Regulation (EU) 2016/426 on appliances burning gaseous fuels (GAR)

Guidance on transition relating issues

The transition from Directive 2009/142/EC (GAD) to Regulation (EU) 2016/426 (GAR) has raised some doubts and questions amongst the gas appliances stakeholders.

In order to ensure the smooth transition from one legal act (GAD – applicable until 20 April 2018) to the other (GAR – fully applicable as from 21 April 2018), the present document intends to provide some clarifications on some of the issues raised and ensure thus legal certainty.

The following issues are treated:

- I) Applicable rules for the placing on the market of an appliance or a fitting;
- II) Conformity assessment during the transitional period (notified bodies, manufacturers):

The GAR provisions

According to Article 46 of GAR (entry into force and application):

- 1. This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.
- 2. This Regulation shall apply from 21 April 2018, with the exception of:
 - a) Articles 4, 19 to 35 and 42 and Annex II, which will apply from 21 October 2016¹;
 - *b)* Article 43(1) which shall apply from 21 March 2018².

As from 21 April 2018, GAD will be repealed (Article 45 of GAR).

According to Article 44 of GAR on transitional provisions, Member States shall not impede the making available on the market or the putting into service of appliances and fittings covered by GAD which are in conformity with that Directive and which were placed on the market before 21 April 2018.

According to Article 31 of GAR (applicable as from 21 October 2016):

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III³.

Article 4 relates to the gas supply conditions, Articles 19 to 35 relate to the notification by Member States to the Commission of conformity assessment bodies (notified bodies), Article 42 relates to the gas appliances Committee and Annex II to the content of the Member States communications of the gas supply conditions.

Article 43(1) relates to the Member States' penalty provisions (to be notified to the Commission by 21 March 2018).

Annex III of GAR relates to conformity assessment procedures for appliances and fittings.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

I) Applicable rules for the placing on the market of an appliance or a fitting

- 1. <u>Until 20 April 2018</u>, GAD is fully applicable. This means that only appliances and fittings complying with it are allowed to be placed on the market⁴ and put into service.
- 2. <u>As from 21 April 2018</u>, date at which GAR becomes fully applicable, only appliances and fittings complying with it will be allowed to be placed on the market.

This means that the concerned appliances and fittings must comply with the GAR essential requirements, have undergone a conformity assessment procedure in accordance with Annex III to the Regulation with the involvement of a GAR notified body, bear the CE marking and the inscriptions provided for in Annex IV and be covered by an EU declaration of conformity signed by the manufacturer and attesting that the appliance/fitting complies with GAR⁵.

- 3. Before 21 April 2018, NOT any appliance or fitting may be placed on the market under the GAR (as GAR will not be fully applicable until that date).
- 4. Although GAR has been adopted on 9 March 2016, published in the *Official Journal* of the European Union on 31 March 2016 and entered into force on 20 April 2016, it will become fully applicable only as from 21 April 2018.

This period of 2 years (or 18 months after the partial applicability of the GAR on 21 October 2016) allows authorities and stakeholders to be prepared for a smooth transition to the new act (GAR) and its legal requirements as regards the appliances and fittings to be placed on the market under the new act as from 21 April 2018 (including as regards the conformity assessment procedures etc.).

- 5. a) Appliances placed on the market until 20 April 2018 under the GAD, will be allowed to be made available on the market (be sold by distributors) and put into service, after that date.
 - b) Fittings placed on the market until 20 April 2018 under the GAD, will be allowed to be made available on the market (in the distribution chain) and incorporated into new appliances that will be subsequently placed on the market under the GAR.

This will allow the smooth absorption of appliances/fittings placed on the market under the GAD⁶.

Placing on the market means the first making available of an appliance or a fitting on the Union market. Attention is brought to the fact that the placing on the market refers to each individual appliance/fitting (and not e.g. to the first product of a series).

For fittings the change means also that they shall be CE marked under GAR and be accompanied by an EU declaration of conformity.

Such appliances/fittings will only be subject to restrictions in case a Member State authority considers that they do not comply to GAD.

