analysers when they are used for payment purposes. In terms of milk component analysers, specific national requirements do not to be fulfilled, e.g. in France. Instruments for bacteria counting must be approved by EU RL as well as NCIMS for official/regulatory use in EU and USA, respectively, too.

Somatic cell counter - Fossomatic

The certification procedure is carried out by the organisation Microval in the EU. In this context, a laboratory with EU expert laboratory status is testing the somatic cell counter according to ISO 13366-1, ISO 13366-2, and ISO 8196-3 (IDF 148-1, IDF 148-2, IDF 128-3). The test results for Fossomatic 7 and Fossomatic FC and the respective specifications of the International Dairy Federation (IDF) are summarised

in Table 1. All IDF specifications were met and both Fossomatic 7 and Fossomatic FC got certified (Fossomatic 7 DC currently pending). The certificates and test reports are available on the following website: <http://microval.org/en/issued-certificates/>.

In the USA, somatic cell counters are mainly tested for their accuracy and repeatability. As a results of the NCIMS approval, the so called 2400 form is published on the following website: <http://ncims.org/forms/>. Laboratories doing payment testing are operating their instruments according to the 2400 form. The instruments Fossomatic 5000 and FC are approved (Fossomatic 7 and Fossomatic 7 DC currently pending).

Table 1. Overview on test parameters and results for Fossomatic 7 as well as Fossomatic FC and IDF specifications.

Item	Fossomatic 7	Fossomatic FC	IDF specification
1. Repeatability (r) in % per cell count level			
low (100 k)	11	16	< 17
medium (500 k)	5	11	≤ 11
high (1,500 k)	3	8	< 8
2. Carry-over (CO) in % per cell count level			
low (500 k)	CO _{H/L} = 0.14; CO _{L/H} = 0.48	CO _{H/L} = 0.45; CO _{L/H} = 0.28	< 2
medium (1,000 k)	CO _{H/L} = 0.07; CO _{L/H} = 0.14	CO _{H/L} = 0.21; CO _{L/H} = 0.05	< 2
high (3,000 k)	CO _{H/L} = 0.05; CO _{L/H} = 0.32	CO _{H/L} = 0.13; CO _{L/H} = 0.14	< 2
3. Linearity (r_c) in %			
	1.8	1.7	< 2
4. Lower limit of quantification			
	17 k cells/ml	37 k cells/ml	-
5. Upper limit of quantification			
	10.000 k cells/ml	10.000 k cells/ml	-
6. Intra-laboratory reproducibility (R_{intra-lab}) in % per cell count level			
low (50-200 k)	11	16	< 19
medium low (201-400 k)	9		≤ 19
medium (401-650 k)	9	11	< 14
medium high (651-1,000 k)	7		≤ 14
high (1,000 -1,500 k)	10	7	< 11

Milk composition analysers must be validated according to ISO 8196-3 (IDF 128-3) and the CNIEL (Centre national interprofessionnel de l'économie laitière) specifications in France. MilkoScan 7 RM and MilkoScan FT+ were tested for accuracy, repeatability, linearity, carry-over, and stability (parameters fat and protein each) and all results obtained were conform with the specifications (Table 2).

Milk composition analyser - MilkoScan

The BactoScan FC/FC+ was tested in the EU as well as the USA. All test results were within the specifications of ISO 4833-1, ISO 4833-2, ISO 16140-2 (Table 3). While a certificate and a summary of the test report are available on Microval's website (<http://microval.org/en/issued-certificates/>), a 2400 form for BactoScan FC/FC+ is published on NCIMS's website (<http://ncims.org/forms/>).

Bacteria counter - BactoScan

Table 2. Comparison among milk composition analysers.

