EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 117

Communication from the Commission - TRIS/(2024) 2103

Directive (EU) 2015/1535

Notification: 2024/0240/DE

Forwarding of a detailed opinion received by a Member State (Belgium) regarding a rule on services (article 6, paragraph 2, third indent, of Directive (EU) 2015/1535)

Detailed opinion - Avis circonstancié - Ausführliche Stellungnahme - Подробно становище - Podrobné stanovisko - Udførlig udtalelse - Εμπεριστατωμένη γνώμη - Dictamen circunstanciado - Üksikasjalik arvamus - Yksityiskohtainen lausunto - Detaljno mišljenje - Részletes vélemény - Parere circostanziato - Išsamiai išdėstyta nuomonė - Sīki izstrādāts atzinums - Opinjoni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Aviz detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 05-09-2024. - Prolonge le délai de statu quo jusqu'au 05-09-2024.- Die Laufzeit des Status quo wird verlängert bis 05-09-2024.- Удължаване на крайния срок на статуквото до 05-09-2024. - Prodlužuje lhůtu současného stavu do 05-09-2024. - Fristen for status quo forlænges til 05-09-2024. - Παρατείνει την προθεσμία του status quo 05-09-2024. - Amplía el plazo de statu quo hasta 05-09-2024. - Praeguse olukorra tähtaega pikendatakse kuni 05-09-2024. - Jatkaa status quon määräaikaa 05-09-2024 asti. - Produžuje se vremensko ograničenje statusa quo do 05-09-2024. - Meghosszabbítja a korábbi állapot határidejét 05-09-2024-ig. - Proroga il termine dello status quo fino al 05-09-2024. - Status quo terminas pratęsiamas iki 05-09-2024. - Pagarina “status quo” laika periodu līdz 05-09-2024. - Jestendi t-terminu tal-istatus quo sa 05-09-2024. - De status-quoperiode wordt verlengd tot 05-09-2024. - Przedłużenie status quo do 05-09-2024. - Prolonga o prazo do statu quo até 05-09-2024. - Prelungește termenul status quo-ului până la 05-09-2024. - Predlžuje sa lehota súčasného stavu do 05-09-2024. - Podaljša rok nespremenjenega stanja do 05-09-2024. - Förlänger tiden för status quo fram till 05-09-2024.

The Commission received this detailed opinion on the 05-08-2024. - La Commission a reçu cet avis circonstancié le 05-08-2024. - Die Kommission hat diese ausführliche Stellungnahme am 05-08-2024 empfangen. - Комисията получи настоящото подробно становище относно 05-08-2024. - Komise obdržela toto podrobné stanovisko dne 05-08-2024. - Kommissionen modtog denne udførlige udtalelse den 05-08-2024. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 05-08-2024. - La Comisión recibió el dictamen circunstanciado el 05-08-2024. - Komisjon sai üksikasjaliku arvamuse 05-08-2024. - Komissio sai tämän yksityiskohtaisen lausunnon 05-08-2024. - Komisija je zaprimila ovo detaljno mišljenje dana 05-08-2024. - A Bizottság 05-08-2024-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 05-08-2024. - Komisija gavo šią išsamiai išdėstytą nuomonę 05-08-2024. - Komisija saņēma šo sīki izstrādāto atzinumu 05-08-2024. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-05-08-2024. - De Commissie heeft deze uitvoerig gemotiveerde mening op 05-08-2024 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 05-08-2024. - A Comissão recebeu o presente parecer circunstanciado em 05-08-2024. - Comisia a primit avizul detaliat privind 05-08-2024. - Komisia dostala toto podrobné stanovisko dňa 05-08-2024. - Komisija je to podrobno mnenje prejela dne 05-08-2024. - Kommissionen mottog detta detaljerade yttrande om 05-08-2024. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 05-08-2024.

MSG: 20242103.EN

1. MSG 117 IND 2024 0240 DE EN 05-09-2024 05-08-2024 BE DO 6.2(3) 05-09-2024

2. Belgium

3A. FPS Economy, SMEs, Self-employed and Energy
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4. 2024/0240/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5. article 6, paragraph 2, third indent, of Directive (EU) 2015/1535

6. Please find below Belgium's detailed opinion on notification 2024/0240/DE (Health IT Interoperability Governance Regulation):

According to the notified text, Germany is in the process of setting up a body (Competence Centre for Interoperability in Healthcare (KIG)) who shall be empowered to accredit conformity assessment bodies (CABs) certifying information technology systems in the healthcare system.

Even if this body is not called ‘accreditation body’ as such, the Competence Centre shall well act as an accreditation body.

The establishment of this body is violating EU law, with significant consequences for DAkkS, and the European Accreditation Infrastructure.

The setting up of this body constitutes a breach of article 4(1) of Regulation (EC) 765/2008, which stipulates that each Member State shall appoint a single national accreditation body.

Furthermore, a national accreditation body is defined in Article 2(11) of this regulation as the sole body in a Member State that performs accreditation. Article 7(1) also set out that where a conformity assessment body requests accreditation it shall do so with the national accreditation body of the Member State in which it is established.

This reasoning is also supported and explained by chapter 6.4.1. of the Blue Guide 2022 (OJEU C 247) that states that Regulation (EC) 765/2008 foresees that each Member State may appoint one single national accreditation body. Only the national accreditation bodies are allowed to perform accreditation of conformity assessment bodies. No other bodies may claim to provide such services, be it according to harmonised standards or non-harmonised standards. This provision is central to the functioning of accreditation in the EU and to the framework of accreditation set up by the Regulation.

The document ‘CERTIF 2013-01 REV3 Non-national accreditation bodies that claim to provide accreditation’ also provides that the Member States and Commission should assist each other to continuously ensure that only the officially appointed national accreditation bodies carry out accreditation of conformity assessment bodies in the Union.

These different elements all converge towards the fact that at no time more than one accreditation body may be active on the territory of a Member State for a given activity.

We would like to point out that Germany has already appointed its single national accreditation body, which is DAkkS (Deutsche Akkreditierungsstelle GmbH). Therefore, any accreditation activities must be entrusted and performed by this national accreditation body

The Federal Republic of Germany must take all necessary measures to ensure that no body based in Germany other than DAkkS – the national accreditation body – may provide accreditation. Consequently, if the Federal Republic of Germany creates a parallel “self-styled” accreditation body, it fails to fulfil its obligations under Articles 2(10), 2(11) and 4(1) of

Regulation (EC) 765/2008.

Furthermore, the principle that only the national accreditation body is allowed to offer accreditation services to conformity assessment bodies has also been confirmed by the CJEU.

The Court ruled in May 2021 that Article 4(1) and (5) as well as Article 7(1) of Regulation (EC) 765/2008 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body, within the meaning of that regulation, which have their seat in a third State, even where those bodies ensure compliance with international standards and demonstrate, inter alia by means of mutual recognition arrangements, that they have a qualification equivalent to that of the said single accreditation body.

The essence of this ruling is that Regulation (EC) No 765/2008 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body.

That means in other words that national legislations cannot allow that accreditation may be performed by bodies other than the single national accreditation body.

Finally, in compliance with Articles 4(1) and 4(10) of Regulation (EC) 765/2008, DAkkS is the German member of EA given that it has been designated as the German single national accreditation body.

The EA member shall be the sole body in its member state that accredits conformity assessment bodies. The creation of a second German accreditation body will therefore question Dakks' membership within EA, with the consequence that certificates and reports issued by conformity assessment bodies accredited by DAkkS will not be recognised anymore within the European Union according to Article 11(2) of Regulation (EC) 765/2008.

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