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Recommendations on setting the expiry period for commercial and in-house-prepared reagents used in the laboratories of the OMCL Network

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Preface

Reagents are an integral part of any laboratory and as such play a vital role in ensuring the validity of analytical results. Reagents must be suitable for the intended use. Consideration should be given to the accompanying documentation and appropriate physico-chemical or biological critical quality attributes for the intended purpose/s.

In the laboratory, two major types of reagents are generally distinguished: commercial (off-the-shelf, ready-to-use) and those prepared in the laboratory (in-house reagents) using the former. These two types of reagents are mainly dealt with separately throughout this document.

It should be noted that the principles of FIFO (First In-First Out) or FEFO (First Expired-First Out) should be applied when using reagents.

The shelf life for an unopened product or expiry period after first opening is usually set taking into account its stability, i.e. how long the quality attributes and chemical integrity of the reagent can be maintained for the intended analytical application. This can be a challenging task because most manufacturers give the shelf life of the unopened product and do not provide information on how long the reagent is stable once the container has been opened.

The recommendations for the shelf life of reagent solutions prepared and used in laboratories and presented in this document were established based on scientific data (including validation data obtained from quality control charts, guidelines, standards, pharmacopoeias, publications, etc.) and on the analytical experience and knowledge of OMCLs. Preparation times, costs, sustainable waste management policies and environmental protection concerns were also considered during the preparation of these recommendations.

This document is based on the laboratory experience of the OMCL Network. Its purpose is to help maintain the quality of the work carried out in the laboratory on a daily basis and ensure that the results obtained are valid.

The recommendations on the shelf life of reagent solutions provided herein should allow laboratories to assess whether a given solution can be used safely and reliably (provided that the storage conditions comply with requirements) as they take into account various factors that contribute to the degradation of some reagents (temperature, air exposure, moisture, etc.).

For the purpose of this document, the expiry period of a reagent solution should be understood as the period of time during which the reagent is stable and can be used for a given type of analysis. It should be noted that the same reagent may be unfit for use for some purposes because it has expired, but still suitable for other purposes.

Purchase or preparation of reagents and reagent solutions in quantities (volumes) not adapted to current needs should be avoided, as unnecessary disposal that does not take into account the possibility of prolonged use potentially constitutes a direct threat to the environment. Hence, if prolonging the use of a given reagent solution for specific purposes is safe and does not compromise the results, such prolongation should always be considered and justified.

1. Purpose

The aim of this document is to describe and, where possible, define how to set expiry periods for reagents (chemicals) used in the OMCL Network (and to guide OMCLs in applying them).
It is also intended to provide guidance on regulating the use, labelling, storage and expiry periods of reagent solutions prepared in OMCLs (in-house solutions) for qualitative, semi-quantitative and quantitative purposes.

2. Scope

Use of commercial reagents (chemicals) and reagent solutions prepared in OMCLs within the OMCL Network.

Commercial reagents or reagent preparations for immediate use are out of the scope of this document as they are not stored and are used within the same day.
In addition, solutions for which there is a certificate by which the traceability to NIST or any other primary etalon can be established are also out of the scope of this document.

3. Reagents (chemicals)

3.1. Definitions

Reagents
Reagents are solids, gases, liquids or solutions of pure chemical or biological substances, organic solvents and water.

Quality criteria
Quality criteria are assumed to be covered by appropriate internal standard operating procedures (SOPs). In general, special consideration should be given to the selection, purchase and receipt of reagents and their storage. The emphasis is on the crucial step of purchasing reagents of an expected quality and, upon receipt, on inspection and verification of compliance with the previously set specifications. These steps precede the labelling and storage of the reagents.

Shelf life of the reagent is a set period or a date given by the manufacturer, which can usually be found on the certificate of analysis (CoA) for that particular reagent. During this period or until that date, it is expected that the reagent will meet the quality specifications found in the CoA if the storage conditions in the material safety data sheet (MSDS) or in any other relevant document, like CoA or label, are respected.

Reagent without a shelf life or a retest date
Sometimes a shelf life is not defined by the manufacturer because the reagent is considered to have an extensive shelf life when stored unopened under the proper conditions, or the manufacturer has no supporting stability data. As the quality of a reagent may be altered due to use (effect of environmental conditions), setting an expiry date is highly recommended. This can be done, for example, by carrying out a risk assessment.

