GNB-CPR GNB-AG	**Co-ordination of the Group of Notified Bodies for the Construction Products Regulation, (EU) No. 305/2011**	**NB-CPR/21/872r4** Issued: 24 February 2022 Revised: 29 April 2022 **Approved Guidance**

Position Paper:

Initial inspections during the COVID-19 pandemic

Note regarding revision 4 of this position paper: In accordance with an agreement at the 51st meeting of the GNB Advisory Group, the validity of this position paper is prolonged until 31 October 2022. See section 5.

1. INTRODUCTION

Since the outbreak of the COVID-19 pandemic, questions have been raised regarding the possibilities, if any, to exceptionally carry out initial inspections without physically visiting the manufacturing plant.

In March 2020, the horizontal Unit B1 of DG GROW communicated to the notifying authorities and the chairs of the notified bodies groups (across sectors) that during the COVID-19 outbreak *notified bodies should continue to carry out their tasks to the extent that this is currently possible in view of the confinement measures taken at Member States level.*

The communication also implicitly opens, during the pandemic, for the possibility of providing services with deviations from the requirements under specific legislation whilst emphasising that such services should not be provided if it would jeopardise the technical validity of that specific activity.

The full text of the communication is found in the Annex of this document.

In addition to the above-mentioned horizontal communication, for the construction products sector, the GNB-CPR Advisory Group has approved the position paper NB-CPR 20/852 (currently revision r3 applies*), Maintaining CPR certificates under the COVID-19*. However, as the title indicates that position paper covers only the maintenance of certificates during the pandemic; it does not at all address the procedures related to the issuance of new certificates. Accordingly, neither does it deal with the conduct of initial inspections.

This position paper seeks to provide guidance to notified bodies considering if an initial inspection could be temporarily carried out by remote auditing techniques during the COVID pandemic, in deviation from the requirements under the CPR.

2. BASIC CONSIDERATIONS

1) CPR Article 52(2) requires notified bodies to operate in accordance with the principle of proportionality. Popularly expressed, notified bodies must keep the right balance between the interests of the manufacturer and the protection of public interests.

2) For AVCP systems 1+, 1, and 2 +, CPR Annex V requires the notified certification body to carry out initial inspection of the manufacturing plant and of factory production control. This is generally understood as requiring the notified body to be physically present at the manufacturing plant. This would generally exclude the use of "multi-site sampling" methods for the initial inspection. As "manufacturing plant" is understood a location where significant manufacturing processes take place.

3) Regarding the methodology for the initial inspection, the approved position paper, NB-CPR 17/722 (currently, revision r8 applies), section 8.2 specifies that inspections shall be carried out as on-site audits.

4) The communication from EC Grow Unit B1 circulated in March 2020 (see Annex) indicates that *notified bodies are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardize the technical validity of that specific activity*.

5) On the basis of above points 2) and 3), it is considered a requirement to carry out initial inspections on-site. Hence, initial inspection by remote means would be a service *with deviations from requirements* under the CPR in the sense of the communication mentioned in point 4) above.

6) The coordination and cooperation between notified bodies, which is assigned to the GNB-CPR, includes the authority to issue guidance regarding the operations of notified bodies within the boundaries of the applicable legislative framework. The GNB-CPR would not have any authority to exempt notified bodies from requirements of the applicable legislation.

7) Under the CPR, notifying authorities of Member States are required to monitor the bodies notified by them, and, if they find *that a notified body no longer meets the requirements laid down in Article 43, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend, or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or to fulfil those obligations*.

8) A notifying authority may consider remote initial inspection as a failure of the notified body to fulfil its obligations and may take actions accordingly. Alternatively, at its own discretion, a notifying authority may consider a particular remote initial inspection well justified during the COVID-19 outbreak and not requiring any such action. Notified bodies may request notifying authorities to indicate their administrative practices in that regard. However, as notified bodies operate in the harmonised sphere Member States are not foreseen to define conditions for the operations of notified bodies; these are set in the EU harmonisation legislation.

9) From above points 4), 6), and 7) it follows that a notified body deciding to carry out an initial inspection by remote means would be solely responsible for that decision.

10) Notwithstanding the absence of authority of the GNB to exempt notified bodies from requirements defined for them (see above point 6), it is considered within the role of the GNB-CPR to define guidance for notified bodies regarding their decision-making processes and their documentation in that regard.

11) CPR Article 52(3) requires the notified body *not* to issue a certificate if it finds that the manufacturer has *not* ensured the constancy of performance. To draw a qualified conclusion in that regard, the notified body would be required to carry out an adequate initial inspection.

