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WK 4086/2024 INIT

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Intellectual Property (Patents)
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N° Cion doc.:	8901/23 + ADD 1-5
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 - Member States comments

Delegations will find attached the consolidated drafting suggestions and comments received so far regarding the above-mentioned proposal.

The working document comprises contributions from the following delegations: PT - AT - EE - PL - NL - DE - CZ - ES - FI - DK - SE - IT - FR - EL - IE - SI.

WK 4086/2024 INIT

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From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
GENERAL COMMENTS TO THE PROPOSAL	<p>CZ (Comments):</p> <p>In general, the Czech Republic welcomes the discussion on improving preparedness, coordination and its effectiveness at EU level for emergencies such as those we have recently witnessed on a global scale.</p> <p>The Czech Republic has no experience of compulsory licensing. The body authorised to grant compulsory licences is the Industrial Property Office. The conditions for granting a compulsory licence, which are in line with the TRIPS Agreement, are laid down in the Patent Act. However, no application for a compulsory licence has yet been filed.</p> <p>The draft regulation is seen by the Czech Republic as a last resort in a situation where a licensing agreement cannot be reached on a voluntary basis. It would therefore appreciate it if this fact were explicitly highlighted in the proposal directly in Article 1.</p> <p>Consequently, the Czech Republic could agree that the Regulation should apply to patents, published patent applications, supplementary protection certificates and utility models as set out in Article 2(1) of the draft Regulation.</p> <p>As regards the basic parameters of EU compulsory licensing (non-exclusivity, non-transferability, right of the patent proprietor to adequate compensation), the draft Regulation respects the international legal framework for compulsory licensing established by the TRIPS Agreement. These parameters are therefore acceptable to the Czech Republic.</p> <p>The Czech Republic considers that conferring the power to grant compulsory licences on the European Commission is acceptable.</p> <p>If the majority of Member States agree to the introduction of compulsory licensing at EU level, the Czech Republic will not oppose the adoption of the draft</p>

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	<p>Regulation. At this stage we have no textual proposals. We are ready to consider proposals from other member states.</p> <p>DE (Comments):</p> <p>The German Federal Government sees no need for regulatory action for the introduction of an EU-wide compulsory licence. Such a licence is neither appropriate nor necessary to ensure effective crisis management within the EU. Compulsory licences are provided for in the legislation of all Member States in line with the TRIPS Agreement. However, the European Commission's statements on transnational aspects do not allow for a fact-based discussion. This applies in particular to the proposed additions to Regulation (EC) No. 816/2006. Confidence in patent protection itself would be disturbed by the proposal. In this respect, compulsory licenses are in no way suitable for eliminating acute production and distribution bottlenecks.</p> <p>Notwithstanding this fundamental position, the German Federal Government wishes to comment on selected substantive aspects as follows while maintaining its general scrutiny reservation and expressly reserving the right to make further comments:</p> <p>DK (Comments):</p> <p>Denmark is yet to obtain a parliamentary mandate on the file, so comments and drafting suggests made are preliminary. Denmark reserves the right to submit further comments at a later point.</p> <p>Denmark questions the need for a compulsory licensing instrument at Union level overall.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>The covid-19 pandemic showed that voluntary agreements were the most effective way to deal with a crisis situation in the EU. Denmark fears that an EU compulsory licensing instrument will lead to legal uncertainty and thereby jeopardise a well-functioning system.</p> <p>NL (Drafting Suggestions):</p> <p>Considering that we have only covered a portion of the proposal (only articles 1-5 and 11-12_ thus far, it is premature to offer specific drafting recommendations at this point. We plan to provide drafting suggestions at a later stage in the process.</p> <p>NL (Comments):</p> <p>Voluntary cooperation and agreements are and remain the most efficient means of enabling rapid production of patent-protected products, even in crisis situations. However, it cannot be excluded that exceptional cases will arise in the future where such voluntary agreements are not available or appropriate. In such circumstances, compulsory licences could potentially offer a solution.</p> <p>The Dutch government therefore welcomes the proposal, which introduces the possibility of compulsory licensing at EU level of products or processes that are indispensable to deal with a cross-border crisis or emergency in the Union. The same goes for expanding the possibilities for exports of medical products to third countries with public health problems. The government is broadly supportive of the measures announced herein, but has a number of concerns as this proposal is further negotiated. Like the Regulatory Review Board (RSB), the government considers that the effects of and consistency with other EU crisis management instruments recently presented or coming into force should be adequately taken into account, more specifically SMEI / IMERA, serious cross-border health threats, Emergency Framework crisis-relevant</p>

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	<p>medical countermeasures , Chips Act and gas supply security measures. NL also not convinced about the usefulness and necessity of including all crisis instruments mentioned on the Annex.</p> <p>Furthermore, the expected exceptional use of the instrument should remain clear. In addition, the definitions and wording used in the proposal lack sufficient clarity on several points. This concerns, for instance, the wording of the different crises covered and the crisis-related critical products. Also, in the relationship between right holder (e.g. patent holder) and licensee, the extent of the principle of good faith cooperation is insufficiently clear, leading to legal uncertainty. It is also important to ensure sufficient knowledge, including in the field of intellectual property, in the competent 'advisory bodies'. Furthermore, the relationship between the proposal and the requirements of parts of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) should be carefully assessed, for instance with regard to determining the appropriate remuneration under the proposal and further examine whether this takes sufficient account of the economic value of the licence and whether review by a separate higher authority is guaranteed. Finally, it should be kept well in mind that the final instrument should not have a negative impact on the willingness of companies to enter into voluntary collaborations and invest in research and innovation of (crisis) products and processes.</p> <p>Finally, under the current proposal, the advisory procedure is used for the adoption of implementing acts granting, supplementing, amending or terminating a compulsory Union license and for implementing acts determining the fee. In view of the Dutch the examination procedure is preferred as it provides better guarantees for the involvement of the Member States.</p> <p>PT (Comments):</p> <p>It is important to ensure that the rules established in the Regulation are completely</p>

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	<p>clear and transparent - avoiding very broadly terms or wording – and defined in a precise manner. They should also be fair to all stakeholders (holders of the right; potential licensees and general public). Therefore the accuracy of the Regulation will determine its efficiency.</p> <p>Regarding this, it is important to mention that there are some points in the proposal that are defined in a general and vague way - which can lead to a lack of clarity -, or that need clarification.</p> <p>Other aspect that should be included, e.g in the recitals, is that priority should always be given to voluntary licenses, and compulsory licenses should be seen as a last resort.</p> <p>Also, shouldn't there be a provision that establishes the possibility of appeal against decisions regarding the grant/refusal of compulsory licences?</p> <p>SE (Comments):</p> <p>Intellectual property protection is a prerequisite for the development of products needed to combat crises, and interventionist measures such as compulsory licenses must always be seen as a last resort when other solutions are not possible.</p> <p>Sweden is not immediately convinced that there is a strong need to change the current IP regime on compulsory licensing. It is clear that patent holders and manufacturers in most situations are able to enter into voluntary agreements, and introduction of new instruments risk decreasing the general trust in a solid IP system.</p> <p>Any new regulation in the area must be predictable, clearly defined and provide for adequate legal certainty. The request for this regulation must also be weighed against the international perspective and it needs to be ensured that this is not communicated as opening the doors for less strict IP regulations in general. The</p>

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<p>Commission proposal 2023/0129 (COD)</p>	<p>Drafting Suggestions and Comments</p>
	<p>proposal should better reflect that compulsory licensing is a means to get access to a specific patent when other routes are unaccessible, and not a general way to get access to specific products when accessability may be an issue. Further to the discussions on the provisions within the proposal, Sweden believes that discussions need to be had on what instruments should be included in the annex.</p>
<p>2023/0129 (COD)</p>	
<p>Proposal for a</p>	
<p>REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</p>	
<p>on compulsory licensing for crisis management and amending Regulation (EC) 816/2006</p>	
<p>(Text with EEA relevance)</p>	
<p>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,</p>	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,	
Having regard to the proposal from the European Commission,	
After transmission of the draft legislative act to the national parliaments,	
Having regard to the opinion of the European Economic and Social Committee ¹ ,	
Having regard to the opinion of the Committee of the Regions ² ,	
Acting in accordance with the ordinary legislative procedure,	
Whereas:	EE (Drafting Suggestions):

¹ OJ C , , p . .

² OJ C , , p . .

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	<p>The explanatory memorandum of the proposal reiterates, in the very first passage, that patent rights play a key role in supporting EU innovation and creating the right environment for investment. However, the regulation itself contains no <i>expressis verbis</i> references to innovation. Perhaps wording, referring <i>expressis verbis</i> to the importance of innovation in the EU, could be added to the recitals of the regulation. We fully trust you to find the appropriate place for this in the recitals.</p>
<p>(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.</p>	<p>EL (Comments):</p> <p>For proportionality purposes, please provide evidence of situations in which a) voluntary agreements were not available and b) were available but only under inadequate conditions (e.g. lengthy delivery times).</p> <p>FR (Drafting Suggestions):</p> <p>(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, in case where access to crisis-relevant products protected by a patent cannot be achieved through voluntary cooperation compulsory licensing can provide in exceptional circumstances, as a last resort, a solution to allow access to patented products, in particular essential products to scale up production and tackle the consequences of</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>a crisis.</p> <p>FR (Comments):</p> <p>It is necessary to recall the principle under which a compulsory licence is a legal tool intended to be applied only in exceptional circumstances, in last resort, when no voluntary agreement could be entered into with the holder of the industrial property right.</p> <p>NL (Drafting Suggestions):</p> <p>(1) Crises require the setting-up of exceptional, swift, and adequate and proportionate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, in case where access to crisis-relevant products protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can provide in exceptional circumstances, as a last resort, a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis..</p> <p>NL (Comments):</p> <p>Recall principle of last resort.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>SE (Drafting Suggestions):</p> <p>(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually normally suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, and should remain the principal recourse even including in crises. Nevertheless, there may be situations where a license to a patent needed for the use of a crisis-relevant product cannot be obtained through voluntary cooperation voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, and as an exceptional measure as a last resort, compulsory licensing can provide a solution to allow access to intellectual property rights needed to ensure a defined production of patented products, in particular products necessary to tackle the consequences of a crisis.</p> <p>SE (Comments):</p> <p>Language added to recall the principle of last resort and shift the focus from access to production of products to access to IP rights when there is a clear indication of this being the bottleneck.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.</p>	<p>FR (Drafting Suggestions):</p> <p>In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can as a last resort facilitate access to patent and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.</p> <p>FR (Comments):</p> <p>To ensure consistency with EU positions in other international fora, patents should not be identified as a barrier to access to products.</p> <p>IE (Comments):</p> <p>The criteria for a “crisis or emergency mode” that would trigger the compulsory</p>

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	<p>licensing option are defined in a vague manner so as it currently stands the compulsory license could be applied to many scenarios outside of those offered as exemplar scenarios. A more precise definition as to what these modes would entail and what criteria would determine how they come into effect is necessary.</p> <p>NL (Drafting Suggestions):</p> <p>(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can allow the use of patented subject matter help in lifting any patent related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.</p> <p>NL (Comments):</p> <p>To ensure consistency with EU positions in other international fora, patents should not be portrayed as a barrier to access to products. Moreover, license alone does not ‘ensure the supply of products or services’.</p>

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	<p>SE (Drafting Suggestions):</p> <p>(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the a possibility to rely on make use of compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can still allow the use of the patented subject matter help in lifting any patent related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of specific said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would favour guarantee a functioning internal market, fostering ensuring the supply and ensuring the free movement of crisis-critical products subject to compulsory licencing in the internal market.</p> <p>SE (Comments):</p> <p>This recital should be changed in order not to unintentionally portray the existence of patents as a barrier to access to products, or to describe compulsory licensing as a way to “waive” IP rights in order to guarantee access to products. This would bring the language in line with EU positions in international foras when discussion IP rights and crisis situations.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement'). ³	
(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.	<p>IT (Drafting Suggestions):</p> <p>(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of crisis or an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.</p> <p>IT (Comments):</p> <p>clarify the definition of “state of crisis and/or emergency” (recitals 4, 5, 9, 16). If crisis and emergency refer to potentially different situations it is more correct to always mention both. Now sometimes they are quoted both and sometimes they are not. This is confusing.</p>

³ OJL 336, 23.12.1994, p. 214

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	<p>NL (Drafting Suggestions):</p> <p>(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when if needed to address addressing a cross-border crisis.</p> <p>NL (Comments):</p> <p>Will only prevent if needed, extreme rare cases, no examples so far where CL was needed to address a crisis.</p> <p>SE (Drafting Suggestions):</p> <p>(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.</p>

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	<p>SE (Comments):</p> <p>Language changed to describe CL as a possible route in very rare situations, and not a main recourse to be taken in any crisis. Sweden understands there to be very few (zero?) cases where a CL has been need to address a crisis.</p> <p>It could also be discussed if this recital is needed, given that this initiative is not to deal with member state fragmentation but the creation of a “new system” on EU level</p>
<p>(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the</p>	<p>FR (Drafting Suggestions):</p> <p>(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to</p>

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<p>current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.</p>	<p>address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.</p> <p>FR (Comments):</p> <p>The terms ‘in particular’ create legal uncertainty. Under such wording, a compulsory licence may be granted not only as a last resort when no voluntary agreements are unavailable but also in other circumstances (which are not identified).</p> <p>IE (Comments):</p> <p>It is unclear how a union wide compulsory licence would operate in conjunction with a pre-existing compulsory licence with a non-EU country or third party. Additional information on the proposed procedural aspects would be appreciated.</p> <p>IT (Drafting Suggestions):</p> <p>(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited</p>

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	<p>territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises <u>or emergency</u>, it is necessary to provide for an optimal compulsory licensing system for crisis <u>or emergency</u> management that takes the full advantage of the internal market and allows Member States to support one another in crises <u>or emergency</u>.</p> <p>IT (Comments): See comments on recital 4</p> <p>NL (Drafting Suggestions): (5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited</p>

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	<p>territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises</p> <p>NL (Comments):</p> <p>The phrase "in particular" introduces legal ambiguity. With such language, it could be argued that a compulsory license could be granted not solely as a final option when voluntary agreements are unattainable but also in unspecified circumstances.</p> <p>SE (Drafting Suggestions):</p> <p>(5) National compulsory licensing systems only operate within the national</p>

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	<p>territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on compulsory licensing an additional instrument when facing crises, in extraordinary situations where particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.</p> <p>SE (Comments):</p> <p>Language changed to reflect the principle of last resort, and to prevent legal ambiguity (such as the phrase “in particular”, which can be interpreted as CL being used even when there are possible voluntary solutions).</p>

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<p>(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').</p>	<p>FR (Drafting Suggestions): Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission, after opinion of the competent advisory body, should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').</p> <p>FR (Comments): It would be necessary to strengthen the role of the competent advisory body in the procedure for granting a Union compulsory licence (the binding/non binding nature of the opinion of the competent advisory body should be discussed).</p> <p>NL (Drafting Suggestions): (6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission, based on the opinion of the competent advisory body, should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').</p>

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	<p>NL (Comments): Clarify role of advisory body in the process.</p>
<p>(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].</p>	<p>EL (Comments): See comment in article 4</p> <p>FR (Comments): This recital does not list all the crises listed in the annex to the regulation and does not specify whether the list of mechanisms in the annex is exhaustive. We request a legal opinion or advice issued by the Commission Legal Service on the conformity of this regulation with article 31 c) of the TRIPS Agreement regarding compulsory licensing (CL) on semiconductors (CL on semi-conductor technology shall only be for public non-commercial use or to remedy to anti-competitive practices).</p> <p>NL (Drafting Suggestions): (7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent</p>

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	<p>mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372.</p> <p>Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].</p> <p>NL (Comments):</p> <p>Note: Crisis instruments listed in recital are not the same as instruments on annex. SMEI should be renamed.</p> <p>Comments:</p> <p>The Dutch government is not convinced about the usefulness and necessity of including all mentioned crisis instruments (more specifically Chips Act and gas supply security measures). In neither the proposal or the impact assessment we were able to find substantiation. As it stands now, NL is inclined not to include the following instruments:</p> <ul style="list-style-type: none"> • Chips Act • Gas supply <p>Scope of annex / choice of crisis-instruments needs to be discussed, taking into account inter alia:</p> <ul style="list-style-type: none"> • Substantiation for the usefulness and necessity of including for each crisis instrument mentioned, including clear examples.

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	<ul style="list-style-type: none"> • What is the relevance of patents in the various areas and which crisis relevant products are intended to be covered; • Global impact / example it sets on the global stage, e.g. for semiconductors. Incentive for other countries to implement similar measures? • Chips Act: We request a legal opinion or advice issued by the Commission Legal Service on the conformity of this regulation with article 31 c) of the TRIPS Agreement regarding compulsory licensing (CL) on semiconductors (CL on semi-conductor technology shall only be for public non-commercial use or to remedy to anti-competitive practices). • <u>Gas Supply</u>: It is not yet entirely clear to us which technologies would fall under the Regulation on the demand side (relevant for gas production) and the supply side (relevant for fuel switching). Previous justification remains somewhat superficial. Subject to further justification, we do not see the added value of the Regulation in a gas crisis. In a gas crisis, quick action is often required to increase supply or decrease demand. Both supply-increasing measures in production and demand-reducing measures such as fuel switching require a lot of time, and our expectation is therefore that they cannot be implemented in time during a gas crisis. <p>SE (Comments): Further discussions needed on what instruments to be included in the annex. The scopes and reasons for the mechanisms are quite different and reflect different types of crises (ie industry shortages, threat to life/health etc)</p>

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<p>(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation.</p>	<p>FR (Drafting Suggestions):</p> <p>(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation. To ensure legal certainty, this Regulation should also contain a definition of “crisis”.</p> <p>FR (Comments):</p> <p>Wording of the recital to be discussed among MS.</p> <p>SE (Drafting Suggestions):</p> <p>(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the relevant existing crisis mechanisms and a Union wide compulsory licencing scheme is</p>

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	<p>achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation.</p> <p>SE (Comments): Language changes to make room for the possibility of not all existing crisis mechanisms being included in the annex.</p>
<p>(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p>	<p>EL (Comments): See comment in article 2 regarding published patent applications.</p> <p>IT (Drafting Suggestions): (9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises <u>or emergency</u>, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p> <p>IT (Comments): See comments on recital 4</p>

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	<p>NL (Drafting Suggestions):</p> <p>(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p> <p>NL (Comments):</p> <p>Patent applications should not be included. (1) Article 31 TRIPS only refers to subject matter <i>of a patent</i>, not to applications and (2) scope of protection can change (significantly) in process from patent application to granted patent (3) need voor inclusion not substantiated.</p> <p>PT (Comments):</p> <p>The scope of the compulsory license is defined as including patents, published patent applications, supplementary protection certificates and utility models. In this recital the granted patents were included, as well as its published applications. However, regarding utility models - another way to protect inventions - only the granted utility models were included. This seems somehow inconsistent. Therefore, for the sake of harmonisation and coherence, we consider that the options regarding patents and utility models should be the same.</p> <p>SE (Drafting Suggestions):</p>

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	<p>(9) To ensure optimal efficiency of the Union compulsory licence as a tool in in addressing crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.</p> <p>SE (Comments):</p> <p>Language changed to lessen the impression of a CL being used as a sole way to access a product. Sweden is not convinced of the inclusion of published patent applications, due to possible non-compliance with TRIPS and to possible de-incentivization of innovation during crises.</p>
<p>(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.</p>	<p>ES (Drafting Suggestions):</p> <p><i>..whose patentability requirements are less stringent than for patents.</i></p> <p>ES (Comments):</p> <p>It is inaccurate to draft that Utility Models do not fulfil patentability requirements, as they are always required to meet the novelty and industrial applicability requirements, although regarding inventive step, in some jurisdictions, these may be lower requirements. It would be more appropriate to say that their patentability requirements are less stringent than those required for patents. The wording should approach to a more impartial definition, and not include definitions that implicitly</p>

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	<p>discredit this industrial property right. For example, from the WIPO Guide "Understanding Industrial Property": <i>"The requirements for acquiring a utility model are less stringent than for patents"</i></p> <p>PT (Comments):</p> <p>In Portugal, utility models have the same patentability requirements as patents, and there is an alternative way to assess the inventive step. Therefore, the recital should be worded in such a way as not to conflict with the various national laws.</p>
<p>(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.</p>	<p>FR (Comments):</p> <p>We request a legal opinion or advice from the Commission Legal Service on this provision. During the last IP working group, the Commission did not reply on the legal feasibility of the automatic transfer of the compulsory license from the patent to the SPC given that SPC is not an extension of the patent, but a different IP right (which would require a separate compulsory license).</p>
<p>(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only</p>	<p>EL (Comments):</p> <p>See comment in article 2 regarding published patent applications.</p>

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<p>inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.</p>	<p>FR (Comments):</p> <p>How does a compulsory license on a patent application work in practice when the patent granted during the license period has a different scope ? Who will be responsible for the technical analysis of patent claims to determine whether the product covered by a compulsory license is still within the scope of the granted patent?</p> <p>NL (Drafting Suggestions):</p> <p>(12) — The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state of the art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis relevant product still falls within the scope</p>

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	<p>of the patent claims.</p> <p>NL (Comments): Patent applications should not be included. See comment at recital 9.</p> <p>SE (Drafting Suggestions): Delete recital</p> <p>SE (Comments): Sweden is not convinced of the inclusion of published patent applications, due to possible non-compliance with TRIPS and to possible de-incentivization of innovation during crises. If patent applications are excluded from possible CL, possible issues relating to the eventual grant or non-grant of the patent are also avoided.</p>
(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9 ⁴ , 2009/24 ⁵ Directives 2001/29/EC ⁶ ,	FR (Drafting Suggestions):

⁴ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (*OJ L 77, 27.3.1996, p. 20*)

⁵ Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (*OJ L 111, 5.5.2009, p. 16*)

⁶ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (*OJ L 167, 22.6.2001, p. 10*).

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<p>2004/48/EC.⁷ and (EU) 2019/790.⁸ of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected.</p>	<p>It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9 , 2009/24 Directives 2001/29/EC , 2004/48/EC and (EU) 2019/790 of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. This Regulation is also without prejudice to the Directive (EU) 2016/943 of the European parliament and of the council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, and to Directive 2004/48/EC of the European parliament and of the council on the enforcement of intellectual property rights.</p> <p>FR (Comments):</p> <p>This regulation should preserve the protection of trade secrets as defined in Article 2 of the Directive (EU) 2016/943. Rules relating to IP rights enforcement should apply to this regulation (including when patent licensee does not comply with the terms of the compulsory license). For the sake of consistency with the proposed modification of Article 2, we suggest this drafting.</p> <p>NL (Drafting Suggestions):</p> <p>(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9⁹, 2009/24.¹⁰</p>

⁷ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

⁸ Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92).

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	<p>Directives 2001/29/EC.¹¹, 2004/48/EC.¹² and (EU) 2019/790.¹³ of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. This Regulation is also without prejudice to the Directive (EU) 2016/943 of the European parliament and of the council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, and to Directive 2004/48/EC of the European parliament and of the council on the enforcement of intellectual property rights.</p> <p>NL (Comments):</p> <p>This proposal addresses solely (theoretical) patent barriers. Trade secrets are not and should not be within its scope, and this needs to be clearly communicated. Even only ambiguity regarding this matter could already have negative effects.</p> <p>SE (Drafting Suggestions):</p> <p>(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9.¹⁴, 2009/24.¹⁵</p>

⁹ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (*OJ L 77, 27.3.1996, p. 20*)

¹⁰ Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (*OJ L 111, 5.5.2009, p. 16*)

¹¹ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (*OJ L 167, 22.6.2001, p. 10*).

