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Amsterdam, 8 July 2021

Privileged and confidential
Version July 2021

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Memorandum

To	ILAC
For the attention of	Etty Feller
Concerning	EU Competition law assessment ILAC Policy

EXECUTIVE SUMMARY

Legal Analysis within the EEA

- In the EEA and the Netherlands, accreditation is fully regulated. Accreditation in each Member State can only be performed by the single national AB. Stringent and mandatory regulation on cross border accreditation activities by AB's applies, which prohibits competition between national AB's within the EEA and as a result excludes the applicability of competition law. The EU requirements prevail over the ILAC Policy. Considering that the EU requirements are more stringent than the requirements of the ILAC Policy, the 43 AB's that are either located in the EEA or bound by an EA bilateral agreement will already comply with the requirements set out in the ILAC Policy. It also means that the potential antitrust issues set out in the Caroll&Weiss legal opinion have in any event no relevance for those 43 AB's.

Legal analysis under EU competition law – outside the EEA

- Outside the EEA, the landscape is much more scattered. Taking into account that EU competition law is internationally considered as a reliable standard and is often copied by national competition authorities worldwide, an assessment under EU competition law provides a useful guidance for jurisdictions outside the EU.

- For those jurisdictions where AB's only perform public (non-economic) activities, competition law will not apply. AB's will in those jurisdictions often be recognized as public authority in local laws. For those AB's the ILAC Policy cannot raise any competition law issues.

- Though also for other ABs we expect that competition law is of little relevance when it comes to accreditation. Considering the nature of accreditation, there seem good arguments for the position that from a competition law perspective accreditation will be considered a non-economic activity. Since the ILAC Policy just applies to accreditation, it would imply that the ILAC Policy would fall outside the scope of competition law.

- Even if the accreditation activities to which the ILAC Policy applies would not be considered public activities, we still do not expect serious competition law issues to arise. Most importantly, the requirements of the ILAC Policy (version 5) do not impede cross-border activities by AB's. It is not very likely that the information requirements set out in the ILAC Policy could lead to a restriction of effective competition or facilitate coordination between AB's.

- However, even if the requirements of the ILAC Policy would be perceived by certain competition authorities as restrictive, the ILAC Policy certainly does not have the objective to restrict competition. Moreover, there are good arguments for the position that any potential negative competitive effects will be largely out weighted by the positive effects and would justify an exemption from the cartel prohibition. The requirement(s) under the ILAC Policy do not go beyond what is necessary to achieve the legitimate (public) objective of products fulfilling requirements needed for a high level of protection of the public interests, e.g. safety, health and labour conditions.

- That said, by making cross-border accreditation subject to certain requirements/conditions the ILAC Policy may lead to scrutiny. We cannot rule out that the ILAC Policy will be challenged (by AB's, CAB's or national competition authorities). However, the line of reasoning under EU competition law will to a large extent also apply outside the EU. Taking that line of reasoning into account, it seems unlikely that national competition authorities will consider the ILAC policy a (by object) restriction of competition.

Recommendations

- Considering the wide use of the ILAC Policy by AB's across the world for whom English is not their first language, we recommend to ensure that both the wording and the sequence of the ILAC Policy is concise and clear. In that respect, we recommend to use consistent definitions, avoid repetitions and clearly describe the process of cross-border accreditation activi-

ties. More detailed suggestions are included in Annex 2.

1 INTRODUCTION

1.1 The International Laboratory Accreditation Cooperation ("**ILAC**") asked us to assess whether the *ILAC Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*[1] (the "**ILAC Policy**") complies with EU and Dutch competition law.

1.2 This memorandum contains a general analysis under EU (and Dutch) competition law of the ILAC Policy and cross-border accreditation and a more in depth analysis of the requirements of the ILAC Policy. We finally provide a few recommendations for revision of the policy to mitigate any potential risks from a competition compliance perspective.

2 BACKGROUND AND AIM OF THE ILAC POLICY

2.1 ILAC is the international organization for Accreditation Bodies ("**AB's**") operating in accordance with ISO/IEC 17011. The ILAC membership consists of AB's and stakeholder organizations throughout the world. ILAC is established in the Netherlands under Dutch law as an Association with full legal capacity (in Dutch: "*Vereniging met volledige rechtsbevoegdheid*"). AB's provide accreditation services to Conformity Assessment Bodies ("**CAB's**").[2] CAB's are not members of ILAC and are no addressees of the ILAC Policy.

