



**2023/0129(COD)**

14.11.2023

# **AMENDMENTS**

## **52 - 300**

**Draft report**

**Adrián Vázquez Lázara**

(PE753.706v01-00)

Compulsory licensing for crisis management and amending Regulation (EC)  
816/2006

Proposal for a regulation

(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))



**Amendment 52**  
**Heidi Hautala**

**Proposal for a regulation**  
**Citation 1**

*Text proposed by the Commission*

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,

*Amendment*

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, **168** and 207 thereof,

Or. en

*Justification*

*Art. 168 TFEU on Public Health policy at Union and Member States levels.*

**Amendment 53**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

(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

*Amendment*

(1) Crises require the setting-up of exceptional, swift and adequate measures able to provide means to address the consequences of the crisis ***without unnecessarily and disproportionately affecting citizens or businesses' rights.*** 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 ***as a***

to tackle the consequences of a crisis.

*last resort* can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.

Or. en

**Amendment 54**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 1**

*Text proposed by the Commission*

(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.

*Amendment*

(1) *The public interest, notably in the context of* crises require the setting-up of exceptional, swift, and adequate measures able to provide *a fair response to the needs at hand*. 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, *and to scale up production*, 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.

Or. en

**Amendment 55**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

(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 licensing in the internal market.

*Amendment*

(2) In the context of the crisis or emergency mechanisms ***having a cross-border effect in the Union and involving two or more Member States***, the Union should therefore have the possibility to rely on compulsory licensing ***to adequately respond to the needs commanded by the public interest***. 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 licensing in the internal market.

Or. en

**Amendment 56**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 2**

*Text proposed by the Commission*

(2) In the context of the Union crisis or emergency mechanisms, the Union should

*Amendment*

(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 licensing in the internal market.

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 ***is a last resort mechanism that*** 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 licensing in the internal market.

Or. en

## Amendment 57 Heidi Hautala

### Proposal for a regulation Recital 3

*Text proposed by the Commission*

(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')***<sup>3</sup>.

*Amendment*

(3) ***The WTO Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPS Agreement')***<sup>3</sup> ***provides for a possibility, under conditions, to issue compulsory licences. This provides governments the authority to grant the use of a patented invention without the consent of the patent owner. The Doha Declaration on the TRIPS Agreement and Public Health makes it clear that each***

***WTO Member has not only the right to grant a compulsory licence, but also the freedom to determine the grounds upon which such licence are granted, including the possibility of using such licence in situations of national emergency or other circumstances of extreme urgency, as provided by the TRIPS Agreement.***

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214.

Or. en

**Amendment 58**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 3**

*Text proposed by the Commission*

(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')<sup>3</sup>.

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214

*Amendment*

(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')<sup>3</sup>. ***The provisions of this Regulation should be consistent with TRIPS Agreement's obligations, in particular with respect to the protection of trade secrets.***

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214

Or. en

**Amendment 59**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 5**

(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 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.

(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 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 ***and*** when voluntary agreements are unavailable ***and cannot be reached in a due time***. 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.

Or. en

**Amendment 60**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**



## Proposal for a regulation

### Recital 6

*Text proposed by the Commission*

(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').

*Amendment*

(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the **Council** should be **the institution** 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').

Or. en

## Amendment 61

Heidi Hautala

## Proposal for a regulation

### Recital 7

*Text proposed by the Commission*

(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

*Amendment*

(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. **Moreover, Regulation (EU) 2022/123, which strengthens the European Medicines Agency's role in crisis preparedness and management,**

means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].

*creates a framework aimed at mitigating shortages of medicinal products during major events.* 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].

Or. en

## Amendment 62 Heidi Hautala

### Proposal for a regulation Recital 8

#### *Text proposed by the Commission*

(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*.

#### *Amendment*

(8) These mechanisms provide for the *grant of compulsory licences to protect the public interest, including in the context of cross-border crisis or emergency situations in the Union, in one or more Member States or at international level* activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. *The Commission may grant a Union compulsory licence in the public interest, including but not limited to national emergency or other circumstances of extreme need, including a health crisis or major events in the meaning of Regulation(EU) 2022/123, situations of shortages, or involving excessive or abnormally high prices of a medical product, or where there is a need to build up a strategic stock, or in other situations where the grant of a compulsory licence should be deemed lawful.* By allowing the Commission to grant a compulsory licence when a crisis or emergency mode, *including in the event of a major event*, 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 on the ***assessment requirements provided under this regulation***. 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 ***not contravene the spirit and provisions of the TRIPS Agreement, especially their Article 31, which should remain the reference on the matter***.

Or. en

**Amendment 63**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 8**

*Text proposed by the Commission*

(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.

*Amendment*

(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 ***the above mentioned*** Union legal ***acts***, 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.

Or. en

## Amendment 64

Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Recital 8

##### *Text proposed by the Commission*

(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.***

##### *Amendment*

(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 **Council** 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 ***punctually*** listed.

Or. en

## Amendment 65

Heidi Hautala

### Proposal for a regulation

#### Recital 9

##### *Text proposed by the Commission*

(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

##### *Amendment*

(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address ***public interest needs and*** crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a

Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.

supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.

Or. en

#### **Amendment 66**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

#### **Proposal for a regulation**

##### **Recital 9**

###### *Text proposed by the Commission*

(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.

###### *Amendment*

(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 or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.

Or. en

#### **Amendment 67**

**Geoffroy Didier**

#### **Proposal for a regulation**

##### **Recital 9**

###### *Text proposed by the Commission*

(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,

###### *Amendment*

(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, or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents

European patents and European patents with unitary effect.

Or. en

## Amendment 68

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

## Proposal for a regulation

## Recital 12

*Text proposed by the Commission*

(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 of the patent claims.*

Or. en

## Amendment 69

## Geoffroy Didier

**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

*Amendment*

**(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 of the patent claims.* **deleted**

Or. en

**Amendment 70**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

*Amendment*

**(14)** *When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective* **deleted**

*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 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.*

Or. en

#### **Amendment 71**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

#### **Proposal for a regulation**

#### **Recital 15**

*Text proposed by the Commission*

*Amendment*

*(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*

*Deleted*



*Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.*

Or. en

**Amendment 72**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

(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**.

*Amendment*

(15) In order to ensure as much coherence as possible **with requirements pertaining to the public interest**, with existing crisis mechanisms and with other Union legislation, the definition of a ‘**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 **situations calling for the grant of Union compulsory licenses**.

Or. en

**Amendment 73**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 15**

*Text proposed by the Commission*

(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

*Amendment*

(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** a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but

be more general in order to cover products related to different kinds of crises or emergencies.

should be more general in order to cover products related to different kinds of crises or emergencies.

Or. en

## Amendment 74

Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Recital 16

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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 ***and the availabilities of possible licensees***. This includes ***an in-depth dialogue phase with the right-holder, a screening of possible licensees***, 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. ***The granting of a compulsory licence is in any case 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.*

Or. en

**Amendment 75**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(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, **as a last resort mechanism**, and under conditions that take into account the interests of the rights-holder. This includes a clear **limitation** 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 **and should not in principle exceed 12 months, unless a renewal is required by the continued existence of the circumstances that led to the granting of the licence**. 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.

Or. en

**Amendment 76**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(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.

*Amendment*

(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 with the purpose to safeguard public health and the public interest*** 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.

Or. en

**Amendment 77**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

(16) A Union compulsory licence authorises the use of a protected invention

*Amendment*

(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.

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 qualified *persons* able to manufacture the *relevant* product and to pay, *when relevant*, a reasonable remuneration to the rights-holder.

Or. en

## Amendment 78

Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Recital 17

##### *Text proposed by the Commission*

(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

##### *Amendment*

(17) When considering the granting of a Union compulsory licence, in order to take a well-informed decision, *the assistance of* an advisory body *must be envisaged*. 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 to convene the

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.

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. *In the latter case, each Member State may indicate one expert on intellectual property to take part in the work of the advisory body.* 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.

Or. en

## Amendment 79 Heidi Hautala

### Proposal for a regulation Recital 17

#### *Text proposed by the Commission*

(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

#### *Amendment*

(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. 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

compulsory licensing at Union level is expressed by the Commission.

expressed by the Commission.

Or. en

## **Amendment 80**

**Gunnar Beck, Gilles Lebreton**

### **Proposal for a regulation**

#### **Recital 18**

##### *Text proposed by the Commission*

(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 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

##### *Amendment*

(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 whether **to propose to the Council** 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



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’).

shall be listed, together with the corresponding crisis mechanisms, in this Regulation. In case the Union crisis mechanism does not provide for an advisory body ***composed by representatives of all Member States***, the Commission should set up an ad hoc advisory body for the granting of the Union (the ‘ad hoc advisory body’).

