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Contents

EN

[1] Text with EEA relevance.

I

(Resolutions, recommendations and opinions)

RECOMMENDATIONS

EUROPEAN SYSTEMIC RISK BOARD

RECOMMENDATION OF THE EUROPEAN SYSTEMIC RISK BOARD

of 15 December 2020

amending Recommendation ESRB/2020/7 on restriction of distributions during the COVID-19 pandemic

(ESRB/2020/15)

(2021/C 27/01)

THE GENERAL BOARD OF THE EUROPEAN SYSTEMIC RISK BOARD,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1092/2010 of the European Parliament and of the Council of 24 November 2010 on European Union macroprudential oversight of the financial system and establishing a European Systemic Risk Board ([1]), and in particular Article 3(2)(b), (d) and (f) and Articles 16 to 18 thereof,

Having regard to Decision ESRB/2011/1 of the European Systemic Risk Board of 20 January 2011 adopting the Rules of Procedure of the European Systemic Risk Board ([2]), and in particular Article 15(3)(e) and Articles 18 to 20 thereof,

Whereas:

(1) At the onset of the COVID-19 pandemic the European Systemic Risk Board (ESRB) acknowledged the need for financial institutions to maintain a robust level of own funds to mitigate systemic risk and contribute to economic recovery. To that end, the ESRB issued Recommendation ESRB/2020/7 on restriction of distributions during the COVID-19 pandemic ([3]), which aimed to ensure that all financial institutions that may pose a risk to financial stability maintain high levels of capital by asking relevant authorities to request financial institutions to refrain from making distributions for the duration of the COVID-19 pandemic and at least until 1 January 2021.

(2) The COVID-19 crisis is still ongoing in Europe and globally, and uncertainty remains about the future impact on the economy and financial institutions, with a risk of further worsening of health and economic conditions. Markets and authorities lack information on the long-term impact of the crisis on the financial sector and credit markets. Financial institutions also remain strongly dependent on public policy support. Ensuring the continuous proper functioning of the financial system is key. An exceptional extension of pay-out restrictions to account for uncertainty about future macroeconomic development serves this objective by allowing financial institutions to maintain a sufficiently high level of capital to mitigate systemic risk and contribute to economic recovery. At the same time, the ESRB recognises the progress made by authorities and financial institutions in dealing with the effects of the pandemic. The ESRB is also aware of the importance of distributions in enabling financial institutions

([1]) OJ L 331, 15.12.2010, p. 1.
([2]) OJ C 58, 24.2.2011, p. 4.
([3]) Recommendation ESRB/2020/7 of the European Systemic Risk Board of 27 May 2020 on restriction of distributions during the COVID-19 pandemic (OJ C 212, 26.6.2020, p. 1).

to raise capital externally, as rewarding investors for their investment is critical for the long-term sustainability of financial institutions and markets. Nevertheless, the ESRB calls for extreme caution as regards distributions so that they do not put the stability of the financial system and the recovery process at risk, and considers that any level of distribution should be significantly lower than in the recent years prior to the COVID-19 crisis.

(3) Recommendation ESRB/2020/7 also covers central counterparties (CCPs) given their systemically important role in clearing financial market transactions. The intended outcome was to prevent shareholders and senior staff from drawing on the CCPs' surplus capital through distributions at a time when operational risk – which CCPs cover with their own resources rather than contributions from clearing members – is at its most severe, also taking into account the restrictions on staff presence in the CCPs' offices. However, the stress test exercise regarding CCPs in the Union conducted by the European Securities and Markets Authority following the outbreak of the COVID-19 pandemic confirmed the overall operational resilience of Union CCPs to common shocks and multiple defaults for credit, liquidity and concentration stress risks ([4]). In addition, to date there has been no evidence of system or process failures. The effectiveness of the measures deployed by CCPs to mitigate operational risk suggests that it is no longer necessary to include CCPs within the scope of Recommendation ESRB/2020/7.

(4) The measures covered by Recommendation ESRB/2020/7 are of a temporary nature and the ESRB will continue to monitor their implications for financial institutions and their ability to contribute to economic recovery. When deciding if and when this Recommendation needs to be amended, the ESRB should take into account, inter alia, macroeconomic developments and new data on the stability of the financial system.

(5) Section 2, Point 5 of Recommendation ESRB/2020/7 provides that the General Board may decide if and when Recommendation ESRB/2020/7 needs to be amended. Such amendments could consist, in particular, in extending the period during which Recommendation A applies.

(6) Therefore, Recommendation ESRB/2020/7 should be amended accordingly,

HAS ADOPTED THIS RECOMMENDATION:

AMENDMENTS

Recommendation ESRB/2020/7 is amended as follows:

1. in Section 1, Recommendation A is replaced by the following:

'**Recommendation A – Restriction of distributions**

It is recommended that relevant authorities request financial institutions under their supervisory remit (*) to refrain until 30 September 2021 from undertaking any of the following actions:

(a) make a dividend distribution or give an irrevocable commitment to make a dividend distribution;

(b) buy-back ordinary shares;

(c) create an obligation to pay variable remuneration to a material risk taker,

which has the effect of reducing the quantity or quality of own funds, unless the financial institutions apply extreme caution in carrying out any of those actions and the resulting reduction does not exceed the conservative threshold set by their competent authority. Competent authorities are recommended to engage in discussions with financial institutions prior to financial institutions taking either of the actions referred to in points (a) or (b).

([4]) See ESMA's press release: 'ESMA's Third EU-Wide CCP Stress Test Finds System Resilient to Shocks', available at: https://www.esma.europa.eu/press-news/esma-news/esma%E2%80%99s-third-eu-wide-ccp-stress-test-finds-system-resilient-shocks.

This Recommendation applies at the EU group level (or at the individual level where the financial institution is not part of an EU group), and, where appropriate, at the sub-consolidated or individual level.

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(*) This does not include branches of financial institutions.';

2. Section 2(1)(1) is amended as follows:

(a) point (b) is replaced by the following:

'(b) "competent authority" means the competent or supervisory authority as defined in point (40) of Article 4(1) of Regulation (EU) No 575/2013 or in Article 13(10) of Directive 2009/138/EC of the European Parliament and of the Council (*), as applicable;

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(*) Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1)';

(b) point (c) is replaced by the following:

'(c) "financial institution" means any of the following undertakings that have their head office or registered office in the Union:

(i) an institution as defined in point (3) of Article 4(1) of Regulation (EU) No 575/2013;

(ii) an insurance undertaking as defined in of Article 13(1) of Directive 2009/138/EC;

(iii) a reinsurance undertaking as defined in Article 13(4) of Directive 2009/138/EC;';

(c) point (d) is replaced by the following:

'(d) "material risk taker" means a member of a category of staff whose professional activities have a material impact on the financial institution's risk profile, including a member of a category of staff referred to in Article 92(2) of Directive 2013/36/EU or point (c) of Article 275(1) of Commission Delegated Regulation (EU) 2015/35 (*), as applicable;

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(*) Commission Delegated Regulation (EU) 2015/35 of 10 October 2014 supplementing Directive 2009/138/EC of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 12, 17.1.2015, p. 1).';

3. In Section 2(3), the following paragraph is inserted:

'1a. In calibrating the conservative threshold, competent authorities should pay due regard to:

(a) the objectives of this Recommendation, in particular the need for financial institutions to maintain a sufficiently high level of capital - including taking into account their capital trajectory - in order to mitigate systemic risk and to contribute to economic recovery, taking into account the risks of a deterioration of the solvency position of corporations and households in view of the pandemic;

(b) the need to ensure that the overall level of distributions of financial institutions under their supervisory remit is significantly lower than in the recent years prior to the COVID-19 crisis;

(c) the specificities of each sector within their remit.'