Recommended retest date for an unopened reagent
If it is possible to obtain a new certificate from the manufacturer, the shelf life of an unopened reagent can be extended until a later date.
Expiry period is a period or a specific date after opening of the reagent during which it is expected to maintain the appropriate physico-chemical or biological critical quality attributes for the intended purpose, in spite of any physical and chemical changes that may occur. The MSDS should be used as a guide on how to store the reagent after opening.

Extension of the expiry period for a reagent
The expiry period can be extended following a retest taking into account the critical quality attributes contributing to the functional characteristics of the reagent, checked by appropriate means or by scientific judgement.

3.2. Establishing shelf life or an expiry date/period for a reagent (ready-to-use)

3.2.1. Unopened reagent container

Usually a reagent is delivered with a stated shelf life for the unopened container.

Where no information is available from the manufacturer, the shelf life for unopened reagent containers can be taken to be the date of receipt plus up to 5 years. This is only applicable if the unopened reagent container is stored under specified conditions found in relevant documents.

3.2.2. After opening of the reagent container

It is necessary to set a rational expiry period in the absence of analytical data on the stability of the product after opening. This could be achieved by "real-time monitoring" of the reagent after opening by gathering experimental analytical data on critical parameters, both chemical and physical, during laboratory use.

In addition, possible sources of information on the stability of a particular reagent are:

- the CoA or MSDS for the storage conditions and possible instability;
- scientific papers;
- chemical knowledge about the nature of the reagents;
- stability data – additional information from the manufacturer or supplier (e.g. certificates, which can be found on manufacturers or suppliers website), guidelines, DIN/ISO Standards, pharmacopoeial texts, etc.

The expiry period after opening should not exceed the shelf life of the unopened reagent container. If it does, a risk assessment should be done based on the scientific literature and experimental data to show that use of the reagent after the end of its shelf life does not compromise its safety or the quality of the measurement results.

Each time a container is opened, the reagent is exposed to various external factors and environmental conditions that may alter its integrity and affect its quality, which may compromise the validity of the results.

Reagent properties, storage conditions, handling and the intended use that have to be considered during the process of establishing the expiry period after opening are:

- Purity of the reagent – this property is very important for establishing the expiry period after opening. In some cases the higher the purity of the reagent, the shorter the expiry period after opening. For example, sodium chloride p.a. will have a longer expiry period after opening than supra-pure sodium chloride, because it is rational to expect that supra-pure solids will deteriorate more quickly and lose their quality attributes. However, the degree of purity needed for the testing should be commensurate with the intended use of the reagent: it is important to select the quality grade that will yield satisfactory results.
- Temperature – should be kept controlled within the range given by the manufacturer/stated in the MSDS and/or in internal SOPs.
- Humidity – should meet the requirements given by the manufacturer/stated in the MSDS and/or in internal SOPs.
- Light exposure.
- Contamination during use of the reagent – each time a reagent is opened, accidental contamination is possible (switching of bottle caps, placing bottle caps on soiled surfaces, transferring reagents to other containers, use of pipettes for withdrawal, etc.)

It is important to state that, regardless of the expiry period established for the opened reagent, a visual inspection/examination should be done before use and if any of the physical properties that can be determined by visual inspection have changed, the reagent should be discarded.

Suggested expiry periods for reagents after opening or for ready-to-use reagent solutions in the absence of manufacturers' instructions (e.g. certificates) or official regulations (DIN/ISO Standards, pharmacopoeial texts) or literature data are presented in Annex 1.

3.3. Decision tree for establishing the expiry period after opening of the reagent

The decision tree presented in Annex 3 demonstrates the decision-making process on how to approach setting the expiry period after opening.

4. In-house-prepared reagent solutions

Preparation of reagent solutions is carried out in accordance with applicable guidelines, compendial methods (e.g. pharmacopoeial texts), test method specifications and procedures (Common Technical Documents [CTDs], SOPs).

4.1. Quality check

It is necessary to ensure that a reagent solution has the properties required for the intended analysis.

Before using prepared reagent solutions, it is strongly recommended to:

- perform a visual inspection – any reagent should be discarded if there is a change in colour or opalescence, or if there is any precipitation (unless it is necessary),
- perform a pH check before the use of buffer solutions (if applicable),
- determine the titre of volumetric solutions (if applicable),
- perform a Ph. Eur. sensitivity test for indicators.

