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Legislation

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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2018/343

of 5 March 2018

concerning the renewal of the Agreement for scientific and technological cooperation between the European Community and the Federative Republic of Brazil

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 186, in conjunction with point (a)(v) of the second subparagraph of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

(1) By Decision 2005/781/EC ([1]), the Council approved the conclusion of the Agreement for scientific and technological cooperation between the European Community and the Federative Republic of Brazil ([2]) (the 'Agreement').

(2) In accordance with Article XII of the Agreement, the Agreement enters into force on the date on which both Parties have notified each other in writing that their respective internal procedures necessary for the Agreement to enter into force have been completed. The Agreement is initially valid for a period of five years and may be renewed by agreement between the Parties after evaluation during the penultimate year of each subsequent renewal period.

(3) By Decision 2012/646/EU ([3]), the Council approved the renewal of the Agreement for an additional period of five years.

(4) The exchange of letters between the Parties, dated 14 November 2016 and 5 January 2017, confirmed their interest in renewing the Agreement for another five years.

(5) The renewal of the Agreement should be approved on behalf of the Union,

HAS ADOPTED THIS DECISION:

Article 1

The renewal of the Agreement for scientific and technological cooperation between the European Community and the Federative Republic of Brazil, for an additional period of five years, is hereby approved on behalf of the Union.

([1]) Council Decision 2005/781/EC of 6 June 2005 on the conclusion of the Agreement for scientific and technological cooperation between the European Community and the Federative Republic of Brazil (OJ L 295, 11.11.2005, p. 37).
([2]) OJ L 295, 11.11.2005, p. 38.
([3]) Council Decision 2012/646/EU of 10 October 2012 concerning the renewal of the Agreement for scientific and technological cooperation between the European Community and the Federative Republic of Brazil (OJ L 287, 18.10.2012, p. 4).

Article 2

The President of the Council shall designate the person(s) empowered to notify the Government of the Federative Republic of Brazil, on behalf of the Union, that the Union has completed its internal procedures necessary for the renewal of the Agreement in accordance with Article XII(2) of the Agreement.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 5 March 2018.

For the Council
The President
N. DIMOV

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2018/344

of 14 November 2017

supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the criteria relating to the methodologies for valuation of difference in treatment in resolution

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 on establishing a framework for the recovery and resolution of credit institutions and investment firms ([1]), and in particular Article 74(4) thereof,

Whereas:

(1) It is appropriate to have rules establishing a methodology for carrying out valuations aimed at determining whether there is any difference between the actual treatment of shareholders and creditors in respect of which resolution action or actions have been effected, and the amount that those shareholders and creditors would have received had the institution or entity as referred to in points (b), (c) or (d) of Article 1(1) of Directive 2014/59/EU ('entity') been subject to normal insolvency proceedings at the date on which the decision to resolve that entity was adopted according to Article 82 of Directive 2014/59/EU.

(2) Any difference in treatment resulting in greater losses in resolution for particular shareholders and creditors should entitle those shareholders and creditors to compensation from the resolution financing arrangements, pursuant to point (e) of Article 101(1) of Directive 2014/59/EU.

(3) The *ex post* valuation is to be carried out by the required independent person meeting the conditions set out in Article 38 of Commission Delegated Regulation (EU) 2016/1075 ([2]) ('valuer'), as soon as possible after the resolution action or actions have been effected, even though its completion could take some time. That valuation should be based on available information relevant to the date when the decision to resolve an entity is adopted, in order to adequately reflect specific circumstances, such as distressed market conditions, existing at that resolution decision date. Information obtained after the resolution decision date should only be used where it could reasonably have been known at that date.

(4) In order to ensure that a comprehensive and credible valuation is carried out, the valuer should have access to any appropriate legal documentation, including to a list of all claims and contingent claims against the entity, classified according to their priority under normal insolvency proceedings. The valuer should be allowed to enter into arrangements to obtain specialist advice or expertise as required by the circumstances.

([1]) OJ L 173, 12.6.2014, p. 190.

([2]) Commission Delegated Regulation (EU) 2016/1075 of 23 March 2016 supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the content of recovery plans, resolution plans and group resolution plans, the minimum criteria that the competent authority is to assess as regards recovery plans and group recovery plans, the conditions for group financial support, the requirements for independent valuers, the contractual recognition of write-down and conversion powers, the procedures and contents of notification requirements and of notice of suspension and the operational functioning of the resolution colleges (OJ L 184, 8.7.2016, p. 1).

(5) For purposes of determining the treatment that shareholders and creditors would have received had the entity been put under normal insolvency proceedings, the valuer should determine the expected timing and amount of net cash flows that each shareholder and creditor would have received from the insolvency proceedings without assuming any State aid, discounted at the relevant discount rate or rates. In determining such estimate, and where available and relevant, the valuer could also refer to information on recent past experiences of insolvency of similar credit institutions.

(6) The actual treatment received by shareholders and creditors in resolution should be determined having regard to whether such shareholders and creditors have respectively received compensation in the form of equity, debt or cash as a result of the adoption of the resolution action.

(7) This Regulation is based on the draft regulatory technical standards submitted by the European Banking Authority (EBA) to the Commission.

(8) EBA has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council [1],

HAS ADOPTED THIS REGULATION:

Article 1

General provisions

1. For the purposes of determining the treatment of shareholders and creditors under normal insolvency proceedings, the valuation shall only be based on information about facts and circumstances which existed and could reasonably have been known at the resolution decision date which, had they been known by the valuer, would have affected the measurement of the assets and liabilities of the entity at that date.

For the purposes of this Regulation, 'resolution decision date' means the date on which the decision to resolve an entity, is adopted pursuant to Article 82 of Directive 2014/59/EU.

2. For purposes of determining the actual treatment of shareholders and creditors in resolution, the valuer shall rely on available information concerning facts and circumstances existing as of the actual treatment date or dates at which shareholders and creditors receive compensation ('actual treatment date or dates').

3. The reference date of the valuation shall be the resolution decision date, which may differ from the actual treatment date. Insofar as the valuer deems the impact of any discounting of the proceeds to be negligible, the undiscounted proceeds at the date the resolution action has been implemented may be directly compared with the discounted amount of hypothetical proceeds that shareholders and creditors would have received had the entity entered normal insolvency proceedings at the resolution decision date.

Article 2

Inventory of assets and claims

1. The valuer shall establish an inventory of all identifiable and contingent assets owned by the entity. Such inventory shall include assets for which the existence of associated cash flows is demonstrated or can reasonably be expected.

[1] Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

2. A list of all claims and contingent claims against the entity, shall be made available to the valuer. That list shall classify all claims and contingent claims according to their priority levels in normal insolvency proceedings. The valuer shall be allowed to enter into arrangements for specialist advice or expertise as regards the consistency of the ranking of claims with the applicable insolvency law.

3. Encumbered assets and claims secured by those assets shall be identified separately by the valuer.

Article 3

Steps of the valuation

For the purposes of determining whether a difference in treatment as referred to in Article 74(2) of Directive 2014/59/EU exists the valuer shall assess:

(a) the treatment that shareholders and creditors in respect of which resolution actions have been effected, or the relevant deposit guarantee scheme, would have received had the entity, entered normal insolvency proceedings at the resolution decision date, disregarding any provision of extraordinary public financial support;

(b) the value of the restructured claims following the application of the bail-in tool or other resolution powers and tools, or of other proceeds received by shareholders and creditors as at the actual treatment date or dates, discounted back to the resolution decision date if deemed necessary to enable a fair comparison with the treatment referred to in point (a);

(c) whether the outcome of the treatment in point (a) exceeds the outcome of the value referred to in point (b) for each creditor in accordance with the priority levels in normal insolvency proceedings as identified according to Article 2.

Article 4

Determination of the treatment of shareholders and creditors under normal insolvency proceedings

1. The methodology for conducting the valuation pursuant to point (a) of Article 3 shall be limited to determining the discounted amount of expected cash flows under normal insolvency proceedings.

2. Expected cash flows shall be discounted at the rate or rates reflecting, as appropriate, the timing associated with expected cash flows, prevailing circumstances as of the resolution decision date, risk-free interest rates, risk premia for similar financial instruments issued by similar entities, market conditions or discount rates applied by potential acquirers and other relevant characteristics of the element or elements being valued ('relevant discount rate'). The relevant discount rate shall not apply where particular rates, if relevant for the purposes of the valuation, are specified in applicable insolvency law or practice.

3. The valuer shall take the following into account in the determination of the discounted amount of expected cash flows under normal insolvency proceedings:

(a) applicable insolvency law and practice in the relevant jurisdiction, which may influence factors such as the expected disposal period or recovery rates;

(b) reasonably foreseeable administration, transaction, maintenance, disposal and other costs which would have been incurred by an administrator or insolvency practitioner, as well as financing costs;

(c) the information on recent past insolvency cases of similar entities, where available and relevant.

4. For assets traded in an active market, the valuer shall use the observed price, except where specific circumstances hamper the marketability of the assets of the entity, such as concentration, saturation and depth of the market.