4. Section 2(4) is replaced by the following:

'4. **Timeline for the follow-up**

In accordance with Article 17(1) of Regulation (EU) No 1092/2010 addressees must communicate to the European Parliament, the Council, the Commission and to the ESRB the actions undertaken in response to this Recommendation or substantiate any inaction. Each addressee is requested to deliver a report on the implementation of Recommendation A by 15 October 2021.';

5. Section 2(5) is replaced by the following:

'5. **Amendments to this Recommendation**

Prior to 30 September 2021, the General Board will decide if and when this Recommendation needs to be amended, taking into account, inter alia, macroeconomic developments and new data on the stability of the financial system.';

6. In Section 2(6) on 'Monitoring and assessment', the following paragraph is added:

'3. The ESRB Secretariat will assist the addressees by ensuring the coordination of reporting and the provision of relevant templates, and detailing, where necessary, the procedure and the timeline for the follow-up.';

7. The Annex entitled 'Communication of the actions undertaken in response to this Recommendation' is deleted.

Done at Frankfurt am Main, 15 December 2020.

The Head of the ESRB Secretariat,
on behalf of the General Board of the ESRB
Francesco MAZZAFERRO

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Non-opposition to a notified concentration

(Case M.10037 — Mitsui/Veolia/JV)

(Text with EEA relevance)

(2021/C 27/02)

On 19 January 2021, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ([1]). The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/homepage.html?locale=en) under document number 32021M10037. EUR-Lex is the on-line access to European law.

([1]) OJ L 24, 29.1.2004, p. 1.

Non-opposition to a notified concentration

(Case M.9995 — Permira Holdings Limited/Neuraxpharm Midco S.C.A.)

(Text with EEA relevance)

(2021/C 27/03)

On 4 December 2020, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ([1]). The full text of the decision is available only in English and will be made public after it is cleared of any business secrets it may contain. It will be available:

— in the merger section of the Competition website of the Commission (http://ec.europa.eu/competition/mergers/cases/). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,

— in electronic form on the EUR-Lex website (http://eur-lex.europa.eu/homepage.html?locale=en) under document number 32020M9995. EUR-Lex is the on-line access to European law.

([1]) OJ L 24, 29.1.2004, p. 1.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COUNCIL

Notice for the attention of the persons subject to restrictive measures provided for in Council Decision 2011/72/CFSP, as amended by Council Decision (CFSP) 2021/55 , and in Council Regulation (EU) 101/2011, as implemented by Council Implementing Regulation (EU) 2021/49 , concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Tunisia

(2021/C 27/04)

The following information is brought to the attention of the persons that appear in the Annex to Council Decision 2011/72/CFSP ([1]), as amended by Council Decision (CFSP) 2021/55 ([2]), and in Annex I to Council Regulation (EU) 101/2011 ([3]), as implemented by Council Implementing Regulation (EU) 2021/49 ([4]) .

The Council of the European Union, after having reviewed the list of designated persons, has decided that the persons that appear in the abovementioned Annexes should continue to be included in the list of persons and entities subject to restrictive measures provided for in Decision 2011/72/CFSP and Regulation (EU) 101/2011.

The attention of the persons concerned is drawn to the possibility of making an application to the competent authorities of the relevant Member State(s) as indicated in the websites in Annex II to Regulation (EU) No 101/2011, in order to obtain an authorisation to use frozen funds for basic needs or specific payments (cf. Article 4 of the Regulation).

The persons concerned may submit a request to the Council before 1 September 2021, together with supporting documentation that the decision to include them on the abovementioned list should be reconsidered to the following address:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

Any observations received will be taken into account for the purpose of the Council's next review, pursuant to Article 5 of Decision 2011/72/CFSP and Article 12(4) of Regulation (EU) No 101/2011, of the list of designated persons.

([1]) OJ L 28, 2.2.2011, p. 62.
([2]) OJ L 023, 25.1.2021, p. 22.
([3]) OJ L 31, 5.2.2011, p. 1.
([4]) OJ L 023, 25.1.2021, p. 5.

Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Decision 2011/72/CFSP and Council Regulation (EU) No 101/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Tunisia apply

(2021/C 27/05)

The attention of data subjects is drawn to the following information in accordance with Article 16 of Regulation (EU) 2018/1725 of the European Parliament and of the Council ([1]).

The legal basis for this processing operation are Council Decision (CFSP) 2011/72/CFSP ([2]), as amended by Council Decision (CFSP) 2021/55 ([3]), and Council Regulation (EU) No 101/2011 ([4]), as implemented by Council Implementing Regulation (EU) 2021/49 ([5]).

The controller of this processing operation is the Department RELEX.1.C in the Directorate-General for Foreign Affairs, Enlargement and Civil Protection - RELEX of the General Secretariat of the Council (GSC), that can be contacted at:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

The GSC's Data Protection Officer can be contacted at:

Data Protection Officer

data.protection@consilium.europa.eu

The purpose of the processing operation is the establishment and updating of the list of persons subject to restrictive measures in accordance with Decision (CFSP) 2011/72/CFSP, as amended by Decision (CFSP) 2021/55, and Regulation (EU) No 101/2011, as implemented by Implementing Regulation (EU) 2021/49.

The data subjects are the natural persons who fulfil the listing criteria as laid down in Decision (CFSP) 2011/72/CFSP and Regulation (EU) No 101/2011.

The personal data collected includes data necessary for the correct identification of the person concerned, the statement of reasons and any other data related thereto.

The personal data collected may be shared as necessary with the European External Action Service and the Commission.

Without prejudice to restrictions pursuant to Article 25 of Regulation (EU) 2018/1725, the exercise of the rights of the data subjects such as the right of access, as well as the rights to rectification or to object will be answered in accordance with Regulation (EU) 2018/1725.

Personal data will be retained for 5 years from the moment the data subject has been removed from the list of persons subject to the restrictive measures or the validity of the measure has expired, or for the duration of court proceedings in the event they had been started.

Without prejudice to any judicial, administrative or non-judicial remedy, data subjects may lodge a complaint with the European Data Protection Supervisor in accordance with Regulation (EU) 2018/1725 (edps@edps.europa.eu).

([1]) OJ L 295, 21.11.2018, p. 39.
([2]) OJ L 28, 2.2.2011, p. 62.
([3]) OJ L 023, 25.1.2021, p. 22.
([4]) OJ L 31, 5.2.2011, p. 1.
([5]) OJ L 023, 25.1.2021, p. 5.

Notice for the attention of a person to whom restrictive measures provided for in Council Decision 2011/172/CFSP and in Council Regulation (EU) No 270/2011 concerning restrictive measures in view of the situation in Egypt apply

(2021/C 27/06)

The following information is brought to the attention of Mrs Elham Sayed Salem Sharshar who appears in the Annex to Council Decision 2011/172/CFSP ([1]) and in Annex I to Council Regulation (EU) No 270/2011 ([2]) concerning restrictive measures in view of the situation in Egypt.

The Council has received information from the Egyptian authorities that will be considered within the framework of the annual review of the restrictive measures. The abovementioned person is hereby informed that she may submit a request to the Council to obtain the elements the Council holds in its file regarding her designation, before 1 February 2021, to the following address:

Council of the European Union
General Secretariat
RELEX.1.C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

Email: sanctions@consilium.europa.eu

In this regard, the attention of the person concerned is drawn to the regular review by the Council of the list of designated persons in Decision 2011/172/CFSP and in Regulation (EU) No 270/2011.

([1]) OJ L 76 22.3.2011, p. 63.
([2]) OJ L 76, 22.3.2011, p. 4.

EUROPEAN COMMISSION

Euro exchange rates ([1])

22 January 2021

(2021/C 27/07)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,2158	CAD	Canadian dollar	1,5458
JPY	Japanese yen	126,19	HKD	Hong Kong dollar	9,4255
DKK	Danish krone	7,4404	NZD	New Zealand dollar	1,6945
GBP	Pound sterling	0,89045	SGD	Singapore dollar	1,6149
SEK	Swedish krona	10,0815	KRW	South Korean won	1 344,48
CHF	Swiss franc	1,0773	ZAR	South African rand	18,3810
ISK	Iceland króna	157,00	CNY	Chinese yuan renminbi	7,8822
NOK	Norwegian krone	10,3308	HRK	Croatian kuna	7,5655
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	17 140,23
CZK	Czech koruna	26,152	MYR	Malaysian ringgit	4,9155
HUF	Hungarian forint	357,61	PHP	Philippine peso	58,444
PLN	Polish zloty	4,5385	RUB	Russian rouble	91,1009
RON	Romanian leu	4,8740	THB	Thai baht	36,486
TRY	Turkish lira	9,0195	BRL	Brazilian real	6,5765
AUD	Australian dollar	1,5770	MXN	Mexican peso	24,2345
			INR	Indian rupee	88,7670

([1]) *Source*: reference exchange rate published by the ECB.

Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period

(2021/C 27/08)

DISCLAIMER

This guidance notice is intended to facilitate the application of the EU's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period by indicating how the Commission will apply to this specific situation the relevant provisions of Directives 2001/82/EC, 2001/83/EC, 2001/20/EC of the European Parliament and of the Council and the Commission Delegated Regulation (EU) 2016/161. While this notice seeks to assist authorities and operators, only the Court of Justice of the European Union is competent to authoritatively interpret Union legislation.

(This text replaces the text of C(2020) 9264 published in OJ C 447, 23.12.2020, p. 10)

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a 'third country' ([1]). The Withdrawal Agreement ([2]) provides for a transition period ending on 31 December 2020. Until that date, Union law in its entirety applies to and in the United Kingdom ([3]). This includes the pharmaceutical *acquis* of the Union, in particular Directive 2001/82/EC of the European Parliament and of the Council ([4]), Directive 2001/83/EC of the European Parliament and of the Council ([5]), Commission Delegated Regulation (EU) 2016/161 ([6]) and Article 13 of Directive 2001/20/EC of the European Parliament and of the Council ([7]), which are of relevance for this Notice.

At the end of the transition period, Union law ceases to apply to the United Kingdom. As the Protocol on Ireland and Northern Ireland ('the IE/NI Protocol') starts to apply, some Union legislation (including the above mentioned legislation), its implementing, amending and replacing measures, however, becomes applicable to and in the United Kingdom in respect of Northern Ireland in accordance with Article 5(4), Annex 2, point 20, of the IE/NI Protocol.

In practical terms, this means, in particular, that:

— Medicinal products (in the scope of the abovementioned legislation) placed on the market in Northern Ireland must comply with the regulatory requirements laid down in Union law (cf. Article 5(4) of the IE/NI Protocol, read in conjunction with Annex 2 to that Protocol);

— Medicinal products must have a valid marketing authorisation in the EU or in Northern Ireland, the holder of which is located in the EU or in Northern Ireland;

— Trade in medicinal products from Great Britain to Northern Ireland or to the Union constitutes an import in the sense of applicable Union law;

— Trade in medicinal products from the Union or Northern Ireland to any other part of the United Kingdom (Great Britain) or any other third country constitutes an export in the sense of applicable Union law;

— Authorisations issued by UK authorities are, in principle, not valid under Union law, but can only be recognised in Northern Ireland if adopted in accordance with applicable Union law (cf. Article 7(3) of the IE/NI Protocol);

([1]) A third country is a country not member of the EU.

([2]) Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7) ('Withdrawal Agreement').

([3]) Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

([4]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([5]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([6]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

([7]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

— Any steps in the supply of medicines which must be carried out in the Union (e.g. batch release) in order to allow for the placing on the market of medicinal products in accordance with Union law must occur in the (geographical) scope of Union law, i.e. in the Union or Northern Ireland, and only actions that may be carried out in third countries may occur in Great Britain.

The Commission and the European Medicines Agency have, since 2017, actively been disseminating all relevant information in order to draw the attention of all relevant stakeholders to the impact of the United Kingdom's withdrawal and to alert them of the need to adapt in time before the end of the transition period. The necessary changes have notably been explained in BREXIT Notices as last amended and published on 7 May 2020 for clinical trials ([8]) and on 13 March 2020 for medicinal products ([9]).

Nonetheless, some markets which have historically relied on supply of medicinal products from or through Great Britain (Cyprus, Ireland, Malta and Northern Ireland) ([10]), may still need some additional time to adapt supply chains and take account of the end of the transition period. Against that background, it is crucial that the Union's pharmaceutical *acquis* is implemented and enforced in a manner that both prevents shortages of medicines and ensures the high level of public health protection foreseen by Union law.

The Commission has identified the following challenges (described below) as the principal difficulties for the abovementioned markets which are historically dependent on medicines supply from or through Great Britain in complying with the Union's pharmaceutical *acquis*:

1. Lack of operators holding a manufacturing authorisation necessary for imports of medicinal products from third countries;

2. Difficulties to carry out quality control testing ('batch testing');

3. Difficulties to comply with the provisions of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161 with respect to the placement and verification of the unique identifier.

Recognising these challenges, and taking into consideration the exceptional circumstances of the COVID-19 pandemic, the Commission takes note of the request, from both private and public stakeholders in the Union and the United Kingdom, for more time in the transition towards full compliance with the Union's pharmaceutical *acquis*.

1. **Lack of operators holding a manufacturing authorisation required for importing medicinal products from third countries**

A. *Human and veterinary medicinal products*

According to Article 40(3) of Directive 2001/83/EC and Article 44(3) of Directive 2001/82/EC, anyone placing medicinal products from third countries on the market in accordance with Union law (in the Union or in Northern Ireland) is an importer in the sense of Union law, and must therefore hold a manufacturing authorisation issued by the Member State where the importer is established or, in the case of importers established in Northern Ireland, by the UK acting in respect of Northern Ireland in accordance with Articles 41 and 42 of Directive 2001/83/EC for human medicines and/or Articles 45 and 46 of Directive 2001/82/EC for veterinary medicines. The conditions for such a manufacturing authorisation include, inter alia, the availability of a qualified person in the Union or Northern Ireland, the inspection of the manufacturer/importer and its compliance with Good Manufacturing Practices.

According to Articles 118 of Directive 2001/83/EC and Article 84(e) of Directive 2001/82/EC, competent authorities applying the Union's pharmaceutical *acquis* are obliged to suspend or revoke the marketing authorisation of a medicinal product where the holder of that authorisation does not have a valid manufacturing authorisation or does not comply with one of the conditions necessary to obtain such manufacturing authorisation.

([8]) https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/clinical-trials_en.pdf

([9]) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-stakeholders-withdrawal-united-kingdom-eu-rules-medicinal-products-human-use-veterinary_en.pdf

([10]) These Member States are singled out in this Notice because of their historical dependence on the UK market for their supply of medicinal products and the fact that a large proportion of their imports of medicinal products is coming from UK.

In order to allow operators in these markets historically dependent on medicines supply from Great Britain additional time to comply in full with the requirements of the Union's pharmaceutical *acquis* in the exceptional circumstances of a global pandemic, the competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland could apply the following practice between January 2021 and 31 December 2021.

In this case, the competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would allow medicinal products to be imported from Great Britain by wholesalers which are not in possession of a manufacturing authorisation as required by Article 40 of Directive 2001/83/EC and Article 44 of Directive 2001/82/EC; and they would not suspend or revoke the marketing authorisations of those medicinal products as required by Articles 118 of Directive 2001/83/EC and Articles 84(e) of Directive 2001/82/EC, provided that the following conditions are fulfilled:

— The medicinal products supplied from or through Great Britain and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have undergone quality control testing ('batch testing' ([11])) either in the Union, as provided for in Article 51(3) of Directive 2001/83/EC for human medicinal products and in Article 44(3) of Directive 2001/82/EC for veterinary medicinal products, or in Great Britain in compliance with Article 20(b) of Directive 2001/83/EC for human medicinal products and with Article 24(b) of Directive 2001/82/EC for veterinary medicinal products (see Section 2 of this Notice);

— The medicinal products supplied from or through Great Britain and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have been subject to batch release by a Qualified Person (QP) in the Union or by a QP in the UK applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human health;

— The operator placing medicinal products supplied from or through Great Britain on the market in accordance with Union law (in the Union or in Northern Ireland) holds a distribution authorisation issued, before the end of the transition period, in accordance with Article 77(1) of Directive 2001/83/EC for human medicinal products and/or Article 65(1)of Directive 2001/82/EC for veterinary medicinal products;

— The marketing authorisation of the medicinal product concerned has been issued, based on and in accordance with Union law, by the competent authority of an EU Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom.

— The medicinal products supplied from or through Great Britain are made available to the end consumer in the same market historically dependent on medicines supply from Great Britain where they are imported, and they are not made available in other EU Member States.

The competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would in this case also report to the Commission, on a monthly basis, as regards the progress made by wholesale distributors importing medicinal products in fulfilling the conditions necessary to obtain a manufacturing authorisation laid down in Article 41 of Directive 2001/83/EC and Article 45 of Directive 2001/82/EC, including, in particular, the conclusion by those wholesale distributors of contractual relationships with qualified persons in the Union.

B. *Investigational medicinal products*

According to Article 13 of Directive 2001/20/EC, the placing on the market of investigational medicinal products from third countries in accordance with Union law also requires the importer to hold a manufacturing authorisation. After the end of the transition period, this also applies to the supply of investigational medicinal products from or through Great Britain in Cyprus, Ireland, Malta and Northern Ireland. Similarly to the requirements for manufacturing authorisations

([11]) According to Article 51(1)(b) of Directive 2001/83/EC and Article 55(1)(b) of Directive 2001/82/EC, medicinal products imported into the EU have to undergo quality control testing ('batch testing') in the EU/EEA. These provisions prescribe that in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Union, that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.

pursuant to Article 41 of Directive 2001/83/EC and Article 44 of Directive 2001/82/EC, Article 13(2) of Directive 2001/20/EC also requires the holder of this manufacturing authorisation to have, permanently and continuously, at his disposal the services of at least one qualified person in the scope of application of Union law, i.e. in the Union or in Northern Ireland.

In order to allow operators in these markets historically dependent on medicines supply from Great Britain additional time to comply in full with the requirements of the Union's pharmaceutical *acquis* in the exceptional circumstances of a global pandemic, the competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland could apply the following practice between January 2021 and 31 December 2021 as regards investigational medicinal products.

In this case, the competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would allow investigational medicinal products to be imported from Great Britain by clinical trial sites or sponsors which are not in possession of a manufacturing authorisation as required by Article 13 of Directive 2001/20/EC, provided that the following conditions are fulfilled:

— The medicinal products supplied from or through Great Britain and approved for use in accordance with Union law (i.e. imported into the EU or Northern Ireland) have undergone batch release either in the Union, as provided for in Article 13(3) of Directive 2001/20/EC, or in Great Britain in compliance with Article 13(3) of Directive 2001/20/EC;

— The medicinal products supplied from or through Great Britain are made available to the end consumer in the same market historically dependent on medicines supply from Great Britain where they are imported, and they are not made available in other EU Member States.

The competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would in this case also report to the Commission, on a monthly basis, as regards progress made by operators importing investigational medicinal products in fulfilling the conditions necessary to obtain a manufacturing authorisation pursuant to Article 13 of Directive 2001/20/EC, including, in particular, the conclusion by those operators of contractual relationships with qualified persons in the Union.

2. **Batch testing of human and veterinary medicinal products**

According to Article 51(1)(b) of Directive 2001/83/EC and Article 55(1)(b) of Directive 2001/82/EC, medicinal products imported into the EU have to undergo quality control testing ('batch testing') in the EU/EEA. The requirement of a batch release site established in the Union is a fundamental pillar of the Union system of ensuring quality of medicinal products being placed on the Union market. However, with regard to the quality control testing there may be objective reasons beyond the control of the marketing authorisation holders that may have prevented the timely transfer of such testing activities to be carried out in the Union or Northern Ireland by the end of the transition period.

In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC allow for importers placing medicinal products supplied from or through Great Britain on the market in Cyprus, Ireland, Malta or Northern Ireland or wholesale distributors placing such medicinal products on those markets as described under Section 1 above, to have, in justifiable cases, certain controls carried out in Great Britain. Taking into account the exceptional circumstances described in this Notice, the Commission considers that a 'justifiable case' within the meaning of Article 20(b) Directive 2001/83/EC and 24(b) of Directive 2001/82/EC occurs when the following conditions are fulfilled:

— Each batch of the medicinal product concerned is released by a qualified person (QP) on a site in the EU or by a QP on a site in the UK applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human or animal health, in cases falling under Section 1 above;

— The establishment designated by the third party conducting the quality control testing is supervised by a competent authority, including on-the-spot checks. Demonstrable progress towards transferring the quality control testing site to the Union or Northern Ireland is shown. Notably the batch testing site should be established within a twelve-month period after the end of the transition period, by the 31 December 2021 at the latest.

In order to make use of the derogation foreseen in Article 20(b) of Directive 2001/83/EC for human medicinal products and Article 24(b) of Directive 2001/82/EC for veterinary medicinal products, marketing authorisation holders should notify the competent authority that granted the marketing authorisation of the product concerned (Cyprus, Ireland, Malta or Northern Ireland), specifying that – and why in their view - the above criteria of a 'justifiable case' in the sense of Article 20(b) of Directive 2001/83/EC, and of Article 24(b) of Directive 2001/82/EC, are fulfilled. For human and veterinary medicinal products to be placed on the market in Northern Ireland, the competent authority are the MHRA and VMD respectively. For centrally authorised products, companies should contact the European Medicines Agency.

Any such notification should be submitted without undue delay and should be received as soon as possible after the end of the transition period, and in no case later than by 30 January 2021.

3. **Requirements relating to the placement of the unique identifier for medicinal products for human use**

As the IE/NI Protocol makes Directive 2001/83/EC applicable to and in the United Kingdom in respect of Northern Ireland in its current version, the safety features (namely the anti-tampering device and the unique identifier) laid down in Articles 54(o) and 54a(1) of Directive 2001/83/EC also apply to medicinal products placed on the market in Northern Ireland. Without prejudice to the application of this Union legislation to and in the United Kingdom in respect of Northern Ireland, the placing on the market of medicinal products in any other part of the United Kingdom than Northern Ireland will not require the use of these safety features, like the unique identifier, foreseen in Union law.

This means that, as from 1 January 2021, packs of medicines destined for Great Britain should be separated from packs destined for Cyprus, Ireland, Malta or Northern Ireland – even where the supply route goes through Great Britain. Like for any medicinal products placed on the market in the Union, the information of the Cypriot, Irish, Maltese and Northern Irish packs needs to be uploaded in the European hub, or the repository systems of the respective territories, but not the information of the packs with a final destination in any other part of the United Kingdom than Northern Ireland (Great Britain).

As regards packs exported from the Union to any third country like the United Kingdom, Article 22 of Delegated Regulation (EU) 2016/161 obliges the economic operator exporting the medicinal products to decommission any unique identifier that may have already been affixed to the pack prior to the export.

Where medicinal products are supplied, through Great Britain, to Cyprus, Ireland, Malta or Northern Ireland, it would then, in principle, be for the importer holding a manufacturing authorisation to affix a new unique identifier on the medicinal products in question when they are placed on the market (cf. Article 4 of Delegated Regulation (EU) 2016/161). Nevertheless, there are currently no importers holding a manufacturing authorisation located in Cyprus, Ireland, Malta and Northern Ireland with capacity to meet the obligation to affix a new unique identifier as required by Union law as of 1 January 2021 so that compliance would be practically impossible. At the same time, allowing medicinal products without safety features on the Union market must be prevented, in order to ensure a high level of public health protection and to avoid the presence of falsified medicinal products in the Union.

The Commission therefore intends to amend Article 22 of Delegated Regulation (EU) 2016/161 to address this situation.

The economic operators responsible for the export of medicinal products (placed on the market in the Union, exported to Great Britain and then imported into Cyprus, Ireland, Malta or Northern Ireland) from the Union to Great Britain would then no longer be obliged to decommission the unique identifier in accordance with Article 22 of Delegated Regulation (EU) 2016/161.

Following this approach, the competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would allow the import of medicinal products from Great Britain bearing non-decommissioned unique identifiers provided that the following conditions are fulfilled:

— the wholesale distributor or the marketing authorisation holder established in the Union and responsible for the export of the medicinal product to the United Kingdom has verified the unique identifier against the European repository or the national repository system;

— the wholesale distributor importing the product into Northern Ireland, Ireland, Cyprus or Malta has verified the unique identifier against the European repository or the national repository system.

The competent authorities of Ireland, Malta, Cyprus and the United Kingdom with respect to Northern Ireland would in this case also report to the Commission, on a monthly basis, as regards the progress made by wholesale distributors importing medicinal products in fulfilling the obligations under Directive 2001/83/EC and Delegated Regulation (EU) 2016/161 relating to placement of the unique identifier.