Or. en

## **Amendment 81**

### **Heidi Hautala**

#### **Proposal for a regulation**

#### **Recital 18**

##### *Text proposed by the Commission*

(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 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

##### *Amendment*

(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, ***independence***, expertise, and ***can rely on the adequate*** 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. 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, ***independence***, 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’).

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 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’).

Or. en

## **Amendment 82**

### **Geoffroy Didier**

#### **Proposal for a regulation**

#### **Recital 18**

##### *Text proposed by the Commission*

(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 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

##### *Amendment*

(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 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’).

Semiconductor Board. Those advisory bodies have 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’).

Or. en

### Amendment 83 Geoffroy Didier

#### Proposal for a regulation Recital 19

##### *Text proposed by the Commission*

(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

##### *Amendment*

(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 *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 , *but they should nevertheless include always representatives of the authorities of the Member States which are competent for the granting of compulsory licences under national law*. When the advisory body is already set up, its existing rules of

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 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.

procedure should apply. As regards ad hoc advisory bodies, *besides including the right holders and potential licensees or their representatives*, they should *also* be composed of *those representatives of national competent authorities* 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 proposals for voluntary solutions. In addition, the advisory body should have the 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.

Or. en

#### **Amendment 84**

**Raffaele Stancanelli, Kosma Zlotowski**

#### **Proposal for a regulation**

##### **Recital 20**

###### *Text proposed by the Commission*

(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

###### *Amendment*

(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 *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*. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate

level.

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.

Or. en

**Amendment 85**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

(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.

*Amendment*

(20) The Commission should grant the Union compulsory licence in the light of the ***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 ***before the issuance of such opinion and 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 licence on their intellectual property rights.*** . 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. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.

Or. en

**Amendment 86**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

(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.

*Amendment*

(20) The Commission should ***propose to the Council to*** 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.

Or. en

**Amendment 87**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

(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

*Amendment*

(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.

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, ***should it be granted***. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.

Or. en

**Amendment 88**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 21**

*Text proposed by the Commission*

(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.

*Amendment*

(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 without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be ***enabled throughout the discussions of the*** advisory body as regards the granting of a Union compulsory licence.

Or. en

**Amendment 89**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

*Amendment*

(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 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.*

(22) *Given that voluntary agreements are the most suitable way to deal with patented products or processes in a time of crisis, then prior to any decision by the Commission on the granting of a Union compulsory licence, the rights-holder **shall be provided a reasonable opportunity to negotiate a voluntary license with potential licensees selected by the rights holder. By allowing a rights-holder to make use its existing business relationships, a more efficient and effective solution can be achieved. The time period allowed should be sufficient so as to enable good faith and meaningful negotiations, taking into account the urgency of the situation.** The rights-holder should also be given the opportunity to **enter into consultation with the Commission, with a view to reaching agreement** 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.

Or. en

## Amendment 90

Heidi Hautala

### Proposal for a regulation

#### Recital 22

##### *Text proposed by the Commission*

(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 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

##### *Amendment*

(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 ***balance to be made between the public interest on the one hand, and the*** situation of the rights-holder ***on the other, and considering*** the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body ***on a timely basis***. 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



granted, the Commission should notify the rights-holder as soon as reasonably practicable.

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.

Or. en

**Amendment 91**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 22**

*Text proposed by the Commission*

(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 Commission shall

*Amendment*

(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, ***which should remain the preferred option***. 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

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.

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. ***The CJEU's judicial review of the grounds and the conditions under which a Union compulsory licensing has been granted should be possible.***

Or. en

## **Amendment 92**

### **Tiemo Wölken**

#### **Proposal for a regulation**

#### **Recital 22**

##### *Text proposed by the Commission*

(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

##### *Amendment*

(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 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 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

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.

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.

Or. en

**Amendment 93**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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***

*Amendment*

(24) The Commission should, assisted by the advisory body, make its best efforts to identify the patent, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights.

*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.*

Or. en

**Amendment 94**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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 intellectual property rights and***

*Amendment*

(24) The Commission should, assisted by the advisory body, identify in its decision the patent, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. ***The*** implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.

***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.

Or. en

**Amendment 95**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

(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 intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also

*Amendment*

(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 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.

identify any necessary safeguards and remuneration to be paid, ***when relevant***, to each identified rights-holder.

Or. en

**Amendment 96**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***

Or. en

**Amendment 97**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

*Amendment*

***(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***

***deleted***

*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.*

Or. en

**Amendment 98**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(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***

*Amendment*

(27) The licensee should pay an adequate remuneration to the rights-holder. 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.



***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.***

Or. en

**Amendment 99**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

(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***

*Amendment*

(27) The licensee should pay an adequate remuneration ***in line with what was previously agreed with*** the rights-holder. ***In case such an agreement has not been reached within a reasonable timeframe, such a remuneration shall be*** determined by the Commission. The amount of the remuneration should be determined considering ***the total gross revenue generated by the licensee through the acts under the Union compulsory licence***, 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. The Commission should ***also*** consider the comments made by the rights-holder and the assessment made by the advisory body with regard to



***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.***

the amount of the remuneration.

Or. en

## **Amendment 100**

### **Heidi Hautala**

#### **Proposal for a regulation**

#### **Recital 27**

##### *Text proposed by the Commission*

(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

##### *Amendment*

(27) The licensee ***may have to*** pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration, ***should it be granted***, 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.

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.

Or. en

### *Justification*

*As per TRIPS, Article 31.F.*

#### **Amendment 101** **Heidi Hautala**

#### **Proposal for a regulation** **Recital 28**

##### *Text proposed by the Commission*

(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<sup>9</sup>. ***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***

##### *Amendment*

(28) It is imperative that products manufactured under a Union compulsory licence reach ***predominantly*** 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<sup>9</sup>.

*that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder.*

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<sup>9</sup> 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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<sup>9</sup> 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).

Or. en

## **Amendment 102** **Heidi Hautala**

### **Proposal for a regulation** **Recital 29**

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(29) A Union compulsory licence should be granted to ***predominantly*** supply the internal market with ***relevant*** products. ***When*** a Union compulsory licence ***has been granted for export to countries with public health problems, the full production should be exported to them.***

Or. en

## **Amendment 103** **Gunnar Beck**

### **Proposal for a regulation** **Recital 31**

#### *Text proposed by the Commission*

(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, ***should be*** subject to

#### *Amendment*

(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, ***are*** subject to judicial

judicial review.

review.

Or. en

## Amendment 104

Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Recital 32

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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 ***propose to the Council*** 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 ***and should ensure the protection of trade secrets as defined in Article 2 of the Directive (EU) 2016/943. Such data should be protected against the disclosure and the use without the consent of trade secrets' holder. Steps should be taken to ensure that the data are protected against unfair commercial use.***

**Amendment 105**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 32**

*Text proposed by the Commission*

(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.

*Amendment*

(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, ***but should preserve the protection of trade secrets and know-how in line with the applicable Union and national law***. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.

**Amendment 106**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 32 a (new)**

*Text proposed by the Commission*

*Amendment*

*(32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. Indeed, it is possible that the detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This may include but may not be limited to the full transfer of needed technology, knowhow, test data, samples and reference products needed for production and market authorization, taking into account the public interest. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. The Commission should require the rights-holders to put in place all appropriate measures, including technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties.*

Or. en

**Amendment 107**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 32 b (new)**

**(32b) This Regulation should guarantee that the Commission has the authority to compel rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, test data, samples and reference products, particularly when it is essential for the effective implementation of compulsory licensing.**

Or. en

**Amendment 108**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 33**

(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***

(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 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 ***shall*** consult the competent advisory body for that purpose, ***as well as the rights-holders and licensees.***



*could be the subject of a separate compulsory licence, it should be required to consult the advisory body.*

Or. en

**Amendment 109**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 33**

*Text proposed by the Commission*

(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 been 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.

*Amendment*

(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 been 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 ***potential*** remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.

Or. en

**Amendment 110**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

### Recital 33

*Text proposed by the Commission*

(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 been 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.

*Amendment*

(33) In order to respond appropriately to the crisis situations, the Commission ***may propose*** 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 been 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 ***is required*** 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 if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.

Or. en

### Amendment 111

Heidi Hautala

#### Proposal for a regulation

### Recital 34

*Text proposed by the Commission*

(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-

*Amendment*

(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.

holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive, ***and should not contravene the usual enforcement measures of Intellectual Property rights as provided by Directive 2004/48/EC.***

Or. en

**Amendment 112**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 35**

*Text proposed by the Commission*

(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 ne bis in idem. 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.