2.2 Accreditation is the independent evaluation of CAB's by AB's against recognized standards to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, government, procurers and consumers can have confidence in the calibration and test results, inspection reports and certifications provided.

2.3 Since 2000, ILAC operates a worldwide mutual recognition arrangement ("**MRA**")[3] among AB's that are members of ILAC. This arrangement facilitates international trade and supports a high level of protection of

[1] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020.
[2] Including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034).
[3] ILAC, *Mutual Recognition Arrangement: Policy and Management*, 2019, ILAC-P4:05/2019; ILAC, *Mutual Recognition Arrangement: Scope and Obligations*, 2019, ILAC-P5:05/2019.

health and safety and other public interests by encouraging consistent accreditation by AB's. Through the MRA data and test results issued by CAB's that are accredited by AB's that are a signatory to the MRA, can be accepted globally. Accordingly, technical barriers to trade, such as the re-testing of products each time they enter a new economy, are reduced in support of realizing the free-trade goal of "*accredited once, accepted everywhere*".

2.4 In general, AB's accredit CAB's in their own country/economy, so-called domestic accreditation. However, AB's may also want to perform these accreditations outside their own country/economy, so-called foreign accreditation. The ILAC Policy aims to provide a framework for the assessment of CAB's by AB's by setting certain requirements related to accreditation services to CAB's located outside an AB's local/domestic economy. In that way, ILAC aims to further facilitate international trade and public interest, such as health and safety, by ensuring that accreditations by different AB's worldwide are equivalent and can be relied upon by regulators and other parties worldwide.

2.5 The ILAC Policy will replace the existing guidance document *Cross Frontier Accreditation by AB's*.[4] The latter is a code of good practice for ILAC members. This guidance document has been in force since 2001 and we understand that the majority of the AB's have been complying with the guidance provided in this document. To date no complaints or investigations have been initiated by competition authorities in relation to conduct of AB's following the guidance provided.

2.6 ILAC guidance documents contain guidance for AB's, but are not mandatory. The proposed ILAC Policy will however be a policy document, rather than a guidance document. Policy and Procedural publications support the operation of the ILAC MRA and contain mandatory requirements. The current proposal of the ILAC Policy, version 5, is the result of extensive feedback and comments from ILAC members on previous versions of the policy. In 2019, ILAC members submitted legal advice which set out potential concerns under U.S. antitrust law.[5] In 2019, ILAC compiled an overview of all comments received in relation to (an earlier) version of the proposed ILAC Policy.[6] For other jurisdictions, no competition law issues were flagged. To mitigate potential concerns raised from an US perspective, the earlier version of the draft ILAC Poli-

[4] ILAC, *Cross Frontier Accreditation - Principles for Cooperation* (under revision), 2012, ILAC G21:09/2012.
[5] Carroll&Weiss, *Opinion on behalf of ANSI*, 22 August 2019.
[6] ILAC, *Compiled Comments*, version 4 – review, 7 April 2020.

cy has been amended. In this memorandum, we will focus on the latest version of the ILAC Policy, version 5, dated April 2020, in which the feedback and comments of the ILAC members have been addressed.

2.7 The current version of the ILAC policy contains obligations for AB's who are requested by CAB's to perform foreign accreditation activities and wish to provide these accreditation services outside their own economy. The CAB's are not part of the ILAC Policy (and the MRA). Under the ILAC Policy (Clause 1.2) AB's are required to:

(1) inform the CAB who applies for foreign accreditation that a domestic AB exists;

(2) where relevant, request information from the CAB on the reasons to apply for foreign accreditation; and

(3) if applicable, request information on the accreditation history, before accepting the application.

Furthermore, the foreign AB is required to cooperate with the domestic AB in relation with the accreditation.[7] Finally, for recognition of the foreign accreditation the CAB needs to agree that the application information and the assessment plan is shared with the domestic AB. The only reason for not recognising the accreditation under the MRA is if the CAB refuses to share this information.[8]

3 US ANTITRUST LAW CONCERNS RAISED IN RELATION TO EARLIER VERSION

3.1 In relation to the concerns raised by one US ILAC member (ANSI National Accreditation Board ("**ANAB**")) we have received (i) the legal opinion by Caroll&Weiss dated 22 August 2019, and (ii) an email from Ms. Gail A. Matthews, Associate General Counsel of ANAB, dated 22 August 2020.