Perform any other suitable qualification test specific to the prepared reagents. The environmental aspect must always be taken into account when deciding to shorten the expiry period and/or dispose of a reagent solution. A solution that is no longer suitable for a given analytical procedure may still be suitable for another purpose.

4.2. Recommended expiry periods

Consideration should always be given to expiry periods:

- for reagent solutions described in compendial methods (e.g. 2 months for *Primary opalescent suspension* in Ph. Eur. chapter *2.2.1*);
- provided in drug manufacturers' documentation;
- for reagent solutions for immediate use given in the test method specification, (e.g. data from the marketing authorisation dossiers).

If no stability data is available, it is recommended to use the expiry periods provided in Annex 2. The expiry periods presented in Annexes 1 and 2 were established on the basis of the analytical experience of OMCLs, method validation, guidelines, scientific publications [1, 4] and chemical knowledge.

OMCLs can also perform an in-house validation study to determine the initial expiry date.

4.3. Extension of adopted expiry period

It may be acceptable to extend the expiry periods provided in this document under the following conditions:

- risk analysis has been performed (see Annex 3);

and/or

- test criteria are established, supporting the extension;
- an in-house validation study to determine the expiry period has been performed.

The extension of the expiry period and the test criteria should be documented according to internal OMCL procedures.

5. Labelling and storage

General information on labelling and storage requirements for reagents is given in GL Management of Reagents, PA/PH/OMCL (11) 157 [3]. Whenever possible, reagent labels should state the expiry period for an opened container.

More specifically, for reagent solutions:

- reagent solutions should be stored under conditions appropriate for their chemical properties;
- reagent solutions should be stored under the prescribed storage conditions: temperature, protected from light, protected from moisture;
- reagent solutions should be stored in tightly closed containers;
- containers must be closed immediately after use;
- alkaline solutions should be stored in plastic containers;
- flammable liquids should only be stored in small quantities.

5.1. Examples of annotations for declared storage conditions

- protect from light
- protect from moisture
- use tightly sealed containers (e.g. bottles with lip seals)
- laboratory cabinets
- refrigerator (2 – 8 °C)
- freezer (below – 15 °C)
- under vacuum
- liquid nitrogen storage

6. Conclusions

In this document, general common practices – mainly derived from published literature and real-life experience – are set out to help OMCL Network members define expiry periods for commercial reagents, ready-to-use solutions and in-house-prepared reagents.

As shown in Annexes 1 and 2, different expiry periods can be set for the same type of reagent or in-house-prepared solution depending on their characteristics and purpose.

Most importantly, when setting the expiry date, traceability and quality must be ensured in order to avoid compromising the final results of the analytical process, meaning the worst-case scenario should be assumed when setting the expiry period of a reagent after opening.

Under the worst-case scenario, it should not be presumed that the opened reagent can be used after the expiry date of the unopened reagent unless valid scientific and experimental analytical evidence of its stability has been provided and a valid risk assessment has been performed.

For in-house-prepared reagent solutions, the expiry period is set mainly taking into account the intended use of the solution, the purity of the starting reagent, scientific data and any validation data that has been properly documented and approved.

Periodic and pre-use quality checks should be conducted regardless of the previously set expiry period both for opened reagents and for in-house-prepared reagent solutions.

As there are few relevant studies demonstrating stability after opening or stability after preparation of in-house reagents, caution is required when setting the expiry period as it may compromise the quality of the final analytical result.

7. References

1. Nogueira JMF, Serôdio P. Determination of the expiration date of chemical solutions. *Accred Qual Assur* 2003;**8**:231-4.
2. Barwick V, editor. Eurachem/CITAC Guide: Guide to quality in analytical chemistry: an aid to accreditation. 3rd edition. 2016. ISBN 978-0-948926-32-7. Available at: https://www.eurachem.org/
3. GL Management of Reagents PA/PH/OMCL 11 (157), EDQM
4. Clontz, L. Quality control systems for the microbiology laboratory. The key to successful inspections. PDA, Baltimore, Maryland, USA; Davis Horwood International Publishing, Godalming, Surrey, UK, 2000.
5. Bartel, D. Use and storage of chemicals, reagents, reagent solutions, samples, primary and secondary standards, and laboratory calibration reagents "The PEI approach" *Paul-Ehrlich-Institut.*
6. DIN/ISO standards (e.g. DIN ISO EN 11732: Water quality: Determination of ammonium nitrogen method by flow analysis.)

Annex 1.