5. For assets not traded in an active market, the valuer shall consider a number of factors when determining the amount and timing of expected cash flows, including:

(a) prices observed in active markets where similar assets are traded;

(b) prices observed in normal insolvency proceedings or otherwise distressed transactions involving assets of a similar nature and condition;

(c) prices observed in transactions involving the sale of business or the transfer to a bridge institution or an asset management vehicle in a resolution context relating to similar entities;

(d) the likelihood of an asset generating net cash inflows under normal insolvency proceedings;

(e) expected market conditions within a given disposal period, including market depth and the ability of the market to exchange the relevant volume of assets within that period; and

(f) the length of a given disposal period shall reflect the implications of the applicable insolvency law, including the expected length of the liquidation process, or the characteristics of the relevant assets.

6. The valuer shall consider whether the financial condition of the entity would have affected the expected cash flows, including through restrictions on the administrator's ability to negotiate terms with potential purchasers.

7. Where possible, and subject to any applicable provision of the relevant insolvency regime, the cash flows shall reflect the contractual, statutory, or other legal rights of creditors or normal insolvency practices.

8. The hypothetical proceeds resulting from the valuation shall be allocated to shareholders and creditors in accordance with their priority level under the applicable insolvency law, as provided for in Article 3.

9. For the purpose of determining any unsecured amount of derivatives claims in insolvency, the valuer shall apply methodologies set out in Commission Delegated Regulation (EU) 2016/1401 ([1]), to the extent consistent with insolvency law and practice.

Article 5

Determination of the actual treatment of shareholders and creditors in resolution

1. The valuer shall identify all claims outstanding after the write-down or conversion of capital instruments and the application of any resolution actions, and shall assign those claims to the legal and natural persons who were the entity's shareholders and creditors at the resolution decision date. Except where the legal and natural persons who were the entity's shareholders and creditors at the resolution decision date receive cash compensation as a result of the resolution, the valuer shall determine their actual treatment in accordance with paragraphs 2 to 4.

2. Where the legal and natural persons who were the entity's shareholders and creditors at the resolution decision date receive equity compensation as a result of the resolution, the valuer shall determine their actual treatment by providing an estimate of the overall value of shares transferred or issued as consideration to the holders of converted capital instruments or to the bailed-in creditors. That estimate may be based on the assessed market price resulting from generally accepted valuation methodologies.

3. Where the legal and natural persons who were the entity's shareholders and creditors at the resolution decision date receive debt compensation as a result of resolution, the valuer shall determine the actual treatment by taking into account factors such as the changes in contractual cash flows that result from the write-down or conversion, or the application of other resolution actions, as well as the relevant discount rate.

([1]) Commission Delegated Regulation (EU) 2016/1401 of 23 May 2016 supplementing Directive 2014/59/EU of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms with regard to regulatory technical standards for methodologies and principles on the valuation of liabilities arising from derivatives (OJ L 228, 23.8.2016, p. 7).

4. For any outstanding claim, the valuer may take into account, where available and together with the factors described in paragraphs 2 and 3, prices observed in active markets for the same or similar instruments issued by the entity under resolution or other similar entities.

Article 6

Valuation report

The valuer shall prepare a valuation report to the resolution authority which shall include at least the following elements:

(a) a summary of the valuation including a presentation of valuation ranges and sources of valuation uncertainty;

(b) an explanation of the key methodologies and assumptions adopted, and how sensitive the valuation is to these choices;

(c) an explanation, where feasible, why the valuation differs from other relevant valuations, including the resolution valuations conducted in accordance with Commission Delegated Regulation (EU) 2018/345 or other regulatory or accounting valuations.

Article 7

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 November 2017.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION DELEGATED REGULATION (EU) 2018/345

of 14 November 2017

supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the criteria relating to the methodology for assessing the value of assets and liabilities of institutions or entities

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 on establishing a framework for the recovery and resolution of credit institutions and investment firms [1], and in particular Article 36(15) thereof,

Whereas:

(1) In a resolution scenario it is important to distinguish between, on the one hand, an initial valuation assessing whether the conditions for the write-down and conversion of capital instruments or the condition for resolution have been met, and, on the other hand, a subsequent valuation forming the basis for the decision to apply one or more resolution tools. In relation to the initial valuation, it is appropriate to ensure that when determining whether the conditions for resolution or for the write-down or conversion of capital instruments are met, a fair and realistic valuation of the entity's assets and liabilities is conducted. For purposes of the subsequent valuation informing the decision on the resolution actions, it is important to ensure that the valuation of the assets and liabilities of the entity, which determines the choice of the resolution action and the extent of any potential write-down or conversion of capital instruments at the point of non-viability, is based on fair, prudent and realistic assumptions.

(2) To ensure that that valuation is fair, prudent and realistic, it is important that it estimates the impact of events prior to any resolution action or prior to the exercise of the power to write-down or convert capital instruments at the point of non-viability, as well as of different actions that might be taken by the resolution authority.

(3) The valuer should have access to any sources of relevant information and expertise, such as the internal records, systems, and models of the institution. The ability of internal capabilities and systems to support resolution valuations should be assessed by the resolution authority as part of the resolvability assessment pursuant to Article 15 of Directive 2014/59/EU. The valuer should as well be allowed to enter into arrangements for specialist advice or expertise. Availability of specialist advice or expertise might be relevant, for instance, for preparing an estimate of the difference in treatment pursuant to Article 36(8) of Directive 2014/59/EU. The resolution authority should therefore be satisfied that the valuer has access to either a list of all claims including contingent claims held against the entity and classified according to their rights and priority under normal insolvency proceedings, or to adequate legal expertise for the preparation of such list.

(4) The determination of whether an entity is failing or likely to fail may be carried out either by the competent authority or by the resolution authority in accordance with the conditions set out in Article 32(1)(a) of Directive 2014/59/EU. For purposes of determining whether an institution is failing or likely to fail, the competent authority should consider the valuation provided for in Chapter II of this Regulation, where already available and should take into account the guidelines issued by the European Banking Authority (EBA) pursuant to Article 32(6) of Directive 2014/59/EU which aim at promoting convergence of practices in relation to the determination of such resolution condition.

(5) Valuations for the purposes of informing the determination by the competent or the resolution authority whether the conditions for resolution or for write-down or conversion of capital instruments are met should be consistent with the applicable accounting and prudential regulatory framework. The valuer, however, should be able to depart from assumptions made by the entity's management under which the financial statements are

[1] OJ L 173, 12.6.2014, p. 190.

prepared to the extent such departure is consistent with the applicable accounting and prudential regulatory framework. When departing from those assumptions, the valuation should be supported by the best available information and be consistent with existing supervisory guidance or other generally recognised sources of interpretation of accounting standards, so as to provide a fair and realistic representation of the entity's financial position.

(6) It is appropriate to have rules that ensure that valuations for the purposes of informing the choice and design of resolution actions or the extent of write-down and conversion of capital instruments at point of non-viability are fair, prudent and realistic, to ensure that all losses are fully recognised at the moment the resolution tools are applied or the power to write-down or convert relevant capital instruments is exercised. The choice of the most appropriate measurement basis (the hold value or the disposal value) should be made for the particular resolution actions being considered by the resolution authority.

(7) It is appropriate that valuations for the purposes of informing the choice and design of resolution actions or the extent of the write-down and conversion of capital instruments at the point of non-viability assess the economic value and not the accounting value. Those valuations should consider the present value of cash flows that the entity can reasonably expect, even where this requires departing from accounting or prudential valuation frameworks.

(8) Valuations for the purposes of informing the choice and the design of resolution actions should reflect that cash flows may arise from continuing to hold the assets, yet should take into account the potential effects of the resolution on future cash flows and fair, prudent and realistic assumptions as to rates of default and severity of losses. Furthermore, to determine the post-conversion equity value of shares, the valuer should be able to take into account reasonable expectations for franchise value.

(9) Alternatively, where the entity lacks the ability to hold the assets or their disposal is considered necessary or appropriate to achieve the resolution objectives, the valuation should reflect that those cash flows may arise from the disposal of assets, liabilities or business lines, assessed over a defined disposal period.

(10) The disposal value should generally be understood as equivalent to the observable market price that could be obtained on the market for a particular asset or group of assets and may reflect a discount that is appropriate in view of the amount of assets being transferred. However, the valuer should be able where appropriate having regard to the actions to be taken under the resolution scheme, to determine the disposal value by applying a reduction to such observable market price for a potential accelerated sale discount. Where the assets do not have a liquid market, the disposal value should be determined by reference to the observable prices on markets where similar assets are traded or to model calculations using observable market parameters with discounts for illiquidity reflected as appropriate. Where the sale of business or the use of the bridge institution tool are contemplated, reasonable expectations for franchise value may be taken into account when determining the disposal value.

(11) For purposes of ensuring consistency between the calculation, required by Article 36(8) of Directive 2014/59/EU, of the estimate of the treatment that shareholders and each class of creditors would have been expected to receive had the institution or entity been wound-up under normal insolvency proceedings, and the valuation following resolution pursuant to Article 74 of that Directive, it is important that the valuer use the criteria set out for that valuation when appropriate.