Item	Milkoscan 7 RM	Milkoscan FT+	IDF specification
1. Accuracy ($s_{y,x}$) in g/l			
Fat	0.37	0.45	< 1.03
Protein	0.49	0.43	≤ 1.03
2. Repeatability (S_r) in g/l			
Fat	0.08	0.10	0.14
Protein	0.08	0.04	0.14
3. Linearity (r_c) in %			
Fat	0.68	0.8	1
Protein	0.26	0.2	1
4. Carry-over (CO) in %			
Fat	0.28-0.34	nd*	1
Protein	0.21-0.45	nd*	1
5. Stability according to ISO 8196-3	Yes	Yes	

* = not determined

ICAR milk analyser certification

ICAR is offering a new services for certification of milk analysers since 2017 (<http://www.icar.org/index.php/certifications/milk-analysis-laboratories-certifications/milk-analysers-icar-certified/>). The service entails certification of instruments for somatic cell count and milk composition analysis according to the ICAR protocol for evaluation of milk analysers and the ISO 8196-3. Above described certifications are primarily focused on payment analyses, whereas the ICAR certification is rather dedicated on analyses of individual cow milk samples in the context of milk recording testing. The key objective of the ICAR certification is to apply a harmonised protocol that serves the interest of milk recording worldwide. This, in turn, should be sufficient to fulfil the various requirements and possibly certifications required on national level in many countries. The procedure for obtaining the ICAR certification of the CombiFoss instrument was initiated.

Spectral analysis of milk

Fourier Transform InfraRed (FTIR) spectrometry is nowadays a commonly applied technique for analysis of milk samples on fat, protein, and lactose. More recently minor components such as urea as well as acetone and β -hydroxybutyrate (BHB) (de Roos *et al.*, 2007) were developed in order to provide additional valuable information for optimising dairy herd management. FTIR technology is more and more used to extract extra information that could be used for improving dairy herd management further. In this context, the prediction of numerous new parameters like lactoferrin or major minerals based on milk spectra and different phenotypes was described in the literature (see Figure 1).

FOSS has developed global models (prediction models) for the parameters fat, protein, lactose, SNF, casein, urea, fatty acids, BHB and acetone. These models have been validated thoroughly over many years. However, in terms of indirect parameters, meaning parameters that cannot be measured directly using FTIR spectrometry due to their low concentrations, such as lactoferrin, correlations between milk spectra and reference values could be established. Nevertheless, such correlations depend on the actual local conditions (e.g., feeding, breeding, etc.) and further validation would be required when applying such calibrations even under slightly different conditions.