NOTICES FROM MEMBER STATES

Communication from the Government of the Republic of Poland concerning Directive 94/22/EC of the European Parliament and of the Council on the conditions for granting and using authorisations for the prospection, exploration and production of hydrocarbons

(2021/C 27/09)

Notice of concession application for the prospection and exploration of oil and natural gas deposits and the extraction of oil and natural gas in the *Toruń* area

SECTION I: LEGAL BASIS

1. Article 49ec(2) of the Geological and Mining Law Act of 9 June 2011 (Journal of Laws (*Dziennik Ustaw*) 2020, item 1064, as amended)

2. Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorisations for the prospection, exploration and production of hydrocarbons (OJ L 164, 30.6.1994, p. 3; Special edition in Polish: Chapter 6, Volume 2, p. 262)

SECTION II: ENTITY INVITING BIDS

Name: Ministry of Climate and the Environment

Postal address: ul. Wawelska 52/54, 00-922 Warsaw, Poland

Tel. +48 223692449; Fax +48 223692460

Website: www.gov.pl/web/klimat

SECTION III: SUBJECT OF THE PROCEDURE

1. **Information on the submission of concession applications**

A concession application for the prospection and exploration of oil and natural gas deposits and the extraction of oil and natural gas in the *Toruń* area has been submitted to the concession authority.

2. **Type of activities for which the concession is to be granted**

Concession for the prospection and exploration of oil and natural gas deposits and the extraction of oil and natural gas in the *Toruń* area, parts of concession blocks Nos 130, 150, 151 and 170.

3. **Area within which the activities are to be conducted**

The boundaries of the area are defined by lines joining points with the following coordinates in the PL-1992 coordinate system:

No	X [PL-1992]	Y [PL-1992]
1	574 011,35	479 951,87
2	565 920,17	481 493,97
3	559 928,32	488 554,90
4	582 994,15	508 172,79
5	600 078,37	489 977,74
6	598 060,30	488 135,90
7	580 011,73	471 696,47

The surface area of the vertical projection of the area is 721,80 km².

Administrative location:

Kujawsko-pomorskie Province,

Toruń Urban District: the urban municipality of Toruń;

Toruń District: the rural municipalities of Chełmża, Lubicz, Łysomice and Obrowo;

Golub-Dobrzyń District: the urban municipality of Golub-Dobrzyń; the rural municipalities of Ciechocin, Golub-Dobrzyń and Kowalewo Pomorskie;

Wąbrzeźno District: the rural municipality of Ryńsk.

4. **Deadline for the submission of concession applications by other entities interested in the activity for which the concession is to be granted, not less than 90 days from the date of publication of the notice in the *Official Journal of the European Union***

Concession applications must be submitted to the Ministry of the Environment no later than 12:00 noon (CET/CEST) on the last day of the 90-day period commencing on the day following the date of publication of the notice in the *Official Journal of the European Union*.

5. **Assessment criteria for concession applications and specification of their weighting, set with due regard toArticle 49k(1), (1a) and (3)of the Geological and Mining Law Act**

Applications received will be assessed on the basis of the following criteria:

30 % - scope and schedule of the geological works, including geological operations, or mining operations proposed;

20 % - scope and schedule of the mandatory collection of samples obtained during geological operations, including drill cores;

20 % - financial capacities offering an adequate guarantee that activities relating to, respectively, the prospection and exploration of hydrocarbon deposits and the extraction of hydrocarbons will be carried out, and in particular the sources and methods of financing the intended activities, including the share of own funds and external financing;

20 % - the proposed technology for conducting geological works, including geological operations, or mining operations;

5 % - technical capacities for, respectively, the prospection and exploration of hydrocarbon deposits and the extraction of hydrocarbons, and in particular the availability of appropriate technical, organisational, logistical and human resources potential (including 2 % for the scope of collaboration, with regard to the development and implementation of innovative solutions for the prospection, exploration and extraction of hydrocarbons, with scientific bodies active in research into the geology of Poland and analytical tools, technologies and methods for prospecting hydrocarbon deposits that take account of the specificity of Polish geological conditions and that may be applied in those conditions, included in the list of scientific bodies referred to in Article 49k(1) of the Geological and Mining Law Act);

5 % - experience in the prospection and exploration of hydrocarbon deposits or the extraction of hydrocarbons, ensuring safe operation, the protection of human and animal life and health, and environmental protection.

If, following the evaluation of applications on the basis of the criteria specified above, two or more bids obtain the same score, the amount of the fee for the establishment of mining usufruct rights due during the prospection and exploration phase will be used as an additional criterion allowing a final choice to be made between the bids concerned.

SECTION IV: ADDITIONAL INFORMATION

IV.1) **Applications should be sent to the following address**

Ministerstwo Klimatu i Środowiska [Ministry of Climate and the Environment]
Departament Geologii i Koncesji Geologicznych [Geology and Geological Concessions Department]
ul. Wawelska 52/54
00-922 Warsaw
Poland

IV.2) **Information may be obtained from**

— the website of the Ministry of Climate and the Environment:

https://www.gov.pl/web/klimat

— Departament Geologii i Koncesji Geologicznych [Geology and Geological Concessions Department]

Ministerstwo Klimatu i Środowiska [Ministry of Climate and the Environment]
ul. Wawelska 52/54
00-922 Warszawa/Warsaw
POLSKA/POLAND

Tel. +48 225792449, Fax +48 225792460

Email: sekretariat.dgk@srodowisko.gov.pl

IV.3) **Qualification decision**

Concession applications may be submitted by entities in respect of which a decision has been issued confirming the positive outcome of a qualification procedure, as provided for in Article 49a(17) of the Geological and Mining Law Act.

IV.4) **Minimum fee for establishing mining usufruct rights**

The minimum amount of the fee for establishing mining usufruct rights for the *Toruń* area during the five-year base period of the prospection and exploration phase is PLN 165 400,47 (one hundred and sixty-five thousand, four hundred zlotys, forty-seven grosz) per annum. The annual fee for establishing mining usufruct rights for the purpose of the prospection and exploration of minerals is indexed to average annual consumer price indices set cumulatively for the period from the conclusion of the agreement until the year preceding the date for payment of the fee, as announced by the President of the Central Statistical Office in the *Monitor Polski* (Official Gazette).

IV.5) **Granting of the concessions and establishment of mining usufruct**

The concession authority, having obtained the opinions or agreements required under the Geological and Mining Law Act, will grant concessions for the prospection and exploration of hydrocarbon deposits and the extraction of hydrocarbons:

1) to the entity whose concession application has been awarded the highest score, or

2) where a concession application submitted jointly by several entities is awarded the highest score, to the parties to the cooperation agreement – once that agreement has been submitted to the concession authority

and, at the same time, will not grant concessions to other entities (Article 49ee(1) of the Geological and Mining Law Act).

The concession authority will conclude a mining usufruct contract with the entity whose concession application has been awarded the highest score and, where a concession application submitted jointly by several entities is awarded the highest score, with all entities which submitted the joint application (Article 49ee(2) of the Geological and Mining Law Act). In order to be able to carry out activities involving the prospection and exploration of hydrocarbon deposits and the extraction of hydrocarbons in Poland, an operator must hold both mining usufruct rights and a concession.

IV.6) **Requirements to be met by concession applications and documents required from applicants**

Article 49eb of the Geological and Mining Law Act specifies the component parts of the concession application.

The geological age of the formations where geological works will be carried out (geological purpose) should be indicated as the purpose of the works, including geological operations.

IV.7) **Minimum deposit exploration category**

Category C is the minimum exploration category for oil and natural gas deposits in the *Toruń* area.

For the Minister
Piotr DZIADZIO
Deputy State Secretary
Ministry of Climate and the Environment

V

(Announcements)

OTHER ACTS

EUROPEAN COMMISSION

Publication of an application for approval of an amendment, which is not minor, to a product specification pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2021/C 27/10)

This publication confers the right to oppose the amendment application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council [1] within three months from the date of this publication.