(12) A provisional valuation pursuant to Article 36(9) of Directive 2014/59/EU forming the basis of the decision on the taking of the appropriate resolution action should include a buffer aimed at approximating the amount of additional losses. That buffer should be based on a fair, prudent, and realistic assessment of those additional losses. The decisions and assumptions supporting the calculation of the buffer should be adequately explained and justified in the valuation report.

(13) For the valuation referred to in points (a) and (c) of Article 36(15) of Directive 2014/59/EU, the valuer should explain and justify key assumptions, uncertainties, and the sensitivity of the valuation to such key assumptions and uncertainties. Significant differences between assumptions used in the valuation and those underlying accounting or regulatory information, where known to the valuer, should be included in the valuation report. In that report the valuer should also record any additional related information which in the valuer's opinion would assist the resolution authority.

(14) The criteria laid down in this Regulation should be exclusively set out for conducting the valuations under Article 36 of Directive 2014/59/EU. They should not replace or amend accounting principles and standards or the prudential regulatory framework that apply to entities in contexts other than resolution. It should however be possible to use the information resulting from the valuation to identify potential misapplications by the entity of accounting standards or of the prudential regulatory framework, or to determine changes in the entity's accounting policies or in the assumptions or judgements driving the measurement of assets and liabilities. Those circumstances, for instance, should be taken into account for the preparation of the updated balance sheet pursuant to Article 36(6) of Directive 2014/59/EU. For that purpose the valuer should provide an adequate explanation of the differences between the existing and the updated balance sheets.

(15) This Regulation is based on the draft regulatory technical standards submitted by the EBA to the Commission.

(16) EBA has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ([1]),

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Definitions

For the purpose of this Regulation the following definitions shall apply:

(a) 'valuation' means either the assessment of an entity's assets and liabilities conducted by a valuer pursuant to Article 36(1) of Directive 2014/59/EU, or the provisional valuation conducted by the resolution authority or the valuer, as the case may be, pursuant respectively to paragraphs (2) and (9) of Article 36 of that Directive.

(b) 'valuer' means either the independent valuer within the meaning of Article 38 of Commission Delegated Regulation (EU) 2016/1075 ([2]) or the resolution authority when conducting a provisional valuation pursuant to paragraphs (2) and (9) of Article 36 of Directive 2014/59/EU.

(c) 'entity' means an institution or an entity as referred to in points (b), (c) or (d) of Article 1(1) of Directive 2014/59/EU.

(d) 'fair value' means the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the valuation date, as defined in the relevant accounting framework.

(e) 'hold value' means the present value, discounted at an appropriate rate, of cash flows that the entity can reasonably expect under fair, prudent and realistic assumptions from retaining particular assets and liabilities, considering factors affecting customer or counterparty behaviour or other valuation parameters in the context of resolution.

(f) 'disposal value' means the measurement basis refered to in Article 12(5).

([1]) Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

([2]) Commission Delegated Regulation (EU) 2016/1075 of 23 March 2016 supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the content of recovery plans, resolution plans and group resolution plans, the minimum criteria that the competent authority is to assess as regards recovery plans and group recovery plans, the conditions for group financial support, the requirements for independent valuers, the contractual recognition of write-down and conversion powers, the procedures and contents of notification requirements and of notice of suspension and the operational functioning of the resolution colleges (OJ L 184, 8.7.2016, p. 1).

(g) 'franchise value' means the net present value of cash flows that can reasonably be expected to result from the maintenance and renewal of assets and liabilities or businesses and includes the impact of any business opportunities, as relevant, including those stemming from the different resolution actions that are assessed by the valuer. Franchise value may be higher or lower than the value arising from the contractual terms and conditions of assets and liabilities existing at the valuation date.

(h) 'equity value' means an estimated market price, for transferred or issued shares, that results from the application of generally accepted valuation methodologies. Depending on the nature of the assets or business, equity value may comprise franchise value.

(i) 'measurement basis' means the approach for determining the monetary amounts at which assets or liabilities are presented by the valuer.

(j) 'resolution date' means the date on which the decision to resolve an entity is adopted, pursuant to Article 82 of Directive 2014/59/EU.

Article 2

General criteria

1. When performing the valuation the valuer shall consider circumstances affecting the expected cash flows of, and discount rates applicable to an entity's assets and liabilities, and shall aim to fairly represent the entity's financial position in the context of the opportunities and risks it deals with.

2. The valuer shall disclose and justify the key assumptions used in the valuation. Any significant deviation in the valuation from the assumptions used by the entity's management in the preparation of financial statements and in the calculation of the entity's regulatory capital and capital requirements shall be supported by the best available information.

3. The valuer shall provide the best point estimate of the value of a given asset, liability, or combinations thereof. Where appropriate, the results of the valuation shall also be provided in the form of value ranges.

4. Criteria laid down in this Regulation for the measurement of individual assets and liabilities of an entity, shall also apply to the measurement of portfolios or groups of assets or combined assets and liabilities, businesses, or the entity considered as a whole, as the circumstances require.

5. The valuation shall subdivide creditors in classes according to their priority ranking under applicable insolvency law, and shall include the following estimates:

(a) the value of claims of each class according to the applicable insolvency law and, where relevant and feasible, according to the contractual rights conferred on claimants;

(b) the proceeds each class would receive if the entity were wound-up under normal insolvency proceedings;

When calculating the estimates pursuant to points (a) and (b) of the first subparagraph, the valuer may apply the criteria set out in Article 4 of Commission Delegated Regulation (EU) 2018/344 of 14 November 2017 supplementing Directive 2014/59/EU of the European Parliament and of the Council with regard to regulatory technical standards specifying the criteria relating to the methodologies for valuation of difference in treatment in resolution as appropriate.

6. Where appropriate and feasible, taking into account timing and credibility of the valuation, the resolution authority may request several valuations. In that case, the resolution authority shall establish the criteria to determine how these valuations shall be used for the purposes set out in Article 36 of Directive 2014/59/EU.

Article 3

Valuation date

The valuation date shall be one of the following dates:

(a) the reference date as determined by the valuer on the basis of the date as close as possible before the expected date of a decision by the resolution authority to put the entity in resolution or to exercise the power to write-down or to convert capital instruments;

(b) where an *ex post* definitive valuation required by Article 36(10) of Directive 2014/59/EU is conducted, the resolution date;

(c) in relation to liabilities arising from derivative contracts, the point in time determined pursuant to Article 8 of Commission Delegated Regulation (EU) 2016/1401 ([1]).

Article 4

Sources of information

The valuation shall be based on any information pertinent to the valuation date which is deemed relevant by the valuer. In addition to the entity's financial statements, related audit reports and regulatory reporting as of a period ending as close as possible to the valuation date, that relevant information may include the following:

(a) the updated financial statements and regulatory reporting prepared by the entity as close as possible to the valuation date;

(b) an explanation of the key methodologies, assumptions and judgements used by the entity in order to prepare the financial statements and regulatory reporting;

(c) data contained in the records of the entity;

(d) relevant market data;

(e) conclusions drawn by the valuer from discussion with management and auditors;

(f) where available, supervisory assessments of the entity's financial condition, including information acquired pursuant to point (h) of Article 27(1) of Directive 2014/59/EU;

(g) industry-wide assessments of asset quality, where relevant to the entity's assets, as well as stress test results;

(h) valuations of peers, adequately adjusted to capture the entity's specific circumstances;

(i) historical information, adequately adjusted to eliminate factors that are no longer relevant, and to incorporate other factors that did not affect the historical information; or

(j) trend analyses, adequately adjusted to reflect the entity's specific circumstances.

Article 5

Impact of group arrangements

1. Where the entity forms part of a group, the valuer shall take into account the impact that existing contractual intra-group support arrangements can have on the value of the assets and liabilities where, on the basis of the circumstances, it is probable that those arrangements will be put into effect.

2. The valuer shall only take into account the impact of other formal or informal arrangements within the group where, on the basis of the circumstances, it is probable that those arrangements shall remain in place in the context of a group's stressed financial condition or in resolution.

3. The valuer shall determine whether the resources of an entity within the group are available to meet losses of other group entities.

Article 6

Valuation report

The valuer shall prepare a valuation report to the resolution authority which shall include at least the following elements:

(a) except as provided in Article 36(9) of Directive 2014/59/EU, the information referred to in points (a) to (c) of Article 36(6) of that Directive;

(b) except as provided in Article 36(9) of Directive 2014/59/EU, the information referred to in Article 36(8) of Directive 2014/59/EU;

([1]) Commission Delegated Regulation (EU) 2016/1401 of 23 May 2016 supplementing Directive 2014/59/EU of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms with regard to regulatory technical standards for methodologies and principles on the valuation of liabilities arising from derivatives (OJ L 228, 23.8.2016, p. 7).