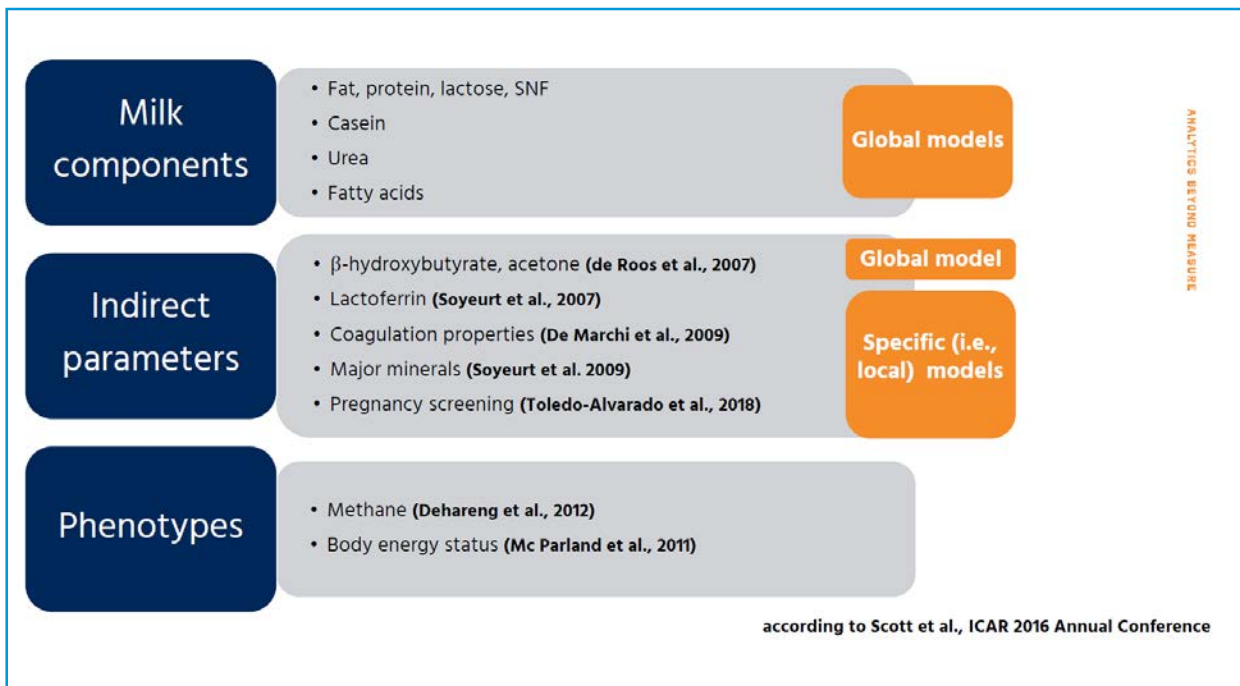


Figure 1. Overview on milk components, indirect parameters, and phenotypes that can be predicted using FTIR spectrometry.

A prerequisite for the global transfer of prediction models is the standardisation of the FTIR instrument. In this context, FOSS introduced a procedure for standardisation of MilkoScan instruments based on the monthly analysis of the so-called FTIR Equalizer in 1995. The procedure is described in detail elsewhere (https://www.fossanalytics.com/-/media/files/documents/papers/dairy-segment/standardization-of-ft-ir-instruments_gb.pdf).

Milk samples hold a wealth of valuable information about dairy herds as well as individual cows. Two examples for new parameters unveiling more information from milk samples are BHB and acetone used for ketosis screening, as well as FOSS's new Differential Somatic Cell Count (DSCC) parameter for mastitis screening. However, in case of both applications official reference methods are not yet available today.

New parameters for milk testing and reference methods

Ketosis screening based on the prediction of milk BHB and acetone was introduced in 2006. Milk BHB and acetone values predicted using FTIR spectrometry showed good correlations with results generated using a wet chemistry method (de Roos et al., 2007). However, there is no official (e.g., IDF recommended) reference method for milk BHB and acetone. Hence, the milk-testing organisations working with milk BHB (and acetone) in Canada and France developed their own quality assurance programmes involving wet chemistry methods as described elsewhere (Schwarz,

Example 1: BHB and acetone - Ketosis screening

2017a). Apart from that, the IDF Action Team S03b: New applications of IR spectrometry is working on a guideline describing, among other things, how to work with prediction models used for ketosis screening (to be published in 2018).

Example 2: Differential somatic cell count

DSCC, representing the combined proportion of polymorphonuclear neutrophils and lymphocytes in percent, was introduced in 2016 and is a new biomarker for mastitis management (Damm *et al.*, 2017; Schwarz, 2017b). DSCC is beyond the scope of the current reference method for total somatic cell count (ISO 13366-1). However, the IDF Action Team S15 Bulletin on improvement of the reference method for somatic cell counting started mapping possibilities/technologies for and improved SCC reference method including the capability of DSCC. A first bulletin describing outcomes of that work is supposed to be published in 2018.

Conclusions

FOSS helps to allow quality assurance working with its milk analysers by obtaining different certifications, offering a standardisation concept for FTIR analysers, and supporting the development of analytical methods, reference materials, and proficiency testing programmes. In general, raw milk holds a wealth of valuable information that can help us to make significant improvements in the dairy milk supply (both milk quality and dairy herd management). Hence, the development of new parameters, associated quality assurance tools, and effective communication of data are clearly in the interest of and supported by FOSS.

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Moving from approval to certification for recording and sampling devices by ICAR - a dynamic approach to connect member organizations and manufacturers while encouraging innovation and testing of new devices

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Traditionally, successful ICAR testing of recording and sampling devices results in a lifetime approval from ICAR for the specific device combination. A recording and sampling device may have many components - milk meter, controller, keypad, sampler, firmware, and software. The approval approach has served the milk recording industry well for many devices, particularly mechanical milk meters. However, changes in one or more of the components of a complete device may affect the accuracy of either the milk yield prediction or the delivery of a representative milk sample. While the current ICAR Guidelines state that manufacturers are required to report these changes to the Subcommittee for Recording and Sampling Devices (RSD-SC), some modifications are not reported in a timely fashion. Further, device installation protocols or routine calibration procedures, which are reviewed during the ICAR testing process, may be altered by manufacturers after the ICAR approval is awarded. Validation of these changes by the RSD-SC along with timely communication to ICAR member organizations of such changes has been identified as an area in need of improvement.