Suggested expiry periods for reagents after opening or for ready-to-use reagent solutions in the absence of manufacturers' instructions (e.g. certificates) or official regulations (DIN/ISO standardspharmacopoeial texts) or literature data.

Reagent / Reagent solution	Expiry period after opening	Exceptions	Risk analysis
Acid and alkaline solutions – inorganic, organic	up to 36 months	Shorter expiry period of max. 12 months is recommended for supra-pure and max. 6 months for ultra-pure solutions after opening	Intake of CO_2 or fuming of gases changing concentration
Ammonia solution	up to 6 months	Depending on the purity: supra- and ultra-pure – max. 1 month	Concentration of ammonia decreases with time
Aqueous salt solutions	up to 6 months	/	Degradation unlikely
Buffer solutions	up to 12 months	Phosphate buffer – 3 months; ready-to-use buffer solutions – manufacturer's CoA and discard if turbid	Degradation possible after longer storage, especially for buffers with pH > 6; Microbiological contamination
Hydrogen peroxide	up to 6 months	Depending on the purity: supra- and ultra-pure – max. 1 month	Concentration of hydrogen peroxide decreases with time
Indicators – organic, inorganic	up to 36 months	/	Visual examination before use; avoid oxidants
Ion-pairs – inorganic, organic	up to 60 months	Sodium lauryl sulfonate – max. 12 months	Possible disintegration, check with SST
Inorganic reagents – solids, salts (not hygroscopic and light-degradable salts and oxides)	from 12 to 36 months	Shorter expiry period of max. 24 months is recommended for supra-pure and max. 12 months for ultra-pure solids after opening	Disintegration unlikely (salts, oxides); Contamination and/or cross-contamination for supra- and ultra-pure reagents
Inorganic reagents – solids, salts (hygroscopic and light-degradable salts and oxides)	Should not exceed expiry date of the unopened containers	Shorter expiry period of max 12 months is recommended for supra-pure and ultra-pure solids after opening	Degradation
Liquid media Culture media	Discard if turbid; shelf life: up to 6 months	Note special preparations	Degradation and sweating possible, depends greatly on the chemical composition of the media
Organic reagents – liquids	up to 24 months	/	Degradation possible only after longer storage
Organic reagents – solids, acids, bases	up to 36 months	Formaldehyde, Glutaraldehyde, Trifluoroacetic acid – expiry period max. 12 months	Degradation and polymerisation possible
Organic reagents – solids, salts (hygroscopic and light-degradable salts and oxides)	Should not exceed expiry date of the unopened containers	Shorter expiry period of max. 12 months is recommended for supra- and ultra-pure solids after opening	Disintegration
Organic reagents – -solids, salts (not hygroscopic and light-degradable salts and oxides)	from 12 to 36 months	Shorter expiry period of max. 24 months is recommended for supra-pure and max. 12 months for ultra-pure solids after opening	Contamination and/or cross-contamination for supra- and ultra-pure reagents
Organic solvents	from 12 to 36 months	Acetone – max. 24 months and Ethanol – max. 36 months expiry period after opening; it also depends on the purity of the reagent: for sensitive methods like LC-MS max. 12 months	Degradation or concentration change due to intake of water due to humidity
Sera (animal or human origin)	up to 10 years, stored as aliquots in air-tight containers at min. −20°C	Modified sera may have a shorter shelf life	Sublimation and disintegration or clotting possible; reduction in activity possible

REMARKS:

1. **Expiry period of the opened container must not exceed the shelf life of the unopened reagent!**
2. All proposed periods are based on the experience of OMCLs (exercise performed by OMCLs) and a document by Detlef Bartel, Paul-Ehrlich-Institut [5].
3. This list is not exhaustive.

Annex 2.

Table 1. Suggested expiry periods for in-house-prepared reagent solutions used for physico-chemical tests, established on the basis of the analytical experience of OMCLs, method validation, guidelines and available literature [1].