(c) the valuation of the liabilities arising from derivatives carried out in accordance with Commission Delegated Regulation (EU) 2016/1401;

(d) a summary of the valuation including an explanation of best point estimate, value ranges and sources of valuation uncertainty;

(e) an explanation of the key methodologies and assumptions used by the valuer when performing the valuation, how sensitive the valuation is to the choices of methodologies and assumptions and, where feasible, an explanation of how those methodologies and assumptions differ from those used for other relevant valuations including any preliminary resolution valuations;

(f) any additional information which in the valuer's opinion would assist the resolution authority or competent authority for purposes of Article 36(1) to (11) of Directive 2014/59/EU.

CHAPTER II

CRITERIA FOR THE VALUATION FOR THE PURPOSE OF ARTICLE 36(4)(a)

Article 7

General principles

1. The valuations for the purpose referred to in point (a) of Article 36(4) of Directive 2014/59/EU shall be based on fair and realistic assumptions and shall seek to ensure that losses under the appropriate scenario are fully recognised. Where such valuation is available, it shall inform the determination of the competent authority or of the resolution authority as appropriate, that an institution is 'failing or likely to fail' as referred to in Article 32(1)(a) of Directive 2014/59/EU. Based on existing supervisory guidance or other generally recognised sources setting out criteria conducive to the fair and realistic measurement of different types of assets and liabilities, the valuer may challenge the assumptions, data, methodologies and judgements on which the entity based its valuations for financial reporting obligations or for the calculation of regulatory capital and capital requirements and disregard them for the purposes of the valuation.

2. The valuer shall determine the most appropriate valuation methodologies which may rely on the entity's internal models where the valuer deems it appropriate taking into account the nature of the entity's risk management framework and the quality of data and information available.

3. The valuations shall be consistent with the applicable accounting and prudential regulatory framework.

Article 8

Areas requiring particular attention in the valuation

The valuer shall particularly focus on areas subject to significant valuation uncertainty which have a significant impact on the overall valuation. For those areas the valuer shall provide the results of the valuation in the form of best point estimates and, where appropriate, value ranges, as laid down in Article 2(3). Those areas shall include:

(a) loans or loan portfolios, the expected cash flows of which depend on a counterparty's ability, willingness or incentive to perform on its obligation, where those expectations are driven by assumptions relating to delinquency rates, probabilities of default, loss given default, or instrument characteristics, especially where evidenced by loss patterns for a portfolio of loans;

(b) repossessed assets, the cash flows of which are affected by both the asset's fair value at the time the entity forecloses on the related security or lien, and the expected evolution of such value after foreclosure;

(c) instruments measured at fair value where the determination of that fair value in accordance with accounting or prudential requirements on their marking to market or marking to model is no longer applicable or valid taking into account the circumstances;

(d) goodwill and intangibles, where the impairment test may depend on subjective judgement, including as regards the reasonably attainable cash flow stream, discount rates, and the perimeter of cash generating units;

(e) legal disputes and regulatory actions, the expected cash flows of which may be subject to varying degrees of uncertainty relating to their amount and/or timing;

(f) items including pension assets and liabilities and deferred tax items.

Article 9

Factors affecting the valuation

1. The valuer shall take into account general factors that may affect the key assumptions on which the values of assets and liabilities in the areas referred to in Article 8 are based, including the following factors:

(a) the economic and industry circumstances affecting the entity, including relevant market developments;

(b) the entity's business model and changes in its strategy;

(c) the entity's asset selection criteria, including loan underwriting policies;

(d) circumstances and practices that are likely to lead to payment shocks;

(e) circumstances affecting the parameters used to determine risk weighted assets for the calculation of minimum capital requirements;

(f) the impact of the entity's financial structure on the capacity of the entity to retain assets for the expected holding period and the entity's ability to generate predictable cash flows;

(g) general or entity-specific liquidity or funding concerns.

2. The valuer shall clearly separate any material unrealised gains identified in the valuation process, to the extent that those gains have not been recognised in the valuation, and shall provide adequate information in the valuation report of the exceptional circumstances that have led to those gains.

CHAPTER III

CRITERIA FOR THE VALUATION FOR THE PURPOSE OF ARTICLE 36(4)(b), (c), (d), (e), (f), (g) AND OF ARTICLE 36(9), SECOND SUBPARAGRAPH

Article 10

General principles

1. The valuer shall assess the impact on the valuation of each resolution action that the resolution authority may adopt to inform the decisions referred to in points (b) to (g) of Article 36(4) of Directive 2014/59/EU. Without prejudice to the valuer's independence, the resolution authority may consult with the valuer in order to identify the range of resolution actions being considered by that authority, including actions contained in the resolution plan or, if different, any proposed resolution scheme.

2. To ensure a fair, prudent and realistic valuation, the valuer shall, where appropriate and in consultation with the resolution authority, present separate valuations that reflect the impact of a sufficiently diverse range of resolution actions.

3. The valuer shall ensure that when the resolution tools are applied or when the power to write-down or convert relevant capital instruments is exercised, any losses on the assets of the entity are fully recognised under scenarios that are relevant to the ranges of resolution actions being considered.

4. Where the values of the valuation diverge significantly from the values presented by the entity in the financial statements, the valuer shall use the assumptions of that valuation, to inform the adjustments to the assumptions and to the accounting policies necessary for the preparation of the updated balance sheet required under Article 36(6) of Directive 2014/59/EU, in a way consistent with the applicable accounting framework. As regards losses identified by the valuer which cannot be recognised in the updated balance sheet, the valuer shall specify the amount, describe the reasons underlying the determination of the losses and the likelihood and time horizon of their occurrence.

5. Where capital instruments or other liabilities are converted to equity, a valuation shall provide an estimate of the post-conversion equity value of new shares transferred or issued as consideration to holders of converted capital instruments or other creditors. That estimate shall form the basis for the determination of the conversion rate or rates pursuant to Article 50 of Directive 2014/59/EU.

Article 11

Selection of the measurement basis

1. In selecting the most appropriate measurement basis or bases, the valuer shall take into account the range of resolution actions to be examined according to Article 10(1).

2. The valuer shall determine the cash flows that the entity can expect on the basis of fair, prudent and realistic assumptions from existing assets and liabilities following adoption of the examined resolution action or actions, discounted at an appropriate rate as determined in accordance with paragraph 6.

3. Cash flows shall be determined at the appropriate level of aggregation, ranging from individual assets and liabilities to portfolios or businesses, with due consideration to differences in the risk profiles.

4. Where the resolution actions referred to in Article 10(1) require that assets and liabilities are to be retained by an entity that continues to be a going concern institution, the valuer shall use the hold value as the appropriate measurement basis. The hold value may, if considered fair, prudent and realistic, anticipate a normalisation of market conditions.

The hold value shall not be used as the measurement basis where assets are transferred to an asset management vehicle pursuant to Article 42 of Directive 2014/59/EU or to a bridge institution pursuant to Article 40 of that Directive, or where a sale of business tool pursuant to Article 38 of Directive 2014/59/EU is used.

5. Where the resolution actions referred to in Article 10(1) envisage the sale of assets the expected cash flows shall correspond to the disposal values envisaged for the expected disposal horizon.

6. The discount rates shall be determined having regard to the timing of cash flows, risk profile, financing costs and market conditions as appropriate to the asset or liability being measured, the disposal strategy considered and the entity's post-resolution financial position.

Article 12

Specific factors relating to the estimation and discounting of expected cash flows

1. For the purpose of estimating cash flows, the valuer shall apply their expert judgement in determining key characteristics of the assets or liabilities being measured. The valuer shall also apply their expert judgement in determining how the continuation, potential renewal or refinancing, run-off or disposal of those assets or liabilities, as envisaged in the examined resolution action, affect those cash flows.

2. Where the resolution action envisages an entity holding an asset, maintaining a liability, or continuing a business, the valuer may take into account factors potentially affecting future cash flows, including the following:

(a) changes in assumptions or expectations, as compared to those prevailing as of the valuation date, consistent with long-term historical trends and a reasonable horizon consistent with the contemplated holding period of assets or for the recovery of the entity; or

(b) additional or alternative valuation bases or methodologies that are considered appropriate by the valuer and consistent with this Regulation, including in the context of assessing the post-conversion equity value of shares.

3. As regards groups of assets and liabilities or businesses envisaged to be run off, the valuer shall take into account workout costs and benefits.

4. Where an entity's situation prevents it from holding an asset or continuing a business, or where the sale is otherwise considered necessary by the resolution authority to achieve the resolution objectives, the expected cash flows shall be referenced to disposal values expected within a given disposal period.

5. The disposal value shall be determined by the valuer on the basis of the cash flows, net of disposal costs and net of the expected value of any guarantees given, that the entity can reasonably expect in the currently prevailing market conditions through an orderly sale or transfer of assets or liabilities. Where appropriate, having regard to the actions to be taken under the resolution scheme, the valuer may determine the disposal value by applying a reduction for a potential accelerated sale discount to the observable market price of that sale or transfer. To determine the disposal value of assets which do not have a liquid market, the valuer shall consider observable prices on markets where similar assets are traded or model calculations using observable market parameters, with discounts for illiquidity reflected as appropriate.