¹² Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (*OJ L 157, 30.4.2004, p. 45*).

¹³ Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (*OJ L 130, 17.5.2019, p. 92*).

¹⁴ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (*OJ L 77, 27.3.1996, p. 20*)

¹⁵ Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (*OJ L 111, 5.5.2009, p. 16*)

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	<p>Directives 2001/29/EC.¹⁶, 2004/48/EC.¹⁷ and (EU) 2019/790.¹⁸ of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. Forced disclosure of trade secrets cannot be inflicted under this regulation.</p> <p>SE (Comments): Should be made clear already here that trade secrets are not part of the scope, in order to sort out any unclarity.</p>
<p>(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health</p>	<p>ES (Drafting Suggestions): Delete paragraph crossed out</p> <p>ES (Comments): This Regulation proposal for a compulsory licensing cannot be linked to the Pharmaceutical Directive that is still under discussion, has not been adopted and the final wording is unknown. The suspension of data exclusivity is not a trivial issue. Many pharmaceutical companies are not based in the EU and clinical data protection legislation may be</p>

¹⁶ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

¹⁷ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

¹⁸ Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92).

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<p>emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.</p>	<p>subject to international laws and face a legal conflict between jurisdictions.</p> <p>FR (Comments): Intellectual Property Working Group should be kept informed of developments in the ongoing discussions relating to revision of pharmaceutical legislation.</p> <p>IE (Comments): Under Art. 80.4 within the proposed Pharmaceutical Strategy it is unclear how consequences for products marketed under a union compulsory license will be realised. A suspension of Regulatory Data Protection will potentially facilitate access to and commercial use of the data to obtain marketing authorisation in the EU or other jurisdictions. This could potentially have significant economic consequences, particularly to SMEs and consideration as to how the compensatory mechanism may account for this should be clarified. As the proposed suspension of RDP under the Pharma Strategy does not result in an equal extension of the original duration of the protection rights, clarity would be appreciated as to what if any mechanism for adequate compensation will be considered for the defined period in question.</p> <p>NL (Comments): The recital should be updated depending on the outcome of the negotiations on the final wording of the pharmaceutical legislation revision. The IP Working Party should continue to be kept informed about any progress in the relevant aspects of the pharmaceutical legislation process.</p>

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	SE (Comments): Only possible to included when the results of the discussions on the pharma legislation revision are known.
(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.	FR (Drafting Suggestions): (15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a crisis and ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) and crisis mode or an emergency mode listed in the Annex to this Regulation. FR (Comments): See comments regarding Article 3. IE (Comments): The definition of a ‘crisis-relevant product’ – ie that it ‘should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies’ provided here is unclear.

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	<p>NL (Drafting Suggestions):</p> <p>(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a crisis and ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.</p> <p>NL (Comments):</p> <p>The definitions and wording used in the proposal seem to lack sufficient clarity on several points. This concerns, for instance, the wording of the different crises covered and the crisis-related critical products. Consistency has to be verified for all crisis-instruments mentioned in the Annex. See also comments below with regard to definitions.</p> <p>SE (Drafting Suggestions):</p> <p>(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to adhere cover products related to different kinds of crises or emergencies.</p> <p>SE (Comments):</p> <p>Language to be updated after renaming of SMEI.</p>

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	Language changed to lessen the focus on access to specific products
<p>(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.</p>	<p>FR (Drafting Suggestions):</p> <p>A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally, in last resort, and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence strictly in line with the duration of the crisis and the purpose for which the compulsory licence was granted. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to efficiently exploit the protected invention and consequently to manufacture the crisis relevant product in sufficient quantity and quality and within appropriate timeframes to fulfil such objective and to pay a reasonable remuneration to the rights-holder. The granting of a compulsory licence is necessarily preceded by a stage enabling the right holder and the possible licensee to negotiate in order to reach a voluntary agreement, which should remain the preferred option.</p> <p>FR (Comments):</p> <p>It is necessary to recall the principle under which a compulsory licence is a legal</p>

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	<p>tool intended to be applied only in exceptional circumstances, in last resort. Scope and duration of compulsory licence should be aligned with scope and duration of the crisis or urgency mode.</p> <p>IT (Drafting Suggestions):</p> <p>(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis or emergency mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person entity able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.</p> <p>IT (Comments):</p> <p>See comments on recital 4 instead of referring to "qualified person capable of manufacturing the product" it would be better to refer to "qualified entity" which is more neutral and can also include e.g. companies</p>

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	<p>NL (Drafting Suggestions):</p> <p>(16) A Union compulsory licence authorises the use of a protected invention the subject matter of a patent without the consent of the rights-holder. Therefore, it must only be granted as a last resort in exceptional circumstances exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the scope and duration of the licence shall be limited to the purpose for which it was authorised and shall in any case not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.</p> <p>NL (Comments):</p> <p>Alternative wording suggested to better align with TRIPS. Important to better define duration / termination.</p> <p>PL (Drafting Suggestions):</p> <p>Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder when other measures that have been</p>

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	<p>taken failed.</p> <p>PL (Comments):</p> <p>It seems important to highlight the need for a precise definition of the conditions under which it is necessary to resort to a Union compulsory licence.</p> <p>SE (Drafting Suggestions):</p> <p>(16) A Union compulsory licence authorises the use of the subject matter of a patent a protected invention without the consent of the rights-holder. Therefore, it must only be granted as a last resort exceptionally and under conditions that observes take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall be limited in line with the purpose for which it was granted and never not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay adequate a reasonable remuneration to the rights-holder.</p> <p>SE (Comments):</p> <p>Language changed to bring in line with TRIPS, to recall the principle of last resort</p>

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	and to more clearly state the position of the rights-holder
<p>(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.</p>	
<p>(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on</p>	<p>NL (Drafting Suggestions): (18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body</p>

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<p>whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the ‘ad hoc advisory body’).</p>	<p>has the right composition, independence expertise, including on patents, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up, but may lack sufficient knowledge of industrial property. Therefore, participation in the advisory body by representatives of the authorities of the Member States which are competent for the granting of compulsory licences under national law will always be ensured. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the ‘ad hoc advisory body’) where in any case participation by representatives of the authorities of the Member States which are competent for the granting of compulsory licences under national law will be ensured.</p>

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	<p>NL (Comments):</p> <p>Exact composition of advisory bodies to be discussed. In any case it should be ensured that the advisory body is independent and consists of / includes sufficient number of experts in the field of industrial property rights / compulsory licensing.</p> <p>SE (Drafting Suggestions):</p> <p>(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, including on patents and licensing, and procedures to advise support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up but may lack relevant knowledge of intellectual property rights and licensing. When compulsory licensing is being discussed in the context of such crisis instrument, the inclusion of such expertise must be ensured so that the Commission can relying on the advisory body set-up for the specific instrument</p>

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	<p>allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the ‘ad hoc advisory body’).</p> <p>SE (Comments):</p> <p>Changes to ensure relevant expertise and also independence of the advisory body. Language need to be changes to include the renaming of SMEI</p>
<p>(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of one representative of each Member State in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition, the advisory body should have the</p>	<p>NL (Comments):</p> <p>Necessary to further clarify / strengthen the role of the competent advisory body in the procedure for granting a compulsory licence. Also TBD the nature of the opinion (binding or non-binding).</p> <p>SE (Comments):</p> <p>The role of the advisory body in the system to grant a CL needs to be clarified. It should be discussed if the Commission should be unable to grant a CL if the opinion from the advisory body is negative.</p>

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function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.	
<p>(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.</p>	<p>FR (Comments): It would be necessary to strengthen the role of the competent advisory body in the procedure for granting a Union compulsory licence (the binding/non binding nature of the opinion of the competent advisory body should be discussed).</p> <p>IT (Drafting Suggestions): (20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comment <u>after being provided with the case file and analyses submitted to or carried out by the advisory body, and with all other relevant information necessary for them to assess the impact of a proposed Union compulsory license on their intellectual property rights.</u> These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level <i>within the internal market.</i></p>

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	<p>IT (Comments):</p> <p>In order to safeguard their rights, including under Article 17 (right to property), Article 41 (right of access to the file and right to be heard) and Article 52 of the Charter (proportionality), rights-holders should be provided with access to the file, and to all relevant information before they provide comments to the proposed Union compulsory licence.</p> <p>NL (Comments):</p> <p>Necessary to further clarify the role of the competent advisory body in the procedure. Also TBD the nature of the opinion (binding or non-binding).</p> <p>SE (Drafting Suggestions):</p> <p>(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation, assess if the possibilities of voluntary solutions are restricted, and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.</p>

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	SE (Comments): Language added to recall the principle of last resort
<p>(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.</p>	NL (Drafting Suggestions): <p>(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.</p> NL (Comments): Right holders should always be informed individually. SE (Drafting Suggestions): <p>(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are</p>

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	<p>ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.</p> <p>SE (Comments):</p> <p>Clear focus and principal rule should be that all rights holders are identified and actively approached</p>
<p>(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the</p>	<p>IT (Comments):</p> <p>At present, only this recital is indicating that the system proposed by the regulation will only be used when voluntary cooperation between MS has failed. This concept is not reproduced in any article. Therefore, it would be useful to clarify also in the articles that this is an instrument of last instance, an exceptional one.</p> <p>NL (Drafting Suggestions):</p> <p>(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of</p>

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<p>Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.</p>	<p>the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.</p> <p>NL (Comments):</p> <p>From the outset compulsory licenses should only be considered if any relevant IP right is identified and the right-holder has had the right to be heard + provided reasonable opportunity to negotiate a voluntary license with potential licensees. Moreover, comments from rightsholders should in any case always be forwarded, including where the Commission considers documents or submissions to be irrelevant.</p> <p>PT (Comments):</p> <p>“(…) the Commission should notify the rights-holder as soon as reasonably practicable.” This is not clear, a time limit should be established.</p>

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	<p>SE (Drafting Suggestions):</p> <p>(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have a clear the possibility to propose a voluntary agreement, taking into account should the circumstances of the Union crisis or emergency and including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.</p> <p>SE (Comments):</p> <p>Changes to strengthen the focus on voluntary solutions even during the discussions on a CL</p>

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<p>(23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.</p>	<p>IT (Drafting Suggestions):</p> <p>(23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism and the identification of crisis-relevant products. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.</p> <p>IT (Comments):</p> <p>If the prerequisite for CL is the activation of the emergency/crisis mechanism and the absence of voluntary agreements, at the commencement of CL proceedings Commission should report in any case the identification of the crisis-relevant products needed in relation to which the evaluations of appropriateness for granting or not a CL will be carried out so that the rights holders can actively participate in the proceedings, reporting their rights during the proceeding. See also recital (25)</p> <p>NL (Drafting Suggestions):</p> <p>The initiation of the compulsory licensing procedure first requires the identification of the intellectual property rights concerned, the rights-holders concerned, as well as potential licensees.</p>

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	<p>should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights holders concerned as well as potential licensees.</p> <p>NL (Comments): Compulsory license should only be considered if any relevant IP right (and right-holder) is identified.</p>
<p>(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the</p>	<p>EE (Drafting Suggestions): Article 2(1)(a) of the regulation refers to not <i>unpublished</i> but only <i>published</i> patent applications. In view of this and for the sake of clarity, could the same reference to not simply <i>applications</i> but <i>published applications</i> also be included in article 8(1)(a) and likewise in recital 24 of the regulation?</p> <p>IT (Drafting Suggestions): (24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the</p>

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<p>Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p>	<p>identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p> <p>NL (Drafting Suggestions):</p> <p>(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights holders would significantly delay the granting of the Union compulsory licence, the</p>

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	<p>Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder before granting the compulsory licence as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p> <p>NL (Comments): See remarks above.</p> <p>SE (Drafting Suggestions):</p> <p>(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant</p>

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	<p>intellectual property rights and their rights-holder before granting a compulsory licensor. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.</p> <p>SE (Comments):</p> <p>Sweden is not convinced about the idea of granting CL without the identification of rights holders. Focus of a CL should be the patent and not the product to be copied.</p>
<p>(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should exceptionally be entitled to grant the Union compulsory licence by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.</p>	<p>NL (Drafting Suggestions):</p> <p>Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should not grant the Union compulsory licence.</p> <p>NL (Comments):</p> <p>Delete or replace with amendment. Compulsory license should only be considered if any relevant IP right + right holder is identified.</p> <p>PT (Comments):</p> <p>In such cases, where the rights-holder is identified after the grant of the license, may he/she still file observations? If so, can the license be declared annulled due to the holders' observations? This situation should be provided for.</p>

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	SE (Drafting Suggestions): delete SE (Comments): No CL should be possible when IP rights and rights holders have not been identified
<p>(26) The Union compulsory licence should also include information allowing the identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.</p>	

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<p>(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.</p>	<p>IT (Drafting Suggestions):</p> <p>In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006.</p> <p>IT (Comments):</p> <p>We do not think that the adoption of the 4% threshold as a general principle is sufficiently justified in this framework.</p> <p>The 4 percent limit, provided for in paragraph 9 of Article 10 of Regulation (EC) No. 816/2006,</p> <ul style="list-style-type: none"> - applies only in cases of exports to non-EU countries of the <u>total price paid</u> by or on behalf of the importing country and <u>only in certain situations</u>, it is not the general rule to be applied; <u>in all other cases</u>, no limits applies and the remuneration shall be determined by considering the <u>economic value</u> of the use authorized to the importing country or countries concerned under the license as well as any humanitarian or extra-commercial circumstances related to the granting of the license." <p>We would like to know so far how many times the 4% criterion has been applied under the EU Reg. 816/2006 and if any case in this framework was submitted to judicial review.</p> <p>We prefer a case by case evaluation of the value of the patent concerned, in line with the TRIPs.</p>

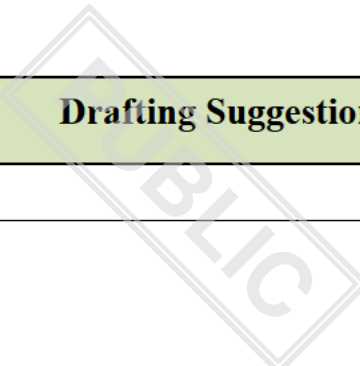
From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>NL (Drafting Suggestions):</p> <p>(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights holder should refund the remuneration it received under the compulsory licence.</p> <p>NL (Comments):</p> <p>See remarks above with regard to patent applications. 4% cap should be removed. Not TRIPS compliant. The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the</p>

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	<p>economic value of the authorisation.</p> <p>SE (Drafting Suggestions):</p> <p>(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights holder should refund the remuneration it received under the compulsory licence.</p> <p>SE (Comments):</p> <p>See previous remarks about patent applications. Any caps on remuneration should be removed, as decisions should be taken based on situation in every relevant case.</p>

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<p>(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council.¹⁹ In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder.</p>	
<p>(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.</p>	<p>NL (Comments): Suggested to clarify options for export under Regulation 816/2006 in this recital.</p>

¹⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

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<p>(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447.²⁰ When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export.</p>	<p>IT (Drafting Suggestions): Where the Commission concludes that a product does not comply with the export prohibition, customs athorities should refuse its export.</p> <p>IT (Comments): Logically speaking, it seems that if an export prohibition occurs, then customs athorities should refuse its export.</p>
<p>(31) The legal validity of the implementing act granting the</p>	

²⁰ Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

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<p>Union compulsory license, or any subsequent implementing act, should be subject to judicial review.</p>	<p>AT (Comments):</p> <p>This is of paramount importance; however, it does not become evident from the text of the proposed regulation how exactly the judicial review would be guaranteed. This needs to be clearer.</p> <p>EL (Comments):</p> <p>See comment in article 21.</p> <p>IT (Drafting Suggestions):</p> <p><i>(31) The present Regulation provides the legal basis for a Union compulsory licence which permits potentially serious interferences with intellectual property rights within the meaning of Article 17(2) of the Charter of Fundamental Rights of the European Union. Therefore, in accordance with Article 52 of the Charter and the caselaw of the Court of Justice, the present Regulation must itself define the scope of the limitations on the exercise of those fundamental rights, and must also provide for minimum safeguards so that rightsholders have sufficient guarantees to protect their rights effectively against the risk of interferences that are disproportionate or otherwise non-compliant with Union law, and to ensure that the essence of their rights is protected.</i></p> <p><i>Therefore, as a minimum guarantee, the legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.</i></p>

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	<p>NL (Drafting Suggestions): Include article on judicial review by a distinct higher authority</p> <p>NL (Comments): Judicial review is of vital importance. Nevertheless, the proposed regulation lacks clarity on how exactly this review would be ensured. It is imperative to include a new article explicitly addressing this aspect. Also to ensure TRIPS compliance (Art. 31(i)).</p> <p>SE (Comments): Could be clarified how this review is to be performed</p>
<p>(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made</p>	<p>IT (Comments): It is unclear what kind of ‘complementary measures’ should be taken by the Commission and whether this would extend to the mandatory disclosure of confidential information, know-how or other trade secrets. In this case, doubts remain on compatibility of this measure with TRIPS Art. 31 and 39:</p> <ul style="list-style-type: none"> • Art 31 Only refers to “patents”, • Art 39 In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information.

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<p>available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.</p>	<p>Moreover, any additional measure should foresee a compensation for the patent owner. No information is provided in this regard in the present proposal.</p> <p>NL (Drafting Suggestions):</p> <p>(32) — The relation between the rights holder and the licensee should be governed by the principle of good faith. The rights holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good faith cooperation between the rights holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.</p> <p>NL (Comments):</p> <p>No need for additional measures. Moreover, concept of good faith and additional measures are unclear. While not expressly mentioned, current proposal might even lead to impression that it includes forced disclosure of trade secrets. This should be expressly excluded. Even the suggestion of inclusion of trade secrets in scope of this proposal might be harmful.</p>

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	<p>Several reasons.</p> <p>(1) TRIPS: Articles 31 and 39 of TRIPS do not allow the compulsory licensing or sharing of trade secrets.</p> <p>(2) The aim of compulsory licensing is solely to eliminate patent-related obstacles (if any), without extending beyond that. Any additional barriers (if any) should be addressed within their respective domains rather than being included in a proposal focused solely on patents.</p> <p>(3) Otherwise, it could also create a peculiar scenario where a company solely holding trade secrets would be immune to compulsory disclosure, whereas if it also possessed patents, it could be compelled to disclose. This might discourage companies from pursuing patents, thus diminishing incentives and the societal benefits of sharing inventions publicly.</p> <p>(4) This stance appears to diverge from the international position of the EU, particularly in light of ongoing and forthcoming negotiations within organizations such as the WHO and WTO. This discrepancy may and will lead to misperceptions regarding alignment with international standards.</p> <p>(5) Lastly, more general: entire concept of “additional measures” is vague and will lead to legal uncertainty. Same applies to ‘adequate safeguards’.</p> <p>PT (Comments):</p> <p>The expression “good faith” is not sufficient clear per se, and it can lead to different interpretations.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>SE (Comments):</p> <p>The ambiguity of this article and principle risks creating further obligations and burdens, potentially risking forced disclosure of trade secrets. If any provision is needed, it should be based on encouragement and voluntary provisions. This would also put this recital in line with the EU position in other international fora, such as within the context of the pandemic treaty.</p>
<p>(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.</p>	<p>SE (Drafting Suggestions):</p> <p>(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where the initial list is inconclusive or incorrect this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Comments): Changes in line with prerequisite that rights holders are identified before granting of CL
(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.	NL (Drafting Suggestions): (34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission may to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive. NL (Comments): The justification for imposing penalties is not substantiated. See more detailed comments below at article 15 – 21. SE (Drafting Suggestions): (34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission may to take action. In addition to the possibility to terminate the Union compulsory licence..

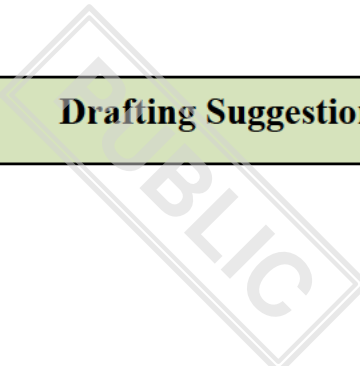
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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>SE (Comments):</p> <p>Not convinced on need and reasons for fines and penalties. Inclusion of fines would strengthen the perspective that regulation is not about access to patents but forced production of certain products.</p>
<p>(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and <i>ne bis in idem</i>. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.</p>	<p>NL (Drafting Suggestions):</p> <p>35) — Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and <i>ne bis in idem</i>. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.</p> <p>NL (Comments):</p> <p>The justification for imposing penalties is not substantiated See more detailed comments below at article 15 – 21.</p>

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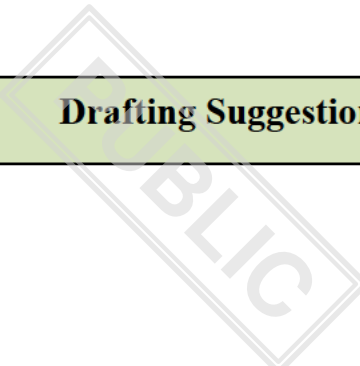
Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): Delete SE (Comments): See comment above
(36) When a national compulsory licence has been granted for the purpose of addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.	SE (Comments): As the application of the regulation is relevant only in certain situations (to quote the Commission, “hopefully never”), it can be discussed if this requirement is necessary at all times or specifically when a Union crisis has been declared under relevant mechanisms. The task of investigating the existence if national CL should normally fall to the advisory body.
(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already	

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<p>regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council²¹. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory</p>	

²¹ Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

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<p>licence under, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.</p>	
<p>(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²². The advisory</p>	<p>AT (Drafting Suggestions):</p> <p>(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²³. The <u>advisory examination</u></p>

²² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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<p>procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.</p>	<p>procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory examination procedure is justified given that <u>the potential infringement on the rights of patent holders are severe and the final decision should be made by both the European Commission and the Council.</u> those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should also be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.</p> <p>NL (Drafting Suggestions):</p> <p>(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.²⁴. The advisory examination</p>

²³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

²⁴ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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	<p>procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.</p> <p>NL (Comments):</p> <p>Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States.</p> <p>SE (Comments):</p> <p>Should be further discussed if not the examination procedure would be better suited in order to ensure member state participation as well as the inclusion of relevant IP expertise.</p>
(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.	<p>AT (Drafting Suggestions):</p> <p>(39) The Commission should adopt immediately applicable implementing acts <u>by use of the advisory procedure</u>, where, in duly justified cases relating to the</p>

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	<p>granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.</p> <p>AT (Comments):</p> <p>In this regard, the question arises what exactly imperative ground of urgency are. In a crisis mode, the situation is always rather urgent. We would like to ask the Commission for further explanations on this.</p>
<p>(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.</p>	<p>FR (Drafting Suggestions):</p> <p>(40) Union compulsory licensing for crisis management is by definition a last resort tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.</p> <p>FR (Comments):</p> <p>See our comments concerning Article 1.</p> <p>NL (Drafting Suggestions):</p> <p>(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances and as a last resort. The evaluation should therefore</p>

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	be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.
(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.	IT (Comments): There is no indication in the articles that follow that the implementation of the Regulation should be postponed. Article 26 does not provide for a postponement of the entry into force of the regulation. We would be in favour of a longer time for the application of the regulation, given its far reaching implications in many different fields.
HAVE ADOPTED THIS REGULATION:	EL (Comments): Scrutiny reservation. Evidence of crises in which access to crisis- relevant products was not plausible, should be provided to justify a limitation to the exercise of a fundamental right as provided in article 17(2) of the EU Charter of fundamental rights for proportionality purposes.
Article 1	PL (Comments): It is necessary to define the concept of a ‘crisis’ more precisely. The specific nature