*Amendment*

(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 ne bis in idem. 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 ***the implementing act granting the compulsory licence, as well as the decisions on*** fines and penalty payments in accordance with Article 261 TFEU.

Or. en

**Amendment 113**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 36**

*Text proposed by the Commission*

(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.

*Amendment*

(36) When a national compulsory licence has been granted, 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.

Or. en

**Amendment 114**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 37**

*Text proposed by the Commission*

(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 regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council<sup>11</sup>. 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)

*Amendment*

(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 regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council<sup>11</sup>. 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 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 licensing 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.

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<sup>11</sup> 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

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 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 licensing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same *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.

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<sup>11</sup> 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

## **Amendment 115**

**Gunnar Beck, Gilles Lebreton**

### **Proposal for a regulation**

#### **Recital 38**

##### *Text proposed by the Commission*

(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<sup>12</sup>. ***The advisory 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***

##### *Amendment*

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the **Council** as regards the granting, complementing, modification or termination of a Union compulsory license and the characteristics allowing the identification of products produced under a Union compulsory licence, ***and to the Commission for the procedural rules for the ad hoc advisory body.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>12</sup>. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body.

*compulsory licence.*

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<sup>12</sup> 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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<sup>12</sup> 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).

Or. en

## **Amendment 116** **Geoffroy Didier**

### **Proposal for a regulation** **Recital 38**

#### *Text proposed by the Commission*

(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 licence, 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<sup>12</sup>. The advisory 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

#### *Amendment*

(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 licence, the determination, ***in the absence of an agreement between the rights-holder and the licensee***, 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<sup>12</sup>. The advisory 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



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.

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<sup>12</sup> 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).

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.

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<sup>12</sup> 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).

Or. en

## **Amendment 117**

### **Heidi Hautala**

#### **Proposal for a regulation**

#### **Recital 38**

##### *Text proposed by the Commission*

(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<sup>12</sup>. The advisory procedure

##### *Amendment*

(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 **that may** 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<sup>12</sup>. The

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.

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<sup>12</sup> 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).

advisory 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, ***should it be granted***. 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.

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<sup>12</sup> 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).

Or. en

## **Amendment 118**

### **Heidi Hautala**

#### **Proposal for a regulation**

#### **Recital 39**

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(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 ***potential*** remuneration, imperative grounds of

urgency so require.

Or. en

**Amendment 119**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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.

*Amendment*

(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. ***It should focus on the efficiency of the procedures set up by this regulation, notably with respect to the promptness in which all stakeholders, including rights-holders, participate in them.*** 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.

Or. en

**Amendment 120**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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

*Amendment*

(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

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.

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.

Or. en

**Amendment 121**  
**Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Recital 40**

*Text proposed by the Commission*

(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.

*Amendment*

(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances **and as a last resort measure**. The evaluation should therefore be conducted only where a Union compulsory licence has been granted. 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.

Or. en

**Amendment 122**  
**Heidi Hautala**

**Proposal for a regulation**  
**Recital 41**

*Text proposed by the Commission*

***(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.***

*Amendment*

***Deleted***

**Amendment 123**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

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*.

*Amendment*

This Regulation has the objective to ensure that *a temporary and non-exclusive Union compulsory license may be granted for the exploitation of the patent or the patent application, to protect the public interest, including in the context of cross-border crisis or emergency situations in the Union or at international level*. 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 *manufacture and* supply of *such relevant* products *and their components* to the Member States *when needed*.

*Justification*

*The scope of the regulation should be broadened and not set EU standards going below the TRIPS standards. Besides, one can never really know when a crisis can become ‘trans-national’. In order to respond quickly to exceptional public interest needs, a ‘crisis’ at national level, it should be possible to give to it the most adequate answer at the earliest stage, even before it becomes cross-border. Furthermore, granting a CL in the EU can have the objective to respond to a public health crisis inside or outside the EU.*

**Amendment 124**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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.

This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, ***if no prior voluntary agreement has been reached between right holder and licensee***, this Regulation lays down rules on the procedure and conditions for the granting ***as a last resort*** 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.

Or. en

**Amendment 125**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

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 products to the Member States in the context of a Union crisis or emergency mechanism.

Or. en

*Justification*

*It should be referred to as "industry property rights" throughout the text, as the relevant rights belong to the group of industrial property rights.*

**Amendment 126**  
**Kosma Zlotowski**

**Proposal for a regulation**

**Article 2 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. This Regulation establishes Union compulsory licensing of the following *intellectual* property rights in force in one or more Member States:

*Amendment*

1. This Regulation establishes Union compulsory licensing of the following *industrial* property rights in force in one or more Member States:

Or. en

**Amendment 127**

**Alessandra Basso, Gunnar Beck**

**Proposal for a regulation**

**Article 2 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) patents, *including published patent applications*;

*Amendment*

(a) patents;

Or. en

**Amendment 128**

**Geoffroy Didier**

**Proposal for a regulation**

**Article 2 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) patents, *including published patent applications*;

*Amendment*

(a) patents;

Or. en

**Amendment 129**

**Kosma Złotowski**

**Proposal for a regulation**



## Article 2 – paragraph 1 – point a

*Text proposed by the Commission*

(a) patents, including **published** patent applications;

*Amendment*

(a) patents, including patent applications;

Or. en

## Amendment 130 Kosma Złotowski

### Proposal for a regulation

#### Article 2 – paragraph 1 – point a a (new)

*Text proposed by the Commission*

*Amendment*

**(aa) industrial design**

Or. en

## Amendment 131 Heidi Hautala

### Proposal for a regulation

#### Article 2 – paragraph 2

*Text proposed by the Commission*

*Amendment*

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 sui generis rights granted by Directive 96/9/EC on the legal protection of databases.

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, **Directive 2004/48/EC** and the sui generis rights granted by Directive 96/9/EC on the legal protection of databases.

Or. en

*Justification*

*IPRED Directive.*

**Amendment 132**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 2 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. This Regulation is without prejudice to the Directive (EU) 2016/943 of the European Parliament and the Council and national legal acts providing for the protection of trade secrets.**

Or. en

**Amendment 133**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(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;

(a) ‘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 accordance with Article 6.**

Or. en

**Amendment 134**  
**Heidi Hautala**

**Proposal for a regulation**

### Article 3 – paragraph 1 – point a

*Text proposed by the Commission*

(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;

*Amendment*

(a) ‘**relevant** products’ means products or processes that are **instrumental for safeguarding the public interest, o** for responding to **exceptional public health needs, such as in** a crisis or emergency, or for addressing the impacts of a crisis or emergency in the Union, **as determined by the Commission through the guidance of the advisory body in accordance with Article 6;**

Or. en

### Amendment 135 Emmanuel Maurel

#### Proposal for a regulation Article 3 – paragraph 1 – point a

*Text proposed by the Commission*

(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;

*Amendment*

(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency, **for safeguarding public interests, for protecting public health** or for addressing the impacts of a crisis or emergency in the Union;

Or. fr

### Amendment 136 Alessandra Basso, Gunnar Beck, Gilles Lebreton

#### Proposal for a regulation Article 3 – paragraph 1 – point a a (new)

*Text proposed by the Commission*

*Amendment*

(aa) **"Crisis" means the following crisis or emergency modes:**

- *Public health emergency at Union level formally recognized by means of a Commission implementing act under Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU;*
- *Emergency framework activated by the adoption of a Council Regulation under Article 3 of Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level;*
- *Crisis stage activated by a Council implementing act under Article 23 of Regulation (EU) 2023/1781 of the European Parliament and the Council of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act).*

Or. en

## **Amendment 137**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point a b (new)**

*Text proposed by the Commission*

*Amendment*

*(ab) "Advisory Body" means the advisory body deemed competent according to the relevant legislation on the crisis mode or emergency instrument triggered, in particular:*

- *the Advisory Committee on public health emergencies under Article 24 of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-*

*border threats to health and repealing  
Decision No 1082/2013/EU;*

*– the Health Crisis Board under Article 5  
of Regulation (EU) 2022/2372 of 24  
October 2022 on a framework of  
measures for ensuring the supply of crisis  
of relevant medical countermeasures in  
the event of a public health emergency at  
Union level;*

*– the European Semiconductor Board  
under Article 28 of Regulation (EU)  
2023/1781 of the European Parliament  
and the Council of 13 September 2023  
establishing a framework of measures for  
strengthening Europe’s semiconductor  
ecosystem and amending Regulation (EU)  
2021/694 (Chips Act).*