6. The valuer shall have regard to factors that might affect disposal values and disposal periods, including the following:

(a) the disposal values and disposal periods observed in similar transactions, adequately adjusted to take into account differences in the business model and in the financial structure of the parties to those transactions;

(b) advantages or disadvantages of a particular transaction that are specific to the parties involved or to a subset of market participants;

(c) particular attributes of an asset or business that may only be relevant to a potential purchaser, or to a subset of market participants;

(d) the likely impact of expected sales on the entity's franchise value.

7. When assessing the value of businesses for purposes of the use of the sale of business or of the bridge institution tool, the valuer may take into account reasonable expectations for franchise value. Such expectation for franchise value shall include that resulting from a renewal of assets, from a refinancing of an open portfolio, or from a continuation or resumption of business in the context of the resolution actions.

8. A valuer assessing that no realistic prospect for the disposal of an asset or business can reasonably be expected, shall not be required to determine the disposal value, but shall estimate the related cash flows on the basis of the relevant prospects for continuation or run-off. This provision shall not apply to the asset separation tool or to the sale of business tool.

9. For parts of a group of assets or of a business that are likely to be liquidated under ordinary insolvency procedures, the valuer may consider the disposal values and disposal periods observed in auctions involving assets of a similar nature and condition. The determination of expected cash flows shall take into account illiquidity, the absence of reliable inputs for the determination of disposal values, and the resulting need to rely on valuation methodologies based on unobservable inputs.

Article 13

Methodology for calculating and including a buffer for additional losses

1. To address the uncertainty of provisional valuations conducted in accordance with points (b) to (g) of Article 36(4) of Directive 2014/59/EU, the valuer shall include in the valuation a buffer to reflect facts and circumstances supporting the existence of additional losses of uncertain amount or timing. In order to avoid double counting of uncertainty, the assumptions supporting the calculation of the buffer shall be adequately explained and justified by the valuer.

2. In order to determine the size of the buffer, the valuer shall identify factors that may affect expected cash flows as a result of resolution actions likely to be adopted.

3. For the purposes of paragraph 2, the valuer may extrapolate losses estimated for a part of the entity's assets to the remainder of the entity's balance sheet. Where available, average losses estimated for assets of peer competitors may also be extrapolated, subject to the necessary adjustments for differences in the business model and financial structure.

Article 14

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 November 2017.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/346

of 5 March 2018

concerning the authorisation of a preparation of *Lactobacillus buchneri* NRRL B-50733 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Lactobacillus buchneri* NRRL B-50733. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of *Lactobacillus buchneri* NRRL B-50733 as a feed additive for all animal species, to be classified in the additive category 'technological additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 July 2017 ([2]) that, under the proposed conditions of use, the preparation of *Lactobacillus buchneri* NRRL B-50733 does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparation concerned has the potential to improve the production of silage from easy, moderately difficult and difficult to ensile forage materials. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Lactobacillus buchneri* NRRL B-50733 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017; 15(7):4934.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU of additive/kg of fresh material			
Technological additives: silage additives								
1k20758	*Lactobacillus buchneri* NRRL B-50733	*Additive composition:* Preparation of *Lactobacillus buchneri* NRRL B-50733 containing a minimum of 1×10^{10} CFU/g additive. *Characterisation of the active substance:* Viable cells of *Lactobacillus buchneri* NRRL B-50733 *Analytical method* (1) Enumeration in the feed additive: spread plate method on MRS agar: EN 15787. Identification of the feed additive: Pulsed Field Gel Electrophoresis (PFGE).	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions shall be indicated. 2. Minimum content of *Lactobacillus buchneri* NRRL B-50733 when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg of fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	29 March 2028

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION IMPLEMENTING REGULATION (EU) 2018/347

of 5 March 2018

concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparation of *Saccharomyces cerevisiae* CNCM I-1079 was authorised without a time limit as feed additive for piglets by Commission Regulation (EC) No 1847/2003 ([3]) and for sows by Commission Regulation (EC) No 2036/2005 ([4]). That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as feed additive for sows and piglets. The applicant requested that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 20 April 2016 and 4 July 2017 ([5]) that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1079 does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive is efficacious in sows in order to have a benefit in suckling piglets and in weaned piglets in order to have a significant improvement of feed to gain ratio. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) Regulations (EC) No 1847/2003 and (EC) No 2036/2005 should be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1847/2003 of 20 October 2003 concerning the provisional authorisation of a new use of an additive and the permanent authorisation of an additive already authorised in feedingstuffs (OJ L 269, 21.10.2003, p. 3).
([4]) Commission Regulation (EC) No 2036/2005 of 14 December 2005 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs (OJ L 328, 15.12.2005, p. 13).
([5]) *EFSA Journal* 2016;14(6):4478 and *EFSA Journal* 2017;15(7):4932.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Regulation (EC) No 1847/2003

Regulation (EC) No 1847/2003 is amended as follows:

(1) Article 2 is deleted;

(2) Annex II is deleted.

Article 3

Amendment to Regulation (EC) No 2036/2005

In Annex I to Regulation (EC) No 2036/2005, entry E1703 is deleted.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 29 September 2018 in accordance with the rules applicable before 29 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4d1703	Danstar Ferment AG represented by Lallemand SAS	*Saccharomyces cerevisiae* CNCM I-1079	*Additive composition:* Preparation of *Saccharomyces cerevisiae* CNCM I-1079 containing a minimum of: — 1×10^{10} CFU/g of additive (coated form); — 2×10^{10} CFU/g of additive (not-coated form); *Characterisation of the active substance:* Viable cells of *Saccharomyces cerevisiae* CNCM I-1079 *Analytical method* (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method 15790:2008.	Sows Weaned piglets	—	1×10^9	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 3. For use in sows in order to have a benefit for suckling piglets. 4. For use in weaned piglets until approximately 35 kg.	29 March 2028

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION IMPLEMENTING REGULATION (EU) 2018/348

of 8 March 2018

on a temporary derogation from the rules of preferential origin laid down in Delegated Regulation (EU) 2015/2446 in respect of bicycles and other cycles produced in Cambodia regarding the use, under cumulation, of parts originating in Malaysia

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]) and in particular Articles 64(6) and 66(b) thereof,

Whereas:

(1) By Regulation (EU) No 978/2012 of the European Parliament and of the Council ([2]) the Union granted generalised tariff preferences ('GSP') to Cambodia. The GSP scheme became applicable on 1 January 2014.

(2) Regulation (EU) No 952/2013 provides for the possibility to grant, in certain precisely defined circumstances and for certain goods, derogations from the rules on preferential origin in favour of GSP beneficiary countries. According to Commission Delegated Regulation (EU) 2015/2446 ([3]), regional cumulation can only apply in the same regional group to countries which, at the time of exportation to the Union, are beneficiaries of the GSP.

(3) On 13 October 2016, Cambodia submitted a request for a 3-year extension of a derogation granted by Commission Implementing Regulation (EU) No 822/2014 ([4]). Under that derogation, Cambodia was entitled, for the purpose of determining the origin of bicycles of HS heading 8712 imported to the Union from Cambodia, to consider parts originating in Malaysia to be materials originating in Cambodia by virtue of regional cumulation under the GSP scheme, even though Malaysia was not a GSP beneficiary country.

(4) In its request, Cambodia considered that considerable efforts had been made by its bicycle industry to gradually comply with the Union rules of origin for the least developed countries (as provided for in Annex 22-03 of Delegated Regulation (EU) 2015/2446), under which in order for a product to be considered originating in the least developed country, the materials used for its production and imported from other countries should not exceed 70 %. However, Cambodia concluded that more time is needed for that industry to reach full compliance with the Union rules of origin for the least developed countries.

(5) By letter of 17 February 2017, the Commission requested Cambodia to submit further information. On 15 June 2017, Cambodia transmitted its answer to that request, as a result of which its application was considered complete.

(6) In its reply, Cambodia demonstrated that efforts had been made to render the bicycle industry more autonomous thanks to investments aiming to set up further part manufacturing lines (such as frames, painting, wielding or rims). Cambodia also explained that manufacturers had been incented to purchase bike accessories as well as packaging material from local suppliers in order to increase the added value created in Cambodia. Consequently, Cambodia has now its own policy to attract investors to set up industrial clusters in special economic zones to support the bicycle industry.

(7) Cambodia underlines that an additional period of time is important to maintain the momentum of the Cambodian bicycle industry and for new projects to take effect, notably in the field of promoting investments in other ASEAN members which will help to meet the needs of the Cambodian bicycle industry with regard to quality and price of the bicycle parts.

([1]) OJ L 269, 10.10.2013, p. 1.
([2]) Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 (OJ L 303, 31.10.2012, p. 1).
([3]) Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code (OJ L 343, 29.12.2015, p. 1).
([4]) Commission Implementing Regulation (EU) No 822/2014 of 28 July 2014 on a derogation from Regulation (EEC) No 2454/93 as regards the rules of origin under the scheme of generalised tariff preferences in respect of bicycles produced in Cambodia regarding the use under cumulation of bicycle parts originating in Malaysia (OJ L 223, 29.7.2014, p. 19).