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	of the Regulation requires a detailed definition of what situations may trigger the initiation of proceedings for the grant of a Union compulsory licence.
Subject matter	
<p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.</p>	<p>DE (Drafting Suggestions):</p> <p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products during an activated or declared crisis or emergency mode pursuant to one of the Union Acts listed in the Annex to this Regulation. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States affected by the underlying crisis or emergency in the context of a Union crisis or emergency mechanism. The granting of a Union compulsory licence serves as a measure of last resort and shall only be considered if no prior voluntary agreement could be reached between the rights-holder and a potential licensee.</p> <p>DE (Comments):</p> <p>Compulsory licences constitute a limitation of the fundamental right to property and must therefore always be kept to an absolute minimum. This must also be made clear with regard to the temporal and territorial scope of application. In particular, it needs to be clarified, that the granting and duration of a Union compulsory licence is inextricably linked to the activation or declaration of a crisis or emergency mode on</p>

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	<p>the basis of one of the EU-crisis instruments listed in the Annex. The granting of an EU-wide compulsory licence can only ever be considered as a last resort and under clearly defined conditions. Against this background, it must be clarified that serious efforts must first be made to reach a voluntary licensing agreement</p> <p>DK (Drafting Suggestions):</p> <p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products in crisis situations. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence for products protected by of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism situation. A compulsory licence can be triggered through one of the crisis mechanisms listed in the annex of this Regulation. The issuance of a Union compulsory licence should always be a last resort if all other options have been exhausted and no voluntary agreements can be reached between a rights holder and a potential licensee.</p> <p>DK (Comments):</p> <p>Denmark is in favour of explicitly stating in article 1 that voluntary agreements should <u>always</u> be sought in a first instance. Compulsory licensing should <u>always</u> be the last resort. Reference should also be made to the crisis mechanism that can trigger a compulsory licence.</p>

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	<p>ES (Comments):</p> <p>The first article raises several doubts that have to do with the precision and scope of the terms used in it.</p> <p>First, it would be necessary to establish a definition of “crisis” and to set up a prior evaluation aimed at determining whether the situation fits into one of the situations contained in the Annex or in the body of the Regulation. We understand that the proposal refers to the definitions contained in other instruments, that’s why it should make an express reference to the definitions of those instruments to give more clarity.</p> <p>It should be clarified whether the crisis that triggers this Regulation needs to occur throughout the Union, in a substantive part, or if it only takes place in one State, as well as the temporal scope and effects of the licenses in case the crisis subsides in a tiered manner in different countries.</p> <p>FI (Comments):</p> <p>FI is in favor of voluntary agreements’ priority to be explicitly mentioned in the text of the Regulation.</p> <p>FR (Drafting Suggestions):</p> <p>1. This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of industrial property rights that are necessary for the supply of crisis-relevant</p>

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	<p>products to the Member States in the context of a Union crisis or emergency mechanism.</p> <p>2. The provisions of this Regulation shall be interpreted in the light of the following principle : a compulsory licence at Union level is a legal tool intended to be applied only in exceptional circumstances and in the public interest, as last resort mechanism, where access to patented crisis-relevant products cannot be achieved through voluntary cooperation.</p> <p>FR (Comments):</p> <p>It is necessary to recall the principle under which a compulsory licence is a legal tool intended to be applied only in exceptional circumstances, in last resort, when no voluntary agreement could be entered into with the holder of the industrial property right, in the public interest.</p> <p>The fact that a compulsory licence must only be granted exceptionally (and under conditions that take into account the interests of the rights-holder), in last resort, is an essential principle.</p> <p>Accordingly, it should not only be mentioned in the recitals of the proposal (Under Recital 16 : “<i>A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. (...)</i>”).</p> <p>Under Recital 40 : “<i>Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. (...)</i>”</p> <p>This principle should be expressly provided for in the articles of the proposal. Such principle could be mentioned in Article 1 and/or in Article 4.</p> <p>It is also important to refer to the fact that the compulsory licence is generally used,</p>

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	<p>in addition to emergency and crisis situations, for purposes of public interest. See recitals 4 and 5 of the proposal :</p> <p>(4) “<i>All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. (...)</i>”</p> <p>(5) “<i>National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. (...)</i>”</p> <p>The rights referred to in Article 2 are industrial property rights. Consequently, it is necessary to replace the term “intellectual” with the term “industrial”.</p> <p>IT (Drafting Suggestions):</p> <p>This Regulation has the objective to ensure that in crisis <i>a temporary and non-exclusive Union compulsory license may be granted to protect the public interest in the context of cross-border crisis or emergency situations</i> in the Union has access to crisis relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. the Commission may grant a Union compulsory license.</p> <p>IT (Comments):</p> <p>Emergency should be included as it is part of the mechanism in annex.</p>

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	<p>NL (Drafting Suggestions):</p> <p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products during an activated or declared crisis or emergency mode pursuant to one of the Union Acts listed in the Annex to this Regulation. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. The granting of a Union compulsory licence serves as a measure of last resort and shall only be considered if no prior voluntary agreement could be reached between the rights-holder and a potential licensee.</p> <p>NL (Comments):</p> <p>Wording should be included to clarify that this new instrument would only be used during major crisis affecting the EU, as a <u>measure of last resort</u>. Support earlier drafting suggestions Germany.</p> <p>SE (Drafting Suggestions):</p> <p>This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products needed to address declared crises or emergencies under the Union Acts listed in the Annex to this regulation. To this end, this Regulation lays down rules on the procedure and conditions for the issuing granting of a Union compulsory licence of intellectual property rights, as a last resort when no voluntary solution can be agreed. that are necessary for the supply of crisis-</p>

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	<p>relevant products to the Member States in the context of a Union crisis or emergency mechanism.</p> <p>SE (Comments):</p> <p>In general, it needs to be made even clearer in the regulation that a compulsory license always is a measure of last resort when voluntary agreements are refused. Possibly, language should be changed from “granting” to “issuing” to reflect that the act is irrelevant of any application from third party but an independent act on the initiative of the Commission</p>
Article 2	<p>PL (Comments):</p> <p>The proposal envisages the possibility of granting a Union compulsory licence across various IPR, such as patents (including published patent applications), utility models, and SPCs. It may be prudent to consider expanding this scope to include industrial designs, given that a “crisis-relevant product” as defined in the Proposal could also be protected as an industrial design.</p> <p>Moreover, as the proposal includes patent applications, in the category mentioned above, it would be sensible to consider analogous approach in the case of utility models.</p>
Scope	

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	<p>IE (Comments):</p> <p>IE notes that there is no explicit exclusion of Trade Secrets/Confidential information within the scope of the proposed texts, and would suggest text to be included to that effect.</p>
<p>1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:</p>	<p>ES (Comments):</p> <p>Article 2 raises doubts regarding the possibility of subjecting patent applications to a compulsory license. Given that the claims presented in the application can be modified during the procedure, it would not be pertinent for the compulsory license to automatically extend to the granted patent, whose object could have been altered. Although a patent application has effects (provisional protection), this is conditional on the patent being finally granted. Furthermore, the scope of protection will be determined retroactively depending on how it was finally granted.</p> <p>FR (Drafting Suggestions):</p> <p>1. This Regulation establishes Union compulsory licensing of the following industrial property rights in force in one or more Member States:</p> <p>FR (Comments):</p> <p>The rights referred to in Article 2 are industrial property rights. Consequently, it is necessary to replace the term “intellectual” with the term “industrial”.</p>

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(a) patents, including published patent applications;	<p>DE (Drafting Suggestions): (a) patents, including published patent applications;</p> <p>DE (Comments): Please delete – here and elsewhere in the text – references to published patent applications. The German Federal Government rejects EU-wide compulsory licences for published patent applications. There is no evidence-based justification for such a broad scope of application.</p> <p>DK (Drafting Suggestions): (a) patents, including published patent applications;</p> <p>DK (Comments): Denmark does not see the need to include patent applications.</p> <p>EL (Comments): Scrutiny reservation as to the compatibility of compulsory licensing of published patent applications with Art. 31 of the TRIPS Agreement, which refers only to patents.</p>

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	<p>FI (Comments): FI has some reservations on the inclusion of patent applications under the scope of the Regulation</p> <p>FR (Comments): See our comments regarding Recital 12 relating to patent applications.</p> <p>NL (Drafting Suggestions): (a) patents, including published patent applications;</p> <p>NL (Comments): Patent applications should not be included. See comments at recitals above.</p> <p>PT (Comments): The scope of the compulsory license is defined in this Article as including patents, published patent applications, supplementary protection certificates and utility models. In this Article, the granted patents were included, as well as its published applications. However, regarding utility models, another way to protect inventions, only the granted utility models were included. This seems somehow inconsistent. Therefore, for the sake of harmonisation and coherence, we consider that the options regarding patents and utility models should be the same.</p>

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	<p>SE (Drafting Suggestions): (a) patents, including published patent applications;</p> <p>SE (Comments): Inclusion of patent applications needs to be discussed from a TRIPS perspective.</p> <p>SI (Comments): Slovenia has some reservations about establishing a Union compulsory licensing of the patent applications. We believe this is not in accordance with TRIPS Agreement.</p>
(b) utility models; or	<p>ES (Comments): Although we do not consider that patent applications should be subject to compulsory licenses, we do not understand why, in that case, the utility model applications are not mentioned.</p>
(c) supplementary protection certificates;	
2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and	

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<p>related rights, including Directive 2001/29, Directive 2009/24 and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases.</p>	<p>DE (Drafting Suggestions):</p> <p>2. This Regulation is without prejudice to the rules laid down by other Union and national legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24, and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases and the protection of trade secrets as defined in Directive (EU) 2016/943.</p> <p>DE (Comments):</p> <p>Please clarify that rights-holders are not obliged to disclose trade secrets under this regulation. In light of the non-specific power of the European Commission to adopt “<i>complementary measures</i>” (Article 8(1)(h) and Article 14(2) of the proposal) as well as the obligation of the rights-holder and licensee to cooperate “<i>in good faith</i>” (Article 13 of the proposal) such clarification seems necessary, as the disclosure of trade secrets is irreversible.</p> <p>DK (Drafting Suggestions):</p> <p>2. This Regulation is without prejudice to the rules laid down by other Union and national legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases and the protection of trade secrets as defined in the Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.</p>

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	<p>DK (Comments):</p> <p>Denmark considers the protection of trade secrets to be essential. Trade secrets may have value way beyond the actual patent, and once they are handed over their value is zero. Therefore, trade secrets <u>must</u> always be protected and explicitly stated in this article.</p> <p>This could for instance be done by including references to Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.</p> <p>FI (Comments):</p> <p>It should be ensured that trade secrets remain outside of the scope of application of the CL regulation.</p> <p>FR (Drafting Suggestions):</p> <p><i>2a. This Regulation is also without prejudice to the Directive (EU) 2016/943 of the European Parliament and of the Council and national legal acts providing for the protection of trade secrets and to the Directive 2004/48/EC of the European Parliament and of the Council on the legal enforcement of intellectual property rights.</i></p> <p>FR (Comments):</p> <p>This regulation should preserve the protection of trade secrets as defined in Article 2 of the Directive (EU) 2016/943.</p>

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	<p>Rules relating to IP rights enforcement should apply to this Regulation (including when patent licensee does not comply with the terms of the compulsory license).</p> <p>NL (Drafting Suggestions):</p> <p>2. This Regulation is without prejudice to the rules laid down by other Union and national legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases and the protection of trade secrets as defined in Directive (EU) 2016/943.</p> <p>NL (Comments):</p> <p>What stands out in the article 2 on scope is that trade secrets are not mentioned. Directive 2001/29, 2009/24 and 96/9 are all mentioned, but relation to Trade Secrets Directive (EU) 2016/943 is unclear. This proposal deals with (theoretical) refusal of patent licenses only. Trade secrets are not and should not be in scope. It is essential to include wording clarifying that this proposed regulation does not affect the rules concerning the protection of undisclosed know-how and business information outlined in Directive 2016/943.</p> <p>SE (Drafting Suggestions):</p> <p>2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the <i>sui generis</i> rights granted by Directive 96/9/EC on the legal protection of databases and to protection of trade secrets.</p>

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	<p>SE (Comments): Should be made clear to exclude trade secrets</p> <p>SI (Comments): This regulation should protect the trade secrets and that should be clearly stated in the text.</p>
Article 3	<p>DE (Comments): As stated above, Germany explicitly reserves the right to make further comments – also on Art. 3. In particular, the Commission has not provided a convincing explanation on the definition of “crisis-relevant products” so far. Nature and scope remain unclear. Against this background, we welcome the Commission’s intention to provide concrete examples during the next session of the WG.</p> <p>DK (Comments): Denmark finds that there is a need to define crisis or emergency situations with reference to the instruments in the Annex.</p>
Definitions	

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	<p>NL (Comments):</p> <p>The definitions and wording used in the proposal seem to lack sufficient clarity on several points. This concerns, for instance, the wording of the different crises covered and the crisis-related critical products. Consistency has to be verified for all crisis-instruments mentioned in the Annex.</p>
<p>For the purposes of this Regulation, the following definitions shall apply:</p>	<p>DE (Drafting Suggestions):</p> <p>For the purposes of this Regulation, the following definitions shall apply: (aa) "crisis or emergency" refers to a crisis or emergency mode which has been activated or declared pursuant to one of the Union Acts listed under Article 4;</p> <p>DE (Comments):</p> <p>The meaning of the term “crisis or emergency” should be clarified.</p> <p>ES (Comments):</p> <p>In general, the definitions are very broad. In particular, as in the case of Article 1, the imprecision of the concept of “crisis-relevant products” combined with the vagueness of the concept “crisis” does not promote legal certainty, since it extends the scope to practically anything. In relation to products, throughout the text it is mentioned “critical product” and “crisis-relevant product”, although in Art. 3 there’s a definition, it is a very</p>

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	<p>subjective concept in which different interests, can come into play. Each country may consider different products as indispensable. These differences should be assessed by the advisory body formed by experts in different fields.</p> <p>NL (Drafting Suggestions):</p> <p>(-a) ‘crisis mode or emergency mode’ means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein;</p> <p>NL (Comments):</p> <p>Definition for ‘crisis mode or emergency mode’ to be discussed. EP amendment could serve as basis for that discussion:</p> <p>SE (Comments):</p> <p>Crucial to make all definitions as precise as possible. The terms crisis and emergency should preferably be defined in this instrument and not only in regulations in the annex, at least a reference to the acts in the annex</p>
	<p>IT (Drafting Suggestions):</p> <p><i>(-a new) ‘crisis mode or emergency mode’ means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein</i></p>

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	<p>IT (Comments):</p> <p>Crisis should be defined in the legislation to ensure consistency with the intent of the legislation. The definition should comply with:</p> <ul style="list-style-type: none"> • Art. 3 SMEI (draft) [COM(2022) 459] • Art. 3 SCBTH Reg. 2022/2371 • Art. 2 Reg 2022/2372 - framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level • Art. 2 Reg. 2017/1938 - concerning measures to safeguard the security of gas supply • Chips act Reg. 2023/1781
<p>(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;</p>	<p>DE (Drafting Suggestions):</p> <p>(a) ‘crisis-relevant products’ means products or processes whose nature and scope is determined by the relevant Union Act listed under Article 4 and that are indispensable for responding to such crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;</p> <p>DE (Comments):</p> <p>In view of discussions during the WG session on 7 and 8 February, it seems appropriate to amend the paragraph respectively, in order to clarify the relationship between the general definition of “crisis-relevant products” and the specific</p>

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	<p>definitions within the relevant Union Acts. Please delete the second half sentence since a reference to “impacts” seems rather vague and too broad – also in light of the already pretty far-reaching definition of “crisis-relevant products”.</p> <p>DK (Drafting Suggestions):</p> <p>(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union as defined in the Annex of this Regulation;</p> <p>DK (Comments):</p> <p>Denmark finds that the reference to processes as part of the ‘crisis-relevant products’ definition should be excluded. A process is not a product.</p> <p>EE (Drafting Suggestions):</p> <p>The proposal doesn’t very specifically clarify which goods qualify as “important in a crisis”. Article 1 of the regulation as well as recitals 2 and 32 speak of crisis-relevant products. The explanatory memorandum, under the heading “Reasons for and objectives of the proposal” also refers to health products, vaccines and therapeutics in the context of COVID-19 lessons. Article 3 gives some guidance in this regard, but not very specifically. We thus <i>consider it necessary that the goods or products encompassed by the proposal be more precisely defined</i> in either the regulation text (possibly here under Article 3) or in the recitals.</p>

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	<p>At the same time we also acknowledge that giving any highly exhaustive definitions in a totally foreseeable manner may be difficult. However, this'd be an important point of clarity for stakeholders.</p> <p>EE (Comments):</p> <p>In addition to giving clearer definitions of the crisis-relevant products to be covered, we'd appreciate a broader overview of the products covered based on the annex regulations (giving examples under each regulation of possible products covered).</p> <p>FI (Comments):</p> <p>FI has concerns about the word 'processes' here. It's significance is broader than that of 'products'. 'Processes' might be understood to include know-how, or even trade secrets.</p> <p>It may be confusing if 'crisis relevant product' can be a process, as the significance of 'process' is different from that of 'product'.</p> <p>Some examples of crisis relevant products could be mentioned here.</p> <p>FR (Drafting Suggestions):</p> <p>b) 'crisis-relevant products' means products or processes that are indispensable and are produced in insufficient quantity for responding to a temporary crisis or emergency or for addressing the impacts of a crisis or emergency in the Union and for which the grant of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes as determined by the Commission through the guidance of the advisory body in</p>

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	<p>accordance with Article 6.</p> <p>FR (Comments):</p> <p>Article 3 should contain a definition of the notion of crisis (and a definition of the notion of “emergency mode” included in the proposal of Regulation).</p> <p>The proposal for a regulation of the European Parliament and of the Council establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98 contains a definition of the notion of crisis. Under Article 3 of this proposal :</p> <p><i>“(1) ‘crisis’ means an exceptional unexpected and sudden, natural or man-made event of extraordinary nature and scale that takes place inside or outside of the Union;”</i></p> <p>This definition could serve as a basis for reaching a consensus on a definition of crisis that could be introduced in this proposal.</p> <p>It should be noted that such approach (relying on SMEI instrument in order to define a crisis) has been used, for a sake of consistency with existing crisis mechanisms and with other Union legislation, as regards the definition of ‘crisis-relevant products’ contained in Article 3, (a) of the proposal. Indeed, under Recital 15:</p> <p><i>(15) “In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies”.</i></p> <p>The definition of the concept of crisis could be supplemented by a reference to the crisis or emergency mechanisms listed in the annex of the proposal of regulation</p> <p>The notion of ‘crisis-relevant products’ should be more precisely defined.</p>

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	<p>IE (Comments): The definition provided here is too broad and has the potential to include products which are excluded in the current crisis instruments.</p> <p>IT (Drafting Suggestions): (a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union <i>and for which the grant of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes, as determined by the Commission through the guidance of the advisory body in accordance with Article 6;</i></p> <p>NL (Comments): Requires better definition. Consistency with all relevant crisis-instruments should be ensured. Does not to be the case under the current proposal. This will lead to legal uncertainty. Examples: <u>Current proposal:</u> ‘products and processes that are indispensable’ <u>IMERA:</u> ‘goods (→same as products?) and services (→same as processes?) that are non substitutable, non diversifiable or indispensable (→ broader than <i>indispensable</i>)’ <u>SCBTH+ Emergency Framework crisis-relevant medical countermeasures:</u> ‘necessary for the response’ (→ is there a difference between ‘necessary’ and <i>indispensable</i>?)</p>

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	<p><u>Chips Act</u>: “ necessary to ensure crucial functions of a critical sector” (→is there a difference between ‘necessary’ and <i>indispensable</i>?)</p> <p><u>Gas supply</u>: no products or processes defined. (→ unclear what is meant, also relevance of patents not substantiated).</p> <p>PL (Comments):</p> <p>Terms “products” and “processes” are used without really defining them. It would be a good idea to clear up what these terms mean the Regulation.</p> <p>SE (Drafting Suggestions):</p> <p>(a) ‘crisis-relevant products’ means products or processes that are immediately indispensable for responding to a declared crisis or emergency or for addressing the impacts of such a crisis or emergency in the Union;</p> <p>SE (Comments):</p> <p>This definition needs to be better defined as to create legal certainty of what products are within the scope.</p>
(b) ‘relevant activities’ means the acts of making, using, offering for sale, selling or importing.	
(c) ‘rights-holder’ means a holder of any of the intellectual	

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property rights referred to in Article 2(1);	<p>FR (Drafting Suggestions):</p> <p>(c) ‘rights-holder’ means a holder of any of the industrial property rights referred to in Article 2(1);</p> <p>FR (Comments):</p> <p>See comments concerning Article 2.</p>
(d) ‘protected invention’ means any invention protected by any of the intellectual property rights referred to in Article 2(1);	<p>FR (Drafting Suggestions):</p> <p>(d) ‘protected invention’ means any invention protected by any of the industrial property rights referred to in Article 2(1);</p> <p>FR (Comments):</p> <p>See comments concerning Article 2.</p> <p>PL (Comments):</p> <p>Generally, inventions are protected by patents. However, other exclusive rights such as utility models, are protected by protection rights, and medicinal products and plant protection products are protected by SPCs. Thus, it does not seem appropriate to categorize all industrial property items under an umbrella term “protected invention”.</p>

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<p>(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;</p>	<p>DE (Drafting Suggestions):</p> <p>(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission as a measure of last resort and subject to the conditions set out in this Regulation, in order to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union Member States affected by the underlying crisis or emergency;</p> <p>DE (Comments):</p> <p>(cf. comment under Art. 1)</p> <p>DK (Drafting Suggestions):</p> <p>(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission as a last resort, following the approval by Member States, to produce a crisis relevant product protected by a patent exploit a protected invention of crisis relevant products for any of the relevant activities in the Union;</p> <p>DK (Comments):</p> <p>Denmark has strong reservations about granting the Commission exclusive competencies to issue compulsory licenses. Denmark proposes to include Member States in the process, as a bare minimum, through the examination procedure. A compulsory licence should only be related to a patent and no further measures that</p>

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	<p>go beyond that.</p> <p>FI (Comments):</p> <p>What does ‘for any of the relevant activities in the Union’ mean here? This seems all-encompassing, a clearer framing is needed here. ‘In the Union’ could be understood imply activities by other bodies of the Union than the COM. Is this intended? If so, it should be clarified.</p> <p>FR (Drafting Suggestions):</p> <p>(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission, after opinion of the competent advisory body, to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;</p> <p>FR (Comments):</p> <p>It would be necessary to strengthen the role of the competent advisory body in the procedure for granting a Union compulsory licence (the binding/non binding nature of the opinion of the competent advisory body should be discussed).</p>
(f) ‘customs authorities’ means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council. ²⁵ ;	

²⁵ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

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Article 4	<p>DE (Comments):</p> <p>As stated above, Germany explicitly reserves the right to make further comments – also on Art. 4 and the Annex.</p> <p>The discussions in the WG have shown so far, that a better understanding of the reasons for the selection and the functioning of the EU-crisis instruments listed in the Annex is particularly necessary before dealing with concrete textual amendments.</p> <p>In any case, the reference to a broad list of EU crisis instruments is not convincing. The character of compulsory licenses as a last resort requires at least further explanations. The selection of the instruments will have to be reconsidered in light of the additional explanations by the Commission during the next WG.</p>
Union compulsory licence	
The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.	<p>AT (Drafting Suggestions):</p> <p>The Commission may, <u>as a last resort and with the approval of the Council,</u> grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex <u>and where voluntary agreements were unsuccessful or would not prove efficient.</u></p>