II) Conformity assessment during the transitional period

The fact that until 20 April 2018 only GAD compliant appliances and fittings may be placed on the market and that as from 21 April 2018 only GAR compliant appliances and fittings may be placed on the market, has raised some discussion on how practically manufacturers and other stakeholders may be prepared for the change.

As not any "automatic" compliance with the GAR is feasible on the basis of the fact that a specific appliance/fitting has already been certified under the GAD, in accordance with GAR, the involved parties have the possibility to timely take the necessary steps so as to ensure that as from 21 April 2018 GAR compliant appliances/fittings are placed on the market following assessment by a GAR notified body.

Article 31 of GAR allows all necessary acts relating to conformity assessment under the GAR to take place before 21 April 2018. It also stipulates that conformity assessment shall be carried out in a proportionate manner. It is indeed important that not any unnecessary and burdensome additional tests and assessments are imposed to manufacturers during the new examination under the GAR requirements, while ensuring a full respect of the GAR provisions.

i) With regard to notified bodies

According to Article 46(2a) of GAR, Articles 19 to 35 apply from 21 October 2016.

It results, that a body notified under the GAR in accordance with the notification procedure provided for in Article 27 of GAR, may ensure compliance of an appliance/fitting with the GAR well before 21 April 2018 (depending from the date its notification became effective and validated in the NANDO database).

This means that such a GAR notified body may timely perform all necessary tests and examinations provided for by the conformity assessment procedures under Annex III to GAR so as to certify that the appliance/fitting concerned complies with GAR.

More particularly, the GAR notified body has to issue an EU-type examination certificate attesting compliance of the type to the GAR requirements. It will take into account the results of the previous tests and certificates issued by a GAD notified body so as to determine the extent of the tests and checks required in view of the issue of the EU type-examination certificate. Only on the basis of such an EU type-examination certificate, the GAR notified body involved in the production control phase will be able to issue any certificates/decisions required in the framework of the production related conformity assessment modules.

The extent of the GAR notified body assessment

The question has been raised what is the extent of the control of the GAR notified body as regards appliances/fittings already certified under the GAD.

The GAR notified body has to assess on a case-by-case-basis the conformity of a specific appliance/fitting with the GAR. The fact that the same appliance/fitting has already been certified by a GAD notified body and placed on the market under the GAD until 20 April 2018, does not pre-determine, as such, its compliance with GAR.

The GAR notified body (which might be the same or another one if e.g. the GAD notified body has not been notified under GAR) must take into account the test results and certificates issued under GAD, as far as relevant, and then consider whether further assessment is required or whether additional documents have to be submitted (as e.g. the risk analysis provided for in points 1.2 and 1.3 of Annex I to GAR, if such a document had not already been submitted) as part of the procedure for the issue of an EU type- examination certificate attesting that the technical design of the appliance/fitting in question meets the requirements of the GAR that apply to it. Furthermore, the technical documentation to be submitted to the GAR notified body as part of the application by the manufacturer (or if relevant his authorised representative) for an EU type-examination certificate might need to be adapted and take into consideration whether the harmonised standards applied in full or in part, provide or not the presumption of conformity to the GAR, or whether adaptations to the design are needed due e.g. to changes in the generally acknowledged state of the art.

It is the responsibility of the GAR notified body to decide whether further assessment/testing is required and the depth of that further assessment in view of issuing a (new) EU type-examination certificate.

However, attention is brought to the fact that the necessary reassessment by the GAR notified body of the appliance/fitting against the GAR requirements cannot be used in an abusive way. The general principle of Article 31(2) of GAR according to which "conformity assessment shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators" applies also to the reassessment due to the change of the legal framework.

This includes an assessment of the compliance of the appliance/fitting with the GAR requirements and not e.g. with the latest version of a hEN (the previous version of which had been used to demonstrate compliance with GAD). In case the latest version of a hEN (or other technical specification) does not relate to any safety aspects relevant for the type as described in the EC type-examination certificate issued under GAD, it cannot be used as such as an argument by the GAR notified body to require a new complete assessment of the product.

