

Land, product:	<b>Noord-Macedonië, gelatine (HC)</b>				
Code:	<b>DPDLH-223</b>	Versie:	1.0.0	Datum:	16 juni 2021
Eigenaar:	NVWA O&O, team Import & Export				

<b>Versie-geschiedenis</b>		
Versie	Datum	Wijziging ten opzichte van vorige versie
1.0.0	16-06-2021	Met Noord-Macedonië zijn afspraken gemaakt over de export van gelatine. Deze instructie en het bijgevoegde certificaat vormen de weerslag van deze afspraken.

## 1 DOEL EN TOEPASSINGSGEBIED

Deze instructie geldt voor het exporteren van gelatine bestemd voor humane consumptie naar Noord-Macedonië. De instructie beschrijft de voorwaarden die gelden voor de invoer in Noord-Macedonië, de controles die de NVWA hiervoor moet uitvoeren, en de gegevens die het bedrijfsleven moet aanleveren aan de NVWA.

Over de certificeringseisen die gelden voor de export van gelatine bestemd voor humane consumptie naar Noord-Macedonië zijn officiële bilaterale afspraken gemaakt. Deze afspraken zijn bindend, van deze afspraken kan dus niet worden afgeweken.

## 2 WETTELIJKE BASIS

### 2.1 EU-regelgeving

- Verordening (EG) nr. 178/2002
- Verordening (EG) nr. 852/2004
- Verordening (EG) nr. 853/2004
- Verordening (EU) 2017/625

### 2.2 Nationale wetgeving

- Gezondheid- en welzijnswet voor dieren, artikel 79
- Wet dieren

### 2.3 Overige

- Bilaterale afspraken tussen Noord-Macedonië en Nederland.

## 3 DEFINITIES

gelatine : Natuurlijk, oplosbaar eiwit, gelerend of niet-gelerend, verkregen door gedeeltelijke hydrolyse van collageen uit beenderen, huiden, ligamenten en pezen van dieren (Verordening (EG) Nr. 853/2004, bijlage I)

Voor de vervaardiging van voor gebruik in levensmiddelen bestemde gelatine mogen de volgende grondstoffen worden gebruikt:

- beenderen die geen specifiek risicomateriaal vormen, als omschreven in artikel 3, lid 1, onder g), van Verordening (EG) Nr. 999/2001;
- huiden van als landbouwhuisdier gehouden herkauwers;
- varkenshuiden;
- huid van pluimvee;
- ligamenten en pezen;
- huiden van vrij wild;
- huiden en graten van vis.

## 4 WERKWIJZE

De export van gelatine bestemd voor humane consumptie naar Noord-Macedonië is toegestaan.

- *Certificaat: zie bijlage*

### Toelichting bij het certificaat:

#### Algemeen:

- Raadpleeg vooraf de instructie Tijdelijke Maatregelen Derde Landen (TMDL-01) op mogelijke exportbeperkingen. Als in de TMDL-01 informatie staat die in strijd is met een landeninstructie dan is de informatie vermeld in de TMDL-01 leidend.

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*I, the undersigned, declare that I am aware of the relevant provisions of the Law food safety and/or equivalent Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the gelatine described above was produced in accordance with those requirements, in particular that:*  
 Deze verklaring kan worden afgegeven indien de certificerende NVA-dierenarts kennis heeft genomen van de relevante bepalingen van de genoemde EU-regelgeving (Verordening (EG) nr. 178/2002, Verordening (EG) nr. 852/2004 en Verordening (EG) nr. 853/2004).

Verklaring 1:

*It comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Law food safety and/or equivalent article 5 of Regulation (EC) No 852/2004;*  
 Deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving voor een product van een bedrijf met een erkenning volgens Verordening (EG) nr. 853/2004 of een registratie volgens Verordening (EG) nr. 852/2004.

Verklaring 2:

*It has been produced from raw material which met the requirements of the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapters I and II of Annex III to Regulation (EC) No 853/2004;*  
 Deze verklaring kan worden afgegeven voor een product van een erkend productiebedrijf van gelatine voor humane consumptie op basis van EU- en nationale regelgeving.