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	<p>AT (Comments):</p> <p>Adding “as a last resort” makes the nature of the instrument more clear. The Council should be involved in the decision-making. One way to ensure Council participation would be to use the examination procedure as opposed to the advisory procedure in the comitology for the implementing act. Alternatively, it should be considered to use an EU court for the granting of the CL.</p> <p>DE (Drafting Suggestions):</p> <p>1. The Commission may only grant, as a measure of last resort and subject to the conditions set out in this Regulation, a Union compulsory licence in case and for the duration of one of the following crises or emergencies pursuant to the relevant Union Acts: where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.</p> <p>(a) a public health emergency at Union level formally recognized by means of a Commission implementing act according to Article 23 of Regulation (EU) 2022/2371;</p> <p>(b) an emergency framework activated by the adoption of a Council Regulation according to Article 3 of Regulation (EU) 2022/2372;</p> <p>2. Without prejudice to Article 7, a Union compulsory licence shall only be granted under the following preconditions:</p> <p>(a) the rights-holder was provided with a reasonable opportunity to negotiate a voluntary license agreement with potential licencees over the permission to exploit a protected invention of crisis-relevant products for any of the relevant</p>

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	<p>activities in the affected MS prior to the granting of a Union compulsory licence;</p> <p>(b) crisis-relevant products are produced in insufficient quantity which results from the exercise of the intellectual property rights referred to in Article 2 (1), in particular a failure to provide a licence;</p> <p>(c) the crisis or emergency causes a public interest which calls for the grant of a Union compulsory licence and that outweighs the rights and interests of the rights-holder.</p> <p>DE (Comments):</p> <p>For the sake of legal clarity, the relevant EU-crisis instruments should be (exhaustively) listed within the Regulation. The additional explanations by the Commission during the last session of the IP WG have confirmed our view that it is necessary to continue discussing how the scope of application should be limited. This also applies to the IMERA Regulation, the EU Chips Act and the Gas supply Regulation. The discussions must be based on factual evidence to determine as to whether there is a specific need and a potential use case for the instruments currently listed in the Annex. We are still waiting for further clarification and further explanation from the Commission. However, this must not be (mis)understood to mean that GER recognizes the need for a Union compulsory licence at all. In this regard, we refer to our general comment on page 1 of the document ("no need for regulatory action"), which remains unaffected by the proposed text changes here and elsewhere in the text.</p> <p>Please add a new Para. 2 to clarify certain conditions for the granting of a compulsory license in order to limit the Commission's room for maneuver to a certain extent.</p>

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	<p>DK (Drafting Suggestions):</p> <p>Following the approval by Member States, the Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex,</p> <p>DK (Comments):</p> <p>As per the comment above, Demark has strong reservations about granting the Commission exclusive competencies over the issuing of compulsory licenses. Member States should be included in the decision making, as a bare minimum, through the examination procedure. It is essential to set out through which mechanisms a CL can be triggered.</p> <p>EE (Comments):</p> <p>We support that the regulation should provide a clear a definition as possible regarding the triggers of the EU compulsory licensing scheme. The whole procedure to be followed and powers granted via it should be as clear as possible for both the public as well as patent holders. I.e. it would be preferable if the triggers would be better set out in the text of this regulation, instead extensive reference be made to the annexed regulations.</p> <p>EL (Comments):</p> <p>Scrutiny reservation in relation to the broad spectrum of crises/emergencies</p>

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	<p>enumerated in the Union Acts listed in the Annex (e.g. semiconductors, gas), under which a compulsory licence will be granted, other than health related ones, as regards compatibility with Art. 31 of the TRIPS Agreement. Furthermore, such broad spectrum extends beyond the scope of pars. 50 & 51 of the European Parliament's Resolution of 11 November 2021 (P9_TA(2021)0453), which calls on the Commission to explore compulsory licensing options to address health emergencies.</p> <p>FI (Comments):</p> <p>The different Union acts/instruments listed in the Annex have different delegated powers. We are not fully convinced of the adequacy of COM issuing the CL. The inter-references between the CL Regulation and the other crisis instruments are potentially confusing and should be clarified. Also, unpredicted crises may fall outside the scope of this Regulation.</p> <p>FR (Drafting Suggestions):</p> <p>The Commission may after opinion of competent advisory body grant a Union compulsory licence, as a last resort in the event no voluntary agreement with a view to ensuring the supply of crisis-relevant products can be reached, where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.</p> <p>FR (Comments):</p> <p>As previously mentioned, it is necessary to recall the principle under which a</p>

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	<p>compulsory licence is a legal tool intended to be applied only in exceptional circumstances, in last resort (when no voluntary agreement could be entered into with the holder of the industrial property right, in the public interest).</p> <p>The fact that a compulsory licence must only be granted exceptionally (and under conditions that take into account the interests of the rights-holder), in last resort, is an essential principle.</p> <p>Accordingly, it should not only be mentioned in the recitals of the proposal (Under Recital 16 : “<i>A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. (...)</i>”).</p> <p>Under Recital 40 : “<i>Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. (...)</i>”</p> <p>This principle must be expressly provided for in the articles of the proposal.</p> <p>As previously mentioned, it would be necessary to strengthen the role of the competent advisory body in the procedure for granting a Union compulsory licence (the binding/non binding nature of the opinion of the competent advisory body should be discussed).</p> <p>IE (Comments):</p> <p>Article 3 of the draft regulation has a specific definition of what constitutes a crisis, but the relevant crisis instruments also have their own definitions of what constitutes a crisis. It is therefore unclear as to how the instruments align, and clarity would be appreciated on the matter.</p>

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	<p>NL (Drafting Suggestions):</p> <p>The Commission shall not issue a Union compulsory license for any crisis or emergency-related product until the rights holder has been given a fair chance to engage in negotiations for a voluntary agreement with the licensee. The timeframe for reaching a voluntary agreement shall be adequate for discussions with potential partners, considering the urgency of the situation, and shall be a reasonable period of time from the initial notification to the relevant rights holder.</p> <p>In the event of a failure of a voluntary agreement between the rights-holder and the licensee pursuant to the first subparagraph, the Commission may grant a Union compulsory licence in the event of a crisis mode or an emergency mode.</p> <p>NL (Comments):</p> <p>Wording should be included to clarify that this new instrument would only be used during major crisis affecting the EU, as a measure of last resort / it must only be granted exceptionally taking into account public interest and under conditions that take into account the interests of the rights-holder.</p> <p>Amendments from EP included, as it can serve as a basis for further discussion.</p> <p>PT (Comments):</p> <p>Specific and practical examples of crisis and its triggering factors should be included in the annex as well, in order to better understand the situations where this Regulation will be applied.</p>

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	<p>SE (Drafting Suggestions):</p> <p>The Commission may grant issue a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex. Such a license can only be issued in exceptional cases where, after adequate discussions, it is clear that no voluntary solution can be agreed. A Union compulsory license cannot be applied to matters related to national security and defence.</p> <p>SE (Comments):</p> <p>Legally ambiguous to define the actual scope and the triggers of the regulation in other regulations. Should preferably be clearly stated that products related to national defence is outside of the scope (even if they are outside of regulations in the annex).</p> <p>Language strengthen to reflect principle of last resort and the need for discussions and possible joint consultations before a decision. Possibly, language should be changed from “granting” to “issuing” to reflect that the act is irrelevant of any application from third party but an independent act on the initiative of the Commission</p>
Article 5	<p>AT (Comments):</p> <p>In Austria’s view, the conditions in this article should be more clear; furthermore, there are additional conditions listed in subsequent articles of the proposal; it could</p>

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	<p>be clarified further how they interact and that they all must be fulfilled.</p> <p>DK (Comments): Denmark generally finds that the language in this article is very unclear.</p> <p>IE (Comments): Article 31 (j) of TRIPS requires that the judicial or administrative review of the decision on the remuneration under a compulsory license must be a full review, including a review of the facts and merits. How will this proposal ensure compliance with that requirement? How can will this proposal ensure the right holder's right to be heard if an EU wide Compulsory License can be issued without having identified the patent holder(s)? Under the proposal as drafted, how would the EU be compliant with the TRIPS agreement if an EU CL could comprise patent applications?</p> <p>PL (Comments): Given the unique nature of a Union compulsory licence, it is crucial to precisely delineate the conditions for granting such a licence. The scope, duration, and territorial extent of the licence should be clearly defined, ensuring that the relevant provisions are worded with maximum precision. A Union compulsory licence constitutes a limitation of exclusive rights, and thus, it is necessary to balance the purpose behind granting it with the rights of the rights-holder. It is essential to clarify whether the scope of information conveyed during the</p>

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	compulsory licence process will also cover the necessary “know-how” for technology transfer especially for the solution seen as a “crisis-relevant product”.
General conditions of a Union compulsory licence	<p>ES (Comments):</p> <p>This article raises two questions. First, although the Regulation mentions non-exclusive licenses, the general conditions and the procedure established for granting them represent an alteration of the usual system of granting licenses since it will be the Commission that initiates and determines who will be the recipient of the licenses. In the Spanish procedure, it is the future licensee who must initiate the procedure. An open licensing framework should be established for other operators to participate.</p> <p>Secondly, we have doubts about the way in which the European system of compulsory licenses will be structured in the event that the invention subject to the compulsory licensing regime is protected in some Member States, but not in others, thus its manufacture in the latter would be free. Questions also arise regarding the duplication of licenses in case of licensing both in a Member State and in the EU. Therefore, a product manufactured under the protection of a CL could circulate freely within the EU, even in those states not affected by the crisis.</p> <p>Finally, doubts are raised about the term of the compulsory license, as well as the territorial scope.</p> <p>SE (Comments):</p> <p>Conditions should be properly defined in relation to the full proposal and contain clear definitions, further discussions might be needed after discussions on other</p>

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	articles
1. The Union compulsory licence shall	<p>IT (Drafting Suggestions): The Union compulsory <i>license that may be granted by the Commission in accordance with Article 4 shall, notwithstanding the obligations to be fulfilled by the licensee in accordance with Article 10:</i></p> <p>NL (Drafting Suggestions): Where a voluntary agreement cannot be reached between the rights-holder and the licensee pursuant to Article 4 (-1a), the Union compulsory license that may be granted by the Commission in accordance with the first subparagraph of Article 4 shall, notwithstanding the obligations to be fulfilled by the licensee in accordance with Article 10</p> <p>NL (Comments): Last resort an proportionality to be included. Amendment from EP included, as it can serve as a basis for further discussion.</p> <p>SE (Drafting Suggestions): 1. As an instrument of last resort, the Union compulsory licence shall</p>

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	SE (Comments): Language included to reflect principle of last resort
(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;	DK (Drafting Suggestions): (a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence; DK (Comments): Denmark does not understand the wording of “enterprise or goodwill which enjoys such compulsory licence”. It is unclear what ‘goodwill’ refers to and what is meant by ‘enjoys’. Denmark suggest that the language is corrected and tightened up. FI (Comments): What does ‘except with that part of the enterprise or goodwill which enjoys such compulsory licence’ mean here?
(b) have a scope and duration that is limited to the purpose for which the compulsory licence is granted and limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;	DE (Drafting Suggestions): (b) have a material and territorial scope and duration that is strictly limited to the purpose and necessities for which the Union compulsory licence is granted and

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	<p>be strictly limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;</p> <p>DE (Comments): Amendments shall reflect that a Union compulsory licence only serves as a last resort mechanism and needs to be strictly limited to what is necessary.</p> <p>DK (Drafting Suggestions): (b) have a scope and duration that is strictly limited to the purpose for which the compulsory licence is granted as a response to a crisis as defined in the crisis mechanisms listed in the Annex, but no longer than 12 months as referred to in article 7.7 and limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;</p> <p>DK (Comments): Denmark finds the wording to be quite unclear. There should be reference to the relevant article (7.7).</p> <p>FR (Drafting Suggestions): (b) have a clear scope and duration that is strictly limited to meet the needs in the Union on the basis of the purpose for which the compulsory licence is granted and strictly limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;</p>

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	<p>FR (Comments):</p> <p>A compulsory licence is a tool which should be used only in exceptional circumstances. This instrument is intended to apply only to the extent strictly necessary to achieve the objective for which it is granted.</p> <p>As indicated in recital 16: (16) <i>“A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence”.</i></p> <p>The drafting suggestions are consistent with the exceptional nature and use of the compulsory licence.</p> <p>The use of the terms “strictly” in (b) of Article 5.1 is also consistent with (c) of such Article (the term “strictly” is used in this provision).</p> <p>IT (Drafting Suggestions):</p> <p>(b) have a <i>strict limitation concerning scope, field of use, necessary quantities, and a duration that is is limited to the fully in line with the specific purpose for which the compulsory licence granted and limited is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode in the framework of under which it is granted <i>within the Union</i></i></p> <p>NL (Drafting Suggestions):</p> <p>(b) have a strict limitation concerning scope, field of application, necessary</p>

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	<p>quantities, and a duration that is closely in line with the specific purpose for which the compulsory licence is issued, as well as strictly linked to the scope and duration of the crisis or emergency mode under which it is granted within the Union.</p> <p>NL (Comments): Clarify that scope includes volume/number of crisis-relevant-products. Consider including a maximum period (which can be extended). With regard to the Chips-act (if included in the Annex, see remarks at recitals), it should be clarified that the scope is limited to non-commercial government use and legal remedies for anti-competitive practices as required by article 31(c) TRIPS. Amendment from EP included, as it can serve as a basis for further discussion.</p> <p>PT (Comments): Considering the extraordinary nature of the compulsory licenses, it is crucial to define their scope, duration and territorial coverage clearly and precisely.</p> <p>SE (Drafting Suggestions): (b) have a strict scope and duration that is limited to the purpose for which the compulsory licence is granted and limited to the scope and duration of the crisis or emergency mode in the framework of which it is granted;</p>
(c) be strictly limited to the relevant activities of crisis-relevant products in the Union;	

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	<p>DE (Drafting Suggestions):</p> <p>(c) be strictly limited to the relevant activities that are necessary for the supply of crisis-relevant products in the Union Member States affected by the underlying crisis or emergency;</p> <p>DE (Comments):</p> <p>(cf. comment under Art. 1)</p> <p>IT (Drafting Suggestions):</p> <p>(c) be strictly limited to the relevant <i>and properly justified</i> activities of crisis-relevant products in the Union;</p>
<p>(d) only be granted against payment of an adequate remuneration to the rights-holder;</p>	<p>DK (Comments):</p> <p>Denmark finds the wording around ‘adequate remuneration’ unclear. Reference should also be made to the relevant article 9. If there is a certain percentage level of remuneration, then the percentage should be explicitly stated here. Denmark would also like clarity on how this will be determined. Too low remuneration could discourage companies from investing in R&D, which is key to safeguard EU crisis resilience.</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>FI (Comments): Reference could be made to Art. 9 on remuneration.</p> <p>FR (Drafting Suggestions): (d) only be granted against payment, to the rights-holder, of an adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”;</p> <p>FR (Comments): The proposal must comply with the provisions of the TRIPS Agreement Under Article 31, h) of the TRIPS Agreement: “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”; Article 5, 1, (d) of the proposal does not refer to the economic value of the authorization. As a consequence, this provision does not comply with Article 31, h) of the TRIPS Agreement. Consequently, Article 5, 1, (d) of the proposal must be amended in order to take into account the aforementioned economic value of the authorization.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>IE (Comments):</p> <p>Under the proposed Pharmaceutical Strategy, Art. 80.4 of the Directive is unclear as to what the is entailed by the “suspension” of data and market protection and its consequences for products marketed under a union compulsory license. Suspension of RDP may facilitate unfair commercial use of the data to obtain marketing authorisation in multiple jurisdictions and may run counter to Article 39 of the International Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Can clarity be provided on this matter? Will the value of disclosed data be included within the assessment of remuneration costs? The proposed suspension of the RDP will not extend the original duration of the protection period by the time under which the compulsory licence s in effect – will the loss of this period of exclusivity be accounted for within the remuneration assessment?</p> <p>IT (Drafting Suggestions):</p> <p>(d) only be granted against payment of an adequate remuneration to the rights-holder <i>determined in accordance with article 9;</i></p> <p>PT (Comments):</p> <p>The expression ‘adequate remuneration’ is not clear <i>per se</i>.</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SI (Comments): This condition should be more clear. Adequate remuneration could be inadequate if we are limited by the 4% threshold, according to the article 9.
(e) be limited to the territory of the Union;	DE (Drafting Suggestions): (e) be strictly limited to the territory of the Union; DE (Comments): Clarification in light of the underlying objective. IT (Drafting Suggestions): (e) be <i>strictly</i> limited to the <i>precisely defined</i> territory of the Union
(f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.	DE (Drafting Suggestions): (f) only be granted to a person deemed to be that is in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DE (Comments): Question: does “person” entail also companies and other entities? It seems rather unlikely, that a compulsory licence would be granted to a natural person, isn’t it? In any case, the wording should be more concrete in order to ensure, that a potential licensee is able to cope with obligations under this Regulation.</p> <p>DK (Drafting Suggestions): (f) only be granted to a person and / or legal entity engaged in commercial activities deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.</p> <p>DK (Comments): Denmark suggests for wording to be added such as ‘legal entity engaged in commercial activities’ or something along those lines, to cover businesses.</p> <p>EL (Comments): It is not clear, how such an evaluation will be implemented.</p> <p>FI (Comments): A ‘person’ should perhaps be ‘legal entity’ instead.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>FR (Drafting Suggestions):</p> <p>(f) only be granted to a person deemed to be in a position to efficiently and quickly exploit the protected invention in a manner that permits the effective proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.</p> <p>PL (Comments):</p> <p>It is worth contemplating whether the definition specifying the entity eligible for the grant of a Union compulsory licence is sufficiently precise, i.e. will advisory bodies be able to discern and effectively assess the capability of the respective entity to fulfil the purpose of the compulsory license grant.</p> <p>PT (Comments):</p> <p>What are the criteria used to decide whether a person is deemed to be in a position to exploit the protected invention and how is that assessment made? Minimum acceptance requirements should be established for a person to be deemed to be in a position to exploit the protected invention</p>
	<p>FR (Drafting Suggestions):</p> <p>g) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, absolving the rights-holder from any claims arising as a result of product liability issues.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>FR (Comments):</p> <p>This provision should be added to state that the licensee should hold responsibility for the production and distribution of crisis-related products and safeguarding the rights holders from undue liability for unrelated business activities over which they have no control.</p> <p>NL (Drafting Suggestions):</p> <p>(fa) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, absolving the rights-holder from any claims arising as a result of product liability issues.</p> <p>NL (Comments):</p> <p>Amendment from EP included, as it can serve as a basis for further discussion.</p>
<p>2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.</p>	<p>DE (Drafting Suggestions):</p> <p>2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.</p> <p>DE (Comments):</p> <p>(cf. comment under Art. 2)</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DK (Drafting Suggestions):</p> <p>2. — A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.</p> <p>DK (Comments):</p> <p>Denmark suggests for this paragraph to be deleted.</p> <p>EL (Comments):</p> <p>Reservation in relation to the compulsory licensing of published patent applications. See relevant comment in Art. 2 par. 1 point (a).</p> <p>FR (Drafting Suggestions):</p> <p>2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the following conditions are fulfilled :</p> <p>(a) the granting of that patent takes place while the Union compulsory licence is valid.</p> <p>(b) the claims of the granted patent cover the protected invention related to crisis-relevant products for which the compulsory licence has been granted</p> <p>(c) when the patent is granted, the Union compulsory licence remains, taking into account the persistence of the crisis or emergency situation and its intensity, necessary to ensure that the Union has access to crisis-relevant</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>products.</p> <p>(d) when the patent is granted, the Union compulsory licence remains necessary as a last resort tool to ensure such access, given the lack of other effective tools, such as voluntary agreements, to reach this objective</p> <p>NL (Drafting Suggestions):</p> <p>2. — A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.</p> <p>NL (Comments):</p> <p>Reservations about inclusion of patent applications. (1) Article 31 TRIPS only refers to subject matter <i>of a patent</i>, not to applications and (2) scope of protection can change (significantly) in process from patent application to granted patent.</p> <p>SE (Drafting Suggestions):</p> <p>delete</p> <p>SE (Comments):</p> <p>Deleted as a consequence of non-inclusion of patent applications</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SI (Comments): In a situation where a patent from a published patent application is not granted, this could cause uncertainty for licensee and numerous issues regarding the return of the remuneration.
3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid.	FR (Drafting Suggestions): 3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the following conditions are fulfilled : (a) The transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid. (b) When the supplementary protection certificate is issued, the Union compulsory licence remains, taking into account the persistence of the crisis or emergency situation and its intensity, necessary to ensure that the Union has access to crisis-relevant products. (c) When the supplementary protection certificate is issued, the Union compulsory licence remains necessary as a last resort tool to ensure such access, given the lack of other effective tools, such as voluntary agreements, to reach this objective FR (Comments): France requests a legal analysis on this provision. During the last IP working group,

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>the Commission did not reply on the legal feasibility of the automatic transfer of the compulsory license from the patent to the SPC given that SPC is not an extension of the patent, but a different IP right (which would require a separate compulsory license).</p> <p>If legal validity of the automatic transfer is not established, the paragraph 3 of Article 5 should be deleted.</p> <p>If legal validity of the automatic transfer is established, the conditions provided for in points (a), (b) and (c) should be fulfilled.</p>
Article 6	
Advisory body	<p>ES (Drafting Suggestions): Advisory Body Expert and Independent.</p> <p>ES (Comments): This "Advisory body" as drafted in the regulations is undefined. While its functions are listed, neither its composition nor its mode of operation is specified. Given the stereotypes about patents, which are present in all media debates, or the political biases associated with the questioning of the patent system, an advisory body constituted without the requirements of quality, professionalism and independence of its members or its rules of operation, may tend to give distorted or flawed results and diagnoses. It can only be constituted by patent experts from the respective national offices, absolutely independent and with previous competences in the</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	analysis and granting of national compulsory licenses. It is suggested that the name be changed to "Advisory Body Expert and Independent".
<p>1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.</p>	<p>DE (Drafting Suggestions):</p> <p>1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an the advisory body competent for the underlying crisis or emergency (the ‘competent advisory body’). In such case, the composition of the competent advisory body shall be modified and include one additional representative per Member State with the necessary expertise regarding the granting of compulsory licences under national law. Member States shall appoint respective experts and notify the Commission thereof.</p> <p>DE (Comments):</p> <p>Clarification which advisory body shall be seen as “competent”; see new definition in Art. 3 lit. aa) Expertise of the competent advisory body needs to be ensured</p> <p>DK (Drafting Suggestions):</p> <p>1. Following the triggering of a crisis as defined in the respective EU legislation in the Annex, the advisory body may propose the issuance of a compulsory licence to the Commission. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DK (Comments): Denmark finds that a recommendation on the issuance of a compulsory license should come from the advisory board of the respective crisis instrument, not from the Commission. Member States should also be involved in the decision-making, as a bare minimum, through the examination procedure.</p> <p>PT (Comments): The expression ‘without undue delay’ is not sufficiently clear. A time limit should be established.</p>
<p>2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the ‘competent advisory body’). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:</p>	<p>AT (Comments): Is this an exhaustive list or are further tasks imaginable?</p> <p>DE (Drafting Suggestions): 2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the ‘competent advisory body’). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks: (aa) the assessment whether the conditions for the rights-holder and potential licensees to conduct meaningful negotiations with a view to reach a voluntary</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>agreement pursuant to Article 4 paragraph 2 are ensured;</p> <p>DE (Comments): See amendments in Para. 1 It needs to be ensured that rights-holder has the possibility for meaningful negotiations with potential licensees (cf. amendments in Art. 4 para. 2).</p> <p>DK (Drafting Suggestions): 2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the ‘competent advisory body’). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:</p> <p>DK (Comments): Denmark suggests for parts of the paragraph to be deleted.</p> <p>ES (Comments): It would be necessary to include within the tasks of the advisory body the mandatory evaluation of the qualifications and capabilities of the licensees in order to guarantee that they can carry out the production tasks of the “crisis-relevant products”. Spanish law establishes the need for the applicant of a compulsory license “to have the means to carry out real and effective exploitation of the patented invention”.</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>NL (Drafting Suggestions):</p> <p>The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation supplemented by expert representatives of the authorities of the Member States which are competent for the granting of compulsory licences under national law (the ‘competent advisory body’) . For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:</p> <p>NL (Comments):</p> <p>See remarks at recital 18. IP expertise to be ensured.</p> <p>PT (Comments):</p> <p>Regarding the advisory body, it is necessary to ensure IP competences</p> <p>SE (Drafting Suggestions):</p> <p>2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the ‘competent advisory body’). In matters related to this regulation, the competent advisory body shall include relevant expertise on intellectual property and licensing. For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Comments): Language added to note need for IP expertise
	NL (Drafting Suggestions): (aa) the assessment of whether the obligation to afford the rights-holder an opportunity to engage in negotiations for a voluntary license, as specified in Article 4 (-1a), has been complied with; NL (Comments): Prior negotiation requirement to be assessed by advisory body. Amendment from EP included, as it can serve as a basis for further discussion.
(a) the gathering of crisis-relevant information, market intelligence and the analysis of those data;	
(b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;	
(c) the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level,	