(8) It appears from that additional information that Cambodia now affords its bicycle industry a satisfactory level of autonomy and the figures presented in its report show that a continuous fulfilment of the rule of origin allowing the use of up to 70 % of non-originating materials is now within reach. Therefore, given that improvement, there is no need for a long period of extension of the derogation or for a high number of units imported into the Union to be covered by that derogation. As the derogation for 2016 concerned 150 000 units, a number of 100 000 units will be sufficient to support Cambodia in completing the autonomy of its industry.

(9) Nevertheless, as Cambodia explained in its request, making full use of the derogation depends on the seasonal rhythm separating the period for ordering parts (October-December) from the period of importation of those parts from the other countries (from May of the following year to March of the third year). Therefore it appears necessary to provide a sufficiently long period of time for the derogation to be beneficial. For the same purposes, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.

(10) In order to allow efficient monitoring of the operation of the derogation, it is necessary to require the authorities of Cambodia to communicate regularly to the Commission the details of the certificates of origin Form A which have been issued within the framework of the derogation.

(11) The derogation should concern all products of HS heading 8712 using parts of HS heading 8714 originating in Malaysia.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

1. By way of derogation from point (a) of Article 55(2) of Delegated Regulation (EU) 2015/2446, Cambodia shall be entitled to rely on regional cumulation of origin in accordance with Title II, Chapter 1, Section 2 of Delegated Regulation (EU) 2015/2446 when using parts of HS heading 8714 originating in Malaysia for the production of bicycles and other cycles of HS heading 8712 to be exported to the Union.

2. The proofs of origin for the parts referred to in paragraph 1 shall be drawn up in accordance with Title II, Chapter 2, Section 2, Subsection 2 of Commission Implementing Regulation (EU) 2015/2447 ([1]).

Article 2

The derogation provided for in Article 1 shall apply to products of HS heading 8712 exported from Cambodia and declared for release for free circulation in the Union during the period and up to the quantities set out in the Annex.

Article 3

The quantities set out in the Annex to this Regulation shall be managed in accordance with Articles 49 to 54 of Implementing Regulation (EU) 2015/2447.

Article 4

Box 4 of certificates of origin Form A issued by the competent authorities of Cambodia or statements on origin made out by the exporters registered in Cambodia with regard to products referred to in Article 2 shall bear the following endorsements:

— 'Derogation — Commission Implementing Regulation (EU) 2018/348',

The competent authorities of Cambodia shall forward to the Commission, by the end of the month following each civil quarter, a quarterly statement of the quantities of products referred to in Article 2 in respect of which certificates of origin Form A have been issued and the serial numbers of those certificates.

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

Article 5

The competent authorities of Cambodia shall take all the necessary measures to ensure compliance with Articles 1 and 4 and to put in place and maintain any administrative structures and systems to ensure the correct implementation of the derogation referred to in Article 1 and administrative cooperation, both with the authorities of Malaysia and with the European Commission and the customs authorities of the Member States of the Union, as specified in Title II, Chapter 2, Section 2, Subsection 2 of Implementing Regulation (EU) 2015/2447.

Article 6

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Order No	CN Code	Description of goods	Period	Quantities (in units)
09.8094	8712	Bicycles and other cycles (including delivery tricycles), not motorised	9 March 2018 to 31 December 2019	100 000

COMMISSION IMPLEMENTING REGULATION (EU) 2018/349

of 8 March 2018

amending for the 282nd time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations [1], and in particular Article 7(1)(a) and Article 7a(1) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 6 March 2018, the Sanctions Committee of the United nations Security Council decided to add three entries to the list of persons, groups and entities to whom the freezing of funds and economic resourced should apply. Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly.

(3) In order to ensure that the measures provided for in this Regulation are effective it should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 March 2018.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

[1] OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

(1) The following entries are added under the heading 'Natural persons':

(a) 'Salim Mustafa Muhammad Al-Mansur (alias: (a) Salim Mustafa Muhammad Mansur Al-Ifri; (b) Saleem Al-Ifri; (c) Salim Mansur Mustafa; (d) Salim Mansur; (e) Hajji Salim Al-Shaklar). Date of birth: (a) 20.2.1962 (b) 1959. Place of birth: (a) Baghdad, Iraq; (b) Tel Afar, Nineveh Province, Iraq. Nationality: Iraqi. Passport no: Iraq number A6489694, issued on 2.9.2013 (expires on 31.8.2021). National identification no: (a) Iraq national identification card 00813602, issued on 18.9.2011; (b) Iraq Certificate of Iraqi Nationality 300397, issued on 25.6.2013. Address: (a) 17 Tamoz, Mosul, Iraq (previous address); (b) Tel Afar – Al-Saad, Mosul, Iraq (previous address). Other information: Physical description: hair colour: black; eye colour: honey; height: 170 cm; speaks Arabic. Date of designation referred to in Article 7d(2)(i): 6.3.2018.'

(b) 'Umar Mahmud Irhayyim Al-Kubaysi (alias: (a) Umar Mahmud Rahim al-Kubaysi; (b) Omar Mahmood Irhayyim Al-Fayyadh; (c) Umar Mahmud Rahim; (d) Umar Mahmud Rahim Al-Qubaysi; (e) Umar Mahmud Al-Kubaysi Arhaym; (f) Umar Mahmud Arhaym; (g) Omar Mahmood Irhayyim; (h) Omar Mahmood Irhayyim Al-Fayyadh Al-Kobaisi; (i) Umar al-Kubaysi). Date of birth: (a) 16.6.1967; (b) 1.1.1967. Place of birth: Al-Qaim, Al-Anbar Province, Iraq. Nationality: Iraqi. Passport no: Iraq number A4059346, issued on 29.5.2013, issued in Baghdad, Iraq (expires on 27.5.2021). National identification no: (a) Iraq national identification card 00405771, issued on 20 May 2013, issued in Iraq; (b) Iraq Certificate of Iraqi Nationality 540763, issued on 13.2.1984. Address: Al-Qaim, Al-Anbar Province, Iraq. Other information: Physical description: sex: male, hair colour: black; height: 175 cm; speaks Arabic. Date of designation referred to in Article 7d(2)(i): 6.3.2018.'

(2) The following entry is added under the heading 'Legal persons, groups and entities':

'Al-Kawthar Money Exchange (alias: (a) Al Kawthar Co.; (b) Al Kawthar Company; (c) Al-Kawthar Hawala). Address: Al-Qaim, Al Anbar Province, Iraq. Other information: Money exchange business and owned by Umar Mahmud Irhayyim al-Kubaysi as of mid-2016. Established in 2000 under License number 202, issued on 17.5.2000, and since withdrawn. Date of designation referred to in Article 7d(2)(i): 6.3.2018.'

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2018/350

of 8 March 2018

amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([1]), and in particular Article 27 thereof,

Whereas:

(1) Directive 2001/18/EC sets out requirements for the environmental risk assessment of genetically modified organisms ('GMOs').

(2) On 4 December 2008, the Council adopted Conclusions on GMOs stressing the need to update and strengthen the environmental risk assessment of GMOs, in particular concerning the assessment of long-term environmental effects.

(3) Following a request from the Commission, the European Food Safety Authority (EFSA) adopted in October 2010 a Scientific opinion establishing guidance on the environmental risk assessment of genetically modified plants ([2]) ('the Guidance'), which is a revision of the previous guidance. Other guidance documents issued by EFSA and by the European Medicines Agency are relevant to the environmental risk assessment of GMOs other than plants.

(4) Article 3 of Directive (EU) 2015/412 of the European Parliament and of the Council ([3]) provides that by 3 April 2017 the Commission has to update the Annexes to Directive 2001/18/EC as regards the environmental risk assessment with a view to incorporating and building upon the Guidance, which is not legally binding.

(5) In order to adapt to technical progress and taking into account the experience gained in the environmental risk assessment of genetically modified plants, the essential elements of the Guidance should be incorporated in Directive 2001/18/EC. In doing so, the principle that the environmental risk assessment should be carried out on a case-by-case basis should be respected.

(6) The Guidance was essentially designed for notifications for the purpose of placing on the market ('Part C notifications') of genetically modified plants, while Annex II to Directive 2001/18/EC applies to both Part C notifications and notifications for other purposes than placing on the market ('Part B notifications'). Therefore, certain requirements resulting from the incorporation of the Guidance in Annex II should only apply to Part C notifications, as they would be irrelevant or disproportionate in the context of Part B notifications, which essentially concern experimental releases.

(7) Part C of Annex II to Directive 2001/18/EC concerns the methodology of the environmental risk assessment. It should be updated in order to incorporate, in particular, the terminology used to describe the six steps of the assessment approach as described in the Guidance.

([1]) OJ L 106, 17.4.2001, p. 1.
([2]) *EFSA Journal* 2010;8(11):1879.
([3]) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.3.2015, p. 1).

(8) Part D of Annex II to Directive 2001/18/EC applies to the conclusions of the environmental risk assessment and contains two distinct sections, concerning GMOs other than higher plants (Section D.1) and genetically modified higher plants (Section D.2) respectively. The Guidance considers seven specific areas of risk to be addressed in the environmental risk assessment of genetically modified plants in order to draw conclusions. The structure and content of Section D.2 of Annex II should therefore be updated to reflect those areas of risk.