3.2 The Caroll&Weiss legal opinion – that is limited to US antitrust law – identifies "*at least three significant issues*" under US antitrust law, being:

a. **an "objective" of favoring domestic AB's over foreign AB's**. According to Caroll&Weiss, this explicit objective could facilitate horizontal agreements between domestic AB's not to compete

[7] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020, clause 2.3.
[8] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020, clause 2.5.

with one another outside their host countries, which would often be regarded as per se illegal;

b. **more facially innocuous, provisions** suspect under the rule of reason;

c. the Policy would **deny international recognition of accreditation** to any CAB that chooses to pursue accreditation from a foreign AB and declines to allow the disclosure of its interest in accreditation to the CAB's domestic AB.

3.3 In her e-mail, Ms. Matthews states: *"ANAB believes ILAC's proposed Policy would violate U.S. antitrust law, and the competition laws of other jurisdictions in which ILAC and its members operate. The draft Policy is designed to eliminate competition by allocating customers and geographic markets and artificially inflating the price of accreditation services."*

3.4 Only the Caroll&Weiss opinion substantiates potential anti-competitive effects. However, this legal opinion is based on an earlier version of the ILAC Policy. Perhaps more importantly, we noted that the Caroll&Weiss opinion does not take into account the legitimate objective of the ILAC Policy and the public interest. Both under the Rule of Reason and under EU law the 'efficiencies' of potential restrictions of competition should be balanced against the negative competitive effects of any potential restriction. . The Caroll&Weiss opinion just states that "the *Policy's Anti-competitive Effects Outweigh Any Procompetitive Effects"*, but fails to assess the pro-competitive effects of the ILAC Policy nor does it compare the legitimate objectives against the potential anti-competitive effects.

4 IN THE EEA – HIGHLY REGULATED ACTIVITIES

4.1 In the European Economic Area ("**EEA**")[9] and in all its member states (including the Netherlands) accreditation is fully regulated in accordance with Regulation (EC) No 765/2008("**Regulation**").[10] Pursuant to EU law, EU regulations do not require any national implementation, but provide direct application and can directly be relied upon by all citizens within all member states. The Regulation defines '*national accreditation body*' as the sole body in a Member State that performs accreditation with authority derived from the State.[11] The Regulation contains stringent and mandatory provisions on cross border accreditation activities by AB's.[12]

[9] The EEA consists of the European Union member states and the EFTA States.
[10] Regulation (EC) 765/2008,setting out the requirements for accreditation and market surveillance relating to the marketing of products.
[11] Regulation (EC) 765/2008, Article 2(11).
[12] Regulation (EC) 765/2008, Article 7.

4.2 Pursuant to the Regulation, AB's in the EEA operate as a public authority regardless of their organizational form.[13] For AB's in the EU, it is prohibited to perform services that may overlap with consultancy or conformity assessment services.

4.3 According to the Regulation the main principles of accreditation - relevant for our assessment - in the EEA are:

- one accreditation body per EU member state[14];
- accreditation is a public sector activity and a not-for-profit activity[15];
- there is no competition between national AB's within the EEA (and also not with conformity assessment bodies)[16];
- no cross border assessment, unless in the exceptional cases set out in the Regulation.

4.4 The third principle implies that pursuant to EU law, there is not a market for accreditation activities and, thus, EU and national competition laws do not apply.

4.5 The aim of the above principle of non-competition is to: "*prevent AB's from shopping around for accreditation certificates, thus creating a "market for accreditation" leading to the commercialization of accreditation which jeopardizes the added value and role of accreditation as a public authority activity and last level of control of the conformity assessment chain.*"[17]

4.6 The principles included in the Regulation apply to all AB's active in the EEA. In addition, the EU entered into government-to-government Mutual recognition agreements ("**G2G-MRA**") with certain countries outside the EEA.[18] In these instances, the national authorities of EEA Member States will accept the test reports and certificates issued by bodies that the foreign party has designated under the G2G-MRA for assessing conformity in the categories of products or sectors covered by the G2G-MRA. All AB's in the EEA and all AB's that signed an EA Bilateral Agreement[19], amount to 43 AB's. The accreditation activities of all these 43 AB's are

[13] Regulation (EC) 765/2008, Article 4(5). See also: EC, *Guidance papers of the European Commission on accreditation*, version July 2014. .
[14] Regulation (EC) 765/2008, Article 4(1).
[15] Regulation (EC) 765/2008, Article 4(5) and Article 4(7).
[16] Regulation (EC) 765/2008, Article 6(1) and Article 6(2).
[17] EC, *Guidance papers of the European Commission on accreditation*, version July 2014, para. 7.2.
[18] Currently G2G-MRAs between the European Union and the following countries are in place: Australia, Canada, Israel, Japan, New Zealand, Switzerland, United States.
[19] EA, *Signatories to the EA Multilateral and Bilateral Agreements, lists the signatories to the EA Multilateral Agreement (EA MLA) and EA Bilateral Agreements (EA BLA)*, 29 October 2020, EA-INF/03.

regulated by the Regulation and fall outside the scope of EU and national competition laws.