Verklaring 3:

*It has been manufactured in compliance with the conditions set out in the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004;*  
 Deze verklaring kan worden afgegeven voor een product van een erkend productiebedrijf van gelatine voor humane consumptie op basis van EU- en nationale regelgeving.

Verklaring 4:

*It satisfies the criteria of the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;*  
 Deze verklaring kan worden afgegeven voor een product van een erkend productiebedrijf van gelatine voor humane consumptie op basis van EU- en nationale regelgeving.

Verklaring 5:

*and<sup>(1)</sup> If of bovine, ovine and caprine animal origin,  
 it has been derived from animals which have passed ante mortem and post mortem inspections;*

Verklaring 5 en verklaring 6 zijn uitsluitend van toepassing voor gelatine afkomstig van runderen, schapen of geiten. Voor gelatine afkomstig van andere diersoorten moeten verklaring 5 en verklaring 6 geheel worden doorgehaald.

Indien sprake is van gelatine afkomstig van runderen, schapen of geiten kan deze verklaring worden afgegeven op basis van EU- en nationale regelgeving. Hierbij mag er vanuit worden gegaan dat de grondstoffen niet afkomstig zijn van wilde runderen, schapen of geiten en dus afkomstig zijn van dieren die in een erkend slachthuis een AM- en PM-keuring hebben ondergaan en zijn goedgekeurd voor humane consumptie.

Verklaring 6:

*and<sup>(1)</sup> Except for gelatine derived from hides and skins,  
 either<sup>(1)</sup> - It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk as a country or region posing a negligible BSE risk;  
 - The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001<sup>(2)</sup>;  
 - The gelatine does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for gelatine derived from animals that were born, continuously reared and slaughtered in a country or*

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*region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases;*

- *The animals from which the gelatine is derived were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing a negligible BSE risk;*
- <sup>(1)</sup> *The animals, from which the gelatine is derived, originate from a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code;*
- <sup>(1)</sup> *The animals, from which the gelatine is derived, originate from a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the gelatine was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process;*

- or*<sup>(1)</sup>
- *It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region posing a controlled BSE risk;*
  - *The animals, from which the gelatine is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;*
  - *The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;*

- or*<sup>(1)</sup>
- *It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region posing a negligible BSE risk;*
  - *The gelatine is derived both from animals were born, continuously reared and slaughtered in a country or region with negligible BSE risk in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC, and from animals born in a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC, as a country or region posing a negligible BSE risk, and which were not killed after stunning by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity or by means of gas injected into the cranial cavity;*
  - *The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;*

- or*<sup>(1)</sup>
- *It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region with an undetermined BSE risk;*
  - *The animals, from which the gelatine is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health;*
  - *The animals, from which the gelatine is derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;*
  - *The gelatine is not derived from:*

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- (i) *specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies health and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001;*
- (ii) *nervous and lymphatic tissues exposed during the deboning process;*
- (iii) *mechanically separated meat obtained from bones of bovine, ovine or caprine animals.*

Verklaring 6 is uitsluitend van toepassing voor gelatine afkomstig van beenderen, ligamenten en/of pezen van runderen, schapen of geiten. Voor gelatine afkomstig van andere grondstoffen (huiden) moet verklaring 6 geheel worden doorgehaald.

Indien sprake is van gelatine afkomstig van beenderen, ligamenten en/of pezen van runderen, schapen of geiten:

Deze verklaring bestaat uit vier opties, met ieder een aantal 'deelverklaringen'. De van toepassing zijnde optie moet worden gekozen en de overige opties moeten worden doorgehaald.

- De eerste optie van deze verklaring kan worden gekozen voor gelatine afkomstig uit landen met een verwaarloosbaar BSE-risico.

De eerste vier bijbehorende deelverklaringen kunnen worden afgegeven op basis van EU- en nationale regelgeving.

Voor de vijfde en zesde deelverklaring moeten de herkomstlanden van de dieren waar de grondstoffen van afkomstig zijn worden aangetoond. Indien deze dieren uit landen met een gecontroleerd of verwaarloosbaar risico komen dan moeten deze deelverklaringen worden doorgehaald. Indien deze dieren uit landen met onbepaald BSE-risico komen moeten deze deelverklaringen open worden gelaten.