Or. en

**Amendment 138**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point e**

*Text proposed by the Commission*

(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;

*Amendment*

(e) ‘Union compulsory licence’ means  
a compulsory licence granted by the  
Commission *or the competent authorities  
of the Member States* to exploit a protected  
invention of crisis-relevant products for  
any of the relevant activities in the Union;

Or. fr

**Amendment 139**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point e**

*Text proposed by the Commission*

(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;

*Amendment*

(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission ***or a relevant authority*** to exploit a protected invention of ***relevant*** products for any of the relevant activities in the Union;

Or. en

**Amendment 140**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(fa) ‘crisis’ means a Union wide emergency caused by an exceptional, unexpected and sudden natural or man-made event of extraordinary nature and scale, which triggers activation of a Union emergency or crisis mode as set out in the Annex to this Regulation.***

Or. en

**Amendment 141**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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.***

The Commission may grant a Union compulsory licence ***in the public interest, in particular in the following situations:***

***(i) a national emergency or other***

*circumstances of extreme necessity; or*  
*(ii) public non-commercial use; or*  
*(iii) a health crisis involving insufficient quantity or quality of supply or availability, excessively or abnormally high prices of a medical product, strategic stockpiling or any other situation considered by the licensee.*

Or. fr

**Amendment 142**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

The Commission may ***only*** 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 between right-holder and the potential licensee pursuant to paragraph 1,*** 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.

Or. en

**Amendment 143**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to

*Amendment*

The Commission may, ***where a voluntary agreement between the rights-holder and the licensee has not been reached within 4***



this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.

**weeks**, 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.

Or. en

#### Amendment 144

Alessandra Basso, Gunnar Beck, Gilles Lebreton

#### Proposal for a regulation Article 4 – paragraph 1

##### *Text proposed by the Commission*

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***.

##### *Amendment*

The **Council** may grant a Union compulsory licence where a crisis mode or an emergency mode ***under in Article 3 (aa)*** has been activated or declared in accordance with one of the Union acts listed ***herein***.

Or. en

#### Amendment 145

Heidi Hautala

#### Proposal for a regulation Article 4 – paragraph 1 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

***The Commission may grant a Union compulsory licence in the public interest, including in but not limited to the following situations:***

***(a) a national emergency or other circumstances of extreme need, including a health crisis;***

***(b) a situation involving problems of supply or availability in insufficient quantity or quality;***

*(c) a situation involving excessive or abnormally high prices of a medical product, building up a strategic stock;*

*(d) in case of lawful uses of the Intellectual Property rights, such as public non-commercial uses;*

*(e) any other situations where considered needed by the applicant of the request for a compulsory licence, following proper examination by the Supervisory Board according to the provisions of this Regulation.*

Or. en

#### **Amendment 146**

**Geoffroy Didier**

#### **Proposal for a regulation**

#### **Article 4 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*The Commission shall not grant a Union compulsory license in respect of any crisis-relevant product without first providing the rights holders with a reasonable opportunity to negotiate a voluntary license with potential licensees. The time frame for reaching an agreement on such a license shall be sufficient to enable meaningful negotiations with potential partners, taking into account the urgency of the matter.*

Or. en

#### **Amendment 147**

**Heidi Hautala**

#### **Proposal for a regulation**

#### **Article 5 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) be non-exclusive and non-assignable, except with that part of the enterprise or ***goodwill*** which enjoys such compulsory licence;

*Amendment*

(a) be non-exclusive and non-assignable, except with that part of the enterprise or ***non-profit*** which enjoys such compulsory licence;

Or. en

**Amendment 148**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) be granted to EU companies;***

Or. fr

**Amendment 149**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(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;

(b) ***be strictly*** limited ***with respect to scope, field of use and quantities (volume) necessary to meet the needs in the Union on the basis of*** the purpose for which the compulsory licence is granted and ***have duration which is strictly*** limited to the duration of the crisis or emergency mode in the framework of which it is granted ***and does not exceed a maximum period of 12 months renewable in case the circumstances that led to it continue to exist;***

Or. en

**Amendment 150**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point b**

*Text proposed by the Commission*

(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;

*Amendment*

(b) have a scope and duration that is ***strictly*** limited to 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;

Or. en

**Amendment 151**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point b**

*Text proposed by the Commission*

(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;

*Amendment*

(b) have a scope and duration that ***are*** limited to the purpose for which the compulsory licence is granted and limited to the framework ***and conditions under*** which it is granted;

Or. en

**Amendment 152**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) be strictly limited to the relevant activities of crisis-relevant products in the Union;

*Amendment*

(c) be strictly limited to the relevant ***and properly justified*** activities of crisis-relevant products in the Union;

**Amendment 153**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) be strictly limited to the **relevant** activities of **crisis-relevant** products in the Union;

*Amendment*

(c) be strictly limited to the **necessary** activities of **relevant** products in the Union;

Or. en

**Amendment 154**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) only be granted against payment of an adequate remuneration to the rights-holder;

*Amendment*

(d) only be granted against payment of an adequate remuneration to the **agreed** **with the** rights-holder **determined in accordance with Article 9**;

Or. en

**Amendment 155**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) **only** be granted against payment of an adequate remuneration to the rights-holder;

*Amendment*

(d) be granted against payment of an adequate remuneration to the rights-holder, **when relevant** ;

**Amendment 156**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) only be granted against payment of an ***adequate*** remuneration to the rights-holder;

*Amendment*

(d) only be granted against payment of an ***fair*** remuneration to the rights-holder;

**Amendment 157**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point e**

*Text proposed by the Commission*

(e) ***be limited to the territory of the Union;***

*Amendment*

***deleted***

**Amendment 158**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point e**

*Text proposed by the Commission*

(e) be limited to the territory of the Union;

*Amendment*

(e) be ***strictly*** limited to the ***precisely defined*** territory of the Union;

**Amendment 159**  
**Kosma Złotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point f**

*Text proposed by the Commission*

(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.

*Amendment*

(f) only be granted to a person deemed to be in a position to **efficiently** exploit the protected invention in a manner that permits the **effective** carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

Or. en

**Amendment 160**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 5 – paragraph 1 – point f**

*Text proposed by the Commission*

(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.

*Amendment*

(f) only be granted to **the persons** 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 **relevant** products and in accordance with the obligations referred to in Article 10.

Or. en

**Amendment 161**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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.* *deleted*

Or. en

**Amendment 162**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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.* *deleted*

Or. en

*Justification*

*The specification is unnecessary, as the common standard is that a patent is effective from the date the invention is filed.*

**Amendment 163**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 5 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

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* *deleted*



*the granting of that patent takes place while the Union compulsory licence is valid.*

Or. en

#### Amendment 164

Alessandra Basso, Gunnar Beck, Gilles Lebreton

#### Proposal for a regulation

##### Article 6 – paragraph 1

###### *Text proposed by the Commission*

1. When the **Commission considers** the granting of a Union compulsory licence, **it** shall without undue delay **consult an advisory body**.

###### *Amendment*

1. When the granting of a Union compulsory licence **is considered, an advisory body** shall **be consulted** without undue delay.

Or. en

#### Amendment 165

Geoffroy Didier

#### Proposal for a regulation

##### Article 6 – paragraph 2 – introductory part

###### *Text proposed by the Commission*

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:

###### *Amendment*

2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency **mode activated or declared in accordance with a Union act** as listed in Annex I to this Regulation (the ‘competent advisory body’). **Notwithstanding the applicable rules on the composition of the competent advisory body, for the purposes of this Regulation, it shall always include representatives of all national authorities which are competent for the granting of compulsory licences under national law. Member States shall notify the Commission of the designated competent authorities. Notifications shall be**

*published in the Official Journal of the European Union*. For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:

Or. en

## Amendment 166

Heidi Hautala

### Proposal for a regulation

#### Article 6 – paragraph 2 – introductory part

##### *Text proposed by the Commission*

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:

##### *Amendment*

2. For the purposes of the present Regulation, the *advisory body referred to in paragraph 1* (*‘the competent advisory body’*) shall assist and advise the Commission as regards the following tasks:

Or. en

## Amendment 167

Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Article 6 – paragraph 2 – introductory part

##### *Text proposed by the Commission*

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

##### *Amendment*

2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism *under Article 3 (ab), with the participation of intellectual property experts appointed by Member States*.

tasks:

For the purposes of the present Regulation, the competent advisory body shall **give assistance** and advise as regards the following tasks:

Or. en

**Amendment 168**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism (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:

Or. fr

**Amendment 169**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point a**

*Text proposed by the Commission*

(a) the gathering of ***crisis-relevant*** information, market intelligence and the analysis of those data;