12) The *technical validity*, cf. above point 4), of the initial inspection would depend on the notified body's adequate assessment, on a case-by-case basis, of all processes of the manufacturer, as carried out in practice, with regard to ensuring the conformity of the product with the declared performance.

13) To act responsibly, notified bodies should minimise their services with deviations, both regarding extent and duration, even if it is found that the technical validity would not be jeopardised. Therefore, also in circumstances of COVID-19 outbreak, remote initial inspections should only be carried out if necessary to serve public interests or the legitimate interests of manufacturers, and if on-site inspection of the manufacturing plant would not be possible due to confinement measures applicable at Member States level.

14) When analysing risks related to remote initial inspection, particular account should be taken of the risks potentially presented by products from that manufacturing plant not having the declared performance. The communication from EC Grow Unit B1 mentioned in point 4) should not be construed as allowing for a lowered level of protection of public interests during the pandemic, in particular the level of safety and overall reliability of assessments and verifications.

15) Generally, notified bodies are required to operate with transparency as regards the manufacturer. Manufacturers should be informed about the procedures that notified bodies will apply for them.
Notified bodies should also be aware of their information obligations, notably towards the notifying authorities, which may apply if a notified body intends to deviate from the procedures forming basis for their notification.

3. RESPONSIBILITY AND ACCOUNTABILITY

If a notified body decides during the pandemic to deviate from the normal procedures for initial inspection and apply remote auditing techniques or other alternative techniques, it will be solely responsible for that decision.

Notified bodies should limit as much as possible their deviations from the normal procedures for the initial inspection. If a notified body decides, during the pandemic, to depart from section 8.2 of the approved position paper NB-CPR 17/722r8, which requires initial inspection to be carried out on-site, that notified body shall still apply as general guidance all other parts of that position paper.

3.1. REASONS

When considering if an initial inspection should be done remotely, as a minimum the below questions should be considered and documented:

1) Is it necessary to carry out the initial inspection now?

    a. Is there a public interest of having the new product available on the market (e.g. in case of identified shortage)?

    b. If the initial inspection were postponed, would anyone suffer any loss? If yes, who would suffer what losses?

2) Are there concrete obstacles preventing initial inspection on site?

    a. Would it be possible for another (local) notified body to carry out an on-site inspection?

    b. Would it be possible to have an on-site inspection carried out by a (local) subcontractor?

        Note: Using a (local) subcontractor would prerequisite an assessment of that subcontractor, cf. CPR Article 45.

3) If considered not possible to carry out an on-site inspection, would the reason be:

    a. Restrictive measures imposed at national level (including restrictions imposed by sectoral, local, or regional authorities)?

    b. Restrictive measures decided by the manufacturer?

    c. Restrictive measures decided by the notified body itself?

If it is considered not possible to carry out on-site inspection due to restrictive measures decided either by the manufacturer or by the notified body, deviations from the normal (on-site) procedure may not be considered well justified.

Generally, emphasis should be given to the public interests. If there is a shortage of the product in question it might be a public interest to have the supply increased. In particular, if the products are required for the purpose of critical infrastructure.

The legitimate interests of the manufacturer may also be considered to provide a valid justification. For instance, it should be considered if the manufacturer's survival through the COVID-19 crisis would depend on making a new product available or on having a new manufacturing facility activated.

If it is considered that on-site inspection would not be impossible, only more cumbersome, or more expensive than normally, it may not be considered justified to deviate from the normally required procedure for initial inspection during the pandemic.

The notified body may have business interests of its own to consider. For instance, a notified body may put at risks its relationship with overseas manufacturers, who might turn to local notified bodies if on-site initial inspection is required. However, such own business interests of the notified body may not be considered to provide a valid justification for deviating from the normal procedural requirements.

Notified bodies remain solely responsible for any decision during the pandemic to deviate from the normal procedural requirements. They may request Member State authorities to indicate their administrative practice but cannot hand over any responsibility.