- Voor gelatine afkomstig van een erkend productiebedrijf gelegen in Nederland moet belanghebbende hiervoor aantonen uit welke landen de grondstoffen voor de vervaardiging van de gelatine afkomstig zijn. Ontvangen grondstoffen uit Nederland en andere EU-lidstaten dienen daartoe begeleid te worden door een "Begeleidend document voor grondstoffen die bestemd zijn voor de productie van gelatine of collageen voor menselijke consumptie", zoals voorgeschreven in het aanhangsel bij bijlage III van Verordening (EG) nr. 853/2004, of een document met verklaringen van gelijke inhoud. Ontvangen grondstoffen uit landen buiten de EU dienen daartoe begeleid te worden door een importcertificaat, zoals voorgeschreven in bijlage II, deel V van Uitvoeringsverordening (EU) 2016/759.
- Voor gelatine afkomstig van een erkend productiebedrijf gelegen in een andere EU-lidstaat dan Nederland geldt dat deze deelverklaringen afgegeven kunnen worden op basis van een veterinaire voorverklaring van gelijke strekking, afgegeven door de bevoegde autoriteit van desbetreffende EU-lidstaat.
- Voor gelatine afkomstig uit derde landen kunnen deze deelverklaringen worden afgegeven op basis van een verklaring van gelijke strekking op het importcertificaat.
- De tweede optie van deze verklaring kan worden gekozen voor gelatine afkomstig uit landen met een gecontroleerd BSE-risico. Bijbehorende twee deelverklaringen kunnen bij herkomst uit een productiebedrijf in de EU worden afgegeven op basis van EU- en nationale regelgeving. Voor herkomst van de gelatine uit een derde land kunnen deze worden afgegeven op basis van een verklaring van gelijke strekking op het importcertificaat.
- De derde optie van deze verklaring kan worden gekozen voor gelatine afkomstig uit landen met een verwaarloosbaar BSE-risico. De eerste bijbehorende deelverklaring kan worden afgegeven indien de dieren waar de grondstoffen van afkomstig zijn, zijn geboren, getogen en geslacht zijn in een land met een verwaarloosbaar BSE-risico. Voor grondstoffen afkomstig uit Nederland kan dit worden aangetoond op basis van geleidebiljetten waarop wordt aangegeven waar de dieren geboren, getogen en geslacht zijn. Voor grondstoffen uit andere EU-lidstaten is hiervoor een veterinaire voorverklaring van gelijke strekking, afgegeven door de bevoegde autoriteit van de desbetreffende EU-lidstaat, benodigd. De tweede bijbehorende deelverklaring kan worden afgegeven op basis van EU- en nationale regelgeving.  
De derde optie van deze verklaring kan niet worden gekozen voor gelatine afkomstig uit derde landen, aangezien deze niet overeenkomt met het importcertificaat.
- De vierde optie van deze verklaring kan worden gekozen voor gelatine afkomstig uit landen met een onbepaald BSE-risico. Het gaat hierbij om import van gelatine uit derde landen. De bijbehorende deelverklaringen kunnen worden afgegeven op basis van een verklaring van gelijke strekking op het importcertificaat.

## 5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN

De NVWA-dierenarts is bevoegd en verantwoordelijk voor het afgeven van het certificaat.

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Bijlage 1: certificaat

ВЕТЕРИНАРНО ЗДРАВСТВЕН СЕРТИФИКАТ  
 ЗА ЖЕЛАТИН НАМЕНЕТ ЗА ИСХРАНА НА ЛУЃЕТО ЗА УВОЗ ВО РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА /  
 VETERINARY CERTIFICATE FOR GELATINE INTENDED FOR HUMAN CONSUMPTION  
 FOR DISPATCH TO THE REPUBLIC OF NORTH MACEDONIA

I. ИДЕНТИФИКАЦИЈА НА ПРОИЗВОДИТЕ / IDENTIFICATION OF THE PRODUCTS

Производ бр. / Product no.	Производ / Product	Вид, сорта / Species	Потекло / Origin	Контролен број / Approval number