REAGENT SOLUTION WITH AN IMPACT ON A RESULT				
	REAGENT SOLUTION	**MAXIMUM EXPIRY PERIOD**	**RISK FACTORS**	**RECOMMENDATIONS**
WATER	Water for chromatography (Ph. Eur. 1095503) (resistivity [25°C] ≥ 18 MΩ/cm) *Water for preparing mobile phases without buffers* and Deionised water (Ph. Eur. 1095508) (resistivity [25°C] ≥ 18 MΩ/cm)	24 hours after production	High-purity water rapidly picks up contaminants Bacterial contamination	Visual inspection Discard if turbid Use from fresh and closed containers SST criteria must be fulfilled
	Water, purified (Ph. Eur. 04/2018:0008) (conductivity [25°C] 5.1 µS/cm) *Water for preparing buffers, diluents (solvents), dissolution media*	3-5 days after production	Bacterial contamination	
	Water for injections and Sterilised water for injections (Ph. Eur. 04/2017:0169) (conductivity [25°C] 1.3 µS/cm)	2 months after production	Bacterial contamination	Visual inspection Discard if turbid Use from fresh and closed containers
MOBILE PHASES and DILUENTS	Pure organic solvent (aliquot transferred from the original container)	6 months or original expiry date (whichever is shorter)	Depletion Precipitation Evaporation of organic phase	Visual inspection SST criteria must be fulfilled
	Organic solvents + water (e.g. acetonitrile/water, methanol/ water) ≥ 50% of organic component < 50% of organic component	 6 months 3 months		SST criteria must be fulfilled
	Organic solvent + buffer or buffers for HPLC	2 weeks		SST criteria must be fulfilled pH check (if applicable)
	Organic solvent + acid/base solution (e.g. phosphoric acid, perchloric acid, methanesulfonic acid, trifluoroacetic acid)	3 months		
ACID SOLUTIONS	for pH adjustment	12 months	Degradation	Visual inspection SST criteria must be fulfilled
	> 0.1 M HCL	7 months [1]		
	≤ 0.1 M HCL	2 months [1]		
	> 0.5 M H_2SO_4	7 months [1]		
	≤ 0.5 M H_2SO_4	2 months [1]		
	Perchloric acid	1 month [1]		
ALKALINE SOLUTIONS	For pH adjustment	6 months	Absorbs CO_2	Keep in tightly closed container Plastic container only SST criteria must be fulfilled
	0.2 M - 5 M NaOH	5 months [1]		
	≤ 0.1 M NaOH	1 month		

REAGENT SOLUTION WITH AN IMPACT ON A RESULT					
REAGENT SOLUTION			MAXIMUM EXPIRY PERIOD	RISK FACTORS	RECOMMENDATIONS
	Ammonia		3 months [1]		
SALT SOLUTIONS	iron(II) and silver salt solutions		6 months	Oxidation Colour change	Visual inspection SST criteria must be fulfilled
	2 M $(NH_4)(CH_3COO)$		5 months [1]		
	0.1 M NaCl and 5 ppm NaCl		5 months [1]	Microbial growth	
	0.1 M Na_2SO_4 and 10 ppm Na_2SO_4		5 months [1]		
VOLUMETRIC SOLUTIONS(*)	COMPLEXOMETRY	0.1 M EDTA	7.5 months [1]	Precipitation	After visual check the titre must be determined before use Plastic container only
		0.01 M EDTA(**)	2 months [1]		
	ARGENTOMETRY	0.1 M $AgNO_3$	7 months [1]	Photochemical degradation	After visual check the titre should be determined before use Protect from light
		0.01 M $AgNO_3$(**)	5 months [1]		
		0.1 M NH_4SCN	7 months [1]		
	REDOXOMETRY	0.1 M I_2	7.5 months [1]	Volatility Air-oxidation processes	After visual check the titre must be determined before use Keep in tightly closed container 0.1 M $Na_2S_2O_3$: prepare at least 2 weeks before use
		0.01 M I_2(**)	5 months [1]		
		0.1 M $Na_2S_2O_3$	5 months [1]		
		0.1 M $KMnO_4$	1 month [1]		After visual check the titre must be determined before use Prepare at least 2 weeks before use Filter before use
	(*) For all volumetric solutions, after visual check the titre must be determined before use and the Ph. Eur. criteria for accuracy must be fulfilled. (**) Diluted solutions should be preferably prepared for immediate and single use.				