4.7 The European Court of Justice ("**ECJ**") recently confirmed that because under the Regulation each Member State is required to appoint a single national AB and that CAB's are in principle required to request accreditation by that AB, a CAB is not allowed to submit an application to a national AB other than that of the Member State.[20] A CAB is, in addition, not allowed to obtain accreditation from a third-country AB for the purpose of carrying out its activity in the EU. The fact that a third-country AB is part of the MRA and has a qualification certifying with international standards does not change this interpretation of the Regulation.[21] This means that under the Regulation accreditation of CAB's in the EEA cannot be performed by third-country AB's and no cross border accreditation is allowed. With regard to cross border accreditation the Regulation is more stringent than the ILAC Policy. Under the Regulation and the guidance provided by the EU, third-country AB's are urged to comply with the requirements of the Regulation. Complying with the Regulation by third-country AB's will therefore never raise any competition law concerns in the EEA.

4.8 The ILAC Policy has the same objectives as the Regulation. The recitals of the Regulation stipulate that: "*The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value.*"[22]

4.9 The recitals of the Regulation furthermore state that it aims: "*to ensure that products on the market covered by Community legislation fulfil requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for accreditation and market surveillance.*"[23]

4.10 Accordingly, when assessing the ILAC Policy from a European and Dutch competition law perspective, the conclusion is that competition

[20] ECJ 6 May 2021, Case C-142/20 (*Analisi G. Caracciolo v Regione Siciliana, Accredia. Azienda sanitaria provinciale di Palermo*), para 32.
[21] ECJ 6 May 2021, Case C-142/20 (*Analisi G. Caracciolo v Regione Siciliana, Accredia. Azienda sanitaria provinciale di Palermo*), para 42-45.
[22] Regulation (EC) 765/2008, rec. 19.
[23] Regulation (EC) 765/2008, rec. 48.

law does not apply. The requirements of the Regulation go beyond – read: are much more stringent than – the requirements of the ILAC Policy. The Regulation (in general) does not allow cross-border accreditation, where the ILAC Policy only requires that some conditions are met in relation to cross-border accreditation. Taking into account the direct application of EU regulations, for the 43 AB's in the EEA or bound by an EA bilateral agreement the ILAC Policy will have limited relevance. The Regulation prevails over the ILAC Policy.[24] It also means that the potential antitrust issues set out in the Caroll&Weiss legal opinion have in any event no relevance for those 43 AB's. Competition (or antitrust) laws do not apply.

In the EEA and the Netherlands, accreditation is fully regulated. Competition law does not apply to accreditation services. The ILAC Policy can thus not raise any competition law issues.

5 OUTSIDE THE EEA – LEGAL ANALYSIS UNDER EU COMPETITION LAW

5.1 The Regulation does not apply outside the EEA and is not addressed to third country AB's.[25] Outside the EEA the landscape is much more scattered. As it will be nearly impossible to make a national competition law assessment for all remaining countries worldwide, it can be relevant to still assess the ILAC Policy from an EU competition law perspective. EU competition law is internationally considered as a reliable standard and is often copied by national competition authorities worldwide. Compared to the US and other national regimes, EU competition law may sometimes be stricter. An EU law assessment of the ILAC Policy may thus be useful guidance for jurisdictions outside the EU.

5.2 European competition law in principle forbids agreements and concerted practices between undertakings which have as their object or effect the prevention, restriction or distortion of competition (the so-called "**cartel prohibition**"). On EU level, this is laid down in Article 101 of the Treaty on the Functioning of the European Union ("**TFEU**").

[24] See also ILAC, *Mutual Recognition Arrangement: Policy and Management*, 2019, ILAC-P4:05/2019, Article 1.4. The MRA states that no AB shall be required to have a policy or practice that is in violation of any existing laws in its economy.
[25] EC, *Guidance papers of the European Commission on accreditation*, version July 2014, para. 2.3.