APPLICATION FOR APPROVAL OF AN AMENDMENT TO THE PRODUCT SPECIFICATION OF PROTECTED DESIGNATIONS OF ORIGIN/PROTECTED GEOGRAPHICAL INDICATIONS WHICH IS NOT MINOR

Application for approval of an amendment in accordance with the first subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

'Aischgründer Karpfen'

EU No: PGI-DE-0689-AM01 – 30.10.2019

PDO ( ) PGI (X)

1. **Applicant group and legitimate interest**

Name:	Teichgenossenschaft Aischgrund [Aischgrund Pond Cooperative], Teichgenossenschaft Neustadt a.d. Aisch – Bad Windsheim [Neustadt an der Aisch – Bad Windsheim Pond Cooperative]
Address:	Brunnenweg 14, 91315 Höchstadt an der Aisch
Country:	Germany
Tel.:	+49 91935012085
Fax:	+49 91935034127
Email:	tg.aischgrund@gmx.de

Legitimate interest:

The applicant is the same as the original applicant. It is an association of producers of the protected products. It therefore has a legitimate interest in this amendment application and is also entitled to apply (Article 53(1) in conjunction with Article 3, point (2), of Regulation (EU) No 1151/2012).

2. **Member State or third country**

Germany

[1] OJ L 343, 14.12.2012, p. 1.

3. **Heading in the product specification affected by the amendment(s)**

☐ Name of product

☒ Description of product

☐ Geographical area

☐ Proof of origin

☒ Method of production

☐ Link

☐ Labelling

☐ Other [to be specified]

4. **Type of amendment(s)**

☒ Amendment to product specification of a registered PDO or PGI not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012.

☐ Amendment to product specification of registered PDO or PGI for which a Single Document (or equivalent) has not been published not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

5. **Amendment(s)**

The amendments concern Sections (b), Description of the product, and (e), Method of production,. of the product specification.

In Section (b), Description of the product (and also under point 3.2 of the Single document), third paragraph, the first sentence, 'The live weight of a 3 year-old fish is between 1 000 g and 1 700 g' is to be amended to 'The live weight of this table carp (from K3) is between 1 000 g and 3 000 g'.

Section (b) (and also point 3.2 of the Single document), now reads:

'The Aischgründer Karpfen, a mirror carp (*Cyprinus carpio*), is a table fish which is sold live or slaughtered.

The Aischgründer Karpfen has a dark green, grey or greyish blue back, yellow-green to gold sides and a yellowish white belly. Its dorsal and caudal fins are grey, the caudal and anal fins have a reddish tone and the pectoral and pelvic fins are yellowish or reddish in colour. A distinguishing feature of the Aischgründer Karpfen is its high back, which develops in particular as a result of the warm weather and the high level of fertility in the ponds. Its typical height-to-length ratio is between 1:2 and 1:2,5.

The live weight of this table carp (from K3) is between 1 000 g and 3 000 g. The Aischgründer Karpfen is a mirror carp characterised by its white meat, which is firm but tender and flavourful, and its low fat content of not more than 10 %. The fat content is kept low by limiting the stocking density (a maximum of 800 carp per ha at the K2 stage) and adapting the feed accordingly.'

The reason for the amendment is that the demand for fillets is said to have soared, larger carp being particularly well suited to filleting using the automatic filleters which have been developed.

The following amendments have been requested in Section (e), Method of production, and are reflected in Section 3.4 of the Single document:

In the last sentence of the first paragraph, the word 'generally' is to be inserted after 'reach the desired weight'.

In the first sentence of the second paragraph, 'starting in April of the year in question' is to be amended to 'starting in most cases in April of the year in question'.

In the second sentence of the second paragraph, the word 'generally' is to be inserted before the word 'decisive' and, in the last sentence, the word 'usually' before 'increases by more than 1 kg per fish'.

In the fourth paragraph, 'In the production of table fish (K2-K3)' is to be amended to 'In the production of table fish (from K2)' and 'from May to September' to ', generally from April to September,'

Section (e) now reads:

'As the carp grow during the warm summer months, their age is counted in summers. Table carp in the Aischgrund generally grow to maturity over the course of three summers. In the first year, what are known as K1 fish are raised from the eggs. After the subsequent winter, the fish grow to K2, are kept for another winter and then reach the desired weight generally in the third summer (i.e. as K3 fish).

Aischgründer Karpfen must be kept in the geographical area for at least one production period (starting in most cases in April of the year in question) from fry (K2) to table fish (K3). The third year (K2 to K3) is generally decisive for the increase in weight and the development of the taste. During this period the weight of the fish usually increases by more than 1 kg per fish.

The stocking density at the K2 stage may not be more than 800 carp per hectare.

The carp feed predominantly on what is naturally available (bottom nutrients, zooplankton, etc.). In the production of table fish (from K2), generally from April to September, this is supplemented by legumes and grain (excluding maize). The feed quotient (added feed quantity (kg) per kilogram of growth) is approximately 2:1.

In addition, mixed feed authorised under applicable national legislation is permitted. The mixed feed must consist of arable crops only and may not contain any ingredients of animal origin. It may not contain more than 16 % raw protein and the total phosphorus content must not be more than 0,6 %. The greenmeal content must be at least 10 %.'

The applicant gives the following reasons for the amendments:

As, in the Aischgrund, carp are farmed extensively (i.e. outdoors) in natural ponds, the weather has a strong influence on the growth of the fish. Table carp have developed very differently over recent years (as a result of climate change).

The applicant maintains that, in some years, early spring was so warm that the fish came out of hibernation early and started to feed. This meant that their natural food sources were not sufficient and had to be supplemented.

As it is not possible to tell how the climate will change in the future, a more flexible set of rules (dispensing with the rigid requirements currently applied) is essential.

SINGLE DOCUMENT

'Aischgründer Karpfen'

EU No: PGI-DE-0689-AM01 – 30.10.2019

PGI (X) PDO ( )

1. **Name(s) [of PDO or PGI]**

'Aischgründer Karpfen'

2. **Member State or third country**

Germany

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product*

Class 1.7 Fresh fish, molluscs and crustaceans and products derived therefrom.

3.2. *Description of the product to which the name in (1) applies*

The Aischgründer Karpfen, a mirror carp (*Cyprinus carpio*), is a table fish which is sold live or slaughtered.

The Aischgründer Karpfen has a dark green, grey or greyish blue back, yellow-green to gold sides and a yellowish white belly. Its dorsal and caudal fins are grey, the caudal and anal fins have a reddish tone and the pectoral and pelvic fins are yellowish or reddish in colour. A distinguishing feature of the Aischgründer Karpfen is its high back, which develops in particular as a result of the warm weather and the high level of fertility in the ponds. Its typical height-to-length ratio is between 1:2 and 1:2,5.

The live weight of this table carp (from K3) is between 1 000 g and 3 000 g. The Aischgründer Karpfen is a mirror carp characterised by its white meat, which is firm but tender and flavourful, and its low fat content of not more than 10 %. The fat content is kept low by limiting the stocking density (a maximum of 800 carp per ha at the K2 stage) and adapting the feed accordingly.

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

The carp feed predominantly on what is naturally available (bottom nutrients, zooplankton, etc.). In the production of table fish (from K2), generally from April to September, this is supplemented by legumes and grain (excluding maize). The feed quotient (added feed quantity (kg) per kilogram of growth) is approximately 2:1.

In addition, mixed feed authorised under applicable national legislation is permitted. The mixed feed must consist of arable crops only and may not contain any ingredients of animal origin. It may not contain more than 16 % raw protein and the total phosphorus content must not be more than 0,6 %. The greenmeal content must be at least 10 %.

3.4. *Specific steps in production that must take place in the identified geographical area*

As the carp grow during the warm summer months, their age is counted in summers. Table carp in the Aischgrund generally grow to maturity over the course of three summers. In the first year, what are known as K1 fish are raised from the eggs. After the subsequent winter, the fish grow to K2, are kept for another winter and then reach the desired weight generally in the third summer (i.e. as K3 fish).