REAGENT SOLUTION WITH AN IMPACT ON A RESULT				
	REAGENT SOLUTION	**MAXIMUM EXPIRY PERIOD**	**RISK FACTORS**	**RECOMMENDATIONS**
INDICATORS	Ferroin	3 years		Perform the sensitivity test after preparation and then periodically (according to Ph. Eur.) Visual inspection Protect from light
	Phenolphthalein solution	3 years		
	Phenol red solution	3 years		
	Methylene blue	3 years		
	Methylthymol blue mixture	2 years		
	Methyl red solution	3 years		
BUFFER SOLUTIONS	pH or conductivity calibration/verification buffers (aliquot transferred from the original container)	3 months or original expiry date (whichever is shortest)	Absorbs CO_2 depending on pH	Visual inspection Keep in tightly closed containers Protect from light
	Buffer solutions (others, e.g. ammonium buffer, acetate buffer)	2 months	Absorbs CO_2 depending on pH Prone to microbial growth depending on pH Depletion possible	Visual inspection Keep in tightly closed containers Protect from light
	0.01 M and 0.2 M K_2HPO_4	1 month and 4 months, respectively [1]	Absorbs CO_2 depending on pH Prone to microbial growth, depending on pH	Visual inspection Keep in tightly closed containers Protect from light
	0.01 M and 1 M KH_2PO_4	1 month and 4 months, respectively [1]		
	0.05 and 0.1 M NaH_2PO_4	5 months [1]		
	2 M and 0.03 M $(NH_4)_2HPO_4$	5 months [1]		
	10% Na_2HPO_4	1 day [1]	Very unstable	Prepare fresh
	SDS buffers or other surfactants	up to 6 months	Precipitation	Visual inspection *[0.2% m/v SDS solution is particularly prone to precipitation depending on the quality of the starting reagent]*
UREA	Urea solution	1 day	Prepare fresh before use	

REAGENT SOLUTION WITHOUT AN IMPACT ON A RESULT			
REAGENT SOLUTION	**MAXIMUM EXPIRY PERIOD**	**RISK FACTORS**	**RECOMMENDATIONS**
Organic solvents and water used as supplementary solutions (e.g. for flushing columns, cleaning HPLC system)			
≥ 50% of organic component	1 year	Precipitation	Visual inspection, discard if turbid
< 50% of organic component	6 months		

Table 2. Suggested expiry periods for in-house solutions, buffers and media used for microbiological tests or cell cultivation. Established on the basis of analytical experience of OMCLs and available literature [4].

FOR MICROBIOLOGICAL AND CELL-BASED METHODS		
REAGENT SOLUTION	**MAX. EXPIRY PERIOD**	**RECOMMENDATION**
Solid or liquid growth media stored in tightly sealed containers (e.g. screw capped flasks)	6 months*	Below 25°C or 2-8°C depending on the medium
Solid or liquid growth media stored in unsealed containers (e.g. bottles with cellulose plug and aluminium foil)	1 month	
BUFFER SOLUTION STORED IN TIGHT CONTAINERS		
Solution of 0.2 M potassium dihydrogen phosphate	6 months	Below 25°C
Solution of 0.2 M sodium hydroxide		
Buffers prepared from buffer solutions**	1 month	Below 25°C
Glucose 6-phosphate solution in various concentrations	1 year	≤ − 15°C
Nicotinamide adenine dinucleotide phosphate (NADP) in various concentrations	1 year	≤ − 15°C
Agarose 5%	3 months	
RESEARCH ON ANTISEPTICS AND DISINFECTANTS		
REAGENT SOLUTION	**MAX. EXPIRY PERIOD**	**RISK FACTORS/RECOMMENDATION**
Neutraliser stored in tightly sealed containers	6 months	Below 25°C or 2-8°C depending on the composition
Diluent stored in tightly sealed containers	6 months	Below 25°C
INTERFERING SUBSTANCE		
Bovine albumin 3 g/100 mL	1 month	2-8°C
Bovine albumin + sheep erythrocytes 3 g/100 mL + 3 mL/100 mL	1 week	2-8°C
SOLUTIONS TO BE PREPARED IN HARD WATER		
Solution A (magnesium chloride and calcium chloride)	1 month	2-8°C
Solution B (sodium bicarbonate)	1 week	2-8°C

* Growth promotion tests must be performed within three months of the time of use.