Undertaking notion – economic activity and public powers

5.3 For our assessment under EU competition law, we will first look into the question whether the ILAC signatories (AB's) are undertakings. Organizations that are not an undertaking under EU competition law are not subject to the cartel prohibition. The concept of an undertaking encompasses every entity engaged in an *economic activity*, regardless of the legal status of the entity or the way it is financed.[26]

5.4 An entity is engaged in an economic activity when it is *'offering goods and services on a given market*'. European case law of ECJtakes a functional approach; it depends on the particular function performed whether the activity in question is economic in nature. Various activities of an undertaking are considered individually. For that matter, the entity in question is not required to have an economic purpose – it can be a non-profit organization.[27] Economic activity covers all commercial functions consisting in offering goods and services on a given market irrespective of the source of remuneration. The fact that services in question are not at the current time offered by private undertakings does not prevent them being described as an economic activity, as long as it is possible for them to be carried out by private entities.[28]

5.5 In addition, public authorities may fall within the scope of competition law insofar as they are engaged in activities of an economic nature. The treatment of some of the activities as powers of public authority does not mean that other activities are not economic in nature.[29] Activities that are connected with the exercise of the powers of a public authority fall outside the scope of competition law. Public activities are defined as a *'task in the public interest which forms part of the essential function of the State and is connected by its nature, its aim and the rules to which it is subject with the exercise of powers which are typically those of a public authority*'. [30]

5.6 Both the MRA and the ILAC Policy only apply to the accreditation of

[26] ECJ 23 April 1991, ECLI:EU:C:1991:161 (*Hofner and Elser v Macroton GmbH)*, para. 21.
[27] ECJ 18 June 1998, ECLI:EU:C:1998: (*Commission v Italy)*, para. 36. See also ECJ 11 July 2006, ECLI:EU:C:2006:453 (*Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities)* [, para. 25 and ECJ 26 March 2019, ECLI:EU:C:2009:191 (*SELEX Sistemi Integrati v Commission and Eurocontrol)*, para. 54.
[28] ECJ 26 March 2019, ECLI:EU:C:2009:191 (*SELEX Sistemi Integrati v Commission and Eurocontrol)*, para. 89.
[29] ECJ 26 March 2019, ECLI:EU:C:2009:191 (*SELEX Sistemi Integrati v Commission and Eurocontrol)*, para. 54.
[30] EJC 18 March 1997, ECLI:EU:C:1997:160 (*Cali & Figli v Servizi Ecologici Porto di Genova)* , para. 23.

CAB's by AB's and not to any other activities of an AB. For the purpose of this EU assessment, which would be used as a guidance outside the EEA, we assume that the Regulation does not apply. However, even without the Regulation we believe there are good arguments for the position that from an EU law perspective accreditation activities would be considered public activities. Accreditation will often be highly regulated by national laws and is typically required by national (or regional) law.

5.7 The Horizontal Guidelines of the European Commission note with respect to the applicability of competition law to activities regulated by national legislation:

> *It is only if anti-competitive conduct is required of companies by national legislation, or if the latter creates a legal framework which precludes all scope for competitive activity on their part, that Article 101 does not apply.*[31] *In such a situation, the restriction of competition is not attributable, as Article 101 implicitly requires, to the autonomous conduct of the companies and they are shielded from all the consequences of an infringement of that article.*[32]

5.8 To the extent that accreditation is considered a public activity, competition law would not apply. Other economic activities performed by AB's may fall within the scope of competition law, insofar as those activities are not ancillary to the non-economic activities. However, other activities or services that may be performed by AB's, do not fall under the ILAC Policy. Note that for AB's in the EEA these type of activities are prohibited.

EU competition law only applies to activities of an economic nature. There seem good arguments for the position that accreditation activities are considered non-economic or public activities. Since the ILAC Policy only applies to accreditation this would imply that the ILAC Policy

[31] ECJ 14 October 2010, ECLI:EU:C:2010:603 (*Deutsche Telekom v European Commission*), paras. 80-81. This possibility has been narrowly interpreted; see, for example, ECJ 29 October 1980, ECLI:EU:C:1980:248 (*Heintz van Landewyck SARL and others v Commission of the European Communities*) paras. 130–134; ECJ 10 December 1985, ECLI:EU:C:1985:488 (*Stichting Sigarettenindustrie and others v Commission of the European Communities*), paras. s 27–29; and ECJ 11 November 1997, ECLI:EU:C:1997:531 (*Commission of the European Communities and French Republic v Ladbroke Racing Ltd*.), paras. 33 et seq.

[32] At least until a decision to disapply the national legislation has been adopted and that decision has become definitive; see ECJ 9 September 2003, ECLI:EU:C:2003:430 (Consorzio Industrie Fiammiferi (CIF) v Autorità Garante della Concorrenza e del Mercato), paras. 54 et seq.

would fall outside the scope of competition law.