(9) Where the environmental risk assessment concerns a genetically modified plant made tolerant to a herbicide, its scope should be consistent with Directive 2001/18/EC. The environmental risk assessment of the use of a plant protection product, including its use on a genetically modified plant, falls under the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([1]) and will be carried out at Member State level to take into account the specific agricultural conditions.

(10) Annex III B to Directive 2001/18/EC lists the information required in notifications concerning releases of genetically modified higher plants and applies to both Part C notifications and Part B notifications. Its structure, content and level of detail should be amended to ensure consistency with the Guidance. As most of the changes induced by the Guidance concern the environmental risk assessment of Part C notifications, and in the interest of clarity and simplification for the notifiers and the competent authorities, it is appropriate to modify the structure of Annex III B by separating the requirements concerning Part C notifications from the requirements concerning Part B notifications.

(11) The majority of the requests for authorisation of the placing on the market of genetically modified plants are submitted in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([2]). In the interest of simplification, it is therefore appropriate to align, to the extent possible, the order of the pieces of information required for Part C notifications in Annex III B to Directive 2001/18/EC with the order followed in Commission Implementing Regulation (EU) No 503/2013 ([3]).

(12) Annex IV to Directive 2001/18/EC sets out additional information requirements only for Part C notifications. The requirements set out in that Annex concerning detection methods should be updated in the light of technical progress, in particular as regards the submission by notifiers of the reference material.

(13) The measures provided for in this Directive are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III, III B and IV to Directive 2001/18/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 September 2019 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

([1]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

([2]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

([3]) Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1).

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Directive 2001/18/EC is amended as follows:

(1) Annex II is amended as follows:

(a) Section C is replaced by the following:

'C. **Methodology**

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

C.1. General and specific considerations for the e.r.a.

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

(i) the requirements of Directive 2004/10/EC; or

(ii) the "OECD Principles on Good Laboratory Practice" (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

(i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

(ii) be conducted by organisations accredited under the relevant ISO standard; or

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various subcombinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

C.2. Characteristics of the GMO and of the releases

The e.r.a. shall take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s),

— the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor,

— the GMO,

— the intended release or use including its scale,

— the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread, and

— the interaction(s) between these characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to Article 6(3) or Article 13(4).

C.3. Steps in the e.r.a.

The e.r.a. referred to in Articles 4, 6, 7 and 13 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under point (a) above;

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

Potential adverse effects will vary from case to case, and may include:

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors,

— compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,

— effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

— disease affecting humans, including allergenic or toxic reactions,

— disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

(i) evidence from previous experiences;

(ii) available data sets or literature;

(iii) mathematical modelling;

(c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

Adverse effects may occur directly or indirectly through exposure pathways or other mechanisms which may include:

— the spread of the GMO(s) in the environment,

— the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,

— phenotypic and genetic instability,

— interactions with other organisms,

— changes in management, including, where applicable, in agricultural practices;

(e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

2. *Hazard characterisation*

The magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the magnitude is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") shall be used and an explanation of the scale of effect represented by each category shall be provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

4. *Risk characterisation*

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ("high", "moderate", "low" or "negligible") of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

5. *Risk management strategies*

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C of the Directive, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.'

(b) The title and the introductory paragraph of Section D are replaced by the following:

'D. **Conclusions on the specific areas of risk of the e.r.a.**

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Annex III.'

(c) Section D.2 is replaced by the following:

'D.2. In the case of genetically modified higher plants (GMHP)

"Higher plants" shall mean plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer

2. Plant to micro-organisms gene transfer

3. Interactions of the GMHP with target organisms

4. Interactions of the GMHP with non-target organisms

5. Impacts of the specific cultivation, management and harvesting techniques

6. Effects on biogeochemical processes

7. Effects on human and animal health.'

(2) Annex III is replaced by the following:

'*ANNEX III*

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C of this Directive shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

(i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;

(ii) for notifications referred to in Part C of this Directive, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example perennial plants and trees, single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Union.'

(3) Annex III B is replaced by the following:

'*ANNEX III B*

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7

A. **General information**

1. Name and address of the notifier (company or institute)

2. Name, qualifications and experience of the responsible scientist(s)

3. Title of the project

4. Information relating to the release

(a) Purpose of the release

(b) Foreseen date(s) and duration of the release

(c) Method by which the GMHP will be released

(d) Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods

(e) Approximate number of plants (or plants per m^2).

5. Information relating to the site of release

(a) Location and size of the release site(s).

(b) Description of the release site ecosystem, including climate, flora and fauna.

(c) Presence of sexually compatible wild relatives or cultivated plant species.

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar or breeding line

(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction

(ii) specific factors affecting reproduction, if any

(iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the GMHP

(i) General description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted/deleted:

— size and copy number of all insert(s) and methods used for its/their characterisation,

— in case of deletion, size and function of the deleted region(s),

— subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination.

(iii) Parts of the plant where the insert is expressed.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of the molecular characterisation

3. Information on specific areas of risk

(a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.

(c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

(g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.

(h) Conclusions on the specific areas of risk.

4. Information on control, monitoring, post-release and waste treatment plans

(a) Any measures taken, including:

(i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;

(ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.

(b) Description of methods for post-release treatment of the site.

(c) Description of post-release treatment methods for the genetically modified plant material including wastes.

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Description of the methods and procedures to:

(i) avoid or minimise the spread of the GMHPs beyond the site of release;

(ii) protect the site from intrusion by unauthorised individuals;

(iii) prevent other organisms from entering the site or minimise such entries.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13

A. **General information**

1. Name and address of the notifier (company or institute).

2. Name, qualifications and experience of the responsible scientist(s).

3. Designation and specification of the GMHP.

4. Scope of the notification.

(a) Cultivation

(b) Other uses (to be specified in the notification).

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar/breeding line

(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction

(ii) specific factors affecting reproduction, if any

(iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in the Union of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination;

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant

(i) Description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted or deleted:

— size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,

— the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,

— in case of deletion, size and function of the deleted region(s),

— subcellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,

— in the case of modifications other than insertion or deletion, function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification,

— sequence information in a standardised electronic format for both 5′ and 3′ flanking regions at each insertion site,

— bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,

— all Open Reading Frames, (hereafter referred to as "ORFs") within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame,

— bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,

— primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,

— bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(iii) Information on the expression of the insert:

— method(s) used for expression analysis together with their performance characteristics,

— information on the developmental expression of the insert during the life cycle of the plant,

— parts of the plant where the insert/modified sequence is expressed,

— potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,

— protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of molecular characterisation

3. Comparative analysis of agronomic and phenotypic characteristics and of composition

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

(c) Experimental design and statistical analysis of data from field trials for comparative analysis:

(i) Description of field studies design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(g) Conclusions of comparative analysis.

4. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

(a) Persistence and invasiveness including plant to plant gene transfer

(i) Assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) Assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) Conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer

(i) Assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) Conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment;

(c) Interactions of the GMHP with target organisms, if relevant

(i) Assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) Assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;

(iii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms.

(i) Assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services.

(ii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.

(e) Impacts of the specific cultivation, management and harvesting techniques

(i) For GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) Conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes

(i) Assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii) Conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health

(i) Assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) For GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) Assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

(iv) Conclusions on the effects on human and animal health.

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.'

(4) Section A of Annex IV is amended as follows:

(a) point 1 is replaced by the following:

'1. proposed commercial names of the products and names of GMOs contained therein, and a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004 (*). After the consent any new commercial names should be provided to the competent authority,

(*) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).'

(b) point 7 is replaced by the following:

'7. methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) should be identified,'.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2018/351

of 8 March 2018

rejecting undertakings offered in connection with the anti-dumping proceeding concerning imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Brazil, Iran, Russia and Ukraine

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union [1] ('the basic Regulation'), and in particular Article 8 thereof,

Informing the Member States,

Whereas:

1. PROCEDURE

(1) By Implementing Regulation (EU) 2017/1795 [2] the European Commission ('the Commission') imposed a definitive anti-dumping duty on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel ('HRF') originating in Brazil, Iran, Russia and Ukraine and terminated the investigation on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Serbia ('the definitive Regulation').

(2) During the investigation that led to the imposition of this duty, five exporting producers from Brazil, Iran, Russia and Ukraine offered price undertakings. As these offers were made after an additional final disclosure that came late in the investigation, the Commission was unable to analyse whether such price undertakings were acceptable, prior to the deadline for the adoption of the definitive Regulation. Therefore, considering this as an exceptional circumstance, the Commission undertook to complete the analysis of these five offers at a later stage. After the conclusion of the investigation and the publication of the definitive Regulation a sixth exporting producer offered a price undertaking.

(3) On 18 December 2017, the Commission informed all interested parties of the assessment of the undertaking offers underlying its intention to reject all undertaking offers ('Commission's assessment'). On the basis of this information, interested parties made written submissions providing comments on the assessment and, in some cases, further amendments to their offers. Interested parties who requested to be heard were also granted a hearing.