*Amendment*

(a) the gathering of ***context-relevant*** information, market intelligence and the analysis of those data;

Or. en

**Amendment 170**

Tiemo Wölken

**Proposal for a regulation**

**Article 6 – paragraph 2 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

**(aa) the confirming that a voluntary agreement between the rights-holder and the licensee has not been reached within four weeks;**

Or. en

**Amendment 171**

**Heidi Hautala**

**Proposal for a regulation**

**Article 6 – paragraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

(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, where appropriate;

(c) the facilitation of exchanges and sharing of information with other relevant ***institutional*** bodies and other ***relevant entities*** at Union and national level, as well as at international level, where appropriate;

Or. en

**Amendment 172**

**Heidi Hautala**

**Proposal for a regulation**

**Article 6 – paragraph 2 – point d**

*Text proposed by the Commission*

*Amendment*

(d) the identification of the rights protecting the ***crisis-relevant*** product;

(d) the identification of the rights protecting the ***relevant*** product;

Or. en

**Amendment 173**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point f**

*Text proposed by the Commission*

(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;

*Amendment*

(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other **stakeholders and** economic operators, **including** industry, **academia and civil society**;

Or. en

**Amendment 174**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point f**

*Text proposed by the Commission*

(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;

*Amendment*

(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, **researchers, members of civil society** and the industry;

Or. fr

**Amendment 175**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point f**

*Text proposed by the Commission*

(f) the identification and consultation of **the representatives of** right holders **or their representatives** as well as potential

*Amendment*

(f) the identification and consultation of **potential** right holders as well as potential licensees **or their respective**

licensees and consulting other economic operators, and the industry;

*representatives* and consulting other economic operators, and the industry;

Or. en

**Amendment 176**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

*(fa) the assessment of whether the potential licensees are qualified and possess sufficient production capacities and resources, namely in terms of access to relevant technologies to perform all the necessary tasks.*

Or. en

**Amendment 177**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 6 – paragraph 2 – point g a (new)**

*Text proposed by the Commission*

*Amendment*

*(ga) to assess whether the conditions for the rights-holder and potential licensees to conduct meaningful negotiations with a view to reach a voluntary agreement pursuant to Article 4(1a) were fulfilled*

Or. en

**Amendment 178**  
**Heidi Hautala**

**Proposal for a regulation**

## Article 6 – paragraph 4 – point a

*Text proposed by the Commission*

(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

*Amendment*

(a) shall ensure participation and invite representatives of other ***relevant institutional*** 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

Or. en

## Amendment 179

Tiemo Wölken

### Proposal for a regulation

#### Article 6 – paragraph 4 – point a a (new)

*Text proposed by the Commission*

*Amendment*

***(aa) shall invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies;***

Or. en

## Amendment 180

Emmanuel Maurel

### Proposal for a regulation

#### Article 6 – paragraph 4 – point b

*Text proposed by the Commission*

*Amendment*

(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.

(b) ***shall*** invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners, ***members of civil society*** and experts to attend meetings of the advisory body as observers.

Or. fr

**Amendment 181**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 6 – paragraph 4 – point b**

*Text proposed by the Commission*

(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.

*Amendment*

(b) may invite representatives of the European Parliament, **to contribute to the meetings of the advisory body**. Representatives of economic operators, potential licensees, stakeholder organisations, social partners and experts **may be invited** as observers.

Or. en

**Amendment 182**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Article 6 – paragraph 4 – point b**

*Text proposed by the Commission*

(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.

*Amendment*

(b) may invite representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.

Or. en

**Amendment 183**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 6 – paragraph 4 – point b**

*Text proposed by the Commission*

(b) **may** invite representatives of the

*Amendment*

(b) **shall** 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.

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.

Or. en

#### **Amendment 184**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

#### **Proposal for a regulation**

#### **Article 6 – paragraph 4 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) shall, in any case, engage in a preliminary dialogue with the right holder, whose right to be heard shall always be guaranteed, and encourage the reaching of voluntary licensing agreements.***

Or. en

#### **Amendment 185**

**Geoffroy Didier**

#### **Proposal for a regulation**

#### **Article 6 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

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.***

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. The ad hoc advisory body ***shall include representatives of all national authorities which are competent for the granting of compulsory licences under national law, as well as the right***

*holders and potential licensees or their representatives. Member States shall notify the Commission of the designated competent authorities. Notifications shall be published in the Official Journal of the European Union.*

Or. en

## **Amendment 186**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

### **Proposal for a regulation**

#### **Article 6 – paragraph 5**

##### *Text proposed by the Commission*

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.

##### *Amendment*

5. In the absence of any existing competent advisory body ***composed by representatives of all Member States***, 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.

Or. en

## **Amendment 187**

**Emmanuel Maurel**

### **Proposal for a regulation**

#### **Article 6 – paragraph 6**

##### *Text proposed by the Commission*

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

##### *Amendment*

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).

period exceeding the duration of the crisis or emergency. ***The rules of procedure shall specify that the ad hoc advisory body must not have any conflicts of interest and shall lay down appropriate transparency measures.*** That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).

Or. fr

**Amendment 188**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 6 – paragraph 6**

*Text proposed by the Commission*

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).

*Amendment*

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 ***enforce stringent safeguards to avoid any potential conflicts of interest, and to ensure accountability and transparency.*** That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).

Or. en

**Amendment 189**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) the nature of the crisis or emergency;

*Amendment*

(a) the nature of the ***public interest,*** crisis or emergency;

**Amendment 190**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the scope of the crisis or emergency and how it is expected to evolve;

*Amendment*

(b) the scope of the **public interest**, crisis or emergency and how it is expected to evolve;

Or. en

**Amendment 191**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 1 – point c**

*Text proposed by the Commission*

(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.

*Amendment*

(c) the shortage of **or lack of access to relevant** products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.

Or. en

**Amendment 192**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 7 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) barriers to the accessibility and affordability of the products concerned, such as excessively high prices or anti-**

*competitive practices;*

Or. fr

## Amendment 193

Geoffroy Didier

### Proposal for a regulation

#### Article 7 – paragraph 2

##### *Text proposed by the Commission*

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.

##### *Amendment*

2. The **final** opinion of the advisory body shall 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.

Or. en

## Amendment 194

Alessandra Basso, Gunnar Beck

### Proposal for a regulation

#### Article 7 – paragraph 3 – introductory part

##### *Text proposed by the Commission*

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:

##### *Amendment*

3. Before **proposing** the granting of a Union compulsory licence, the Commission shall **first notify the relevant rights-holder that a Union compulsory licence may be granted. The right to be heard of the right holder before adopting a proposal pursuant to Article 7(7) shall be ensured. Article 19 shall apply mutatis mutandis.**

**The Commission shall then** give the rights-holder and the **identified licensees** an opportunity to comment on the following:

**Amendment 195**  
**Raffaele Stancanelli, Kosma Złotowski**

**Proposal for a regulation**  
**Article 7 – paragraph 3 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

3. Before the granting of a Union compulsory licence, ***the Commission shall provide the rights-holders and the licensee with the case file and analyses submitted to or carried out by the advisory body referred to in Article 6, and with all other relevant information necessary for them to assess the impact of a proposed Union compulsory license on their intellectual property rights, and*** the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:

Or. en

**Amendment 196**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 3 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment ***in a reasonable delay*** on the following:

Or. en

**Amendment 197**  
**Geoffroy Didier**

## Proposal for a regulation

### Article 7 – paragraph 3 – introductory part

*Text proposed by the Commission*

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:

*Amendment*

3. Before the ***issuance of the opinion of the advisory body, the advisory body*** shall give the rights-holder and the licensee an opportunity to comment on the following:

Or. en

## Amendment 198

Geoffroy Didier

## Proposal for a regulation

### Article 7 – paragraph 3 – point a

*Text proposed by the Commission*

(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;

*Amendment*

(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 ***and the fulfilment of the conditions referred to in pursuant to Article 4(1a) for conducting meaningful negotiations for that purpose;***

Or. en

## Amendment 199

Tiemo Wölken

## Proposal for a regulation

### Article 7 – paragraph 3 – point a

*Text proposed by the Commission*

(a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing

*Amendment*

(a) the possibility to reach a voluntary licensing agreement ***within 4 weeks*** with manufacturers on intellectual property rights for the purpose of manufacturing,

the crisis-relevant products;

using and distributing the crisis-relevant products;

Or. en

**Amendment 200**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 7 – paragraph 3 – point a**

*Text proposed by the Commission*

(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;

*Amendment*

(a) the possibility to reach ***as soon as possible*** a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;

Or. fr

**Amendment 201**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 3 – point a**

*Text proposed by the Commission*

(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;

*Amendment*

(a) the possibility to ***promptly*** reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the ***relevant*** products;

Or. en

**Amendment 202**  
**Emmanuel Maurel**

**Proposal for a regulation**



## Article 7 – paragraph 3 – point b

*Text proposed by the Commission*

*Amendment*

**(b) the need to grant the Union compulsory licence;**

**deleted**

Or. fr

## Amendment 203 Emmanuel Maurel

### Proposal for a regulation Article 7 – paragraph 3 – point c

*Text proposed by the Commission*

*Amendment*

(c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.