The requirements of the ILAC Policy do not restrict competition

5.9 Even if the accreditation activities to which the ILAC Policy applies would not be considered public activities, we would still not expect any competition law issues to arise. The obligations under the ILAC Policy do not restrict cross-border activities by AB's. The domestic AB can perform accreditation activities outside its own economy, throughout the world. The AB's however do need to inform the domestic AB and ensure that the foreign accreditations fulfil the expected requirements. If the CAB wants the accreditation to be recognised under the MRA, it needs to agree that the information relating to the foreign accreditation - the application information and the assessment plan - is shared with the domestic AB. Only if the CAB refuses to share such information with the domestic AB and the domestic AB remains uninformed of an accreditation that relates to its own economy, the accreditation cannot be recognised under the MRA.

5.10 The ILAC Policy does not have any objective to restrict competition. It solely serves the objectives of facilitating international trade, ensuring impartiality of AB's and encouraging consistent accreditation by AB's. It seems moreover not very likely that the ILAC Policy may by effect restrict competition. Although sharing strategic or other sensitive information between competitors may sometimes have the effect to restrict competition or could lead to coordination, the information shared with the domestic AB does not seem competitively sensitive and is needed to safeguard the legitimate objectives of the ILAC Policy. We do not see how the information requirements set out in the ILAC Policy would impede competition between AB's or encourage anticompetitive coordination, causing potential price increases, lower quality or slowdown innovation. In any event, we do not see how the type of information exchanged would facilitate horizontal agreements between domestic AB's not to compete with one another outside their host countries, which was (one of the) issues raised by Caroll&Weiss.

Even if EU competition law would apply to the ILAC Policy, it is not very likely that the information requirements set out in the ILAC Policy could lead to a restriction of effective competition or facilitate coordination between AB's.

Positive effects outweigh any potential negative effects

5.11 In the unlikely situation that the obligations in the ILAC Policy would be considered to have a restrictive effect on competition between the AB's and would infringe the cartel prohibition, we believe that positive effects would outweigh any potential restrictions and we would still not expect any competition law issues to arise. We will further substantiate below why the obligation(s) under the ILAC Policy do not go beyond what is necessary to achieve the legitimate (public) objective of products fulfilling requirements needed for a high level of protection of the public interests, in relation to e.g. safety and health.

Article 101(3) exception to the cartel prohibition

5.12 An assessment of the cartel prohibition laid down in Article 101 TFEU consists of two steps. The first step is to assess whether an agreement or arrangement between undertakings has an anti-competitive object or actual or potential restrictive effects on competition. The second step, which only becomes relevant when an agreement is found to be restrictive of competition, is to determine the pro-competitive benefits produced by that agreement and to assess whether those pro-competitive effects outweigh the restrictive effects on competition. This is the exception rule of Article 101(3).

5.13 The application of the exception rule of Article 101(3) is subject to four cumulative conditions, two positive and two negative:

1. The agreement must contribute to improving the production or distribution of products **or** contribute to promoting technical or economic progress, that is to say, lead to **efficiency gains**;
2. The **restrictions must be indispensable** to the attainment of those objectives, that is to say, the efficiency gains;
3. The resulting **benefits should be sufficiently passed on** to consumers so that they are at least compensated for the restrictive effects of the agreement; hence, efficiencies only accruing to the parties to the agreement will not suffice; for the purposes of these guidelines, the concept of 'consumers' encompasses the customers, potential and/or actual, of the parties to the agreement; and

4. The agreement must **not** afford the parties the possibility of **eliminating competition** in respect of a substantial part of the products in question.

5.14 The Horizontal Guidelines of the European Commission (the "**Guidelines**") provide an analytical framework for the assessment of co-operation between competitors under EU competition law.[33] The Guidelines also provide guidance for the application of Article 101(3) for different types of horizontal co-operation agreements. Section 7 contains guidance for Standardization agreements. Standardization agreements have as their primary objective the definition of technical or quality requirements and can cover various issues, such as standardization of different grades or sizes of a particular product or technical specifications in product. The terms of access to a particular quality mark or for approval by a regulatory body can also be regarded as a standard.