Производ бр. / Product no.	XC-натпис <sup>(3)</sup> / HS-heading <sup>(3)</sup>	XC-описување (XC-4) / HS-description (HS-4)

Серија бр. / Batch no.	Датум на производство / Production date	Пакување / Packing	Нето тежина / Nett weight	Бруто тежина / Gross weight	Чување/складирање / Storage

Ознаки / Marks :  
 Број на контејнер<sup>(4)</sup> / :  
 Container number<sup>(4)</sup>  
 Број на печатот<sup>(4)</sup> / :  
 Seal number<sup>(4)</sup>

II. ПОТЕКЛО НА ПРОИЗВОДИТЕ / ORIGIN OF THE PRODUCTS

Производ бр. / Product no.	Бр. на одобрение / Approval no.	Име и Адреса / Name and Address

Име и Адреса Испраќач / :  
 Name and address consignor  
 Датум експедирање на или :  
 околу /  
 Date of shipment on or about  
 Место на товарење / :  
 Place of loading

III. ДЕСТИНАЦИЈА НА ПРОИЗВОДИТЕ / DESTINATION OF THE PRODUCTS

Превозни средства / :  
 Means of conveyance  
 Идентификација Превозни :  
 средства<sup>(5)</sup> /  
 Identification of the means of  
 conveyance<sup>(5)</sup>  
 Држава на определување / :  
 Country of destination  
 Граничен влез / :  
 Point of entry  
 Место на определување / :  
 Place of destination  
 Име и Адреса Примач / :  
 Name and address consignee

IV. ЗДРАВСТВЕНО ИЗВЕСТУВАЊЕ / HEALTH ATTESTATION

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Јас, долупотпишаниот, изјавувам дека сум запознаен за релевантните одредби во Законот за безбедност на храната односно еквивалентните Регулативи (ЕК) Бр 178/2002, (ЕК) Бр 852/2004 и (ЕК) Бр 853/2004 и потврдувам дека желатинот опишан погоре е произведен во согласност со тие услови, поточно дека: / I, the undersigned, declare that I am aware of the relevant provisions of the Law food safety and/or equivalent Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the gelatine described above was produced in accordance with those requirements, in particular that:

1. Потекнува од објект(и) со имплементиран програм заснована на HACCP принципите во согласност со Законот за безбедност на храната односно еквивалентниот член 5 од Регулатива (ЕК) Бр 852/2004; /  
It comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Law food safety and/or equivalent article 5 of Regulation (EC) No 852/2004;
2. Е произведен од суровина која ги исполнува условите од Правилникот за посебните барања за храната од животинско потекло односно еквивалентната Секција XIV, Глава I и II од Анекс III од Регулативата (ЕК) Бр 853/2004; /  
It has been produced from raw material which met the requirements of the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapters I and II of Annex III to Regulation (EC) No 853/2004;
3. Е произведен во согласност со условите од Правилникот за посебните барања за храната од животинско потекло односно еквивалентната Секција XIV, Глава III од Анекс III од Регулативата (ЕК) Бр 853/2004; /  
It has been manufactured in compliance with the conditions set out in the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004;
4. Ги задоволува критериумите од Правилникот за посебните барања за храната од животинско потекло односно еквивалентната Секција XIV, Глава IV од Анекс III од Регулативата (ЕК) бр 853/2004 и на Регулативата (ЕК) бр 2073/2005 за микробиолошката исправност на прехранбените производи; /  
It satisfies the criteria of the Book of Rules on specific requirements for food of animal origin and/or equivalent Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
5. и / and<sup>(1)</sup>
  1. Доколку е од говедско, овчо и козјо потекло, /
  2. If of bovine, ovine and caprine animal origin, е добиен од животни кои поминале ante-mortem и post-mortem преглед;
  3. it has been derived from animals which have passed ante mortem and post mortem inspections;
6. и / and<sup>(1)</sup> Освен за желатин добиен за кожи и подкожја, /  
Except for gelatine derived from hides and skins,  
или/  
either<sup>(1)</sup>
  - Потекнува од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/EЗ за утврдување на БСЕ статусот на земјите членки и трети земји во согласност со нивниот ризик од БСЕ, како земја или регион со занемарлив ризик од БСЕ; /  
It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk as a country or region posing a negligible BSE risk;
  - Желатинот не содржи и не е добиен од специфично ризичен материјал како што е дефинирано во Правилникот за мерки за сузбивање и искоренување на трансмисивни спонгиоформни енцефалопатии односно еквивалентната точка 1 од Анекс V на Регулатива (ЕЗ) бр. 999/2001<sup>(2)</sup>; /  
The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001<sup>(2)</sup>;
  - Желатинот не содржи и не е добиен од механички одвоено месо добиено од говеда, овци или кози, освен желатин добиен од животни кои биле родени, континуирано одгледувани и заклани во земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/EЗ како земја или