Aischgründer Karpfen must be kept in the geographical area for at least one production period (starting in most cases in April of the year in question) from fry (K2) to table fish (K3). The third year (K2 to K3) is generally decisive for the increase in weight and the development of the taste. During this period the weight of the fish usually increases by more than 1 kg per fish. The stocking density at the K2 stage may not be more than 800 carp per hectare.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

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3.6. *Specific rules concerning labelling of the product the registered name refers to*

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4. **Concise definition of the geographical area**

The geographical area includes all carp ponds in the rural districts of Erlangen-Höchstadt, Neustadt an der Aisch – Bad Windsheim, Fürth, Kitzingen, Bamberg, Forchheim and Nürnberger Land and the urban districts of Erlangen, Forchheim, Bamberg, Nuremberg and Fürth.

5. **Link with the geographical area**

5.1. *Specificity of the geographical area*

The development of pond farming in the Aischgrund can be traced back to the appearance of the area's many monasteries in the Middle Ages and the resulting demand for fish during periods of fasting, which lasted for months at a time. For the monks the main thing was to have fish to put on the refectory table – the profitability of fish farming as a business was less of an issue.

In the centre of the Aischgrund the ground beneath the numerous ponds consists of impervious Late Triassic clay. The emergence and survival of this pond-rich region owed a lot to a number of basic physical/geographical factors: the complex alternation of sandstone deposits and layers of clayey, impermeable 'Burgsandstein', the gentle gradients of the valleys, the myriad swamp-prone springs, and soil that was not particularly suitable for farming.

While in other areas carp yields are restricted by the temperature profile, the same does not apply to the Aischgrund, which is the warmest pond-farming area in Germany. Annual temperatures average around 8 or 9 °C, depending on altitude. The limiting factor in the Aischgrund, on the other hand, is the supply of water to the ponds. Average precipitation is 600-650 mm a year, but this figure falls to about 530 mm as one moves from the north-west to the south-east. The ponds extend over an area of rain shadow to the east of the Frankenhöhe hills and the Steigerwald, where precipitation levels vary from year to year. Water supply to the majority of the ponds consists only of rainfall and snowmelt. The climate is warmer than in the Oberpfalz and the ponds are more fertile and give better yields as a result.

Carp farming is a distinctive feature not only of the landscape of the geographical area (which is the largest continuous area of ponds in Germany), but also of its culture. There are books of fish-farming anecdotes, songs about carp and even (art) exhibitions dedicated to the carp. The world's largest carp statue has been erected in Höchstadt an der Aisch as a symbol of the region. Confectioners sell chocolate carp and it is also possible to buy 'Aischgründer Kärpfla', or carp-shaped fruit gums. Carp also adorn doorbell plates, carnival paraphernalia, club T-shirts, etc.

Aischgründer Karpfen is a traditional meal served in hostelries all over Franconia, many of which – like the delicacy itself – have been there for hundreds of years. Most of the innkeepers, who follow in a long family tradition of serving carp, keep them in tanks or basins so that they always have a ready supply of fresh fish.

5.2. *Specificity of the product*

The Aischgründer Karpfen is known throughout the region and beyond and is highly regarded among consumers. The fish has a number of other special characteristics: it has a height-to-length ratio of 1:2 to 1:2,5 and is therefore higher-backed than carp from elsewhere. This is due to the warm weather and the level of fertility in the ponds. Another distinctive feature of the Aischgründer Karpfen is its firm white flesh, which has its own typical flavour (not earthy or musty, pleasantly palatable and reminiscent of freshly boiled potatoes). As a result of the prescribed stocking density, Aischgründer Karpfen has a low fat content of practically no more than 10 % when filleted.

5.3. *Causal link between the geographical area and a specific quality, the reputation or other characteristics of the product*

The fish's high back, which is a characteristic feature of Aischgründer Karpfen, is also due to the good breeding conditions in the Aischgrund, the warmest carp-farming area in Germany.

The high regard in which the Aischgründer Karpfen is held stems from the importance of pond farming in the region and from centuries of tradition.

Opinion polls conducted by Weihenstephan University of Applied Sciences and the Technical University of Munich show that Aischgründer Karpfen is highly regarded as a foodstuff throughout the region. The traditional carp season in Aischgrund runs from 1 September to 30 April and its opening is marked by numerous festivities. The carp is an integral part of cultural life in the geographical area. It is a highly prized foodstuff and a key component of the traditional cuisine – these factors too make the Aischgründer Karpfen a speciality of the region and give it a reputation that extends far beyond it.

Surveys conducted by Weihenstephan University of Applied Sciences in 2002 show that 79 % of those asked in Aischgrund and 49 % of those asked in Nuremberg prefer Aischgründer Karpfen to carp from other areas.

Reference to publication of the specification

(the second subparagraph of Article 6(1) of this Regulation)

Trade Mark Journal No 24 of 14 June 2019, Part 7a-bb, p. 17222

https://register.dpma.de/DPMAregister/geo/detail.pdfdownload/41798

Publication of an application for registration of a name pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2021/C 27/11)

This publication confers the right to oppose the application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council ([1]) within three months from the date of this publication.

SINGLE DOCUMENT

'Nagykun rizs'

EU No: PGI-HU-02416 – 22.8.2018

PDO ( ) PGI (X)

1. **Name(s) [of PDO or PGI]**

'Nagykun rizs'

2. **Member State or third country**

Hungary

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product*

Class 1.6: Fruit, vegetables and cereals, fresh or processed

3.2. *Description of the product to which the name in (1) applies*

The protected geographical indication 'Nagykun rizs' may be used for the following white or whole-grain (brown) grains of the Hungarian-bred varieties of the species *Oryza sativa* L: M-225, M-488, Fruzsina M, Sandora, Dáma, Risabell, Janka, Ábel and Bioryza. It may also be used for all other varieties of rice grown in the geographical area whose white or whole-grain (brown) grains meet the following quality characteristics:

In the case of white rice: purity, at least 99,9 % (m/m); blend, maximum 0,1 % (m/m); red-striped grains, maximum 4 % (m/m); and

In the case of brown rice: purity, at least 99,9 % (m/m); blend, maximum 0,1 % (m/m); milled grains, maximum 1,5 % (m/m); cracked grains, maximum 2 % (m/m).

The arsenic content of 'Nagykun rizs' is extremely low, due to the soil characteristics of the geographical areas. It does not exceed 0,1 mg/kg, which is well below the EU limit value.

According to the shape of the rice grain, the grains of each variety may be round, semi-round and long.

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

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3.4. *Specific steps in production that must take place in the identified geographical area*

All production steps: sowing, harvesting, drying and processing.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

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([1]) OJ L 343, 14.12.2012, p. 1.

3.6. *Specific rules concerning labelling of the product the registered name refers to*

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4. **Concise definition of the geographical area**

'Nagykun rizs' is produced within the administrative boundary of the town of Kisújszállás in the northern area of the Nagykunság in Jász-Nagykun-Szolnok County.

5. **Link with the geographical area**

The product's link with the geographical area is based on quality.

Natural factors:

Kisújszállás is situated on the Great Plain. Production technology benefits from the fact that arable land in the municipality of Kisújszállás is bordered by canals fed by the Hortobágy-Berettyó River, also providing irrigation of the rice fields.

The soil in the production area of 'Nagykun rizs' has the following characteristics: up to a depth of 1 m, it has a clay content of between 50 and 60 % and even below 1 m the clay content remains above 40 %. The soil profile is highly compacted; it is very hard when dry, and malleable and sticky when wet. Due to the temporary drainage of the surface soil levels, water will cause the soil – which is high in clay – to swell and become impermeable (Fuchs, 2012).

The development of the rice fields and continued safe production involved installing defence against river and inland flooding, reducing groundwater levels, and constructing irrigation canals. Technical and other work spanning over 150 years established the conditions for rice production in the geographical area, which currently produces high-quality rice thanks to low levels of contamination from biologically harmful heavy metals and to rich supplies of minerals required for rice production.

Human factors:

Rice production in Hungary began after the Second World War, following research by Lajos Kreybig and Ernő Obermayer, and spread in the valley of the Hortobágy-Berettyó River from 1948 onwards. Kisújszállás Város Története [History of the Town of Kisújszállás] mentions that 'the first leaseholder groups were set up under the Farmers' Cooperative in Kisújszállás in 1948, chiefly with a view to producing rice' (p. 161). Later these formed the core of the new cooperative groups.'