(c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.

***The Commission shall not be required to examine the comments received.***

***The procedure laid down in paragraph 3(a) shall not be required if it risks delaying, beyond a reasonable period of time, the granting of a compulsory licence and access to the crisis-critical products.***

Or. fr

## Amendment 204 Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation Article 7 – paragraph 3 – point c

*Text proposed by the Commission*

*Amendment*

(c) the conditions under which the Commission intends to grant the Union compulsory licence, ***including the amount of the remuneration.***

(c) the conditions under which the Commission intends to ***propose to the Council the grant of*** the Union compulsory licence.

**Amendment 205**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 7 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**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.*** ***deleted***

**Amendment 206**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**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.***

**4. The Commission shall *identify and* notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. The Commission shall notify them individually.**

**Amendment 207**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 7 – paragraph 5**

*Text proposed by the Commission*

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.

*Amendment*

5. When the Commission considers ***that the conditions for*** the granting of a Union compulsory licence ***are met***, 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.

Or. en

**Amendment 208**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 7 – paragraph 5**

*Text proposed by the Commission*

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.

*Amendment*

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, ***and translated if necessary***, in the Official Journal of the European Union.

Or. fr

**Amendment 209**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – introductory part**

*Text proposed by the Commission*

6. When assessing whether a Union compulsory licence is to be granted, the Commission shall ***consider the following***:

*Amendment*

6. When assessing whether a Union compulsory licence is to be granted, the Commission shall:

Or. en

**Amendment 210**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point a**

*Text proposed by the Commission*

(a) the opinion referred to in paragraph 2;

*Amendment*

(a) ***follow*** the opinion referred to in paragraph 2;

Or. en

**Amendment 211**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point b**

*Text proposed by the Commission*

(b) the rights and interests of the rights-holder and the licensee;

*Amendment*

(b) ***consider*** the rights and interests of the rights-holder and the licensee;

Or. en

**Amendment 212**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point b**

*Text proposed by the Commission*

(b) the rights ***and interests*** of the rights-holder and the licensee;

*Amendment*

(b) the rights of the rights-holder and the licensee;

Or. en

**Amendment 213**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point c**

*Text proposed by the Commission*

(c) existing national compulsory licences reported to the Commission in accordance with Article 22.

*Amendment*

(c) ***take into account*** existing national compulsory licences reported to the Commission in accordance with Article 22 ***in order to prevent overlaps and a situation of overproduction.***

Or. en

**Amendment 214**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point c**

*Text proposed by the Commission*

(c) existing national compulsory licences reported to the Commission in accordance with Article 22.

*Amendment*

(c) existing national compulsory licences ***and relevant procedures*** reported to the Commission in accordance with Article 22.

Or. en

**Amendment 215**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) the public interest identified.**

Or. en

**Amendment 216**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 7 – paragraph 6 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) the identified public interest.**

Or. fr

**Amendment 217**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 7 – paragraph 7**

*Text proposed by the Commission*

*Amendment*

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 shall remain in force for a period not exceeding

7. Where the Commission, ***taking into consideration the opinion provided by the advisory body, considers*** that the requirements for a Union compulsory licence are met, the Commission shall ***propose to the Council to*** grant it. ***The Council may grant a Union compulsory licensing*** by means of ***a Council*** implementing act. The ***duration and the definition of the crisis-relevant products shall be specified in the*** implementing act.

12 months.

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.

Or. en

**Amendment 218**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 7 – paragraph 7**

*Text proposed by the Commission*

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 shall remain in force for a period not exceeding 12 months.

*Amendment*

7. Where the **advisory body concludes, after duly considering the comments submitted by rights-holder and the licensee pursuant to paragraph 3**, 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 shall remain in force for a period not exceeding 12 months.

Or. en

**Amendment 219**

Alessandra Basso, Gunnar Beck, Gilles Lebreton

**Proposal for a regulation**  
**Article 7 – paragraph 8**

*Text proposed by the Commission*

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.

*Amendment*

8. When adopting the implementing act, confidential information ***shall be protected***. While respecting the confidentiality of the information, ***it*** shall ***be ensured*** 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.

Or. en

**Amendment 220**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

(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;***

*Amendment*

(a) the patent, supplementary protection certificate or utility model for which the licence is granted;

Or. en

**Amendment 221**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point a**



*Text proposed by the Commission*

(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;***

*Amendment*

(a) the patent, supplementary protection certificate or utility model for which the licence is granted;

Or. en

**Amendment 222**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

(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;

*Amendment*

(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or the non-proprietary name of the products which are to be manufactured under the licence;

Or. fr

**Amendment 223**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

(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***

*Amendment*

(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted or the non-proprietary name of the products which are to be manufactured

**granting of the licence**, the non-proprietary name of the products which are to be manufactured under the licence;

under the licence;

Or. en

#### **Amendment 224**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

#### **Proposal for a regulation**

#### **Article 8 – paragraph 1 – point a**

##### *Text proposed by the Commission*

(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;

##### *Amendment*

(a) the patent, 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;

Or. en

#### **Amendment 225**

**Geoffroy Didier**

#### **Proposal for a regulation**

#### **Article 8 – paragraph 1 – point b**

##### *Text proposed by the Commission*

(b) the right-holder, ***provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation***;

##### *Amendment*

(b) the right-holder;

Or. en

#### **Amendment 226**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 8 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the right-holder, ***provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;***

*Amendment*

(b) the right-holder;

Or. en

**Amendment 227**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 8 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) the duration for which the Union compulsory licence is granted;

*Amendment*

(d) the duration for which the Union compulsory licence is granted, ***with an initial suspension period the duration of which shall not be less than ten days from the day following the day of publication of the Union compulsory license in the Official Journal of the European Union, for the purpose of a possible judicial review;***

Or. en

**Amendment 228**

**Geoffroy Didier**

**Proposal for a regulation**

**Article 8 – paragraph 1 – point f**

*Text proposed by the Commission*

(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

*Amendment*

(f) the ***international*** non-proprietary name ***if any*** of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which

classified, as defined in Council Regulation (EEC) No 2658/87;

the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;

Or. en

**Amendment 229**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point h**

*Text proposed by the Commission*

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.

*Amendment*

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence. ***These measures shall be without prejudice to the applicable Union and national legal acts on protection of trade secrets and know-how, including Directive (EU) 2016/943.***

Or. en

*Justification*

*Measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence, shall clearly exclude trade secrets and know-hows.*

**Amendment 230**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – point h**

*Text proposed by the Commission*

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.

*Amendment*

(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence, ***such as the requirement for the right-holder to share with the licensee the know-how needed to manufacture the product.***

**Amendment 231**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 8 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**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).** **deleted**

Or. en

**Amendment 232**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 8 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 8a**

**Review by the Court of Justice of the European Union**

- 1. The Court of Justice of the European Union has jurisdiction to review the grounds and the conditions under which a Union compulsory licence has been granted.**
- 2. An implementing act granting a Union compulsory licence shall not take effect before the end of an initial suspension period which shall not be less than 10 calendar days from the day**

*following the day of publication of the Union compulsory license in the Official Journal of the European Union.*

*3. The right-holder or the licensee may lodge, before the expiry of the suspension period, an application for annulment of the implementing act. Such an application shall have a suspensive effect.*

Or. en

**Amendment 233**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Article 9 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration ***and corresponding timeframe of the use of the compulsory licence*** shall be determined by the Commission and specified in the Union compulsory licence.

Or. en

**Amendment 234**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 9 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by ***agreement between the right holder and the licensee*** and specified in the Union compulsory licence.

**Amendment 235**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 9 – paragraph 1**

*Text proposed by the Commission*

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.*

*Amendment*

1. The *right holder* shall *be paid* adequate remuneration *in the circumstances of each case, taking into account the economic value* of the *authorization.*

**Amendment 236**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 9 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. The licensee *may* 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.