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where appropriate;	
(d) the identification of the rights protecting the crisis-relevant product;	<p>DE (Drafting Suggestions):</p> <p>(d) the determination of a crisis-relevant product and the identification of the rights protecting the crisis-relevant such product;</p> <p>DE (Comments):</p> <p>As a first step, a “crisis-relevant product” would have to be identified.</p> <p>SE (Drafting Suggestions):</p> <p>(d) the identification of the rights protecting the crisis-relevant product and any existing national compulsory licenses relating to that right;</p> <p>SE (Comments):</p> <p>It should be a task included in the general investigation before a grant of Union CL to gather information on national CL, see link to art 22</p>
(e) the establishment of whether there is a need to grant a Union compulsory licence;	<p>SE (Drafting Suggestions):</p> <p>(e) the establishment of whether there is a need to grant a Union compulsory licence, taking into account possible voluntary solutions and adequate</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>opportunities for rights-holders and licensees to engage in negotiations;</p> <p>SE (Comments): Requirement of prior negotiations and preference for voluntary solutions should be assessed by the advisory body</p>
<p>(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;</p>	<p>DE (Drafting Suggestions): (f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees, including the assessment if such potential licensees are in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products in accordance with the obligations referred to in Article 10; (fa) and consulting other stakeholders and economic operators, including academia, civil society and the industry;</p> <p>DE (Comments): It needs to be ensured, that potential licensees are qualified and possess sufficient production capacities and resources Clarification that relevant stakeholders are consulted to ensure complete assessment</p> <p>DK (Drafting Suggestions): (f) the identification and consultation of representatives of right holders or their</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>representatives as well as potential licensees or their representatives, and consulting other further economic operators, and in the industry”</p> <p>DK (Comments):</p> <p>Denmark suggests for the language to be tightened up. There is no need to reference representatives twice and it should be elaborated, what ‘economic operators’ refers to.</p> <p>PT (Comments):</p> <p>How is the identification and consultation of potential licensees carried out? And of the rights-holders?</p>
<p>(g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.</p>	<p>DK (Drafting Suggestions):</p> <p>(g) the establishment, establish, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 14 have been fulfilled.</p> <p>DK (Comments):</p> <p>Denmark suggests for the language to be simplified and / or corrected. Denmark wonders whether the reference to article 15 is correct - should this not be article 14 instead “Review and termination of the Union compulsory licence”?</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>3. The advisory body shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.</p>	<p>DK (Drafting Suggestions):</p> <p>3. The advisory body must shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with Intellectual property offices at Union and national level. Intellectual property offices at Union and national level must be invited to all meetings related to intellectual property and their opinion must form part of the advisory body's recommendation related to a compulsory licence.</p> <p>DK (Comments):</p> <p>Denmark suggests that IP offices at Union and national level are <u>always</u> included in the process as they have the knowledge and expertise on IP matters. Also, the opinion of the offices should always be reflected in the recommendation of the advisory board.</p> <p>EL (Comments):</p> <p>National IP offices, as the competent bodies for granting national compulsory licenses should have a more active role and participation in the consultation process, due to their expertise. It is not clear how such cooperation with IP offices will take place.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>NL (Comments): Advisory body should on a mandatory basis include relevant IP experts. See proposal art. 6(2)</p> <p>PT (Comments): The expression “where appropriate” raises clarity issues, namely in regard to the extension of the cooperation</p> <p>SE (Comments): Needs to be ensured that relevant IP knowledge is included in the advisory body when matters relating to this regulation are discussed. Role of national IP offices should be discussed, as national regulations may differ in how CLs are granted and what institutions are involved</p>
<p>4. For the purpose of the present Regulation, the Commission:</p>	<p>DE (Drafting Suggestions):</p> <p>4. For the purpose of the present Regulation, the Commission: (aa) shall ensure the participation and involvement of the rights-holder and potential licensees in the relevant advisory body meetings;</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DE (Comments): It needs to be ensured, that rights-holder and potential licensees are fully involved in the process.</p>
	<p>NL (Drafting Suggestions): (aa) shall guarantee involvement of rights-holders by extending invitations to their representatives for the pertinent advisory body meetings, ensuring that the rights-holders are granted a timely and fair chance to provide comments; and</p> <p>NL (Comments): Involvement of rights-holders to be ensured. Amendment from EP included, as it can serve as a basis for further discussion.</p> <p>SE (Drafting Suggestions): aa) shall guarantee the principle of compulsory licensing as an extraordinary measure of last resort, and the fair inclusion of rights-holders to comment on voluntary solutions as well as terms of a compulsory license</p> <p>SE (Comments): Language added to recall principle of last resort and make sure that the Commission</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>(a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and</p>	<p>acts in good faith, as an enabler of discussions on voluntary solutions</p> <p>DK (Drafting Suggestions):</p> <p>(a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and</p> <p>DK (Comments):</p> <p>Denmark suggests for the wording the be amended.</p> <p>IE (Comments):</p> <p>Coherence with EU crisis instruments will be ensured by the possibility to use their trigger and by reference to the (advisory) bodies set-up by the EU crisis instruments to discuss a Union compulsory licence. The proposed procedure would also cover crises with a cross-border dimension in the EU but which do not reach the activation threshold for an EU crisis instrument (e.g. a crisis spreading across several Member States) In this context it would be useful for an elaboration or some examples of the type of compulsory licences envisaged that the difference advisory bodies eg the GCG would advise on.</p>
<p>(b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts</p>	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
to attend meetings of the advisory body as observers.	<p>AT (Drafting Suggestions): <u>(b) shall ensure participation, as far as possible, and invite representatives of right holders and potential licensees to attend meetings of the advisory body;</u> (c) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.</p> <p>AT (Comments): The participation of rights holders and potential licensees from the earliest moment possible is crucial. We propose to strengthen the wording of para. 4 in this regard.</p> <p>DE (Drafting Suggestions): (b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.</p> <p>DE (Comments): Cf. new paragraph (aa)</p> <p>DK (Drafting Suggestions): (b) may invite representatives of the European Parliament, representatives of economic operators and / or their representatives, right holders and / or their</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>representatives, potential licensees and / or their representatives, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.</p> <p>DK (Comments): Denmark suggests for the language to be tightened up so that it is in line with the rest of proposal.</p> <p>EL (Comments): Experts of national IP offices should also be invited in meetings of the Advisory Body. IP offices as competent bodies for granting national compulsory licenses, should have the opportunity not only to attend meetings but also- and most importantly- to be consulted and express their opinion before the advisory body.</p> <p>ES (Comments): Section 4 b) indicates the possibility of inviting experts to the meetings of the advisory body. We stress that technical experts should not be invited, they should rather be members of the ad hoc advisory body.</p> <p>PT (Comments): Instead of being invited, IP experts should be members of the advisory body</p>
5. In the absence of any existing competent advisory body,	

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<p>the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the ‘ad hoc advisory body’). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.</p>	<p>AT (Comments):</p> <p>Various delegations have expressed concerns on this paragraph – as all crisis instruments listed in the annex have advisory bodies as described in Art. 6 para. 2. Thus, para. 5 is merely directed towards the future, anticipating possible amendments to the annex. With regards to legal certainty, would it not be ‘cleaner’ to delete the paragraphs pertaining to the Ad Hoc advisory body and only include them – if necessary – once the annex is amended? We share the concerns expressed by many delegations in this regard and would like to ask the Commission for further details on how the Annex would be amended and if an eventual Art. 6 para. 5 could not be introduced in the same procedure, should this become necessary.</p> <p>DE (Drafting Suggestions):</p> <p>5. — In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the ‘ad hoc advisory body’). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.</p> <p>DE (Comments):</p> <p>Deletion for reasons of legal clarity, as there is no specific scope of application. In case that a new EU crises instrument will refer to the present Regulation, it seems preferable for such a future instrument to contain specific provisions regarding the advisory body.</p>

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	<p>DK (Drafting Suggestions):</p> <p>In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the ‘ad hoc advisory body’). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State and their respective IP offices shall have the right to be represented in the ad hoc advisory body.</p> <p>DK (Comments):</p> <p>Denmark suggests that reference is made to MS’s IP experts as they should be represented at the ad hoc board.</p> <p>ES (Comments):</p> <p>With regard to the ad hoc advisory body provided for in this Regulation, the following clarifications should be made: In order to guarantee the impartiality and rigor of the decisions of both the advisory body and the Commission, it should be composed of representatives of the organizations of the Member States that are in charge of studying and granting national compulsory licenses. The participation of national experts in the field of industrial property, providing technical criteria, constitutes a guarantee both for the rights of the owners of the industrial property and for the correct functioning of the European system of compulsory licenses.</p>

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	<p>NL (Drafting Suggestions):</p> <p>In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the ‘ad hoc advisory body’). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body. The ad hoc advisory body shall be composed of representatives of the institutions and bodies of each Member State that exercise the competence to grant national compulsory licences under national law</p> <p>NL (Comments):</p> <p>Need for ad hoc bodies to be discussed. If included, IP expertise to be ensured, also in ad hoc bodies. Amendment from EP included, as it can serve as a basis for further discussion.</p> <p>PT (Comments):</p> <p>It is necessary to ensure IP competences of the ad hoc advisory body.</p> <p>SE (Comments):</p> <p>Need for ad hoc bodies, and their composition, should possibly be discussed</p>
6. The Commission shall adopt an implementing act	

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<p>laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).</p>	<p>DE (Drafting Suggestions):</p> <p>6. — The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).</p> <p>DE (Comments):</p> <p>Cf. comment above</p> <p>ES (Comments):</p> <p>We consider that section 6 of the article should structure the advisory body within a professional, technical and independent framework that guarantees the integrity of its resolutions.</p> <p>The proposed Regulation suffers from the fact that the final decision must be taken by the Commission, which, given that the opinion of the advisory body is not binding, may eventually disregard rigorous technical reasons and impose arbitrary reasons to satisfy political or image needs before the public opinion of the moment.</p>
Article 7	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
Procedure for granting a Union compulsory licence	<p>SE (Drafting Suggestions): Procedure for issuing granting a Union compulsory licence</p> <p>SE (Comments): Possibly, language should be changed from “granting” to “issuing” to reflect that the act is irrelevant of any application from third party but an independent act on the initiative of the Commission</p>
<p>1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:</p>	<p>AT (Drafting Suggestions): 1. The competent or], where relevant ad hoc,] advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:</p> <p>AT (Comments): Part in brackets may be deleted in accordance with what has been expressed under Art. 6 para. 5.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DE (Drafting Suggestions):</p> <p>1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. Before providing an opinion, the rights-holder and potential licensees shall be identified and notified, in order to ensure their participation in the process and to provide for an opportunity to engage in negotiations of a voluntary licence agreement according to Article 4 paragraph 2.</p> <p>1a. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need necessity and proportionality for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following, inter alia:</p> <p>DE (Comments):</p> <p>Cf. deletion of Art. 6 para. 5 and 6. Clarification that rights-holder and potential licensees have to be identified before issuing an opinion. Otherwise, neither prior negotiations over a voluntary licence nor an overall assessment could be ensured</p> <p>DK (Drafting Suggestions):</p> <p>1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. A compulsory licence can only be considered based on a recommendation from the advisory board. That opinion shall be issued in accordance with the rules of</p>

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	<p>procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:</p> <p>DK (Comments):</p> <p>DK proposes for the advisory body to be the one initiating a CL.</p> <p>PT (Comments):</p> <p>The expression ‘without undue delay’ is not sufficiently clear. A time limit should be established.</p> <p>SE (Drafting Suggestions):</p> <p>1. When the subject matter of an intellectual property right included in this regulation is required for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism, and when access to such a right through voluntary measures is limited, the competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:</p>

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	SE (Comments): It should be set out in a clear way how the process for a CL is set up and what the prerequisites are, possibly here or in a separate point under this article
	NL (Drafting Suggestions): (aa) Whether the subject matter of the intellectual property right involved is required for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. NL (Comments): This is a key question when assessing the need for a compulsory license.
(a) the nature of the crisis or emergency;	
(b) the scope of the crisis or emergency and how it is expected to evolve;	
(c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.	DE (Drafting Suggestions): (c) the shortage of crisis-relevant products, its reasons, in particular if it results from the exercise of the intellectual property rights referred to in Article 2 (1),

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	<p>(d) and the necessity and proportionality of a Union compulsory licence, in particular taking into account the rights and interests of the rights-holder and the potential licensee as well as the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.</p> <p>DE (Comments): The assessment should take a broader view to align the Union compulsory licence with the idea of a last-resort mechanism</p>
<p>2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.</p>	<p>AT (Comments): The non-binding nature of the opinion remains a concern. At the very least, guidance should be included in the regulation regarding the extent to which the Commission should take into account the opinion of the body. At the very least, the Commission should not deviate from the opinion without due reasoning.</p> <p>DK (Comments): DK finds that the advisory body's opinion is defined in a vague and unclear way. It should be explicitly stated under what circumstances the Commission may decide to grant a CL that goes against the recommendation of the advisory board.</p> <p>EL (Comments): The fact that the opinion of the Advisory Body is not binding raises concerns</p>

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	<p>regarding the consistency of the decisions taken by the Commission for granting compulsory licenses. Moreover, questions are raised in relation to the necessity of such a body, if it has no binding power.</p> <p>ES (Comments): ((According to section 2 of the article “the opinion of the advisory body shall not be binding on the Commission”, in our opinion it is necessary to establish the binding nature of the opinion of the body. It should not be possible to grant compulsory licenses without the advisory body, made up of technically trained people and experts in the field, giving approval. Otherwise, it is not appreciated what value an opinion without technical criteria and not binding on the decision-making body can provide. The participation of the body throughout the process of granting compulsory licenses (articles 1 to 11) and the imposition of fines (articles 16 and 17) should be mandatory and its opinion binding.)) If a binding opinion is discarded, then the Commission should propose the Council the initiation of a Compulsory Licensing process through an implementing act like article 14.2 of the Proposal for a Regulation establishing a SMEI On the other hand, art. 7, section 2 provides that the opinion by the advisory body must be issued within a reasonable time, but it does not indicate a maximum period although it would be an emergency situation.</p> <p>NL (Comments): Binding or non-binding nature to be discussed.</p>

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	<p>PT (Comments):</p> <p>‘The time limit shall be reasonable and appropriate’ is not sufficiently clear. A time limit should be established. Given that the opinion of the advisory body is not binding, it is not clear what happens when the COM does not agree with the opinion. What is the next step? And why is this opinion not binding?</p> <p>SE (Comments):</p> <p>Could be discussed whether the opinion should be binding at least in circumstances where the opinion from the advisory body is negative</p>
<p>3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:</p>	<p>DE (Drafting Suggestions):</p> <p>3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the potential licensee an additional opportunity to comment, inter alia on the following and in view of the opinion of the advisory body:</p> <p>DE (Comments):</p> <p>Clarification that it’s just another possibility to comment, since rights-holder and licensee are already fully involved in the advisory body. Clarification that list is not exhaustive. Should be left up to rights-holder and the</p>

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	<p>licensee.</p> <p>DK (Comments):</p> <p>Denmark would like to know how this information will be used – it is not clear. Will the Commission take it into consideration when assessing the case and the recommendation from the respective advisory board?</p> <p>ES (Comments):</p> <p>The procedure established in article 7 only allows the owner to be informed and to be heard without the possibility of entering the procedure. The possibility of active participation of the holder in the procedure is a basic characteristic of the Spanish system of compulsory licenses. The procedure established in this article begets legal insecurity for the owner since it does not allow him to present his arguments or receive a motivated response in one sense or another. The holder should not only be able to refute the arguments, but should be able to access all the documents in the file as early as possible.</p> <p>NL (Drafting Suggestions):</p> <p>3. Before issuing the opinion, the advisory body the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:</p> <p>PT (Comments):</p> <p>It is necessary to ensure that the rights-holder will always be heard before the</p>

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	<p>granting of a compulsory licence. In addition to the right to be heard, the rights-holder should be kept up to date on all proceedings.</p> <p>SE (Drafting Suggestions):</p> <p>3. Before the issuing granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:</p> <p>SE (Comments):</p> <p>language should be changed from “granting” to “issuing” to reflect that the act is irrelevant of any application from third party but an independent act on the initiative of the Commission</p> <p>Should be assessed and discussed if there should be an obligation for the advisory body to hear the rights-holders and possible licensees aswell</p>
(a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;	<p>DE (Drafting Suggestions):</p> <p>(a) the possibility to reach the state of play of the negotiations over a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products pursuant to Article 4 paragraph 2;</p>

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	<p>DE (Comments): The possibility of prior negotiations needs to be clearly reflected within the text.</p> <p>DK (Drafting Suggestions): (a) the possibility to reach a voluntary licensing agreement between the right holder and the potential licensee with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;</p> <p>DK (Comments): Denmark suggests for the language to be tightened up.</p> <p>EL (Drafting Suggestions): the possibility unsuccessful efforts of the licensee to reach a voluntary licensing agreement with manufacturers on intellectual property rights within a reasonable period of time for the purpose of manufacturing, using and distributing the crisis-relevant products;</p> <p>EL (Comments): An amendment is proposed, so that the provision is compatible with article 31 (b) of the TRIPS Agreement.</p>

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	<p>ES (Comments):</p> <p>Prior negotiation should be mandatory between the owner of the IP subject to a compulsory license and the future licensee in order to comply with the exceptionality and last resort tool requirements that the Commission intends to establish. If the negotiation of voluntary agreements is considered to be the most effective option (Recital 1), it is necessary for the Regulation to promote this preliminary phase before initiating the administrative procedure for granting a compulsory license.</p>
(b) the need to grant the Union compulsory licence;	<p>DE (Drafting Suggestions):</p> <p>(b) the need necessity and proportionality to grant the Union compulsory licence;</p> <p>DE (Comments):</p> <p>Principles of “necessity” and “proportionality” should be included to provide for an overall assessment.</p>
(c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.	<p>SE (Drafting Suggestions):</p> <p>(c) the conditions under which the Commission proposes intends to issue grant</p>

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	<p>the Union compulsory licence, including the amount of the remuneration.</p> <p>SE (Comments):</p> <p>As a CL should always be a measure of last resort, the opportunity to find voluntary solutions should be kept open for as long as possible. It needs to be ensured that the parties are able to provide input on all relevant circumstances, including possible conditions, before the Commission announces its own opinion.</p>
<p>4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.</p>	<p>AT (Comments):</p> <p>As other delegations have stated, the second sentence of this paragraph raises question as to its TRIPS conformity. Rights-holders who are not identified before their rights are subjected to a CL have neither the opportunity to comment on their situation nor to negotiate a voluntary agreement. This situation is highly unsatisfactory and raises concerns on our side. If it absolutely has to be included, the phrasing should at the very least be clarified to better reflect that this is an absolute last resort and can only happen under very limited circumstances. For example, it could be clarified how the term “significant delay” could be interpreted, as this seems rather broad.</p> <p>In our view, it is perhaps not a question of “significant delay”, but significant and irreversible consequences.</p> <p>DE (Drafting Suggestions):</p> <p>4. — The Commission shall notify the rights holder and the licensee as soon as</p>

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	<p>possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights holders is possible and does not cause significant delay, the Commission shall notify them individually.</p> <p>DE (Comments):</p> <p>See amendments in Art. 7 para. 1. In any case, the prompt and correct identification constitutes a necessary requirement to guarantee the rights of the owners, e.g. to allow for prior negotiations of a voluntary agreement.</p> <p>DK (Drafting Suggestions):</p> <p>4. The Commission must shall notify the rights-holder and the licensee individually as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights holders is possible and does not cause significant delay, the Commission shall notify them individually.</p> <p>DK (Comments):</p> <p>Denmark finds the wording to be unclear. The rights holder should <u>always</u> be notified directly about a possible issuance of a compulsory license that affects their products.</p> <p>ES (Drafting Suggestions):</p> <p>Delete sentence crossed out</p>

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	<p>ES (Comments):</p> <p>To preserve the owner’s rights, it is necessary to know which titles IP rights can be subject to the procedure. In section 4, the Regulation states that “Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.”</p> <p>It must be taken into account that industrial property rights are registration rights, whose data are free accessible in all public databases. This data includes the patent holder, its duration, the countries to which it extends and to which it does not, and of course its detailed technical content in such a way that it can be put into practice. Patent databases are commonly used and are well known by all stakeholders involved in the R&D system or technological industry. It is naive and shows a great ignorance of the IP system to show that patent data are unknown or confusing or are hidden.</p> <p>We consider that in order to begin any compulsory licensing procedure it is necessary to determine what the necessary product is and what patents are involved in its production. Their prompt and correct identification constitutes a necessary requirement to guarantee the rights of the owners, to allow a prior negotiation that leads to an amicable agreement and avoid the process of granting a compulsory license.</p> <p>NL (Drafting Suggestions):</p> <p>4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights holders is possible and does not cause significant</p>

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	<p>delay, The Commission shall notify them the rights-holders individually.</p> <p>NL (Comments): See remarks above.</p> <p>PT (Comments): 'as soon as possible' is not sufficiently clear. A time limit should be established for the Commission to notify the rights-holder and the licensee. We consider important to identify the product and all patents which were involved in its production before the granting of a compulsory licence. Only thus can the rights of the holders be ensured, and a previous negotiation leading to a voluntary licence be enabled. Likewise, we consider that rights-holders should be individually notified in all cases.</p> <p>SE (Drafting Suggestions): 4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights holders is possible and does not cause significant delay, The Commission shall notify the rights-holders them individually.</p> <p>SE (Comments): Not convinced of possibility to issue CL without identifying rights-holders</p>

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<p>5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.</p>	<p>DE (Drafting Suggestions):</p> <p>5. When the Commission considers the granting of a Union compulsory licence and after having consulted the competent advisory body, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.</p> <p>DE (Comments):</p> <p>Clarification that the publication should be linked to the consultation of the competent advisory body. In addition, it might be worth considering to move the paragraph to Art. 6 since the publication of the notice must take place before the procedures under Art. 7.</p> <p>ES (Comments):</p> <p>It would be necessary for the announcement in the Official Journal of EU referred to in section 5 to mention the fact that the compulsory license is “non-exclusive” and that the entry of new economic operators is permitted.</p>