** Prepared from sterile solution.

Annex 3. Risk analysis

A list of questions supporting the risk analysis of a decision on expiry date extension (can be extended depending on the intended use) of in-house-prepared reagent solutions (open catalogue):

1. Is the reagent solution used:
    a. for quantitative purposes?
    b. for qualitative purposes?
    c. as an auxiliary reagent?
2. Is the reagent prone to:
    a. oxidation?
    b. hydrolysis?
    c. photo- or other degradation?
    d. evaporation?
    e. pH change (e.g. as a result of CO_2 absorption)?
    f. microbial growth?
3. Is the reagent solution stored properly?
4. Is the buffering capacity/ion strength important for the purpose of use?
5. Is the pH of the solution important for the purpose of use?
6. Is the exact concentration of the solution important for the purpose of use?
7. Was the reagent solution prepared in a sterile manner?
8. Is the reagent solution used in a way that preserves sterility?
9. Is sterility important for the intended use?
10. Can the reagent solution attributes be easily verified/controlled before use (e.g. pH check, osmolality, absorbance)?
11. Will control tests be performed during the use of the reagent solution that will allow its suitability to be verified?
12. Are the SST criteria fulfilled while the reagent solution is used?
13. Purity of the reagent?

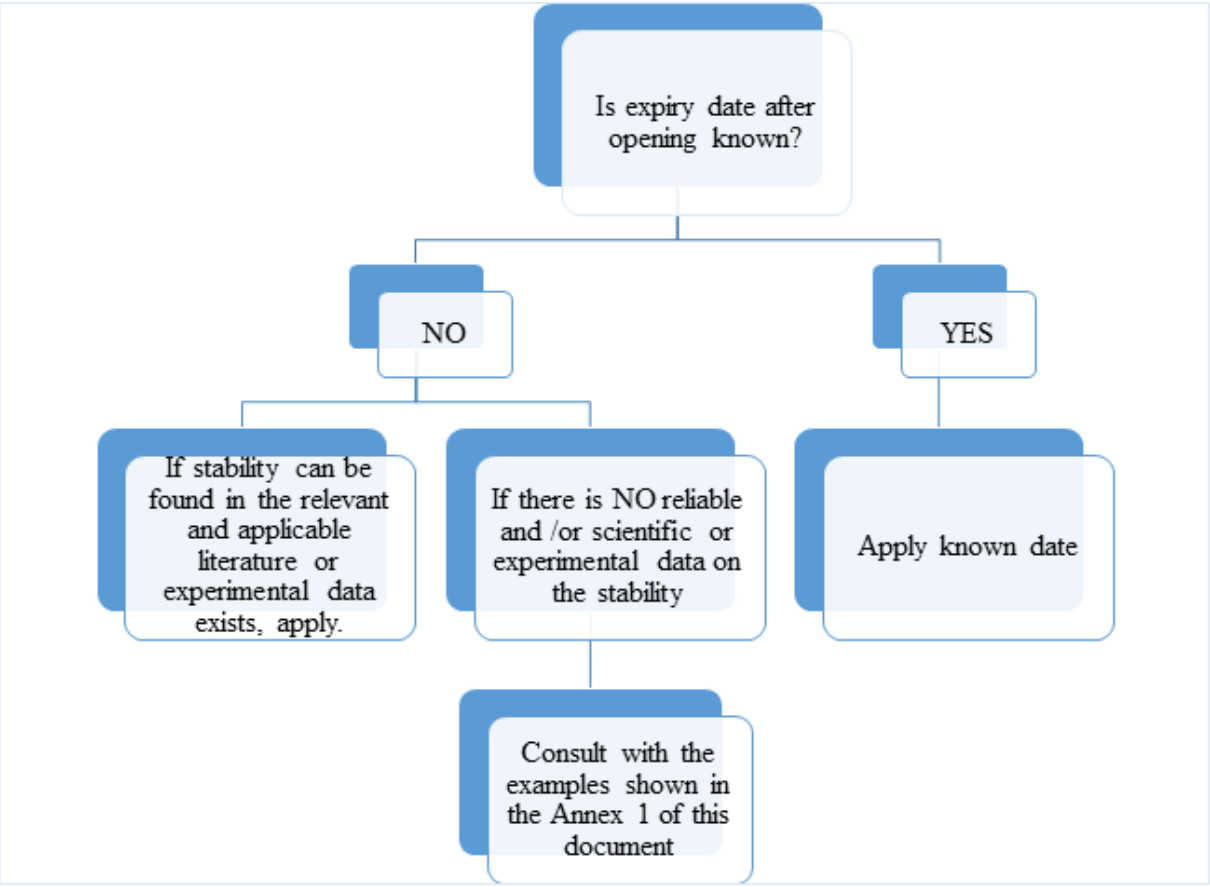

Figure 1. Graphical representation of the decision-making process for determining the expiry period of a reagent after opening.