The current ICAR Guidelines include language for annual reporting by both device manufacturers and member organizations. Building on these existing reporting Guidelines, the RSD-SC is moving to an annual review of certification for all recording and sampling devices. This dynamic approach is designed to increase the responsiveness of the RSD-SC to member organizations' challenges or concerns as well as facilitate timely resolution by device manufacturers. Further, this certification plan is desirable when compared to re-testing and re-certification of every recording and sampling device after a specific time frame or certification period expires. Rather, manufacturers are encouraged to invest resources into ICAR testing of both modified and new devices rather than in testing of current devices that have not undergone any changes in design or components. This approach to device certification is also expandable to include sensor devices in the future. The RSD-SC is committed to meeting the needs of ICAR member organizations and building strong relationships with device manufacturers.

Keywords: milk recording, recording devices, sampling devices, certification, milk sampling

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Summary

Background and perspective

As one of the standing subcommittees of ICAR, the Recording and Sampling Devices Subcommittee (RSD-SC) is responsible for the testing of milk recording and sampling devices at various ICAR-qualified test centres. Currently these test centres are based in France, Germany and The Netherlands and work cooperatively under the direction of the RSD-SC and Service-ICAR. Testing of devices involves both laboratory and field (farm) testing in accordance with Section 11 of the ICAR Guidelines (<https://www.icar.org/index.php/icar-recording-guidelines>), whose review and maintenance is also the responsibility of the RSD-SC. In addition to testing of the device with respect to specific metrics outlined in the Guidelines, an evaluation of both the installation and routine calibration procedures for the recording and sampling device is conducted. After completion of an ICAR test, a full report of the recording and sampling device is reviewed in detail by the RSD-SC with a resulting recommendation for approval that is forwarded to the ICAR Board for endorsement. Finally, this approval is published on the ICAR website as a reference for all ICAR member organizations.

Traditionally this ICAR 'approval' has been for the lifetime of the recording and sampling device. The RSD-SC does offer the opportunity for device manufacturers to report and apply to modification testing or desk review(s) of changes to devices over time. Some manufacturers embrace this opportunity as modifications or improvements to the originally approved device are brought to the marketplace. Other manufacturers provide only limited updates to the RSD-SC, mostly in response to queries or concerns raised by ICAR members. A lifetime approval for a recording and sampling device is not practical nor in the best interest of ICAR and its members, noting that changes or improvements in devices occur through the normal business practices of device manufacturers. The challenges noted by the RSD-SC include, but are not limited to the following:

- Change in design of meter and/or sampler.
- Change in firmware and/or software.
- Availability of original components.
- Changes or deviations in specific parts.
- Change in installation or routine calibration procedures.
- Quality control issues.
- Change in branding, device name, or mounting position.

Approval versus Certification

While some organizations or businesses may use the terms approval and certification interchangeably, the differences that exist in the application of these terms for positioning in the marketplace are notable. The traditional term 'approved' as used by the RSD-SC denotes that the recording and sampling device has met minimum standards after testing. While in accordance with the specific tests or metrics outlined in the ICAR Guidelines for laboratory and field testing. The term 'certified' is more appropriate in the case of ICAR whose mission involves continuous improvement in systems and practices. Certified or certification implies that not only has the device met minimum testing standards but is also in compliance with all of the ICAR Guidelines including manufacturer reporting and device labelling. Further, certification is a recognition of continued compliance and quality with a specific time frame associated with said certification.



Embracing that the role of ICAR is certification for devices, the ICAR Subcommittee for Animal Identification moved from identification device approval to certification in 2015. This change, as outlined at previous ICAR sessions and on the ICAR website, designates a five-year certification period for an identification device with a specific expiry date. With the goal of maintaining clarity of ICAR certification services for various device categories, the RSD-SC reviewed this approach in the context of retesting and recertification of recording and sampling devices. Noting that the lifespan of these devices is longer and not practical in many situations due to device availability, the RSD-SC concluded that a different approach was warranted. Further, the investment of testing recording and sampling devices made by manufacturers should be focused on new or innovative devices rather than retesting of either current or out of production devices where none of the previously described challenges exist.