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	<p>PT (Comments): it shall without undue delay publish a notice' is not sufficiently clear. A time limit should be established for publication</p> <p>SE (Drafting Suggestions): 5. When the Commission considers the issuing granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.</p>
<p>6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:</p>	<p>DE (Drafting Suggestions): 6. Provided that a voluntary licensing agreement could not be reached in accordance with Article 4 paragraph 2 and without prejudice to additional preconditions set out thereof, the Commission shall consider the following, When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:</p> <p>DE (Comments): Clear reference to prior negotiations over a voluntary license agreement as a</p>

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	prerequisite. SE (Drafting Suggestions): 6. When assessing whether a Union compulsory licence is to be issued granted , the Commission shall consider the following:
(a) the opinion referred to in paragraph 2;	AT (Comments): It should be further clarified how the opinion is to be taken into account, also considering the content of the opinion according to Art. 6(1) a-c. Potentially, a new para. could be included to hold that the Commission may only divert from the opinion with due reasoning.
(b) the rights and interests of the rights-holder and the licensee;	DE (Drafting Suggestions): (b) the necessity and proportionality of a Union compulsory licence, in particular taking into account the rights and interests of the rights-holder and the potential licensee as well as the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage; DE (Comments): The assessment should take a broader view to align the Union compulsory licence

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	<p>with the idea of a last-resort mechanism Rather of editorial nature since it will only be a “licensee” if the Union compulsory licence has been granted</p> <p>SE (Comments): This should be a task also for the advisory body</p>
<p>(c) existing national compulsory licences reported to the Commission in accordance with Article 22.</p>	<p>NL (Comments): Should this not be a task for the advisory body already?</p> <p>SE (Comments): This should be a task for the advisory body</p>
<p>7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act</p>	<p>AT (Drafting Suggestions):</p> <p>7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory examination procedure referred to in Article 24(23). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the examination</p>

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shall remain in force for a period not exceeding 12 months.	<p>procedure referred to in Article 24(42). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.</p> <p>DE (Drafting Suggestions):</p> <p>7. Where the Commission finds that, despite a dissenting opinion of the advisory body, the requirements for a Union compulsory licence are met, the Commission shall provide detailed reasons for doing so.</p> <p>7a. ‡The Commission shall grant ‡ the Union compulsory licence by means of an implementing act. The implementing act shall be adopted in accordance with the advisory examination procedure referred to in Article 24(23). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.</p> <p>DE (Comments):</p> <p>Insertion of additional process if Commission wants to grant a compulsory licence despite dissenting opinion of the advisory body. The implementing act shall be adopted in accordance with the examination procedure in order to ensure the participation of MS. Besides, cf. amendments in Art. 24 regarding the “non-opinion” clause. The reasons and details for an immediate applicable implementing act remain unclear. Especially as the mechanism requires an activated crises or emergency mode, which is likely to be associated with a certain “urgency” from the outset.</p>

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	<p>DK (Drafting Suggestions):</p> <p>7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the examination advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.</p> <p>DK (Comments):</p> <p>DK finds that Member States should be involved in the process, as a bare minimum, through the examination procedure.</p> <p>EL (Comments):</p> <p>It should be clarified when the implementing act will enter into force i.e. from the publication of the act or from the notification of the act to the licensee.</p> <p>NL (Drafting Suggestions):</p> <p>7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory examination procedure referred to in Article 24(2)(3). On duly justified imperative grounds of</p>

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	<p>urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.</p> <p>NL (Comments): Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States. In case of extreme urgency, Article 24(4) already provides possibilities.</p> <p>PT (Comments): What are the requirements for the grant of a Union compulsory license? The requirements should be properly defined.</p> <p>SE (Drafting Suggestions): 7. Where the Commission finds that the reasons for issuing requirements for a Union compulsory licence take precedent over the interests of the right-holder are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the <i>advisory</i> procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for</p>

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	<p>a period not exceeding 12 months.</p> <p>SE (Comments):</p> <p>As there are no strict requirements to adhere to, it should be better reflected that this is an exercise of balancing interests against each other, with the main rule being voluntary solutions</p> <p>In order to better guarantee the involvement of member states, the examination procedure should be discussed instead of the advisory procedure</p>
<p>8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act.</p>	<p>DK (Drafting Suggestions):</p> <p>8. When adopting the implementing act, the Commission must shall ensure the protection of confidential information including trade secrets and only disclose information that is strictly necessary for the given case. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act.</p> <p>DK (Comments):</p> <p>DK is very concerned that this provision may create obligations for right holders to disclose trade secrets and know-how as this can have irreversible economic consequences. Competitors would gain access to the information, which could have significant ramifications for a company's competitiveness. It should never be</p>

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	<p>mandatory for the patentholder to hand over trade secrets and know how as part of a compulsory license.</p> <p>EL (Comments): It is not clear, how the protection of confidential information is ensured.</p>
Article 8	
Content of the Union compulsory licence	
1. The Union compulsory licence shall specify the following:	
(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;	<p>AT (Comments): We agree with the Polish delegation's doubts about the use of the term 'non-proprietary name', as this stems from the pharmaceutical sector and may not apply to other products. This could be rephrased. In the same vein, there is the question of TRIPS conformity when granting a CL for a product without having identified the IP right pertaining to it, using only the non-proprietary name. Using the non-proprietary name would, according to the WHO definition, be the indication of an active ingredient of a medicinal product. It should</p>

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	<p>be noted that active ingredients are often not only protected by one specific patent, but fall within the scope of protection of several patents. For example, active ingredients may be protected not only by substance patents but also by use patents (2nd medical indication) or active ingredients may also be protected by patents in combination with other active ingredients (combinations of active ingredients). It therefore seems necessary in the interests of legal certainty to clearly identify the industrial property rights that are to be restricted.</p> <p>In this context, reference is also made to the wording of Regulation (EC) No 816/2006 (compulsory licenses for export to countries with public health problems), recital 14 of which reads as follows:</p> <p>(14) In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic form.</p> <p>At the time of drafting this regulation, it was obviously assumed that the patents or SPCs for which a compulsory license is granted must be precisely defined.</p> <p>Art. 6 (1) of the aforementioned Regulation also makes close reference to the connection with industrial property rights: “Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.”</p> <p>While Art. 3 para. 3 (b) of the aforementioned regulation refers to the non-proprietary name, this regulation has, to the extent of our knowledge, never been applied and therefore has never been interpreted. It is therefore unclear whether the regulation would be interpreted to allow compulsory licenses to be granted only on products / ingredients, without identification of the concrete IP right(s).</p> <p>However, being able to grant a compulsory license to an industrial property right</p>

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	<p>without determining the specific industrial property right that is to be restricted would mean that the scope of application for a CL could be extremely broad rather than clearly and precisely defined.</p> <p>It could also be concluded from the wording of Art. 31 of the TRIPS Agreement itself that it is aimed at restricting certain - thus clearly identifiable - industrial property rights.</p> <p>“ Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder.”</p> <p>DE (Drafting Suggestions):</p> <p>(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non proprietary name of the products which are to be manufactured under the licensee;</p> <p>DE (Comments):</p> <p>Cf comment under Art. 2 Cf. comment under Art. 7 para. 1, according to which rights-holder and potential licensees shall be identified before issuing an opinion. In this regard, the identification of the rights affected is a necessary prerequisite.</p> <p>DK (Drafting Suggestions):</p> <p>(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights</p>

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	<p>would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;</p> <p>DK (Comments):</p> <p>Denmark wonders how a license can be drafted if the IP rights of a given product have not been determined yet?</p> <p>EE (Drafting Suggestions):</p> <p>Article 2(1)(a) of the regulation refers to not <i>unpublished</i> but only <i>published</i> patent applications. In view of this and for the sake of clarity, could the same reference to not simply <i>applications</i> but <i>published applications</i> also be included in article 8(1)(a) and likewise in recital 24 of the regulation?</p> <p>EL (Comments):</p> <p>Reservation in relation to the compulsory licensing of patent applications. See relevant comment in Art. 2 par. 1 point (a).</p> <p>ES (Drafting Suggestions):</p> <p>Delete sentence crossed out</p> <p>ES (Comments):</p> <p>As in the previous article, section a) of this article does not promote legal certainty by stating that “where the identification of those rights would significantly delay the</p>

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	<p>granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence.” It is necessary to identify the patents, the territories they cover and the remaining validity periods. The inclusion of the NPOs in the advisory body and their participation throughout the process must be guaranteed in order to maintain technical criteria in accordance with the law.</p> <p>NL (Drafting Suggestions):</p> <p>(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;</p> <p>NL (Comments):</p> <p>See remarks above. No patent applications and rights need to be identified before considering/granting CL.</p> <p>PL (Comments):</p> <p>It seems that specifying the subject-matter of a Union compulsory licence solely by referencing “the non-proprietary name of the products which are to be manufactured under the licence” may be excessively broad. Such a licence could automatically apply to all rights pertaining to the designated product without necessitating the identification of these rights.</p>

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	<p>PT (Comments):</p> <p>We consider that IP rights should always be specified in the compulsory licence. It is not clear how a compulsory licence may be granted without the previous identification of the rights. It may occur that there are no IP rights. The expression “non-proprietary name” is not appropriate to characterise all kinds of products which may be subject of a compulsory licence, for instance if the licence is triggered by the semiconductors Regulation.</p> <p>SE (Drafting Suggestions):</p> <p>(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;</p> <p>SE (Comments):</p> <p>Exclusion of patent application Rights-holders should be identified. CL should also be <i>issued for IP rights</i>, and not for products in general as such</p>
(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;	<p>AT (Comments):</p> <p>Concern about the non-identification of the right-holder, same comment as Art. 7</p>

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	<p>para. 4.</p> <p>DE (Drafting Suggestions):</p> <p>(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;</p> <p>DE (Comments):</p> <p>Cf. comment under Art. 7 para. 1, according to which rights-holder and potential licensees shall be identified before issuing an opinion.</p> <p>DK (Comments):</p> <p>Same as above.</p> <p>ES (Comments):</p> <p>Section b) establishes the possibility that the name of the holder may not appear on the compulsory license. The mention of the owner of the affected rights in the license must be a necessary and unavoidable condition for its granting.</p> <p>NL (Drafting Suggestions):</p> <p>(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;</p>

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	<p>NL (Comments): See remarks above. Right holder needs to be identified and included in process before considering/granting CL.</p> <p>PT (Comments): with reasonable efforts' is not sufficiently clear <i>per se</i>. Furthermore, rights-holders should always be previously identified.</p> <p>SE (Drafting Suggestions): (b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;</p> <p>SE (Comments): As above</p>
(c) the licensee, in particular the following information:	
(1) name, trade name and registered trade mark;	<p>NL (Comments): What is the relevance of the trademark? Refers to trademark under which the</p>

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	(generic) product will be placed on market? Please specify. SE (Comments): Why inclusion of trade mark? Possibly be made sure that this is for reason of clarification/identification
(2) contact details;	SE (Comments): To who? Licensee? Rights holders?
(3) unique identification number in the country where the licensee is established;	
(4) where available, the Economic Operators Registration and Identification (EORI) number;	
(d) the duration for which the Union compulsory licence is granted;	DE (Drafting Suggestions): (d) the reasons for granting the Union compulsory licence, its material and territorial scope and its provisional duration for which the Union compulsory licence is granted;

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	<p>DE (Comments): Cf. comments under Art. 5 para. 1 lit. b; As a result, list should be extended. Clarification that compulsory licence can only specify the provisional duration, since it is linked to the activation of an EU crisis or emergency mode that does not always provide for a concrete period of time.</p> <p>EL (Drafting Suggestions): (d) the duration for which the Union compulsory licence is granted and the expiry date of the license;</p> <p>EL (Comments): It is proposed to add the expiry date of the compulsory license.</p> <p>SE (Comments): Possibly also other limitations, such as number of products to be produced?</p>
	<p>NL (Drafting Suggestions): the number of crisis-relevant products manufactured under the Union</p> <p>NL (Comments): Consider including the max. number of products, to make sure it does not exceed</p>

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	what is necessary to meet the needs of the Union;also taking into account the possibility of several licensees.
(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;	
(f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;	<p>NL (Drafting Suggestions): If available (...)</p> <p>NL (Comments): Consider clarifying, will not always be available.</p>
(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification.	<p>PL (Comments):</p> <p>The meaning of the term: “other specific requirements under Union legislation” remains unclear. The absence of precise regulation in this regard raises the question of whether such measures could potentially encompass the obligation to disclose confidential and commercially sensitive know-how or trade secrets. Clarification is needed</p>
(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.	

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	<p>AT (Comments):</p> <p>The possibility for the Commission to include measures complementing the CL is rather broad and the extent of it remains unclear. In relation to trade secrets, Part II., Section 7. Of the TRIPS agreement (“Protection of Undisclosed Information”) can be cited. Article 39 provides for a detailed regulation of the protection of trade secrets/undisclosed information; in any case, the “measures complementing” the CL should not go beyond this. In a patent, the invention must already be disclosed in such detail that a specialist can reproduce it; the additional disclosure of trade secrets to competitors could be an excessive burden on the rights-holder.</p> <p>DE (Drafting Suggestions):</p> <p>(h) — measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.</p> <p>DE (Comments):</p> <p>Added value of provision remains unclear. For the sake of legal clarity, the paragraph should be deleted, as long as it’s not further specified.</p> <p>DK (Drafting Suggestions):</p> <p>(h) — measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.</p>

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	<p>DK (Comments): Denmark suggests for this to be deleted as it is unclear what it refers to. Right holders should never be forced to disclose trade secrets as part of a compulsory licence.</p> <p>ES (Comments): In article h) it would be appropriate to indicate what exactly is meant by “measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence”. It could be understood that the compulsory license would extend to technical know-how or other commercial secrets. In this regard, it is necessary to remember that in the Directive 2016/943, it is stated that a commercial secret include a “diverse range of information that extends beyond technological knowledge to commercial data such as information on customers and suppliers, business plans, and market research and strategies”. If technical knowledge is understood to be affected by compulsory licenses, it could go against the provisions of Article 31 TRIPS, which provides for compulsory licenses only in the case of patents, not for other modalities such as trade secrets, designs or trademarks.</p> <p>NL (Drafting Suggestions): (h) — measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.</p>

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	<p>NL (Comments):</p> <p>The sole purpose of compulsory licensing is to grant a patent license if necessary, without extending beyond that scope. Any additional requirements to ensure the supply of products should be addressed within their respective domains rather than being incorporated into a proposal solely focused on patents. See also remarks at recitals regarding trade secrets and remarks below at art. 13.</p> <p>PL (Comments):</p> <p>The meaning of the term: “measures complementing the compulsory licence“remains unclear. The absence of precise regulation in this regard raises the question of whether such measures could potentially encompass the obligation to disclose confidential and commercially sensitive know-how or trade secrets. Clarification is needed.</p> <p>PT (Comments):</p> <p>It is not clear which complementing measures are possible. Is there a risk to publish confidential information?</p> <p>SE (Drafting Suggestions):</p> <p>delete</p>

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	<p>SE (Comments):</p> <p>A CL should be granted to provide access to a patent, not as such to force other requirements/duties to the parties. Additional duties, if any, should be addressed in other ways than by being connected to licensing of IP rights If this provision is at all to stay/be further discussed, “complementing measures” needs to be much better defined in a strict and limited way just to ensure aspects relating to the actual patent (excluding forced transfer of trade secrets)</p>
<p>2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).</p>	<p>DE (Drafting Suggestions):</p> <p>2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).</p> <p>DE (Comments):</p> <p>Should be removed to Article 9 (cf. new para. 1a)</p> <p>DK (Comments):</p> <p>Denmark finds the wording to be unclear and suggests for this to be clarified.</p>

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	<p>EL (Drafting Suggestions):</p> <p>2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).</p> <p>EL (Comments):</p> <p>Reservation regarding the determination of the remuneration of the patent holder at a later stage after the granting of the compulsory license. The payment of adequate remuneration is a condition for granting a compulsory license under the TRIPS Agreement (Art. 31(h)). The remuneration should thus be decided when issuing a compulsory license.</p> <p>NL (Comments):</p> <p>Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States. See suggested amendment in Article 7.</p> <p>SE (Comments):</p> <p>Questions remain on reasons for, and possibilities to, determine remuneration after the issuing of a CL.</p>

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Article 9	
Remuneration	<p>IE (Comments):</p> <p>As the proposal extends beyond any singular domain, a 4% remuneration cap may not be appropriate in all circumstances. The exposure of regulatory data and trade secrets may lead to a loss overall greater than the proposed cap of 4% remuneration, which in turn could have a detrimental impact on smaller organisations. Additional conversations on the remuneration cap to be offered are requested.</p>
	<p>PT (Comments):</p> <p>Portuguese IP Law expressly provides for the possibility of an appeal on the decision regarding remuneration. It might be appropriate to include in this proposal the possibility of an appeal as well.</p>
<p>1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.</p>	<p>DE (Drafting Suggestions):</p> <p>1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission in accordance with the rules referred to in Article 7(6) (a) and (b) and by way of an implementing act that shall be adopted in accordance with the examination procedure referred to in Article 24 paragraph 3. The amount shall be and specified in the Union compulsory licence.</p>

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	<p>1a. By way of derogation from Article 5 paragraph 1, point (d) and Article 8 paragraph 1 point (e), the Commission may determine, in accordance with the procedure set out in paragraph 1, the remuneration after the granting of the licence where that determination requires further investigation and consultation. In such a case, the Union compulsory licence shall only be granted if the licensee provides for an adequate security which is determined by the Commission.</p> <p>DE (Comments): Clarification that determination of remuneration takes place by way of an implementing act. Insertion of new para 1a, that contains elements from Art. 8 para. 2. In addition, the licensee shall be obliged to provide an adequate security if the remuneration is determined at a later stage.</p> <p>DK (Comments): DK finds that wording around ‘adequate remuneration’ to be unprecise. Remuneration should be proportionate, so that companies are not discouraged to invest in R&D. How does the Commission envisage to compensate right holders that have been forced to share trade secrets and know-how that cannot be reversed and would have significant financial implications for them?</p>
2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant	

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activities under the Union compulsory licence.	<p>AT (Drafting Suggestions):</p> <p>2. The remuneration shall not exceed be around 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.</p> <p>AT (Comments):</p> <p>A fixed cap of 4% may not always adequately reflect the economic value. Perhaps a benchmark number would provide more flexibility on a case-by-case basis. We would like to ask for further explanations as to why the Commission deems a fixed cap to be necessary.</p> <p>DE (Drafting Suggestions):</p> <p>2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.</p> <p>DE (Comments):</p> <p>Upper-limit for remuneration shall be deleted since it is likely to undermine the conclusion of voluntary agreements.</p> <p>DK (Comments):</p> <p>At the last working group on CL, the Commission elaborated that the 4% was taken from EU legislation on pharmaceuticals. Given that other sectors could be subject to</p>

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	<p>a CL too the figure may not be suitable and should be reconsidered. It also seems disproportionate that the remuneration is lower than the fines (6%). The figure should be at the same level as any fines.</p> <p>EE (Drafting Suggestions):</p> <p>Cap of 4% ought to be <i>changed</i> or the rationale behind it and its connection with the goods/products covered by the regulation <i>better explained</i>. This'd be an important point of clarity for stakeholders.</p> <p>EE (Comments):</p> <p>This number seems to be quite rigid. As per the explanations given, it seems to stem from the pharmaceuticals sector. However, the exact rationale behind it and the connection between it <i>other goods or products covered by this regulation</i> is know exactly known. It is important that the remuneration provisions be juts and fair in the setting of global competitiveness.</p> <p>EL (Comments):</p> <p>The ceiling of 4% of total gross revenue may not be considered adequate remuneration to a right- holder for all the products covered by the Proposed Regulation (e.g. semiconductors).</p> <p>ES (Comments):</p> <p>The consideration of a cap of 4% of the total gross revenue generated by the licensee does not seem reasonable taking into account that this Regulation goes</p>

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	<p>beyond the health and pharmaceutical field from which this figure comes (Regulation 816/ 2006). Therefore, the assessment of remuneration should be based on the type of product to which the compulsory license is being applied to.</p> <p>NL (Drafting Suggestions):</p> <p>———— The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.</p> <p>NL (Comments):</p> <p>4% cap should be removed. Not TRIPS compliant. The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.</p> <p>PL (Comments):</p> <p>It is worth considering the introduction of a mechanism allowing for a more flexible determination of the amount of remuneration in cases where the remuneration set at the specified level proves inadequate. The introduction of an indexation mechanism enabling an increase in remuneration in justified cases may be worthy of consideration.</p> <p>PT (Comments):</p> <p>What was the reasoning behind the level of 4%?</p>

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	<p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): No reason for a specified cap. Adequate remuneration should be based on all relevant factors and take full account of the economic value</p> <p>SI (Comments): The amount of compensation shall be determined with regard to the circumstances of each case, while taking into account the economic value of the compulsory licence.</p>
<p>3. When determining the remuneration, the Commission shall consider the following:</p>	<p>DE (Drafting Suggestions):</p> <p>3. When determining the remuneration, the Commission shall consider the following: (aa) the total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence. (ab) the hypothetical amount that a reasonable rights-holder would demand and a reasonable licensee would grant under a voluntary license agreement.</p>

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	<p>DE (Comments): Insertion of an additional element that is to be considered – in light of deletion of para. 2.</p> <p>DK (Drafting Suggestions): 3. When determining the remuneration, the Commission shall must involve external IP valuation experts, and consider the following:</p> <p>DK (Comments): Denmark wonders whether the Commission has the required knowledge and understanding to carry out a qualified assessment on remuneration? External IP valuation experts may be better placed to make such an assessment.</p> <p>EL (Drafting Suggestions): When determining the remuneration, the Commission shall in particular consider the following:</p> <p>EL (Comments): An indicative enumeration of the factors determining the remuneration is proposed, in compliance with art. 31(h) of the TRIPS Agreement, which provides for the consideration of the circumstances of each case.</p>

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	<p>NL (Drafting Suggestions): When determining the adequate remuneration, the Commission shall consider the following</p> <p>SE (Drafting Suggestions): 3. When determining the adequate remuneration, the Commission shall consider all relevant factors of the authorisation, including the following:</p> <p>SE (Comments): Important not to be perceived as an exhaustive list</p>
(a) the economic value of the relevant activities authorised under the Union compulsory licence.	
(b) whether the rights-holder has received public support to develop the invention.	<p>DE (Drafting Suggestions): (b) whether the rights holder has received public support to develop the invention.</p> <p>DE (Comments): Does not seem to be an adequate criterion and should be deleted.</p>

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	<p>EL (Comments): It is not clear how public support will affect the determination of the remuneration.</p> <p>SE (Comments): Relevance may differ depending on kind of support, and on role of the public body responsible for the support</p>
(c) the degree to which development costs have been amortized by the rights-holder.	<p>DE (Drafting Suggestions): (c) — the degree to which development costs have been amortized by the rights-holder.</p> <p>DE (Comments): Does not seem to be an adequate criterion and should be deleted.</p>
(d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.	<p>DE (Drafting Suggestions): (d) — where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.</p>

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	<p>DE (Comments): Does not seem to be an adequate criterion and should be deleted.</p> <p>DK (Comments): It remains unclear how the Commission intends to factor this in and what exactly it will mean for remuneration of a given product.</p>
<p>4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.</p>	<p>DE (Drafting Suggestions): 4. — If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights holder shall refund the remuneration paid under this article to the licensee.</p> <p>DE (Comments): Cf comment under Art. 2</p> <p>DK (Drafting Suggestions): 4. — If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights holder shall refund the remuneration paid under this article to the licensee.</p>