In any case, wherever a change in the state of the art as reflected in a new version of a (harmonised or not) standard or other technical specification would raise any safety issue affecting the type as described in the EC type-examination certificate and possibly the need for un update/addition to the original certificate (or the issue of a new certificate), the GAD notified body should have already raised the issue and performed, on request of the manufacturer, the necessary tests and checks leading possibly to an update/addition to the original EC type-examination certificate or to its replacement by a new one.

In this context, a GAR notified body may proceed to all necessary actions to perform the conformity assessment in order e.g. to issue before 21 April 2018 EU type-examination certificates attesting compliance to GAR of the appliances/fittings concerned as from 21 April 2018. This will allow timely manufacture of GAR compliant products covered by the manufacturer's declaration of conformity to GAR, ready to be legally placed on the market under the GAR as from 21 April 2018.

Type-examination certificates issued under the GAD

All EC type-examination certificates issued under the GAD will expire the date on which GAD, the legal act on which they are based, is repealed (21 April 2018).

The lack of a specific time-limit of the validity of such certificates under GAD is not relevant in this case, as the legal instrument on which those certificates are based will cease to exist and the new legal instrument (GAR) that will fully apply as from that same date (21 April 2018) provides for some changes in relation to GAD.

As a result, certificates issued under GAD will cease to apply, but the related tests/assessments etc. shall be taken into account as far as possible and relevant so as to determine the compliance of the product with GAR in view of the issue of the new certificates under the new Regulation.

EU type-examination certificates under the GAR

As a GAR notified body may start well before 21 April 2018 all acts relating to conformity assessment, the following may apply:

It is allowed to issue an EU type-examination certificate or take any other approval decision under the GAR before 21 April 2018.

This means that both the design and construction of a gas appliance/fitting may be finalized before 21 April 2018. However, the concerned compliant to GAR manufactured products will only be allowed to be placed on the market as from 21 April 2018.

For example, an EU type-examination certificate under GAR issued before 21 April 2018 (dated e.g. 1 December 2017) must stipulate that it will be valid only for appliances/fittings placed on the market as from 21 April 2018.

Such an EU type-examination certificate will therefore be valid only for appliances/fittings placed on the market as from 21 April 2018, even though those products may be manufactured before that date (and kept in the manufacturer's warehouse).

The 10-year maximum validity period of such an EU type-examination certificate will start from the date of its issue (e.g. on 1 December 2017), in accordance with point 1.6 of Annex III to GAR.

ii) With regard to manufacturers

In order to ensure that appliances and fittings compliant with GAR are ready to be placed on the market as from 21 April 2018, manufacturers, may before that date, take all necessary measures preparatory measures and actions allowing them to timely have finished products ready to be placed on the market.

They may already contact a GAR notified body in order to ask for an EU type-examination certificate under GAR and/or to start production of appliances/fittings conforming to the type as approved.

In case a product has been verified both under the GAD and the GAR (by respectively a GAD and a GAR notified body) manufacturers may, as a matter of flexibility, issue before 21 April 2018 a declaration of conformity referring to both legal acts, GAD and GAR and indicating the corresponding periods of application for each of them. They could use for example the following formulation based on the new model structure of EU Declaration of conformity: "The object of the declaration described above is in conformity with the relevant Union harmonization legislation: Directive 2009/142/EC (until 20 April 2018) and Regulation (EU) 2016/426 (from 21 April 2018)".

Such a practice should after 21 April 2018 be phased out within a reasonable period (e.g. one year) and such a (dual) declaration of conformity should be replaced by an EU declaration of conformity attesting compliance to GAR.

Additionally, in order to avoid unnecessary administrative burdens for manufacturers who wish that their appliance/fitting is subject only to the GAR requirements (and not to the GAD considering the very short remaining period – and provided that the product will be placed on the market as from 21 April 2018), it would not be excluded that for a short period before 21 April 2018 such manufactures may make use of flexibility and issue an EU declaration of conformity declaring compliance with GAR of their appliance or fitting (already been subject to conformity assessment by a GAR notified body). Such a declaration of conformity dated e.g. 1 February 2018 would follow the EU declaration of conformity model structure provided for in Annex V of GAR adapted as follows: "The object of the declaration described above is in conformity with Regulation (EU) 2016/426 and applies as from 21 April 2018".

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