



## MA SC

ICAR Sub-Committee  
on Milk Analysis

# Approval procedure for milk analysers in milk recording

## Foreword

It is defined two ways to achieve the international approval of a milk analyser by ICAR :

- a- Step-by-step nationally :** Relates to already existing national evaluation and approvals got in three different countries that allows to proceed to evaluation throughout time progressively as described in the ICAR Protocol for milk analyser evaluation.

It presents advantages in limiting costs and risk to one evaluation at the time and, where national approvals for milk recording and milk payment are interdependent, evaluation on behalf of one purpose can serve to the other depending on the agreement between respective relevant national bodies and specific national approvals pronounced by national bodies for each purpose.

- b- Direct internationally :** Based on three evaluations carried out simultaneously (or within short windows of time) in parallel in three different countries.

It presents risks in that any instrument modification decided to overcome possible technical failure should be applied to all the instrument under evaluation and impact to the overall cost.

Advantage can be found in that the overall organisation can be made by ICAR so as to simplified the task of the manufacturer in finding adequate laboratories and countries. Direct ICAR management allows direct international approval for milk recording. Nevertheless for any other purpose (eg milk payment) where specific approval are needed, an agreement/recognition of the protocol between the respective national bodies should exist in each country to avoid replicating same studies.

The evaluation of milk analyser has to be performed according to the ICAR Protocol for milk analyser evaluation which covers the scope of milk analysers dedicated to from large routine testing in milk recording laboratories. Nevertheless special cases are considered and benefit of special adaptations of the protocol with regard to the purpose.

## Special situations – Complement to the protocol from 2008

**- Manual analysers :** The field of ICAR milk analyser evaluation includes also small scale testing analysers (manual) that can be suitable to master laboratories to operate lab monitoring or relay/produce calibration samples. In such a case the second phase of evaluation in two routine laboratories for two months is replaced by the similar assessment of practical and economical aspects in the laboratory of the test bed evaluation for a same period of time.

### - Modification of existing approved milk analysers :

In case of configuration changes or the instrument is a new version of a former instrument with no significant change in analytical principle and main functions, the proof should be brought that it does not affect the precision and the accuracy beyond acceptable limits. This is verified through adequate comparison with an instrument of the former approved version.

The ICAR protocol is to be followed but with replacing in accuracy evaluation the reference analyses by analyses with the former approved instrument. Both instruments should be identically calibrated (same calibration materials) and compliance should be assessed through the mean difference not statistically different from zero, the slope from 1,00 and the standard deviation of differences  $s_d$  and the standard deviation of repeatability  $s_r$  from the limit of standard deviation of repeatability  $r$ .

## **1. Step-by-step procedure through national evaluation / approval**

### **1.1 Before the approval request to ICAR :**

Instrument has been submitted to evaluations in three countries according to the milk analyser evaluation protocol of ICAR and with results meeting requirements as defined in the protocol. Reports are to be collected by the manufacturer or the requesting organisation.

### **1.2 Request for approval :**

The approval request is sent to the General Secretariat by the manufacturer or the requesting organisation together with the (three) evaluation reports and the subsequent national approvals by competent bodies.

General Secretariat registers the request and transmits it to the examination committee with the appropriate documents (files). The examination committee is composed of at least three experts designated by and possibly members of MA SC.

### **1.3 Examination and decision delivery :**

Reports are examined by the experts and, if needed, discussed at the occasion of a meeting with MA SC. Otherwise, general position (positive or negative) and eventual comments can be made by examiners through a standard template for every point evaluated. In case a negative position is provided it is fully explained and argued. The period of examination should not exceed two months from ICAR Secretariat dispatch.

The examination committee comes to her conclusion which is then circulated for agreement to the working group. When not agreed, a further re-examination is required to reach final consensus (within two months) otherwise the chair informs the General Secretariat of the decision of the group :

a- Positive : Endorsement by ICAR Board, addition into the list of instrument approved by ICAR, publication in ICAR Newsletter and on the website space of MA SC (list of instruments with date of ICAR approval delivery) ; three reports available on request.

b- Negative : Every possible remarks and comments on elements of the instrument/method or the evaluation necessary to be improved before a further approval request.

### **1.4 Cost of administrative accounting and technical examination :**

> The requesting organisation is charged for the covering of the administrative costs of the whole processing (i.e. registration, examination of technical data, publication). A fixed amount in Euros (out of VAT) is established by Service-ICAR SRL and reviewed every year. It is invoiced to the requester at the opening of each case.

## 2. Direct international evaluation / approval

### 2.1 Request for evaluation and approval :

The manufacturer addresses a formal request to the General Secretary of ICAR for the evaluation in the purpose of ICAR approval of a well defined analyser.

Any technical description and information on the measurement principle and functioning must be joined to the request.

### 2.2 Process :

General Secretariat registers and transmits the request with the appropriate documents to the Sub-Committee on Milk Analysis that advises ICAR on technical admissibility (principle, functionality, fit-to-purpose) within one month. The consultation committee is composed of at least three expert members of MA SC.

ICAR liaises with the manufacturer in order agree on the organisation and costs of the evaluation. Especially decision is made on three countries and competent laboratories from a list of accredited laboratories recognised competent in analyser evaluation by ICAR.

ICAR establishes contacts with the evaluation laboratories to get the agreement on the task to undertake according to the ICAR evaluation protocol for milk analysers and agree on respective cost amounts for further invoicing to ICAR.