Working with existing sections of the ICAR Guidelines and recognizing the needs of ICAR members, the RSD-SC has implemented a dynamic approach to continued certification of recording and sampling devices. It should be noted that no changes to the application or testing of new or modified recording and sampling devices will be implemented. Those processes will continue as described though manufacturers will note potential restructuring of the ICAR Guidelines as part of a larger effort by ICAR to modernize the functionality of all ICAR Guidelines. This dynamic approach was developed using the reporting options that currently exist with a focus on ICAR member engagement and device manufacturer responsibility. The certification of all recording and sampling devices will be reviewed by the RSD-SC on an annual basis. The documentation for this review will be the ICAR member reports and manufacturer reports on ICAR-certified devices in the marketplace. Both of these reports are described in the current ICAR Guidelines. To aid in this reporting, the RSD-SC has developed templates for both groups to complete and submit.

The dynamic approach to recording and sampling device certification

ICAR members are not required to complete an annual report of satisfaction but are strongly encouraged to communicate their concerns to the RSD-SC using this tool. With completion and submission of a member report, the RSD-SC acknowledges a desire for timely resolution to known and relevant issues. In addition to ICAR member reporting on an annual basis, device manufacturers are required to submit a report on ICAR-certified devices in the marketplace. This report will include devices sold and in which countries they are sold, modifications in any and all device components, and alternative market names including private-labelling or branding of said devices.

Using the information provided in the annual reports, the RSD-SC will review all recording and sampling devices for continued certification. For any device with no noted concerns from the member aspect and no reported modifications or changes, ICAR-certification will continue. For those devices that do continue as certified, the RSD-SC will suspend the certification of the device until the concern is resolved. The time frame required for resolution will be at the discretion of the RSD-SC and mutually agreed upon by the manufacturer and the RSD-SC, noting that each case needs to be evaluated on both the merits of concern and scope of the response from the manufacturer. In the case where resolution cannot be achieved, either after attempts by the manufacturer or by the unwillingness of the manufacturer, the certification of that recording and sampling device, including those devices manufactured or marketed under alternative names, will be withdrawn.

As previously noted, certification requires compliance with all the ICAR Guidelines. In addition to the required manufacturer report, a critical component of the Guidelines is labelling of ICAR-certified devices with an appropriate label. This requirement exists



in the current Guidelines (Section 11.5.4 - <https://www.icar.org/index.php/icar-recording-guidelines/>) and will continue moving forward. To aid manufacturers and ICAR members alike, the RSD-SC has redesigned the ICAR label to include device name, year of initial certification, species, and use or mounting position (high-line, low-line or AMS). The application of labels to ICAR-certified devices not only adds value to the device but assists the users of the device in proper installation and use.

The change from lifetime approval of recording and sampling devices to a review and certification process is designed to provide benefits to both ICAR member and device manufacturers. Central to this process is communication between the RSD-SC, building synergy between device manufacturers and device users, resolving issues of concern, and encouraging manufacturers to invest in testing new and innovative devices rather than retesting of devices that have not changed but are currently in the marketplace.



Strategic udder health monitoring and benchmarking based on national SCC data in Germany

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Udder health still is one of the most problematic areas in dairying, although a lot of efforts have been spent over the last fifty years to improve the situation. As udder health management is a complex task, depending on a multitude of influencing factors, a strategic approach is needed to effectively control the situation, both on single farm level and on a population or national level. In any case reliable, standardized and globally available data are needed to facilitate strategic approaches, whatever the relevant management level may be.

In Germany a new udder health monitoring report, based on SCC data from the national DHI system, has been introduced in 2015. For this report six new key figures are being computed and summarized to help the farmer keeping an objective eye on important risk factors in the life of his dairy cows. These key figures show the proportion of cows with healthy udders in the herd, the new infection rate during lactation, chronically ill cows with poor prognosis, the new infection rate and the cure rate during dry period as well as the rate of heifer mastitis in the herd.

These key figures are presented for the herd level, for the regional and the national level to facilitate benchmarking as a management tool. Fact sheets and checklists, developed in the same frame of *milchQplus* (www.milchqplus.de), a national project funded by the Federal Ministry for Food and Agriculture and DLQ e.V., the national umbrella association of all regional DHI organizations, support the dairy farmers and advisors in identifying the relevant influencing factors and selecting the right measures and actions to be taken.

Keywords: Udder health, strategic management, monitoring, benchmarking, SCC data, key figures, milchQplus, DLQ.

Summary

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