**Amendment 237**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 9 – paragraph 1**

*Text proposed by the Commission*

1. The licensee shall pay *an adequate*

*Amendment*

1. The licensee shall pay *a fair*

remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.

remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.

Or. en

**Amendment 238**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.**

**deleted**

Or. en

**Amendment 239**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

**2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.**

**2. The remuneration shall not exceed 5 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence *unless the benefits accruing to the compulsory licensee would be significantly higher than those accruing to the right-holder from the licensed solution;***

Or. en

**Amendment 240**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**



**Proposal for a regulation**  
**Article 9 – paragraph 2**

*Text proposed by the Commission*

2. The remuneration shall ***not exceed 4 % of*** total gross revenue generated by the licensee ***through the relevant*** activities under the Union compulsory licence.

*Amendment*

2. The remuneration shall ***be determined based on the*** total gross revenue generated by the licensee ***from the pertinent*** activities under the Union compulsory licence.

Or. en

**Amendment 241**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 9 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. In case an agreement pursuant to paragraph 1 cannot be reached in due time, the remuneration shall be determined by the Commission, taking into account the total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence, as well as the additional elements defined in paragraph 3.***

Or. en

**Amendment 242**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 9 – paragraph 3 – introductory part**

*Text proposed by the Commission*

*Amendment*

3. When determining the remuneration, the ***Commission shall***

3. When determining the remuneration, the following ***elements shall***

*consider the* following:

*be considered:*

Or. en

**Amendment 243**  
**Kosma Złotowski**

**Proposal for a regulation**  
**Article 9 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) whether the rights-holder has received public support *to develop* the invention.

*Amendment*

(b) whether the rights-holder has received public support *for the process of developing* the invention *at any stage of the research and development phase*;

Or. en

**Amendment 244**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 9 – paragraph 3 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

*(da) the possible disclosure of trade secrets for the purpose of exercising the Union compulsory licence pursuant to Article 13a(1), and the relevant limitations to the protection of trade secrets according to Directive (EU) 2016/943.*

Or. en

*Justification*

*Compulsory licenses, when granted, should be considered as being part of the lawful uses and limitations to Trade Secret protection, as provided in the Trade Secrets Directive itself (such as for the general public interest; cf. TS Directive, Art. 3 (lawful uses), Art. 5 (exceptions) and Art. 11 (safeguards, incl. the public interest)).*

**Amendment 245**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 9 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**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.** **deleted**

Or. en

**Amendment 246**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 9 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**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.** **deleted**

Or. en

**Amendment 247**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

<b>(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what</b>	<b>(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed <i>the</i></b>
--	--

is necessary to meet the needs of the Union;

***defined quantities and*** what is necessary to meet the needs of the Union;

Or. en

**Amendment 248**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(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;

(a) the number of ***relevant*** products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union;

Or. en

*Justification*

*TRIPS wording, Article 31.F: any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use.*

**Amendment 249**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 10 – paragraph 1 – subparagraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) provide detailed account of the products produced under the Union compulsory license***

Or. en

**Amendment 250**  
**Heidi Hautala**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1 – point b**

*Text proposed by the Commission*

(b) the relevant activities are carried out ***solely*** for the supply of the ***crisis-relevant*** products in the Union market;

*Amendment*

(b) the relevant activities are carried out ***predominantly*** for the supply of the ***relevant*** products in the Union market, ***unless intended for export for countries facing public health challenges regulated under Regulation 816/2006;***

Or. en

**Amendment 251**

**Geoffroy Didier**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) treat information acquired within the Union compulsory license with utmost confidentiality and implement all measures to safeguard such information.***

Or. en

**Amendment 252**

**Heidi Hautala**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

***(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.***

***deleted***

Or. en

*Justification*

*These are TRIPS Art. 31bis requirements on the rules for export not for domestic use, which would limit here the feasibility of an effective compulsory license meant to have cross-border effects.*

**Amendment 253**

**Heidi Hautala**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1 – point d**

*Text proposed by the Commission*

*Amendment*

**(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;** **deleted**

Or. en

*Justification*

*Same justification than for deletion of sub-para c).*

**Amendment 254**

**Heidi Hautala**

**Proposal for a regulation**

**Article 10 – paragraph 1 – subparagraph 1 – point e**

*Text proposed by the Commission*

*Amendment*

**(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 compulsory licence under this Regulation and specify clearly that the products are** **deleted**

*exclusively for distribution in the Union  
and are not to be exported.*

Or. en

*Justification*

*Same justification than for deletion of sub-para c).*

**Amendment 255**  
**Kosma Złotowski**

**Proposal for a regulation**  
**Article 10 – paragraph 2 – point a**

*Text proposed by the Commission*

(a) terminate the Union compulsory  
licence in accordance with Article 14(3); or

*Amendment*

(a) ***immediately*** terminate the Union  
compulsory licence in accordance with  
Article 14(3); or

Or. en

**Amendment 256**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 10 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) impose fines ***or*** periodic penalties  
on the licensee in accordance with Articles  
15 and 16.

*Amendment*

(b) impose fines ***and*** periodic penalties  
on the licensee in accordance with Articles  
15 and 16.

Or. en

**Amendment 257**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 10 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

**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.**

**deleted**

Or. en

#### **Amendment 258**

**Heidi Hautala**

#### **Proposal for a regulation**

#### **Article 10 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

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.

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, **and on the basis of sufficient elements of proof of misuse**, 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.

Or. en

#### **Amendment 259**

**Heidi Hautala**

#### **Proposal for a regulation**

#### **Article 10 – paragraph 4**



*Text proposed by the Commission*

*Amendment*

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).

4. The Commission is empowered to adopt implementing acts establishing rules ***regarding the conditions applicable under this Regulation, in accordance with the requirements enshrined in the TRIPS Agreement.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).

Or. en

*Justification*

*The Commission wording seems to go beyond TRIPS requirements (cf. above our deletion of c) and d)).*

**Amendment 260**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 11 – title**

*Text proposed by the Commission*

*Amendment*

***Prohibition of*** export

***Conditions for*** export

Or. en

**Amendment 261**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

***The export of*** products manufactured under a Union compulsory licence ***is prohibited.***

Products manufactured under a Union compulsory licence ***shall be authorised primarily to supply the internal market, except for products manufactured under a Union compulsory license for export***

*under Regulation (EC) No 816/2006.*

Or. fr

## **Amendment 262**

**Heidi Hautala**

### **Proposal for a regulation**

#### **Article 11 – paragraph 1**

*Text proposed by the Commission*

The **export of** products manufactured under a Union compulsory licence **is prohibited**.

*Amendment*

The products manufactured under a Union compulsory licence ***shall be authorised predominantly for the supply of the internal market, except for products manufactured under a Union compulsory license for export under Regulation (EC) No 816/2006.***

Or. en

## **Amendment 263**

**Emmanuel Maurel**

### **Proposal for a regulation**

#### **Article 12 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, ***with the exception of the crisis-critical products covered by Regulation (EC) No 816/2006,*** 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.

Or. fr

## Amendment 264

Heidi Hautala

### Proposal for a regulation

#### Article 12 – paragraph 3

*Text proposed by the Commission*

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.

*Amendment*

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall immediately notify the Commission 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 products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder ***and refer to the requirements provided under Directive 2004/48/EC.***

Or. en

## Amendment 265

Emmanuel Maurel

### Proposal for a regulation

#### Article 12 – paragraph 5

*Text proposed by the Commission*

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.

*Amendment*

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, ***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.

Or. fr

**Amendment 266**  
**Heidi Hautala**

**Proposal for a regulation**  
**Article 13 – paragraph 2**

*Text proposed by the Commission*

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*.

*Amendment*

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. ***This may include but may not be limited to the full transfer of needed technology, knowhow, test data, samples and reference products needed for production and market authorisation,*** taking into account ***the public interest***.

Or. en

**Amendment 267**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 13 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best ***reasonable*** efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.