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регион со занемарлив ризик од БСЕ и во која немало случаи на појава на БСЕ изворно од земјата или регионот; /

The gelatine does not contain and is not derived from mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except for gelatine derived from animals that were born, continuously reared and slaughtered in a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing a negligible BSE risk in which there have been no BSE indigenous cases;

- Животните од кои е добиен желатинот, не се заклани со зашеметување со гасен пиштол, или убиени на истиот начин, или заколени после зашеметување со разорување на ткивото на ЦНС со употреба на клин кој ја пробива кранијалната шуплина, освен доколку животните биле родени, континуирано одгледувани и заклани во земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ како земја или регион со занемарлив ризик од БСЕ; /

The animals from which the gelatine is derived were not slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, except if the animals were born, continuously reared and slaughtered in a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing a negligible BSE risk;

- <sup>(1)</sup> Животните од кои е добиен желатинот, потекнуваат од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлуката 2007/453/ЕЗ, како земја или регион со неопределен ризик од БСЕ, и животните не се хранети со коскено и месно брашно или други преработки како што е дефинирано во Кодот за здравствена заштита на копнени животни (Terrestrial Animal Health Code) на Светската организација за здравствена заштита на животните (OIE); /  
The animals, from which the gelatine is derived, originate from a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the animals were not fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code;

- <sup>(1)</sup> Животните од кои е добиен желатинот, потекнуваат од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ како земја или регион со неопределен ризик од БСЕ и желатинот е произведен и со него се ракувало на начин со кој се обезбедува производите да не содржат и да не се контаминирани со нервно и лимфно ткиво изложено за време на процесот на обескотување; /

The animals, from which the gelatine is derived, originate from a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as a country or region posing an undetermined BSE risk, and the gelatine was produced and handled in a manner which ensures that it did not contain and was not contaminated with nervous and lymphatic tissues exposed during the deboning process;

- или / or<sup>(1)</sup> - Потекнува од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ за утврдување на БСЕ статусот на земјите членки и трети земји во согласност со нивниот ризик од БСЕ, како земја или регион со контролиран ризик од БСЕ; /

It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June

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- 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region posing a controlled BSE risk;
- Животните од кои е добиен желатинот, не се заклани после зашеметување, со разорување на ткивото на ЦНС со употреба на клин кој ја пробива кранијалната шуплина или со гасен пиштол директно во кранијалната шуплина; /  
The animals, from which the gelatine is derived, were not killed, after stunning, by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;
  - Желатинот не содржи и не е добиен од специфично ризичен материјал како што е дефинирано во Правилникот за мерки за сузбивање и искоренување на трансмисивни спонгиозни енцефалопatii односно еквивалентната точка 1 од Анекс V на Регулатива (ЕЗ) бр. 999/2001, или не е добиен од механички одвоено месо добиено од говеда, овци или кози; /  
The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;
- или / or<sup>(1)</sup> - Потекнува од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ за утврдување на БСЕ статусот на земјите членки и трети земји во согласност со нивниот ризик од БСЕ, како земја или регион со занемарлив ризик од БСЕ; /  
It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region posing a negligible BSE risk;
- Желатинот е добиен од животни кои иле родени, континуирано одгледувани и заклани во земја или регион со занемарлив ризик од БСЕ, во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ, и од животни родени во земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/ЕЗ како земја или регион со занемарлив ризик од БСЕ, и кои не се заклани после зашеметување со разорување на ткивото на ЦНС со употреба на клин кој ја пробива кранијалната шуплина, или со гасен пиштол директно во кранијалната шуплина; /  
The gelatine is derived both from animals were born, continuously reared and slaughtered in a country or region with negligible BSE risk in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC, and from animals born in a country or region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC, as a country or region posing a negligible BSE risk, and which were not killed after stunning by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity or by means of gas injected into the cranial cavity;
  - Желатинот не содржи и не е добиен од специфично ризичен материјал како што е дефинирано во Правилникот за мерки за сузбивање и искоренување на трансмисивни спонгиозни енцефалопatii односно еквивалентната точка 1 од Анекс V на Регулатива (ЕЗ) бр. 999/2001, или не е добиен од механички одвоено месо добиено од говеда, овци или кози; /  
The gelatine does not contain and is not derived from specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies and/or equivalent point 1 of



