



Notification on the implementation of EA-3/12 M:2022 NF37

EA-3/12 M: 2022 has recently been published (9th March 2022) and is available from <https://european-accreditation.org/wp-content/uploads/2018/10/ea-3-12-m.pdf>.

It is a mandatory document, with an implementation date of 9th March 2023 (publication date plus one year), and it provides information for use by accreditation bodies on the application of ISO/IEC 17065.

Between 01/01/2022 and 01/01/2023, certificates against Regulation (EC) No 834/2007 are still valid until the next control performed against Regulation (EU) No 2018/848. However, all controls in the EU shall be performed against Regulation (EU) No 2018/848 starting from 01/01/2022. For this reason, accreditation for Regulation (EU) No 834/2007 is still valid for certificates issued before 01/01/2021 and will expire on 31/12/2022.

Concerning third countries, Regulation (EC) No 1235/2008 is replaced by Regulation (EU) 2021/1697 and 1698 for purpose of compliance and by Regulation (EU) 2021/1342 for purpose of equivalency.

The following is a synopsis of the main changes in this edition of EA-3/12:

- Sites vs locations – the word ‘site’ is now defined and has replaced the word ‘location’ throughout.
- Tables A and B remain unchanged, but EA-3/12: 2022 now clarifies that the minimum number of CB files checked by the AB during surveillance must be at least 50% of the minimum calculated using these tables.
- Clause 3.10 (suspending, withdrawing or reducing accreditation) has been removed.
- Clause 4.1b has added two more bullet points with references to regulations related to Regulation (EU) 2018/848.
- Clause 4.2 c has been removed.
- Clause 4.4 paragraph 2 now refers to Regulation (EU) 2021/1698 (annex I).
- Clause 4.5 has changed considerably; now requiring each office where certification decisions are taken to be assessed annually.
- Clause 4.7.1 has changed considerably, regarding calculation of the amount of witnessing to be performed.
- Clause 4.8.1 now includes more detail on witnessing.
- Clause 4.8.4 recognises the start of the transition period as 1/1/2022
- Clause 4.10 – the procedure for withdrawal of the element of the scope of accreditation if the CB has no clients for a given category for 4 consecutive years has been removed.

Two annexes have been added, giving example scopes of accreditation.

INAB will perform its assessments in accordance with the requirements of this revised publication during routine surveillance activity, beginning on 9th March 2023.

If you have any queries, please contact your assessment manager.