The production of 'Nagykun rizs' in the geographical area has come with a wealth of knowledge and know-how in the past 70 years, creating numerous technical solutions for production, including the sound and proper preparation of land, nutrient supply, care and selection of varieties, effective disease control and the timely application of appropriate flooding techniques for cultivation, and a careful harvesting process.

'Nagykun rizs' is the product of nearly thirty years of development of a strain, and is produced from varieties which have adapted excellently to the soil and climate of the region. In the course of breeding, valuable characteristics were genetically fixed into the varieties which enable them to adapt to the geographical conditions and make use of them. The length of the growing season adapts to the effective amount of heat available on average each year. In the early stages of development they are cold resistant, so that they can withstand the damaging effects of cold snaps in early May. Their roots and metabolism are resistant to the high salt concentration in the soil. In addition, they contain high concentrations of micro-elements important for nutrition.

Special production technologies have been developed in the geographical area (know-how):

— Due to the compacted soil with a high salt content, the seeds require a long period of germination, 40 days. During this time, to promote germination, they need to be flooded up to three or four times. Typically, the plant will not be permanently flooded until it has 6 to 8 leaves. In other geographical areas, where the seeds are sown, this is performed as early as 3 to 4 leaves.

— The rice is harvested when the grains reach a moisture content of 20-24 %, because this results in considerably higher purity. In other geographical areas, harvesting is performed at a drier stage, when the grains have a moisture content of 16 %.

The link between the quality of the product and the geographical environment:

The production technology of 'Nagykun rizs' involves flooding the area during the growing period. In consequence, the soil – which has a high clay content even at depths of 1 m – becomes impermeable. Thanks to this, the plant cannot absorb the arsenic released into the groundwater from rocks. This way, the arsenic content of 'Nagykun rizs' is significantly lower than rice grown elsewhere.

As a result of the cultivation techniques applied in the geographical area, 'Nagykun rizs' meets considerably more stringent quality requirements than rice produced in other geographical areas.

The low arsenic content in the case of 'Nagykun rizs' (less than 0,1 mg/kg) is unique in Europe. Thanks to this, exports of 'Nagykun rizs' are long-term and continuous to well-known international baby-food producing companies in Germany. In the case of rice used to make food for babies and infants the permitted limit value for arsenic content is 0,1 mg/kg, which 'Nagykun rizs' is able to maintain consistently.

Reference to publication of the specification

(the second subparagraph of Article 6(1) of this Regulation)

http://eredetvedelem.kormany.hu/download/f/27/02000/11%20FM%20értesítő.pdf

Publication of an application for registration of a name pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2021/C 27/12)

This publication confers the right to oppose the application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council [1] within 3 months from the date of this publication.

SINGLE DOCUMENT

'Aito saunapalvikinkku'/'Äkta basturökt skinka'

EU No: PGI-FI-02462 – 10.7.2019

PDO ( ) PGI (X)

1. **Name(s) [of PDO or PGI]**

'Aito saunapalvikinkku'/'Äkta basturökt skinka'

2. **Member State or Third Country**

Finland

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product [listed in Annex XI]*

Class 1.2. Meat products (cooked, salted, smoked, etc.)

3.2. *Description of product to which the name in (1) applies*

'Aito saunapalvikinkku'/'Äkta basturökt skinka' is a meat product made from whole-muscle ham or round slices of ham from fattening pigs. The ham's fat and rind may also form part of the product. The product is smoked on alder wood using a direct smoking method in a smoke sauna, which distinguishes it from other smoked hams in terms of both its method of preparation and the product's characteristics.

The meat content of the finished product is always at least 90 %. The product has a protein content of at least 17 % and a maximum fat content of 5 %. The lard-covered ham has a protein content of at least 15 % and a maximum fat content of 10 %.

'Aito saunapalvikinkku'/'Äkta basturökt skinka' has a fairly dry surface, but a succulent texture. As a result of the long smoking period and direct smoking method, its outer surface is a dark reddish-brown. It is reddish in colour inside. In the lard-covered product, the colour of the fat varies from white to yellowish white. The product has the typical aroma and taste of alder wood smoke.

'Aito saunapalvikinkku'/'Äkta basturökt skinka' is put on sale whole, in portions or in slices and is either vacuum-packed, packaged in a controlled atmosphere or wrapped in film.

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

Only whole-muscle ham or portions of sliced ham from fattening pigs are used in the making of the product. The ham's fat and rind may also form part of the product. The raw meat must come from a bacon pig; neither processed (from sows or hogs) nor wild boar meat may be used.

[1] OJ L 343, 14.12.2012, p. 1.

In addition to the raw ham, only water, salt, glucose and food additives authorised for use in meat products under Commission Regulation (EU) No 1129/2011 ([2]) may be used as raw materials. Nitrate may be added to the product either in the form of nitrate curing salt or as a 10 % aqueous solution.

3.4. *Specific steps in production that must take place in the identified geographical area*

The following production steps take place in Finland:

— preparation of the raw ham;

— salting and curing of the raw ham;

— stuffing into netting, wrapping or other smoke- and water-permeable covering;

— curing in a sauna, i.e. the smoking and cooking of the product in a smoke sauna on alder logs using the direct smoking method.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

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3.6. *Specific rules concerning labelling of the product the registered name refers to*

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4. Concise definition of the geographical area

Finland

5. Link with the geographical area

The causal link between the product and its geographical area of production is based on Finnish know-how and a Finnish method for smoking meat on alder wood logs in smoke saunas. This specific process is strongly rooted in Finnish sauna culture, which underpins the distinction from other countries and their smoked products.

Finland is located in northern latitudes where, owing to the coldness of the winter weather, people could not bathe outdoors. Saunas were built for washing oneself, but were also used for slaughtering animals, curing meat, sweetening malt, drying flax, washing laundry, resting and preserving one's health. Salt was valuable and expensive to import to Finland. The shelf life of meat products, for instance, could be ensured more cheaply by smoking the meat in a smoke sauna.

Sauna-cured ham is prepared in Finland in accordance with long-standing traditional recipes passed down from one generation to the next. It was customary in Finland to dry meat under the beams of smoke sauna cabins. While hanging, the meat was slowly smoked over an open fire situated in the middle of the cabin. The curing of ham in saunas began in Finland in the 1800s, as a way of curing meat at home. Salted meat was smoked in a warm sauna, the final result being a product with a fairly dry surface and a strong smoky taste. The saunas used for curing the meat were made entirely of wood, but housed a stone stove. The alder wood used for heating gave the cured meat its distinctive aroma.

Curing in smoke saunas gradually converted to an industrial operation in the 1950s. The wish to preserve the traditional smoking method has led to 'Aito saunapalvikinkku'/'Äkta basturökt skinka' being made in a smoke sauna on alder wood using a direct smoking method nowadays as well. With the advent of industrial production, however, smoke saunas are now bigger than they once were.

In the direct smoking method, the sauna stove is in the smoking room. Alder wood is used to heat the sauna rocks on the stove, which generate smoke and radiate heat into the surroundings. These days the sauna stove's firebox is, as a rule, located outside the smoking room, making the smoking process easier to control. The curing time is long (at least 12 hours), during which time the internal temperature of the product rises gradually to at least 72 °C.

([2]) OJ L 295, 12.11.2011, p. 1.

Curing in a smoke sauna gives the 'Aito saunapalvikinkku'/'Äkta basturökt skinka' product its typical alder wood smoke aroma and flavour, which distinguishes it from other hams prepared using modern smoking and curing technology; those are smoked using the indirect smoking method or liquid smoke preparations.

As a result of the long smoking period and direct smoking method, the outer surface of the product is a reddish-brown. The product differs from other cured hams also in terms of taste, aroma and texture. The texture is typically a little dry, but nonetheless succulent. The product's surface layer in particular is dry because of the long smoking period. Both the taste and aroma of the product are brought out strongly by the alder wood which is used to smoke it.

Reference to publication of the product specification

(the second subparagraph of Article 6(1) of this Regulation)

https://www.ruokavirasto.fi/yritykset/elintarvikeala/valmistus/elintarvikkeista-annettavat-tiedot/eun-nimisuojajarjestelma/suomalaiset-nimisuojatuotteet/

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