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	<p>DK (Comments): DK suggests for this subparagraph to be deleted as patent applications should not be included.</p> <p>EL (Comments): Reservation in relation to the compulsory licensing of published patent applications. See relevant comment in Art. 2 par. 1 point (a).</p> <p>NL (Drafting Suggestions): 4. — If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights holder shall refund the remuneration paid under this article to the licensee.</p> <p>NL (Comments): Applications should be out of scope, see remarks above.</p> <p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): Deleted due to exclusion of patent applications</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
Article 10	<p>PL (Comments):</p> <p>There seems to be the need for a precise delineation of the scope of actions to be undertaken by the licensee, as it will facilitate the achievement of the compulsory license's objective and mitigate the risk of disputes over allegations of improper license execution or undue restriction of the rights of the rights-holder. In this regard, particular importance should be accorded to the executive act granting the compulsory licence, wherein it will be imperative to specify the exact number of products that may be manufactured under the licence, principles for designating such products, and the extent of activities permissible under the licence. It is also crucial to establish effective mechanisms for monitoring the execution of the compulsory licence and preventing abuses, including clear principles for judicial oversight of a compulsory licence.</p>
Obligations to be fulfilled by the licensee	<p>IE (Comments):</p> <p>The licensee should explicitly undertake the provision for manufacturing and distributing the product. A provision should be included to encompass this.</p>
1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory license only under the following obligations:	<p>DE (Drafting Suggestions):</p> <p>1. The licensee shall be authorised to exploit the protected invention covered</p>

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	<p>by the Union compulsory license for any of the relevant activities in the affected Member States only under the following obligations:</p> <p>DE (Comments):</p> <p>Alignment with definition in Art. 3 lit. e Cf. our amendment in Art. 5 para. 1 lit. b, according to which territorial scope of Unitary compulsory licence shall be limited on MS affected by underlying crisis or emergency. Instrument can only serve as a last resort mechanism</p>
<p>(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union;</p>	<p>DE (Drafting Suggestions):</p> <p>(a) the number of crisis-relevant products manufactured under the Union compulsory licence does shall not exceed the defined quantities in light of what is necessary to meet the needs of the affected Member States Union;</p> <p>DE (Comments):</p> <p>Cf. amendment under Art. 5 para. 1 (“necessities”). Quantities should be predefined by Commission Cf. comment under para 1</p> <p>NL (Comments):</p> <p>See remark above. Consider including the max. number of products in the CL, to make sure it does not exceed what is necessary to meet the needs of the Union;also</p>

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	<p>taking into account the possibility of several licensees.</p> <p>PT (Comments): How is this number established and by whom?</p>
(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;	
(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.	
(d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;	
(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union	

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compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.	
(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:	<p>ES (Comments):</p> <p>In article 6, we pointed out the need for the advisory body to have among its powers the evaluation of the licensee's capabilities and wherewithal to manufacture the product protected by the patent. In section f) of this article it is necessary to establish the obligation for the licensee to have and demonstrate that capacity to manufacture the invention under the terms established in the compulsory license. This capacity must be previously assessed by the advisory body.</p>
(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;	
(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;	
(3) the distinguishing features of the products under the Union compulsory licence.	
The address of the website shall be communicated to the	

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Commission. The Commission shall communicate the address of the website to the Member States.	
2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:	<p>DE (Drafting Suggestions):</p> <p>2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may shall:</p> <p>DE (Comments):</p> <p>Failure by the licensee to fulfil the obligations must have consequences</p>
(a) terminate the Union compulsory licence in accordance with Article 14(3); or	
(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.	<p>NL (Drafting Suggestions):</p> <p>(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.</p> <p>NL (Comments):</p> <p>See remarks below at article 15-21</p>

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	SE (Drafting Suggestions): delete SE (Comments): Not convinced about reasons to include fines and penalties
3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.	
4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).	DE (Drafting Suggestions): 4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(23).

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	DE (Comments): Editorial
Article 11	
Prohibition of export	
The export of products manufactured under a Union compulsory licence is prohibited.	IE (Comments): In combination with the criteria outlined in Article 5, and Article 22, it is unclear as to the impact this may have on Northern Ireland in a crisis situation as it is considered under the customs territory of the UK but is also aligned to the EU across multiple areas where EU law continues to apply. Clarity on the proposed mechanism of application would be appreciated. IT (Drafting Suggestions): The export of products manufactured under a Union compulsory licence is prohibited, <i>except for products exclusively destined for export under Regulation 816/2006.</i> IT (Comments):

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	We are waiting for comments from customs authority
Article 12	
Customs control	
1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013. ²⁶ .	IT (Comments): We are waiting for comments from customs authority
2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.	DE (Comments): We ask for clarification as to whether the risk-related information from the compulsory license (published by means of an implementing act pursuant to Art. 7 (7) of the draft regulation) should be entered into the European customs risk management system (CRMS2) or into the national risk management system of the customs administration.

²⁶ REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

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	<p>DK (Comments): Denmark finds that the division between the competent authorities and the customs authorities should remain a national matter. It should be the competent authority who is responsible for inserting information on compulsory licensing into the “relevant customs risk management system,” understood as CRMS, as set out in the preamble (30).</p> <p>FI (Comments): FI finds that the relationship between national and EU risk management is somewhat unclear.</p> <p>IT (Comments): We are waiting for comments from customs authority</p>
<p>3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.</p>	<p>DE (Comments): We ask for clarification as to who should be informed about the suspension of the export procedure. It should be defined whether the owner of the goods concerned, the declarant for export or the owner and the declarant should be informed about the suspension? The Commission has already announced that the data will be transmitted by email. In view of the fact that sensitive data could also be transmitted, it is necessary to</p>

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	<p>include a secure (data protection-compliant) and uninterrupted transmission channel in Article 12 of the draft regulation. From our point of view, this is not possible with a standard e-mail. A secure, possibly end-to-end secure connection must be provided.</p> <p>Furthermore, the competent Commission department that is to be informed must be named. For this purpose, an article or paragraph should be created in which the competent Commission department is named.</p> <p>In addition, it should be defined which "relevant" information should be transmitted to the (competent) Commission department in the event of a violation of Article 11 of the draft regulation being suspected. From our point of view, the relevant information should be specified precisely (e.g. commodity code, type of goods, quantity, country of receipt, photos of the goods/invoices/delivery bills, etc.). Since it is assumed that personal information of the consignor/customs declarant or, if applicable, consignee should also be transmitted, it would also be necessary to specify which personal data (e.g. name, address, EORI number, etc.) of which persons (e.g. exporter/consignor, consignee, if applicable, owner) should be transmitted to the (competent) Commission department.</p> <p>The precise identification of the information that needs to be transmitted would also ensure a standardized transmission of information among the Member States. We request that a clear timeframe be specified in the draft regulation for the transmission of information by the customs authority to the COM.</p> <p>DK (Comments):</p> <p>Denmark finds that it should be clarified in what way customs authorities are to inform the Commission when a goods has been suspended.</p>

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	<p>FI (Comments):</p> <p>How is the export prohibition communicated to the COM? epäselvää miten viennin keskeyttämisestä ilmoitetaan komissiolle? Traditionally Finnish Customs authorities are not directly in contact with the COM. Will a new interface be created for that purpose?</p> <p>IT (Drafting Suggestions):</p> <p>3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, <i>with the exception of products necessary in case of a crisis covered by Regulation (EC) No 816/2006</i>, they suspend its exportation they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.</p> <p>IT (Comments):</p> <p>We are waiting for comments from customs authority</p> <p>NL (Comments):</p> <p>Consider clarifying the relationship to the exception of the crisis-critical products covered by Regulation (EC) No 816/2006.</p>

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4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:	IT (Comments): We are waiting for comments from customs authority
(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;	
(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.	
5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.	DK (Comments): Denmark notes that with this wording the Commission is seen to be the competent authority, which is unusual and may give rise to new processes. IT (Drafting Suggestions): 5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11,

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	<p><i>without prejudice to the exceptions listed in Regulation (EC) No 816/2006, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.</i></p> <p>IT (Comments): We are waiting for comments from customs authority</p>
<p>6. Where the release for export of a product has not been authorised:</p>	<p>IE (Comments): This places an additional administrative burden on customs. The customs role should be confined to controlling the goods at export for verification of the licence and that any compliance matters should be dealt with by the national competent authority as relevant.</p> <p>IT (Comments): We are waiting for comments from customs authority</p>
<p>(a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.</p>	<p>DK (Comments): Denmark notes that it should be clarified that the competent authority is responsible for obliging the exporter to take specific actions at their own costs, and what the delimitation is for “specific actions”.</p>

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	<p>NL (Comments):</p> <p>More clarity and safeguards should be provided in order to prevent inappropriate disposal of crisis-relevant products in times of crisis (based on Article 12(6)(b)). Which other actions could be required besides supply to designated MS, what are the timelines, when is it 'appropriate', can the decision of the Commission be challenged? And what if there is a surplus of products after the crisis situation is resolved in the EU, but where non-EU countries can still benefit? Consider clarifying the relationship to the exception of the crisis-critical products covered by Regulation (EC) No 816/2006 in that respect as well.</p>
<p>(b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.</p>	<p>DK (Drafting Suggestions):</p> <p>(b) — in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.</p> <p>DK (Comments):</p> <p>Denmark finds that paragraph 6(b) should not appear in Article 12 on Customs control. It should not be for the customs authorities to decide on either disposal or destruction. The competent authority must make this decision, which with the wording in this article seems to be the Commission.</p>

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	<p>The Customs Agency in Denmark has no authority to dispose or destroy goods. This may also be the case for other customs agencies. For this reason, the paragraph 6(b) should not contain a reference to customs authorities as it is a national matter to determine the division of responsibility and competences for disposal and destruction.</p> <p>NL (Comments): See remark above.</p>
Article 13	<p>DE (Comments): There's no doubt, that the rights-holder has to tolerate the use of his/her invention in case a Union compulsory licence was granted. Therefore, the added value of the provision remains unclear. As long as the provision is not further specified, an infringement of the (vague) principle of "good faith and cooperation" should not be subject to fines or periodic penalty payments (cf. amendments in Art. 15 an 16)</p> <p>NL (Drafting Suggestions): Article 13</p> <p>SE (Drafting Suggestions): delete</p>

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Relations between rights-holder and licensee	NL (Drafting Suggestions): Relations between rights-holder and licensee SE (Drafting Suggestions): delete
1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.	AT (Comments): This bona fide provision is phrased rather broadly and the extent of it remains unclear. It raises the question of what “in good faith” means and what the good faith should refer to. An additional problem is terminology; in the German legal language, there is a difference between “gutgläubig” and “Treu und Glauben”. And while “good faith” is a term that stems from contract law, no contract exists in case of a CL. Instead, the rights-holder must tolerate use by order of the authorities. In addition, Art. 31 TRIPS does not actually explicitly prescribe such a requirement for the rights-holder in the case of compulsory licensing, which raises the question of whether such a provision could result in an excessive obligation on the part of the rights-holder. In view of this, it should be more closely determined what this bona fide provision entails.

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	<p>Previously, the Commission has stated that the transfer of trade secrets may be necessary, even though the scope of application of the regulation does not extend to trade secrets – what legal grounds would the Commission base this on?</p> <p>DK (Drafting Suggestions):</p> <p>1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation. The rights holder shall not be obliged to share trade secrets and know-how.</p> <p>DK (Comments):</p> <p>DK finds that the concept of “good faith” is unclear and can be interpreted in various ways. Reference to a formal legal standard should be made if possible, and it should be explicitly stated that it does not include <i>any</i> obligation to transfer trade secrets or know-how.</p> <p>EL (Comments):</p> <p>The obligation to act in good faith is not a safe ground for the protection of both parties’ rights, especially those of the right- holder.</p> <p>ES (Comments):</p> <p>Good faith is considered necessary in any contractual relationship, not only once the compulsory license has been granted, but throughout the entire process leading to the granting of the license, whether voluntary (through the mandatory negotiation)</p>

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	<p>or compulsory.</p> <p>NL (Drafting Suggestions):</p> <p>1. — The relations between the rights holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.</p> <p>NL (Comments):</p> <p>The application of the "good faith" concept in this context is not necessary. In addition, it lacks clarity, which consequently introduces legal ambiguity. As stated above, the aim of compulsory licensing is solely to grant a patent license if necessary, without extending beyond that scope. Any additional requirements or barriers to ensure the supply of products should be addressed within their respective domains rather than being incorporated into a proposal solely focused on patents.</p> <p>PL (Comments):</p> <p>It may be worth considering clarifying the concept of "acting and cooperating with each other in good faith" between the right-holder and the licensee.</p> <p>PT (Comments):</p> <p>The expression "good-faith" is not sufficiently clear <i>per se</i>, and it may lead to different interpretations.</p>

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	<p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): Principle of good faith creates uncertainty and risks moving the focus on CL as a way to eliminate possible barriers created by inaccessibility to patents to CL as a duty to solve different aims on a general level</p> <p>SI (Comments): It should be stated that the term “good faith” does not include obligation to transfer trade secrets</p>
<p>2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.</p>	<p>AT (Comments): Same comment as Art. 13 para. 1; “make their best efforts” is very strong language.</p> <p>DK (Drafting Suggestions): 2. In compliance with the good faith obligation, the rights holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.</p>

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	<p>DK (Comments): It seems unclear what is meant by “best effort”, which could be potentially very burdensome, especially since the objective of the CL may not be entirely clear to the parties. DK suggests for the subparagraph to be deleted. Alternatively, “their best effort” should be rephrased as “reasonable efforts”.</p> <p>NL (Drafting Suggestions): 2. — In compliance with the good faith obligation, the rights holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.</p> <p>PT (Comments): The expression “best efforts” is not clear.</p> <p>SE (Drafting Suggestions): delete</p>
Article 14	
Review and termination of the Union compulsory licence	

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<p>1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.</p>	<p>DE (Drafting Suggestions):</p> <p>1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act in accordance with the examination procedure referred to in Article 24 paragraph 3. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights holders covered by the compulsory licence.</p> <p>DE (Comments):</p> <p>Clarification which procedure shall apply in comitology. Deletion of last phrase in order to clarify that rights as well as rights holders have to be identified <u>before</u> granting a compulsory licence.</p> <p>DK (Drafting Suggestions):</p> <p>1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act following the examination procedure. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence. Trade secrets and know-how must be excluded.</p>

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	<p>DK (Comments): As per previous comments, Denmark has strong reservations about granting the Commission exclusive competence on the issuance of CLs. The examination procedure should apply as a bare minimum.</p> <p>EE (Drafting Suggestions): [See right column]</p> <p>EE (Comments): The Commissions rights in reviewing or modifying the compulsory rights are worded in a rather open-ended fashion. A member state proposed in the 07/02 WP meeting that perhaps the Advisory Body should be consulted in this case (i.e. not they <i>may</i> be consulted in this case but that the <i>should be consulted with</i> in this case). This would give MS more say in such a review or modification. Also, in the 07/02 WP meeting, it was noted in conjunction with Article 14 by COM that when essential components of a CL are modified, the Advisory Body <i>must</i> be consulted with. Could this be <i>expressis verbis</i> noted somewhere in Article 14?</p>
<p>2. Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between</p>	<p>AT (Comments): The possibility for the Commission to decide upon “additional measures complementing the Union compulsory license” is too broad and remains unclear.</p>

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the rights-holder and the licensee.	<p>See also comment under Art. 8 para. 1 (h).</p> <p>DE (Drafting Suggestions):</p> <p>2. Where necessary, the Commission shall decide upon reasoned request by the rights holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights holder and the licensee.</p> <p>DE (Comments):</p> <p>Added value of provision remains unclear. For the sake of legal clarity, the paragraph should be deleted as long as it's not further specified.</p> <p>DK (Drafting Suggestions):</p> <p>2. Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee. This shall exclude the sharing of trade secrets or know-how.</p> <p>DK (Comments):</p> <p>DK would like the Commission to elaborate on the scope of 'additional measures'. This is again highly unspecific and broad terminology, which could be interpreted in various ways.</p>

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	<p>It is important that this is clearly defined and does not lead to right holders having to release know-how or trade secrets.</p> <p>EE (Drafting Suggestions): [See right column]</p> <p>EE (Comments): Same comment as above. The Commissions right to adopt additional measures on its own initiative is worded in a rather open-ended fashion. This should be made more clearer or the wording should read that in such a case the Commission <i>will consult with</i> the Advisory Body.</p> <p>ES (Comments): It would be necessary to clarify the scope of the additional measures that the Commission can take in order to complement the Union compulsory license to ensure that it achieves its objective (Article 14.2). Otherwise, legal uncertainty may arise regarding the limits of the Commission.</p> <p>NL (Drafting Suggestions): 2. — Where necessary, the Commission shall decide upon reasoned request by the rights holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights holder and the licensee.</p>

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<p>Commission proposal 2023/0129 (COD)</p>	<p>Drafting Suggestions and Comments</p>
	<p>NL (Comments): See remarks above. The proposal appears to grant significant discretionary powers to the Commission, allowing it to decide on additional measures to complement the Union compulsory license. However, as explained above, for the purposes of granting compulsory licenses ‘additional measures’ are not necessary. Furthermore, the concept of "additional measures complementing" is ambiguous and susceptible to interpretation. This ambiguity further complicates the ability to anticipate and regulate the scope of the Commission's authority in this matter.</p> <p>PT (Comments): It is not clear which additional measures may complement the Union compulsory license.</p> <p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): Not convinced about inclusion of vague “additional measures”</p>
<p>3. A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to</p>	

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<p>recur or where the licensee fails to comply with the obligations laid down in this Regulation.</p>	<p>AT (Drafting Suggestions):</p> <p>3. A Union compulsory licence mayshall be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.</p> <p>AT (Comments):</p> <p>A CL can never be in force longer than the duration of a crisis mode, see Art. 5 (1) b. How is Art. 5(1)b in conjunction with Art. 14(3) to be understood; does the compulsory license automatically expire if the crisis mode ceases to apply or does the EC always have to adopt an implementing act in accordance with Art. 14 (3)? Or why was only the possibility of revocation chosen here? In our view, the circumstances described require a withdrawal.</p> <p>DE (Drafting Suggestions):</p> <p>3. In accordance with Article 5 paragraph 1 point b, the Union compulsory licence shall automatically expire if the underlying crisis or emergency mode ceases to exist. The rights-holder and the licensee shall be notified of such expiry by the Commission without undue delay.</p> <p>3a. A Union compulsory licence may be terminated by the Commission by means of an implementing act in accordance with the examination procedure referred to in Article 24 paragraph 3 where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the</p>

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	<p>obligations laid down in this Regulation.</p> <p>DE (Comments):</p> <p>Clarification that duration of Union compulsory licence is strictly limited to duration of underlying crisis or emergency mode. As a consequence, there's no need for an additional implementing act. Rather, the Union compulsory licence should automatically expire.</p> <p>The Commission should only have discretion to terminate a Union compulsory licence for reasons, that are not linked to the duration of the underlying crisis or emergency mode. Against this background, the meaning of "circumstances" remains unclear and should be deleted to avoid confusion.</p> <p>Clarification which procedure shall apply in comitology.</p> <p>NL (Drafting Suggestions):</p> <p>3. A Union compulsory licence may will, subject to adequate protection of the legitimate interests of the persons so authorised, be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation</p> <p>NL (Comments):</p> <p>TRIPS 31(g) requires that authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are</p>

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	unlikely to recur.
<p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.</p>	<p>AT (Drafting Suggestions):</p> <p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may shall consult the advisory body referred to in Article 6.</p> <p>AT (Comments):</p> <p>In Austria's view, the Advisory Body should always be consulted.</p> <p>DE (Drafting Suggestions):</p> <p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence pursuant to paragraph 1 or 3a, it may shall consult the advisory body referred to in Article 6. Article 7 paragraph 6 and 8 shall apply accordingly.</p> <p>DE (Comments):</p> <p>Cf deletion of "additional measures" in Art. 8 and 14 Prior consultation of advisory body should be mandatory Please add reference to cover meaning of para. 6</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DK (Drafting Suggestions):</p> <p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it must may consult the advisory body referred to in Article 6.</p> <p>DK (Comments):</p> <p>Denmark finds that the advisory body must be consulted.</p> <p>EE (Drafting Suggestions):</p> <p>[See right column]</p> <p>EE (Comments):</p> <p>As per above, perhaps this should read “it <i>consults with</i>” the advisory body instead of “<i>may consult</i>”. And also possibly include both paragraphs 1 <i>and</i> 2.</p> <p>ES (Comments):</p> <p>In the event that the compulsory license has to be modified, it needs additional measures or has to be terminated (section 4), the participation of the advisory body must be mandatory and its opinion, based on criteria technical, should be binding.</p>

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	<p>NL (Drafting Suggestions):</p> <p>4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.</p> <p>NL (Comments):</p> <p>Additional measures not necessary, see above.</p> <p>PT (Comments):</p> <p>Why is the advisory body consultation optional and not mandatory?</p>
<p>5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee.</p>	<p>DE (Drafting Suggestions):</p> <p>5. When terminating the a Union compulsory licence ceases to exist, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and the licensee and at the expense of the licensee.</p> <p>DE (Comments):</p> <p>Amendments in order to cover termination of Union compulsory licence due to</p>

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	<p>“deactivation” of underlying crisis or emergency mode (cf. ne para. 3) Consultation should include the licensee</p> <p>PT (Comments): The expression “within a reasonable period of time” is not clear. The time limit for a rights-holder to adopt measures should be specified.</p>
<p>6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).</p>	<p>DE (Drafting Suggestions): 6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).</p> <p>DE (Comments): In light of our amendments in para. 1-3 and the insertion in para. 4, the provision has become irrelevant.</p> <p>NL (Comments): Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States. See suggested amendment in Article 7.</p>
Article 15	

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	<p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): Not convinced about reasons to include fines and penalties, so this and following articles should be deleted</p>
Fines	<p>ES (Comments): Four articles of the Regulation refer to fines, which will certainly have to be applied. It should be borne in mind that the Regulation does not provide for an exhaustive analysis of the licensee's capacities prior to the granting of the licence. Not only the industrial capacities, but in the case of pharmaceuticals, the capacity to obtain the corresponding health marketing authorisation from the health agencies. The regulation is based on the premise, which has been proven wrong in the pandemic, that once the patent licence has been obtained, anyone can manufacture the product. Without requiring a rigorous examination of the licensee's capabilities, bad practices are encouraged and the proliferation of many licensees who are ultimately unable to manufacture the product is possible.</p> <p>PL (Comments): It seems necessary to introduce clear criteria for imposing fines and monetary</p>

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	<p>penalties; currently, these criteria are not clear, for example, in the case of the possibility of imposing a fine when parties do not adhere to the principle of good faith, it is difficult to predict what actions may be considered as violating the principle of good faith and consequently lead to the imposition of a fine.</p> <p>SE (Drafting Suggestions): delete</p> <p>SE (Comments): Not convinced about reasons to include fines and penalties</p>
<p>1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:</p>	<p>DK (Drafting Suggestions):</p> <p>1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of the their respective total turnover for the product that is subject to a compulsory licence in the preceding business year where, intentionally or negligently:</p> <p>DK (Comments):</p> <p>DK finds it inconsistent that fines can be issued in relation to EU CL, while this is not the case for a CL related to the export to third countries with public health issues. The conditions should be the same, so the fines should either be removed in this regulation or added to 816/2006.</p>