3.2. RISK ASSESSMENT

Before deciding during the pandemic to carry out a remote initial inspection, the notified body shall, on a case-by-case basis, carry out and duly document a thorough risk assessment to analyse whether carrying out an initial inspection remotely would jeopardise the technical validity of that activity and reliability of its assessments. Duly substantiated and documented risk assessment should comprise at least the following elements and how the risks have been counteracted (see point 3.3 below):

1) Reliability of evidence of physical location of manufacturing processes;

2) Risk that the manufacturer's selection of processes for demonstration may omit, fully or partially, critical processes;

3) Risk of overlooking manufacturing and controlling processes;

4) Inability to inspect processes to the required level of detail;

5) Impeded dialogue with operators, e.g. because of noise or insufficient network coverage;

6) Inspectors not able to "use their senses" in the manufacturing location;

In conducting risk assessment, the notified body may take into consideration reliable information from any source. This may comprise the manufacturer's technical documentation, documentation on the activities previously conducted at the site to be audited, including the level of compliance from previous audits/inspections, as well as evidence forming basis for a previous certification, e.g. by a ceased notified body.

3.3. COUNTERACTING RISKS

The notified body shall decide how to counteract all identified risks.

A mandatory element is that an on-site inspection shall be carried out as soon as possible.

Further actions to counteract risks may include, but would not be limited to, the following:

1) Additional AVCP activities, cf. NB-CPR 20/852r3 section 6.3

    a. Submission of information and evidence (See cf. NB-CPR 20/852r3 section 6.3.1)

b. Remote sampling for the assessment of performance (See cf. NB-CPR 20/852r3 section 6.3.4)

The notified body may also consider if it would be reasonable to give more weight to other activities. For instance, it may be reasonable to carry out a deeper scrutiny of the manufacturer's FPC documentation than normally.

The principle of proportionality shall apply to the use of additional AVCP activities, which should be applied only if considered necessary to effectively counteract identified risks. However, if considered necessary, the additional AVCP activities may go beyond the applicable system of AVCP. For instance, testing by a laboratory chosen by the notified body may be considered necessary to counteract risks, even if not required by the applicable system of AVCP.

2) Special conditions agreed with the manufacturer

a. Continuing submission of information and evidence (See cf. NB-CPR 20/852r3 section 6.3.1)

b. Time frames for carrying out on-site inspection.

Notified bodies should be aware that conditions agreed with the manufacturer may not limit the responsibilities and potential liabilities towards 3rd-parties.

4. DECISION

During the pandemic, the notified body shall decide to carry out an initial inspection remotely only when considered necessary and only when the risk assessment, made on a case-by case basis, demonstrates that all risks have been effectively counteracted and the technical validity of the initial inspection is not jeopardised.

A separate decision shall be made with regard to each manufacturing plant.

Notified bodies shall duly document their decisions, including their reasons and risk assessments applied. All decisions shall be available to the notifying authority.

The notified body shall inform the manufacturer about its decision. Any decision to carry out initial inspection remotely should be limited in duration. Any certification decision on the basis of remote initial inspection should be limited to the time strictly necessary to allow for a proper on-site inspection as soon as possible.

5. EXPIRY

This position paper will expire on 31 October 2022.

Annex

Communication from the EC DG Grow Unit B1

Below is reproduced in full the text of a communication from the horizontal unit B1 of DG Growth circulated in March 2020 addressing notifying authorities and notified bodies of all sectors. The communication is also found in the document NB-CPR/ALL/20/173 (Available on CIRCABC).

> *Dear Notifying Authorities, dear Chairs of Notified Bodies Groups, dear colleagues,*
> *In the context of the current COVID-19 outbreak, we understand that the activities of notified bodies may be affected, in particular insofar as this requires performing visits to manufacturers premises. Due to the exceptional circumstances we are facing, some of you have been asking us whether we should provide for flexibility and specific guidance on this issue.*
> *We believe that notified bodies should continue to carry out their tasks to the extent that this is currently possible in view of the confinement measures taken at Member States level. Notified bodies are encouraged to perform remote assessment techniques, including document reviews, as far as possible to substitute or complement on-site assessments. However, remote or virtual assessments will not always provide a substitute to on-site visits which are required by notified bodies under specific modules. When faced with such situations, Notified Bodies are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardize the technical validity of that specific activity. Notified Bodies should also act with full transparency, informing affected clients of any change in the procedures and keeping records justifying the decisions taken.*
> *These arrangements should however not put at risk the health and safety of products in the EU and the role that Notified Bodies play in conformity assessment. Notified Bodies are requested to inform the relevant authorities of any relevant issues relating to possible non-conformity of products, including where this may be relevant due to the need to postpone specific on-site visits in the context of the conformity assessment activities.*
> *For information, please find attached the communication that EA has distributed to its members on this same issue.*
> *Kind regards,*
> *European Commission*
>
> *DG for Internal Market, Industry, Entrepreneurship and SMEs Goods in the Single Market and Enforcement Unit B1 Free movement of goods*