5.15 The co-operation between the AB's in the ILAC Policy can be assessed along the lines provided by the European Commission for the assessment of standardization agreements.[34] Standardization agreements have important positive effects. The Guidelines stipulate: *"Standardisation agreements usually produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions."*

Application Article 101(3) exception to ILAC Policy

5.16 The ILAC policy does not have the objective to restrict competition. However, by making cross-border accreditation subject to certain requirements/conditions the policy may have a potential restrictive effect. The ILAC Policy therefore must be analyzed in its legal and economic context with regard to its actual and likely effects on competition. There is only one standard for the accreditation of CAB's. This standard is set by public authorities and all CAB's meeting the criteria will be accredited. The access to the standard (for CAB's) is transparent and non-discriminatory. If we assume that the ILAC Policy may have the effect of market partitioning (by favoring domestic AB's) and may therefore been seen as restrictive, we need to assess if the exception rule of Article

[33] EC, *Guidelines on the applicability of Article 101 of the Treaty on the Function-ing of the European Union to horizontal co-operation agreements*, 2011.
[34] Note that the Guidelines explicitly state that the preparation and production of technical standards as part of the execution of public powers are not covered by the Guidelines (see previous section on Undertaking notion and Article 106 TFEU).

101(3) applies.

5.17 The objective of the ILAC MRA and the ILAC Policy is: *to allow products and services accompanied by accredited conformity attestations to enter foreign markets without a re-testing or re-certification in the import country. The objective of such recognition arrangement/agreements between AB's is therefore to contribute to reinforce the acceptance of conformity assessment certificates*.

5.18 This objective is in line with the objectives of the Regulation. Although we assume for the purpose of this assessment that the Regulation does not apply, the Regulation does provide a relevant assessment of the importance of cooperation in the field of accreditation:

> *(…) to ensure that products on the market covered by Community legislation fulfil requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for accreditation and market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective*.

5.19 In the Wouters case[35] the ECJ also weighed public interests:

> "*More particularly, account must be taken of its objectives, which are here connected to the need to make rules relating to organisation, qualifications, professional ethics, supervision and liability, in order to ensure that the ultimate consumers of legal services and the sound administration of justice are provided with the necessary guarantees in relation to integrity and experience […]. It has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives.*"[36]

[35] ECJ 19 February 2002, ECLI:EU:C:2002:98 (J.C.J. Wouters, J.W. Savelbergh and Price WaterhousBelastingadviseurs BV v. Algemene Raad van de Nederlandse Orde van Advocaten).
[36] ECJ 19 February 2002, ECLI:EU:C:2002:98 (J.C.J. Wouters, J.W. Savelbergh and Price WaterhousBelastingadviseurs BV v. Algemene Raad van de Nederlandse Orde van Advocaten), para. 97.

5.20 The CJEU concludes that the Bar "*could have reasonably considered that that regulation, despite the effects restrictive of competition that are inherent in it, is necessary for the proper practice of the legal profession, as organised in the Member State concerned*" and that therefore art.101(1) TFEU was not infringed.[37] The same type of reasoning was applied in several other CJEU-cases.

5.21 The CNG judgment was quite similar.[38] That case concerned professional rules for geologists concerning reference fees. Those rules were again liable to restrict competition, but could potentially be justified by the objective of ensuring that the ultimate consumers of the services by geologists are provided with the necessary guarantees.

5.22 The ILAC Policy clearly has important and legitimate objectives, which are passed on to consumers and ultimately protects the legitimate interests of consumers. Restrictions arising therefrom - if any - are inherent in the pursuit of these legitimate objectives and are proportionate to those objectives. Under the ILAC Policy AB's are required to (1) inform the applicant (CAB) that a domestic AB exists, (2) where relevant, request information from the CAB on the reasons to apply for foreign accreditation and (3) if applicable, request information on the accreditation history, before accepting the application.[39] Furthermore, the foreign AB needs to cooperate with the domestic AB in relation with the accreditation.[40] Finally, the only reason for not recognising the accreditation under the MRA is if the CAB refuses to share the information relating to the accreditation with the domestic AB.[41]

5.23 Taking into account the above, we believe that – even if the ILAC Policy would potentially restrict competition – it would be able to benefit from an exception to the cartel prohibition. The ILAC Policy clearly has important and legitimate objectives, which are passed on to consumers and ultimately protects the legitimate interests of consumers. The information and cooperation requirements are needed to ensure the quality of the accreditation in the 'foreign' economy and the connected public interests.