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- Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;
- или / or<sup>(1)</sup> - Потекнува од земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/EЗ за утврдување на БСЕ статусот на земјите членки и трети земји во согласност со нивниот ризик од БСЕ, како земја или регион со неопределен ризик од БСЕ; /
- It comes from a country or a region classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, as a country or region with an undetermined BSE risk;
- Животните од кои е добиен желатинот, не се хранети со коскено и месно брашно или други преработки добиени од преживари како што е дефинирано во Кодот за здравствена заштита на копнени животни (Terrestrial Animal Health Code) на Светската организација за здравствена заштита на животните (OIE); /  
The animals, from which the gelatine is derived, were not fed meat-and-bone meal or greaves derived from ruminants, as defined in the Terrestrial Animal health Code of the World Organisation for Animal Health;
  - Животните од кои е добиен желатинот, не се заклани после зашеметување, со разорување на ткивото на ЦНС со употреба на клин кој ја пробива кранијалната шуплина или со гасен пиштол директно во кранијалната шуплина; /  
The animals, from which the gelatine is derived, were not killed after stunning by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity;
  - Желатинот не е добиен од: /  
The gelatine is not derived from:
    - (i) специфично ризични материјали како што е наведено во Правилникот за мерки за сузбивање и искоренување на трансмисивни спонгиоформни енцефалопатии односно еквивалентната точка 1 од Анекс V од Регулативата (ЕЗ) Бр. 999/2001; /  
specified risk material as defined in the Book of Rules for the measures for control and eradication of transmissible spongiform encephalopathies health and/or equivalent point 1 of Annex V to Regulation (EC) No 999/2001;
    - (ii) нервно и лимфно ткиво изложено за време на процесот на обескостување; /  
nervous and lymphatic tissues exposed during the deboning process;
    - (iii) механички одвоено месо добиено од коски од говеда, овци и кози. /  
mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

#### Notes

- (1) Прецртај го непотребното. /  
Delete as appropriate.
- (2) Отстранувањето на специфичен ризичен материјал не се бара за желатин кој се добива од животни кои биле родени, континуирано одгледувани и заклани во земја или регион класифициран во согласност со прописите од областа на ветеринарното здравство односно еквивалентната Одлука 2007/453/EЗ како земја или регион со занемарлив ризик од БСЕ. /  
The removal of specified risk material is not required if the gelatine derives from animals born, continuously reared and slaughtered in a third country or region of a third country classified in accordance with national veterinary legislation and/or equivalent Decision 2007/453/EC as posing a negligible BSE risk.
- (3) Користи го соодветниот хармонизиран систем (HS) на кодови на Светската Царинска Организација под глава 35.03. /  
Use the appropriate Harmonised System (HS) code under the heading of 35.03.
- (4) Идентификација на контејнер/број на плomba: само каде што е возможно. /

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Identification of container/seal number: only where applicable.

- (5) Регистарски број (железнички вагони или контејнери и камиони), број на лет (авион) или име (брод). /  
Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship).

Печатот и потписот мора да биде во боја различна од бојата со која е испечатен образецот. /  
The colour of the stamp and signature must be different to that of the other particulars in the certificate.