Or. en

**Amendment 268**

**Heidi Hautala**

**Proposal for a regulation  
Article 13 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 13a**

***Additional measures complementing the  
Union compulsory licence***

- 1. Where necessary , the Commission shall decide, upon a 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.***
- 2. Where necessary, the Commission shall request from the rights-holders the disclosure of trade secrets to the licensee in order to provide them with the necessary know-how, test data, samples and reference products to strictly achieve the objective of the Union compulsory licence as provided for in this Regulation. In such cases, the Commission shall order all appropriate measures necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties.***
- 3. Where the Commission considers modifying or adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.***
- 4. Appropriate remuneration to the rights-holders in compensation for the disclosure of their trade secrets may be granted in accordance with Directive (EU) 2016/943.***

Or. en

**Amendment 269**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Article 13 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 13a**

***Additional measures complementing the  
Union compulsory licence***

- 1. Where necessary, the Commission shall decide, upon a 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.***
- 2. Where necessary, the Commission shall request from the rights-holder the disclosure of trade secrets to the licensee in order to provide him with the necessary know-how to strictly achieve the objective of the Union compulsory licence as provided for in this Regulation. In such cases, the Commission shall order all appropriate measures necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties***
- 3. Where the Commission considers modifying or adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.***
- 4. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).***

Or. en

## Amendment 270

Alessandra Basso, Gunnar Beck, Gilles Lebreton

### Proposal for a regulation

#### Article 14 – paragraph 1

##### *Text proposed by the Commission*

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.

##### *Amendment*

1. The Commission shall ***propose to the Council to*** review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and, where needed, ***to*** modify the specifications referred to in Article 8 ***or to establish additional measures complementing the Union compulsory licensing to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee. The Council shall act*** 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.

Or. en

## Amendment 271

Geoffroy Didier

### Proposal for a regulation

#### Article 14 – paragraph 1

##### *Text proposed by the Commission*

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***

##### *Amendment*

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.

*compulsory licence.*

Or. en

**Amendment 272**

**Heidi Hautala**

**Proposal for a regulation**

**Article 14 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. The Commission shall review the Union compulsory licence 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 ***and feasible***, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.

Or. en

**Amendment 273**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 14 – paragraph 2**

*Text proposed by the Commission*

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.***

*Amendment*

***deleted***

Or. en



**Amendment 274**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 14 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

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 *of accelerating the crisis response* as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee. *Any such additional measures shall be without prejudice to the applicable Union and national legal acts on protection of trade secrets and know how including Directive (EU) 2016/943.*

Or. en

**Amendment 275**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 14 – paragraph 3**

*Text proposed by the Commission*

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 recur or where the licensee fails to comply with the obligations laid down in this Regulation.

*Amendment*

3. A Union compulsory licence may be terminated by the **Council** 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.

Or. en

**Amendment 276**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

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.

*Amendment*

4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it **shall** consult the advisory body referred to in Article 6 **as well as the rights-holders and licensees**.

Or. en

**Amendment 277**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

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.

*Amendment*

4. When the Commission considers **the proposal of** modifying, adopting additional measures as referred to in paragraph **1**, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.

Or. en

**Amendment 278**  
**Tiemo Wölken**

**Proposal for a regulation**  
**Article 14 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**4a. When the Commission considers terminating the Union compulsory licence**

*it shall ensure that there is a sufficient transitional period put in place.*

Or. en

**Amendment 279**

**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**

**Article 14 – paragraph 6**

*Text proposed by the Commission*

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).

*Amendment*

6. The implementing acts referred to in paragraph 1 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Or. en

**Amendment 280**

**Kosma Zlotowski**

**Proposal for a regulation**

**Article 15 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding **10** % of their respective total turnover in the preceding business year where, intentionally or negligently:

Or. en

**Amendment 281**

**Kosma Zlotowski**

**Proposal for a regulation**

**Article 15 – paragraph 1 – point a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) the licensee does not comply with the prohibition as referred in Article 11;***

Or. en

**Amendment 282**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 16 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

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:

1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding **8** % 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:

Or. en

**Amendment 283**  
**Kosma Zlotowski**

**Proposal for a regulation**  
**Article 16 – paragraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) the licensee to put an end to an infringement of the prohibition as referred in Article 11;***

Or. en

**Amendment 284**  
**Geoffroy Didier**

**Proposal for a regulation**

## Article 19 – paragraph 1

### *Text proposed by the Commission*

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.

### *Amendment*

1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall **fully involve** the licensee or the rights-holder **in the procedure and give them** the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.

Or. en

## Amendment 285 Kosma Zlotowski

### Proposal for a regulation Article 19 – paragraph 4

### *Text proposed by the Commission*

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.

### *Amendment*

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, **fully in line with existing legislation for the protection of data and trade secrets**, 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.

Or. en

**Amendment 286**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 20 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. Interim measures, including for the suspension of the implementing act granting a compulsory amendments, should be made available in accordance with the rules applicable to the corresponding proceedings before the Court of Justice of the European Union.**

Or. en

**Amendment 287**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 20 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

**2b. Should the Court of Justice of the European Union decide to annul the implementing act granting a compulsory licence, the right holders should be entitled to compensation for damages in order to restore their position ex-ante.**

Or. en

**Amendment 288**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 21 – paragraph 1**

*Text proposed by the Commission*

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.***

*Amendment*

In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission:

Or. en

**Amendment 289**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 21 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***has granted a compulsory licence. It may cancel or amend its terms and conditions.***

Or. en

**Amendment 290**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 21 – paragraph 1 b (new)**

*Text proposed by the Commission*

*Amendment*

***has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.***

Or. en

**Amendment 291**  
**Geoffroy Didier**

**Proposal for a regulation**  
**Article 21 a (new)**

*Text proposed by the Commission*

*Amendment*

**Article 21a**

**Standstill period**

- 1. For the purposes of Article 21, paragraph 1, point (a) and point (b), an implementing act granting a Union compulsory license shall not take effect before the end of an initial standstill period of no less than 10 calendar days from the day following the day of publication of the Union compulsory license in the Official Journal of the European Union.**
- 2. If a rights-holder, before the expiry of the initial standstill period, lodges an application for annulment of the implementing act and an application to suspend the implementing act before the General Court of the European Union, the implementing act shall not take effect during a subsequent standstill period which shall commence on the day of lodgement of the application for annulment and the application to suspend the implementing act and/or the application for interim measures and shall end either on the day after the day on which the General Court has taken a decision on the application to suspend the implementing act and/or on the application for interim measures, or, if no such decision has been taken by the General Court, within eight weeks, on the day after the last day of the eighth week.**

Or. en

**Amendment 292**  
**Heidi Hautala**



**Proposal for a regulation**

**Article 22 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

When a national compulsory licence has been granted ***for the public interest or*** 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:

Or. en

**Amendment 293**

**Heidi Hautala**

**Proposal for a regulation**

**Article 22 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) the remuneration to be paid to the rights-holder;

*Amendment*

(d) the remuneration to be paid to the rights-holder, ***when relevant***;

Or. en

**Amendment 294**

**Heidi Hautala**

**Proposal for a regulation**

**Article 23 – paragraph 1 – point a**

Regulation (EC) No 816/2006

Article 18a

*Text proposed by the Commission*

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***

*Amendment*

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).

*covered by the compulsory licence.*

Or. en

*Justification*

*A third country does not necessarily know where in the EU a medical products or its components should be best produced and which member states the CL should cover exactly. Moreover, such requirement would not be compliant with the TRIPS Agreement.*

**Amendment 295**

**Heidi Hautala**

**Proposal for a regulation**

**Article 26 – title**

*Text proposed by the Commission*

*Amendment*

Entry into force

Entry into force ***and application***

Or. en

**Amendment 296**

**Heidi Hautala**

**Proposal for a regulation**

**Article 26 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***It shall apply from [the first day of the month following the period of twelve months after the date of entry into force].***

Or. en

**Amendment 297**

**Adrián Vázquez Lázara**

**Proposal for a regulation**

**Annex – line 2 – column 3**

*Text proposed by the Commission*

*Amendment*

**Health Security Committee** [Article 4 of Regulation (EU) 2022/2371]

**Health Security Committee** [Article 24 of Regulation (EU) 2022/2371]

Or. en

*Justification*

*Justification: It appears that for the purposes of the "advisory body" as per article 6 of the proposed regulation on compulsory licensing, it would be the Advisory Committee under art. 24 of Reg. (EU) 2022/2371 that is competent.*

**Amendment 298**  
**Emmanuel Maurel**

**Proposal for a regulation**  
**Annex I**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

Or. fr

**Amendment 299**  
**Alessandra Basso, Gunnar Beck, Gilles Lebreton**

**Proposal for a regulation**  
**Annex I**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

Or. en

**Amendment 300**  
**Heidi Hautala**

**Proposal for a regulation**  
**Annex I**

*Text proposed by the Commission*

*Amendment*

[...]

*deleted*

Or. en

*Justification*

*As per our Group position, we want to broaden the scope of the regulation and make it stick to TRIPS standards. The grant of compulsory licenses, even in crisis situations, should not exclusively depend on and be restricted to narrow conditions defined in Union acts that will likely not allow to grasp all the conditions under which compulsory licenses may be needed, in a near and more distant future to address public interest needs and challenges.*