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	<p>DK would like the Commission to elaborate on the threshold of 6%. It seems arbitrary and disproportionate.</p> <p>Companies subject to a compulsory license can be big multinational companies with a broad portfolio, where only small parts would be subject to the crisis at hand.</p> <p>What are the reasons for basing fines on total turnover? Would it not be more relevant to look at CL-product turnover, profits or other?</p> <p>The provision, as it is, may keep large companies to venture into niche or low profit markets due to the risk of receiving excessive fines.</p> <p>EL (Comments):</p> <p>It is not clear how a 6% of annual turnover is justified. Furthermore, apart from the percentage, the crisis- relevant products of the compulsory license may correspond only to a percentage of the total turnover of a licensee or rights holder. In such a situation, how would a fine be calculated?</p> <p>ES (Comments):</p> <p>It should be indicated whether the fines will be imposed by the same DG or if it will vary depending on the nature of the crisis.</p> <p>NL (Drafting Suggestions):</p> <p>1. The Commission may by decision impose on the licensee or the rights holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:</p>

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	<p>NL (Comments):</p> <p>The imposition of fines for compulsory licensing is redundant. If a licensee fails to fulfil its obligations, the license can be terminated outright, rendering additional penalties unnecessary. There is no need for extra pressure on the rights holder, as the Commission has already authorised the use of its intellectual property. As previously discussed, no additional measures or adherence to concepts like 'good faith' are required in this context.</p> <p>Regulation 816/2006 also lacks any provisions for fines, as do the national legislations of many Member States. Unless further convincing justification is provided, this article should be removed.</p> <p>If it would nevertheless be included, fine needs to be set much lower. Fine in proposal is arbitrary and very disproportionate. Right holder on one hand only entitled to limited <i>adequate remuneration</i>, on other hand risks fine of 6% of total turnover (in addition to limitation of its IP rights). Comparison to DSA not convincing. Totally different situation.</p> <p>SE (Drafting Suggestions):</p> <p>delete</p> <p>SE (Comments):</p> <p>Not convinced about reasons to include fines and penalties</p>

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<p>(a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);</p>	<p>DE (Drafting Suggestions): (a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1) or the prohibition pursuant to Article 11;</p> <p>DE (Comments): Violation of Art. 11 should also be subject to fines or periodic penalty payments</p> <p>NL (Drafting Suggestions): (a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);</p> <p>PT (Comments): The requirements to impose fines should be defined in a more clear and precise manner, given that, for instance, it is difficult to foreseen which actions may be considered to having violated the principle of good-faith. This expression – good-faith - is not sufficiently clear <i>per se</i>, and it may lead to different interpretations.</p> <p>SE (Drafting Suggestions): delete</p>

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<p>(b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or</p>	<p>AT (Comments): Depending on what can be included under Art. 13, it could be very problematic for the rights holder to face a fine if they do not comply with the obligations under Art. 13. Assuming that the transfer of trade secrets or know-how could also be covered by it, it would be all the more worrying if such a high fine could be imposed. A clarification of Art. 13 is absolutely crucial, in the interest of legal certainty.</p> <p>DE (Drafting Suggestions): (b) — the rights holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or</p> <p>DE (Comments): As long as the concept of “good faith” remains that vague and is not further specified, an infringement of such principle should not be subject to fines or periodic penalty payments. In light of the deletion it’s up for further discussions if there’s a necessity to include a specific paragraph referring to the rights holder and its obligation to tolerate the use of the protected invention</p> <p>DK (Drafting Suggestions): (b) — the rights holder or the licensee fail to comply with the principle of good</p>

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	<p>faith and cooperation referred to in Article 13; or</p> <p>DK (Comments): Denmark suggests for this subparagraph to be deleted. It seems unreasonable that companies potentially face huge fines for not complying with a vaguely defined principle of good faith.</p> <p>EL (Comments): How will such non-compliance be assessed?</p> <p>NL (Drafting Suggestions): (b) — the rights holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or</p> <p>SE (Drafting Suggestions): delete</p>
<p>(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.</p>	<p>AT (Comments): Same comment as under Art. 8(1)(h) and 14(2); it is not sufficiently clear what (additional) measures complementing the CL are.</p>

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	<p>DE (Drafting Suggestions): (c) — the rights holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.</p> <p>DE (Comments): Cf. deletion of “additional measures” in Art. 8 and Art. 14</p> <p>DK (Drafting Suggestions): (c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act. This excludes sharing of trade secrets and know-how.</p> <p>DK (Comments): As per previous comment, Denmark finds that it needs to be specified what ‘additional measures’ refer to. Trade secrets and know-how must be protected.</p> <p>NL (Drafting Suggestions): (c) — the rights holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory</p>

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	<p>licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.</p> <p>SE (Drafting Suggestions): delete</p>
<p>2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.</p>	<p>DE (Drafting Suggestions):</p> <p>2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement. When determining the amount of the fine, the Commission shall take into consideration, where relevant, the following circumstances:</p> <ul style="list-style-type: none"> (a) nature, gravity and duration of the infringement; (b) the intentional or negligent character of the infringement; (c) any action taken to mitigate the damage; (d) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement. <p>DE (Comments): Criteria for fixing the amount should be more concrete</p>

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	<p>DK (Drafting Suggestions):</p> <p>2. In fixing the amount of the fine, the Commission shall consult the advisory body. regard shall be had Attention shall be given to the gravity, to the recurrence of the infringement and to the duration of the infringement.</p> <p>DK (Comments):</p> <p>Denmark suggests for the advisory body to be consulted as it is doubtful whether the Commission will have the right knowledge and understanding to fix the amount.</p> <p>NL (Drafting Suggestions):</p> <p>2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.</p> <p>SE (Drafting Suggestions):</p> <p>delete</p>
Article 16	<p>NL (Drafting Suggestions):</p> <p>Article 16</p>

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	SE (Drafting Suggestions): Delete
Periodic penalty payments	NL (Drafting Suggestions): Periodic penalty payments PL (Comments): It seems necessary to introduce clear criteria for imposing fines and monetary penalties. PT (Comments): The requirements to impose periodic penalty payments should be established in a more clear and precise manner SE (Drafting Suggestions): Delete
1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>preceding business year per day and calculated from the date appointed by the decision, in order to compel:</p>	<p>AT (Comments): Same comments as under Art. 15</p> <p>DK (Comments): DK would like the Commission to elaborate on the threshold of 5% of daily turnover – what considerations have been made in relation to proportionality? It appears arbitrary and disproportionate.</p> <p>EL (Comments): The criteria for setting a 5% of average daily turnover, as a basis for the calculation of penalties, are not clear.</p> <p>IE (Comments): Clarity should be provided as to if this pertains to gross or net revenue.</p> <p>NL (Drafting Suggestions): 1. — The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel:</p> <p>NL</p>

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>(Comments):</p> <p>See remark at Article 15. The imposition of fines is neither necessary nor desirable in the context of compulsory licensing.</p> <p>SE</p> <p>(Drafting Suggestions):</p> <p>Delete</p>
<p>(a) the licensee to put an end to an infringement of its obligations under Article 10(1);</p>	<p>DE</p> <p>(Drafting Suggestions):</p> <p>(a) the licensee to put an end to an infringement of its obligations under Article 9 (1) or Article 10(1) or an infringement of the prohibition pursuant to Article 11;</p> <p>DE</p> <p>(Comments):</p> <p>Not clear, why Art. 9 shouldn't be mentioned under Art. 16. Violation of Art. 11 should also be subject to fines or periodic penalty payments</p> <p>NL</p> <p>(Drafting Suggestions):</p> <p>(a) the licensee to put an end to an infringement of its obligations under Article 10(1);</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): delete
(b) the licensee and the rights-holder to put an end to the infringement of Article 13; or	DE (Drafting Suggestions): (b) the licensee and the rights holder to put an end to the infringement of Article 13; or DE (Comments): As long as the concept of “good faith” remains that vague and is not further specified, an infringement of such principle should not be subject to fines or periodic penalty payments. In light of the deletion it’s up for further discussions if there’s a necessity to include a specific paragraph referring to the rights holder and its obligation to tolerate the use of the protected invention NL (Drafting Suggestions): (b) the licensee and the rights holder to put an end to the infringement of Article 13; or

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): Delete
(c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.	DE (Drafting Suggestions): (c) — the rights holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act. DE (Comments): Cf. deletion of “additional measures” in Art. 8 and Art. 14 NL (Drafting Suggestions): (c) — the rights holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act. SE (Drafting Suggestions): delete

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.</p>	<p>DE (Drafting Suggestions):</p> <p>2. Article 15 paragraph 2 shall be applied accordingly. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.</p> <p>DE (Comments):</p> <p>Currently, Art. 16 does not provide for criteria for fixing the amount of the periodic penalty payments</p> <p>NL (Drafting Suggestions):</p> <p>2. — Where the licensee or the rights holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
Article 17	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	NL (Drafting Suggestions): Article 17 NL (Comments): In light of previous comments, articles 17 – 21 should also be removed. SE (Drafting Suggestions): Delete
Limitation period for the imposition of fines and periodic penalty payments	NL (Drafting Suggestions): Limitation period for the imposition of fines and periodic penalty payments SE (Drafting Suggestions): Delete
1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.	DK (Comments): Denmark finds the wording in this article to be very unclear. It is unclear when the various periods begin. Why is it set at five years? Denmark suggests for the

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>language in this article to be tightened up.</p> <p>NL (Drafting Suggestions):</p> <p>1. — The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
<p>2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.</p>	<p>NL (Drafting Suggestions):</p> <p>2. — Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.</p> <p>SE (Drafting Suggestions):</p> <p>delete</p>
<p>3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the</p>	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.</p>	<p>NL (Drafting Suggestions): 3. — Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.</p> <p>SE (Drafting Suggestions): Delete</p>
<p>4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the limitation period has been suspended pursuant to paragraph 5.</p>	<p>NL (Drafting Suggestions): 4. — Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the limitation period has been suspended pursuant to paragraph 5.</p> <p>SE (Drafting Suggestions): Delete</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.</p>	<p>NL (Drafting Suggestions): 5. — The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.</p> <p>SE (Drafting Suggestions): Delete</p>
<p>Article 18</p>	<p>NL (Drafting Suggestions): Article 18</p> <p>SE (Drafting Suggestions): Delete</p>
<p>Limitation period for the enforcement of fines and periodic penalty payments</p>	<p>NL (Drafting Suggestions): Limitation period for the enforcement of fines and periodic penalty payments</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): delete
1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years.	DK (Comments): As per previous comment, Denmark finds the wording in this article to be very unclear, especially the time periods and suggests for the language to be tightened up. NL (Drafting Suggestions): 1. — The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years. SE (Drafting Suggestions): delete
2. Time shall begin to run on the day on which the decision becomes final.	NL (Drafting Suggestions): 2. — Time shall begin to run on the day on which the decision becomes final. SE (Drafting Suggestions):

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	Delete
3. The limitation period for the enforcement of penalties shall be interrupted:	NL (Drafting Suggestions): 3. — The limitation period for the enforcement of penalties shall be interrupted: SE (Drafting Suggestions): Delete
(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;	NL (Drafting Suggestions): (a) — by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation; SE (Drafting Suggestions): Delete
(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.	NL (Drafting Suggestions): (b) — by any action of the Commission, or of a Member State acting at the

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>request of the Commission, designed to enforce payment of the fine or periodic penalty payment.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
<p>4. Each interruption shall start time running afresh.</p>	<p>NL (Drafting Suggestions):</p> <p>4. — Each interruption shall start time running afresh.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
<p>5. The limitation period for the enforcement of penalties shall be suspended for so long as:</p>	<p>NL (Drafting Suggestions):</p> <p>5. — The limitation period for the enforcement of penalties shall be suspended for so long as:</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
(a) time to pay is allowed;	NL (Drafting Suggestions): (a) — time to pay is allowed; SE (Drafting Suggestions): Delete
(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.	NL (Drafting Suggestions): (b) — enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court. SE (Drafting Suggestions): delete
Article 19	NL (Drafting Suggestions): Article 19

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): Delete
Right to be heard and access to the file	NL (Drafting Suggestions): Right to be heard and access to the file SE (Drafting Suggestions): Delete
1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.	AT (Comments): The provision under Art. 19 on the Right to be heard and access to the file should not merely refer to EC decisions under Art. 15 and 16, but also the procedure to grant a CL. The infringement of rights that a granting of a CL can mean is significant. For this reason, it is all the more important to uphold, to the largest extent possible, the procedural rights of the parties concerned. ES (Comments): This article should guarantee the procedural rights of the owner. Not only must he be heard, but he should be able to be a full party to the procedure and his arguments

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>should be answered through a reasoned resolution, giving him the possibility of appealing the resolutions he considers appropriate.</p> <p>NL (Drafting Suggestions):</p> <p>1. — Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights holder the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.</p> <p>PT (Comments):</p> <p>The rights-holder should not only be given the opportunity to being heard, but also should be kept up to date on all proceedings.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
<p>2. The licensee or the rights-holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days.</p>	<p>DK (Drafting Suggestions):</p> <p>2. The licensee or the rights-holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days, starting on the day on which the licensee or rights holder was contacted by the Commission about the infringement.</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DK (Comments): Denmark suggests for the wording to be clearer on when this period begins.</p> <p>NL (Drafting Suggestions): 2. — The licensee or the rights holder may submit its observations on the alleged infringement within a reasonable period set by the Commission, which may not be less than 14 days.</p> <p>SE (Drafting Suggestions): Delete</p>
<p>3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.</p>	<p>NL (Drafting Suggestions): 3. — The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.</p> <p>SE (Drafting Suggestions): Delete</p>
<p>4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to</p>	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
<p>have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.</p>	<p>DK (Drafting Suggestions):</p> <p>4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement. Trade secrets and know-how shall not be disclosed.</p> <p>DK (Comments):</p> <p>Denmark suggests to add that trade secrets and know-how shall not be disclosed.</p> <p>NL (Drafting Suggestions):</p> <p>4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights holder or other person concerned in the protection of</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.</p> <p>SE (Drafting Suggestions): delete</p>
<p>5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.</p>	<p>NL (Drafting Suggestions):</p> <p>5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.</p> <p>SE (Drafting Suggestions): delete</p>
Article 20	

From: AT, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, NL, PL, PT, SE, SI

Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	NL (Drafting Suggestions): Article 20 SE (Drafting Suggestions): Delete
Publication of decisions	NL (Drafting Suggestions): Publication of decisions SE (Drafting Suggestions): Delete
1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.	DK (Drafting Suggestions): 1. The Commission shall contact the licensee or rights holder individually to inform about a decision on a fine or periodic penalty payment. Once relevant parties have been contacted, it shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>DK (Comments): Denmark finds that the right holder or licensee must be contacted individually about the fines before it is published.</p> <p>IE (Comments): Clarity is sought as to where this will be published,</p> <p>NL (Drafting Suggestions): 1. — The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.</p> <p>SE (Drafting Suggestions): delete</p>
<p>2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.</p>	<p>NL (Drafting Suggestions): 2. — The publication shall have regard to the rights and legitimate interests of the licensee, the rights holder or any third parties in the protection of their confidential information.</p>

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	SE (Drafting Suggestions): Delete
Article 21	DE (Comments): <div style="background-color: black; height: 15px; width: 100%;"></div> <p>that Art. 263 TFEU does provide for a sufficient individual judicial review in this context, inter alia regarding the validity of the implementing act granting the Union compulsory licence. Nevertheless, we think it is unfortunate that the proposal contains several Articles dealing explicitly with judicial review – limited to fines and periodic penalty payments. In our view, however, a reference to Art. 263 TFEU within the legal text would seem rather unusual. For the sake of legal clarity, we would be open for a clarification in the recitals – in light of the potential significant impact of the initiative on the Right to property (Art. 17 of the EU Charter of fundamental rights). In addition, a clarification regarding interim measures might be useful.</p> NL (Drafting Suggestions): Article 21
	SE (Drafting Suggestions): Delete

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
Review by the Court of Justice of the European Union	NL (Drafting Suggestions): Review by the Court of Justice of the European Union SE (Drafting Suggestions): Delete
In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	DK (Drafting Suggestions): In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions made by the Commission on a compulsory licence , by which the Commission has imposed fines or periodic penalty payments. It may cancel a compulsory licence , reduce or increase the fine or periodic penalty payment imposed. DK (Comments): Denmark suggest for wording to be included on the possibility for judicial reviews on CLs. In the recitals this is mentioned, but not included in this article. EL (Drafting Suggestions): 1. In accordance with Article 263 TFEU, decisions by which the Commission has

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	<p>granted a compulsory license or has determined the remuneration of a rights holder shall be subject to an action for annulment before the Court of Justice of the European Union.</p> <p>2. In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.</p> <p>EL</p> <p>(Comments):</p> <p>The article provides for unlimited jurisdiction of the Court of Justice of the EU to review decisions of the Commission imposing fines (Art. 17) or periodic penalty payments (Art.18). However, according to Art. 31 (i) and (j) of the TRIPS Agreement, it is also “<i>the legal validity of any decision relating to authorization of such use</i>” (<i>i.e.</i> without the authorization of the right holder) as well as “<i>any decision relating to the remuneration provided in respect of such use</i>”, which is subject to judicial review.</p> <p>In this context, this article should explicitly provide for actions for annulment within the meaning of Article 263 TFEU before the Court of Justice of the EU against (a) the legal validity of the decisions issued by the European Commission granting a compulsory license and (b) any decision on the remuneration granted pursuant to article 8(1) (e) of the proposal.</p> <p>For reasons of legal certainty, the text should explicitly provide for the right as well as the legal means by which the right-holder or the licensee may challenge such decisions. In view of the above, an amendment is proposed, to align the provision with the TRIPS Agreement.</p>

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	<p>ES (Comments):</p> <p>Recital 31 states that “The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review”. Recital 35, relating to fines, states that “All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU”. Despite these indications, throughout the Regulation, the Court of Justice only appears in this article relating to fines imposed by the Commission. It seems appropriate to modify the article in order to clarify that the reasoned decisions that have determined the granting of the license may be subject to appeal so as not to deprive the holder of this tool during the procedure.</p> <p>NL (Drafting Suggestions):</p> <p>In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.</p> <p>SE (Drafting Suggestions):</p> <p>Delete</p>
Article 22	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	SE (Drafting Suggestions): Delete
Reporting on national compulsory licences	DE (Comments): As a follow-up to our discussion within the working group, we would suggest a clarification within the recitals that this Regulation leaves the national compulsory licensing systems untouched.
When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following:	DE (Drafting Suggestions): When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency concerning the scope of this Regulation , the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following: DE (Comments): Clarification that obligation to report on national compulsory licences shall not go beyond of what might have a potential effect on this Regulation. In particular, the area of national security would be out of scope.

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	<p>ES (Comments): If a Member State has granted or is planning to grant a Compulsory License on the same patents. Would this be proportional to the patent holder? If there's both a national and an EU Compulsory License this procedure loses its exceptional nature.</p> <p>IE (Comments): It is unclear as to the mechanisms necessary to inform the Commission of the grant of a national compulsory license. Clarity as to how that is proposed to be undertaken is requested.</p> <p>PT (Comments): What is the time limit for a Member-State to inform the COM on the granting of a national compulsory licence? What are the consequences if a Member-State fails to notify those national compulsory licences? This Article mentions that the notification shall be addressed to the COM, however it seems the competence for gathering that information belongs to the advisory body, as established in Article 6. It seems to be a contradiction.</p> <p>SE (Comments): Not convinced about general need for this, investigation about relevant national CL should be task for advisory body and given the small amount of relevant CL, no need for general register on existing CLs</p>

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
(a) the purpose of the national compulsory licence and its legal basis in national law;	
(b) the name and address of the licensee;	
(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;	
(d) the remuneration to be paid to the rights-holder;	<p>IE (Comments):</p> <p>In IE, the Controller of Intellectual Property determines among other aspects, the level of remuneration subject to certain terms for a national compulsory licence. If a rate of remuneration was agreed prior to a union licence coming into effect, and exceeded the proposed 4% cap, which would take precedence? If any terms of a pre established national licence are more favourable, which would take precedence if a union wide licence for the same product was required?</p>
(e) the quantity of products to be supplied under the licence;	
(f) the duration of the licence.	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
Article 23	<p>DE (Drafting Suggestions):</p> <p>Article 23</p> <p>DE (Comments):</p> <p>Art. 23 should be deleted. Amendments to Regulation (EC) No. 816/2006 require a prior assessment to provide for factual based discussions (cf. also Art. 19 of Regulation (EC) No. 816/2006, according to which the Commission shall present a review report three years after it's entry into force – such review has not beend conducted so far).</p>
Amendments to Regulation (EC) No 816/2006	<p>DE (Drafting Suggestions):</p> <p>Amendments to Regulation (EC) No 816/2006</p> <p>DK (Comments):</p> <p>As per previous comment, DK suggest for the conditions for an EU CL and CL for exports should be the same, so the fines should either be removed in this regulation or added to 816/2006.</p>

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Regulation (EC) No 816/2006 is amended as follows:	
(a) The following Article 18a is inserted:	
“Article 18a	
Union compulsory licence	
1. The Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.	<p>ES (Comments):</p> <p>Will Member States be able to continue granting this type of compulsory licenses when manufacturing and sales activities for export are not carried out in different Member States? Is there any plan to avoid duplication of regimes in this case?</p>
2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.	<p>DK (Drafting Suggestions):</p> <p>2. Any person or legal entity with commercial interests person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.</p>

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	<p>DK (Comments): As per previous comment, Denmark suggest for wording to be added around ‘a legal entity with commercial interests’ or something along those lines.</p> <p>NL (Comments): Question, is it possible to submit one (1) application for both an EU compulsory license and an export license under Regulation 816/2006?</p>
3. The compulsory licence granted in accordance with paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.	
4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.	
5. The Commission is empowered to adopt implementing acts in order to:	
(a) grant a compulsory licence;	

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(b) reject the application for a compulsory licence;	DK (Comments): Denmark wonders whether it is necessary to adopt an implementing act if an application is being rejected?
(c) amend or terminate the compulsory licence.	
Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).”	AT (Drafting Suggestions): Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 18b (2 3). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the advisory procedure referred to in Article 18b (3).” NL (Drafting Suggestions): Those implementing acts shall be adopted in accordance with the advisory procedure examination procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).”

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	NL (Comments): Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States.
(b) The following Article 18b is inserted:	
“Article 18b Committee Procedure	
1. The Commission shall be assisted by a committee (‘the Compulsory Licensing Committee’). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	NL (Drafting Suggestions): 2. Where reference is made to this paragraph, Article 5 4 of Regulation (EU) No 182/2011 shall apply.

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
	NL (Comments): Subject to further justification of the choice for the advisory procedure, the examination procedure should be followed, as it provides better guarantees for the involvement of the Member States.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.”	AT (Drafting Suggestions): 32. Where reference is made to this paragraph, Article 54 of Regulation (EU) No 182/2011 shall apply. 3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.”
Article 24	
Committee Procedure	DK (Comments): DK finds that the examination produce should be applied in all situations that require an implementing act. Member States should have a say in the process.
1. The Commission shall be assisted by a committee. That	

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Commission proposal 2023/0129 (COD)	Drafting Suggestions and Comments
committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	<p>DE (Drafting Suggestions):</p> <p>3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. In accordance with Article 5 paragraph 4 of Regulation (EU) No 182/2011, a draft implementing act may not be adopted where no opinion is delivered.</p> <p>DE (Comments):</p> <p>Insertion of “no-opinion” clause in order to ensure role of MS.</p>
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.	
Article 25	

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Evaluation	
The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.	
Article 26	
Entry into force	
This Regulation shall enter into force on the day following that of its publication in the <i>Official Journal of the European Union</i> .	<p>NL (Comments):</p> <p>As set out in recital 41, since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred. We ask, consideration for a timeframe that allows for a careful legislative process, also on the national level.</p>
This Regulation shall be binding in its entirety and directly applicable in all Member States.	

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Done at Brussels,	
For the European Parliament For the Council	
The President The President	
	End