ICAR makes a quotation of all the costs for further invoicing to manufacturer and establishes a contract on the bases defined with the manufacturer.

Laboratories carry out evaluations and produce reports according to the ICAR protocol and requirements. They are requested to fill in the summary table of results for their respective parts that will be collated in a single table by ICAR Secretariat.

ICAR (Service ICAR) pays laboratories for their services and invoices the manufacturer for the same amounts added to the cost amount of overall organisation by ICAR and technical examination.

**2.3 Examination and decision delivery :** re § 1

**2.4 Cost of administrative accounting and technical examination :** re § 1

## 3. ICAR approval delivery :

On the basis of a positive conclusion of Sub-Committee on Milk Analyser, ICAR Board endorsed the ICAR approval which is officially delivered to manufacture and announced usual ICAR communication media.

*Appended :*

- 1- Request form for milk analyser approval by ICAR
- 2- Summary table of results of three national evaluations
- 3- Reporting form for examiners

*Disclaimer :* Through this procedure and using the protocol, ICAR recognises and ascertains users that the method evaluated in these conditions and fulfilling the technical requirements is appropriate for the use and purposes of milk recording, therefore allow ICAR organisation members to refer to that recognition – so-called ICAR approval – with no more need for complementary evaluations (unless it be locally demanded). This approval for use covers the field of application and the instrument configuration tested during the evaluation and cannot constitute itself an agreement for any use other than milk recording within ICAR.



**- REQUEST FORM FOR MILK ANALYSER APPROVAL BY ICAR -**

**Requesting organisation (name):** .....

**Country:** .....

**Address:** .....

**Phone:** .....

.....

**Fax:** .....

.....

**E-mail :** .....

**represented by (Mr, Mrs) :** .....

**Function :** .....

hereby

makes the request to ICAR for granting ICAR international approval to the milk analyser designated here below for the application in milk recording specified in the following :

Manufacturer (name) :	
Instrument (name) :	
- Type :	
- Configuration (*) :	
- Analytical principle :	

Animal species	Cow	Sheep	Goat	Buffalo	Other
- milk components / criteria tested :					
⇒ Fat (F)					
⇒ Protein (P)					
⇒ Lactose (L)					
⇒ Urea (U)					
⇒ Somatic cells (SCC)					
⇒					
⇒					
- maximum testing rate (nb test/hour)					

(\*) e.g. alone / combined

Enclosed documents as proof of the three required national approvals :

Countries (name)			
Evaluation centers/organisations (name)			
Official national approval certificates (doc n°)			
Technical reports (doc n°)			

Date: 20....

Signature :

Return to:

**ICAR Secretariat, Via G. Tomassetti 3, 1/A , I-00161 Rome, Italy  
Tel : +39/ 06 44 20 26 39 – Fax : +39/ 06 86 32 92 63 – e-mail : icar@eaap.org**

- Summary form for assessment results of a milk analyser evaluation -

Requesting organisation :

Instrument / Type / Manufacturer :

Animal species :

	Evaluation 1	Evaluation 2	Evaluation 3
Evaluation center			
Country			

Evaluation criteria (units)	ESTIMATED VALUES FOR STATISTICAL PARAMETERS OF THE EVALUATION														
	FAT (g/100 g)			PROTEIN (g/100 g)			LACTOSE (g/100 g)			UREA (mg/100 g)			SOMATIC CELLS (1000 cells/ml or %relative)		
	Eval 1	Eval 2	Eval 3	Eval 1	Eval 2	Eval 3	Eval 1	Eval 2	Eval 3	Eval 1	Eval 2	Eval 3	Eval 1	Eval 2	Eval 3
Range : min. – max.															
Mean of reference values $\bar{y}$															
SD of reference values $S_y$															
Carry over															
Linearity De/DC															
<u>Repeatability</u>															
Average SD : $S_r$															
Relative $S_r$ :															
Average $S_r\%$															
Low level $S_r\%$															
Medium level $S_r\%$															
High level $S_r\%$															
<u>Within lab reproducibility</u>															
Average SD : $S_R$															
Relative $S_R$ :															
Average $S_R\%$															
Low level $S_R\%$															
Medium level $S_R\%$															
High level $S_R\%$															
<u>Accuracy</u>															
Animal samples $S_{y,x}$															
$N^{ber}$ animal samples $N_a$															
$N^{ber}$ herds $N_{h1}$															
Herd samples : $S_{y,x}$															
$N^{ber}$ herd samples : $N_{h2}$															
<u>Calibration</u>															
Mean bias : $d$															
Slope : $b$ $S_b$															

## Examination Committee of Milk Analyser Evaluation Reports

### - Reporting form for examiners -

Name of the examiner :

Country :

Date of the examination :

Instrument / Type / Manufacturer : / /

Animal species :

Milk component(s) :

<b>Specific comments :</b>
1- Daily precision (repeatability and short-term stability) :
2- Carry-over effect :
3- Linearity :
4- Measurement limits (lower and/or upper limits) :
5- Repeatability :
6- Accuracy / Trueness :
7- Ruggedness :
8- Practical convenience :

**Advice of the expert :** 1- Valid for approval : Yes / No 2- Invalid for approval : Yes / No

<b>Comments :</b> (i.e. justification of negative position / advice for manufacturer, ...)