[37] ECJ 19 February 2002, ECLI:EU:C:2002:98 (J.C.J. Wouters, J.W. Savelbergh and Price WaterhousBelastingadviseurs BV v. Algemene Raad van de Nederlandse Orde van Advocaten), para. 110.
[38] ECJ 18 July 2013, ECLI:EU:C:2013:489 (Consiglio Nazionale dei Geologi (CNG) v Autorita Garante della Concorrenza e del Mercato), para. 40.
[39] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020, clause 1.2.
[40] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020, clause 2.3.
[41] ILAC, *Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy*, version 5, April 2020, clause 2.5.

The consequence of the accreditation not being recognized under the MRA – if the requirements are not met – is also necessary to ensure the quality and serve the public interests of e.g. health, safety and labour conditions.

The ILAC Policy will likely fulfill all criteria of an individual exemption of Article 101(3). This would imply that – even if the ILAC Policy would potentially restrict competition – the ILAC Policy would be exempted from the cartel prohibition.

6 CONCLUSIONS & RECOMMENDATIONS

6.1 We do not expect that the ILAC Policy version 5, dated April 2020, would raise serious competition law issues. First of all, competition law does not apply to the accreditation activities in the EEA, including the Netherlands. In the EEA, accreditation is fully regulated. The same applies to the AB's outside the EEA bound by an EA bilateral agreement. For all 43 AB's that are either located in the EEA or bound by an EA bilateral agreement the ILAC Policy can thus not raise any competition law issues.

6.2 Outside the EEA, the landscape is much more scattered. Taking into account that EU competition law is internationally considered as a reliable standard and is often copied by national competition authorities worldwide, an assessment under EU competition law provides a useful guidance for jurisdictions outside the EU.

6.3 Competition law only applies to activities of an economic nature. We expect that accreditation activities are likely considered non-economic or public activities. For those jurisdictions where AB's only perform public (non-economic) activities, competition law will not apply. AB's will in those jurisdictions often be recognized as public authority in local laws. Though also for other ABs we expect that competition law is of little relevance when it comes to accreditation. Considering the nature of accreditation, there seem good arguments for the position that accreditation activities will pursuant to EU competition law not be considered economic activities. Since the ILAC Policy only applies to accreditation this would imply that the ILAC Policy would fall outside the scope of competition law.

6.4 Even if EU competition law would apply to the ILAC Policy, it is not very likely that the information requirements set out in the ILAC Policy could lead to a restriction of effective competition between AB's. And, finally, even in the unlikely situation that the ILAC Policy would be considered to restrict competition, the ILAC Policy will likely fulfill all criteria of an individual exemption of Article 101(3). The ILAC Policy would thus be exempted from the cartel prohibition.

6.5 Of course, we cannot rule out that the ILAC Policy will nevertheless be challenged, either by AB's, CAB's or national competition authorities. However, the line of reasoning under EU competition law will to a large extent also apply outside the EU. Taking that line of reasoning into account is seems unlikely that national competition authorities will find the ILAC policy an (by object) restriction of competition.

6.6 Taking these conclusions into account, we do not see a need to amend or change the current requirements/conditions relating to cross-border accreditation in the ILAC Policy.

6.7 However, we would recommend reviewing the wording and the sequence of the ILAC Policy. Although a policy document will – after many revisions – show marks of the history of such document and the concessions made, the users will not necessarily be aware of the history or what should be read between the lines. Considering the wide use of the ILAC Policy by AB's across the world for whom English is not their first language, we recommend to ensure that both the wording and the sequence of the ILAC Policy is concise and clear. In particular, we would ensure that all obligations under the policy, including the consequences, are clear for all AB's and cannot be misinterpreted. In addition, we would recommend to make the policy more concise, use consistent definitions and clearly describe the process of cross-border accreditation activities. In Annex 2 we have included some initial suggestions and comments on version 5 of the ILAC Policy.

Annex 1: Policies, opinions and regulations

- ILAC Policy for cooperation between ILAC Arrangement Signatories when conducting assessments outside its own economy, version 4 and 5;
- ILAC-P4:05/2019 ILAC Mutual Recognition Arrangement: Policy and Management
- ILAC-P5:05/2019 ILAC Mutual Recognition Arrangement: Scope and Obligations
- 2.5 ILAC Procedure for foreign assessments - draft 2
- ILAC: cross-frontier accreditation principles for cooperation, 2012

- Squire Patton and Boggs (unconfirmed) opinion, 24 July 2019
- TIC Council position, 19 August 2019
- Carroll&Weiss opinion on behalf of ANSI, 22 August 2019
- Email Gail A. Matthews, Associate General Counsel ANSI, 25 November 2020

Annex 2: DRAFT ILAC Policy version 6