(4) On 3 January 2018, the Commission received a request from the Government of Ukraine for consultation pursuant to Article 50 *bis* EU-Ukraine Association Agreement [3]. The consultations were held on 26 January 2018. Written comments were submitted on 31 January 2018.

2. UNDERTAKINGS

(5) The adequacy and practicability of all offers were assessed in the light of the applicable legal framework, including the EU-Ukraine Association Agreement in the case of the Ukrainian exporting producer.

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[1] OJ L 176, 30.6.2016, p. 21.

[2] Commission Implementing Regulation (EU) 2017/1795 of 5 October 2017 imposing a definitive antidumping duty on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Brazil, Iran, Russia and Ukraine and terminating the investigation on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Serbia (OJ L 258, 6.10.2017, p. 24).

[3] OJ L 161, 29.5.2014, p. 3.

2.1. **Undertaking offers and their assessment**

2.1.1. *Companhia Siderúrgica Nacional (Brazil)*

(6) The exporting producer offered one minimum import price ('MIP') per tonne for a certain volume of exports to the Union and another — higher — MIP for a volume above that. The exporting producer also offered a price adjustment mechanism.

(7) The offer based on one average MIP is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injury caused by the exporting producer found to be dumping more accurately than a MIP. It also ensures that, unlike a MIP, the duty removes injury entirely, giving immediate protection to the Union industry. Furthermore, the offer covers transactions between related entities. The very nature of such relations presents numerous possibilities for cross-compensation. Any other transaction, loan or grant between the two related entities could be used to offset the MIP. The Commission is unable to monitor these transactions and it lacks appropriate benchmarks that would enable it to verify whether they are genuine or compensatory.

(8) Furthermore, the acceptance of the offer would be impractical. The exporting producer has related companies in several Member States, some of which further process the product concerned. The exporting producer also sells other products to the Union customers and its related importer sells like products from other sources. It is thus impossible for the Commission to monitor these activities effectively, as well as the implementation of two different MIPs depending on the export volume.

(9) In response to the Commission's assessment, the exporting producer argued that the MIP proposed in its offer removes the injurious effect of dumping, as the same MIP was proposed by the Commission at a stage of the investigation. The exporting producer pointed out that the MIP is based on weighted average import prices of all product types. Consequently, the MIP would not be to the detriment of the Union producers since, lower-tier priced product types would be placed at a higher level prices than they should have been, thus compensating for the higher-tier priced product types. If this logic were to be applied to the product type composition of its exports during the investigation period, according to the exporting producer the MIP would be sufficient to remove the injurious effect of dumping. Furthermore, the exporting producer argued that the MIP should not be adjusted on the account of sales via a related company, due to, amongst others, the way its export price was established in the definitive Regulation. The exporting producer then argued that cross-compensation is impossible for a number of reasons, in particular because cross-compensation would show in the annual reports of the exporting producer and its related companies. The exporting producer also amended its undertaking offer. In the new offer the exporting producer undertook to cease resales of HRF via its related entity in the Union and to report on sales of other products to the Union.

(10) Concerning the comment that the proposed MIP removes the injurious effect of dumping because it is identical to the one proposed by the Commission at a stage of the investigation, the Commission noted that ultimately that solution was rejected. The reasons for this rejection were given in, among others, recitals 632 and 655 of the definitive Regulation, which are summarised in recital 7 above. The Comment regarding MIP being based on weighted average import prices, did not affect the conclusion that the MIP does not remove the injurious effect of dumping for the most expensive product types. The Commission was not able to retrieve data to support the claim that the injurious effect of dumping would have been removed by the MIP due to the product-type composition of the exports during the investigation period. Nor did the Applicant provide such data. Even if it had available to it the data supporting this claim, the Commission found that there is nothing preventing the product-type composition to shift towards the higher-tier priced product types. Indeed, the very application of the MIP could favour such shift. Concerning the comment that the MIP should not be adjusted on the account of sales via a related company, the Commission could agree that indeed, considering the circumstances of the case in the investigation period and, in particular, the way the export price for the exporting producer was established in the definitive Regulation, this adjustment would not be warranted. However, there is no guarantee that the circumstances will not change in particular since the companies are related. Finally, concerning the amendment of the offer and the risks of cross-compensation, the Commission noted that, whilst the commitment not to re-sell the product concerned would limit some of the cross-compensation risks the principal issue, namely the MIP being applied to transactions between related entities, remains. Such association between two entities offers

numerous possibilities for cross-compensation that cannot be effectively monitored by the Commission. Not all of these would be shown in the annual reports, and for those that would the Commission would lack the appropriate benchmarks capable of assessing whether they are of compensatory nature. An undertaking covering related sales may be accepted only if the product concerned is eventually re-sold to an independent customer and the MIP, appropriately adjusted, can be applied to those transactions. This is impossible if the product concerned is transformed into another product.

2.1.2. *Usinas Siderurgicas de Minas Gerais SA (Brazil)*

(11) The exporting producer offered one MIP per tonne for all of its exports.

(12) The offer based on one average MIP is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injury caused by the exporting producer found to be dumping more accurately than a single MIP. It also ensures that, unlike a single MIP, the duty removes injury entirely, giving immediate protection to the Union industry. The offer is also inadequate as the exporting producer did not propose an adjustment mechanism while the prices of HRF tend to vary significantly over time.

(13) Furthermore, the acceptance of the offer would be impractical. Due to the global structure and sales activities of the exporting producer, the price undertaking proposed could not be effectively monitored, offering several opportunities for price cross-compensation. The exporting producer has a number of related companies in several Member States and outside the Union. Furthermore, the exporting producer sells also other products to the Union. It is thus impossible for the Commission to monitor these activities effectively.

2.1.3. *Mobarakeh Steel Company (Iran)*

(14) The exporting producer offered one MIP per tonne for all of its exports, adjusted for sales via its trader in the Union.

(15) The offer based on one average MIP is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injurious dumping found for the exporting producer more accurately than a MIP. It also ensures that, unlike a MIP, the duty removes the injurious dumping entirely, giving immediate protection to the Union industry. The offer is also inadequate as the exporting producer did not propose an adjustment mechanism while the prices of HRF tend to vary significantly over time.

(16) Furthermore, the acceptance of the offer would be impractical. Due to the fact that the exporting producer sells to the Union other products, the price undertaking proposed would be impossible to be effectively monitored, offering opportunities for price cross-compensation. It is thus impossible for the Commission to monitor these activities effectively.

(17) In response to the Commission's assessment, the exporting producer argued that the Commission was silent on the fact that its offer mirrored Commission's proposal at a stage of the investigation. The exporting producer requested an explanation as to why an offer mirroring that proposal is not suitable. The exporting producer argued that the MIP it proposed is higher than that proposed by the Commission during the investigation and thus the MIP proposed in the undertaking, by definition, removes the injury to the Union industry. Furthermore, the exporting producer argued that there is no difference between a MIP and a specific duty per tonne as far as removal of injurious effect of dumping for the most expensive product is concerned, thus this argument is

irrelevant. The exporting producer argued the fact that it sells other products to the Union does not automatically create a risk of cross-compensation. Finally, it argued that the undertaking invoices would remove any risk of circumvention or cross-compensation just in the same way as the valid commercial invoice proposed in the final general disclosure document would.

(18) The Commission noted that its assessment is not only vocal on the similarities between the undertaking offer and an option being considered at a stage of the investigation, in recital 15 above it points to and summarises the part of the definitive Regulation explaining why that option was rejected. The same reasoning applies to the exporting producer's comment comparing undertaking invoices to one of the solutions being considered during the investigation and ultimately rejected by the Commission. The fact that the MIP proposed by the exporting producer is higher than the one considered by the Commission at one point during the investigation does not mean that it, by definition, removes the injurious effect of dumping. The difference is minor and it did not affect the reasoning that an average MIP is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. The comment that the MIP and a specific duty are equally ineffective in this respect is also misplaced. Unlike a MIP, a specific duty forces importers to pay more for more expensive product type, as the market price of a product type is a part of the price they pay, the other part being the duty. This is different in case of a MIP that is the same for all product types. Finally, indeed, sales of other products to the Union may be used for cross-compensation only if they are sold to the same customers as the HRF. However the Commission noted that cross-compensation and the risk of cross-compensation are two different concepts. For instance, the Commission knows that the exporting producer sells other products to the Union but does not have data concerning the exporting producer's customers for those products. Notably, the exporting producer did not deny selling other products to its HRF customers nor did it undertake not to do that in the future. This situation, whilst not proving cross-compensation, clearly presents a risk of cross-compensation that the Commission is unable to monitor.

2.1.4. *PJSC Magnitogorsk Iron and Steel Works (Russia)*

(19) The exporting producer offered two MIPs per tonne, one for sheets and one for coils. The exporting producer also offered a price adjustment mechanism and, in an amendment to its offer, undertook to sell the product concerned only directly to independent customers in the Union and not to sell other products to its HRF customers in the Union.

(20) The exporting producer's offer was submitted after the conclusion of the investigation and as such should be rejected. Whilst, according to Article 8(2) of the basic Regulation, in exceptional circumstances, undertakings may be offered after the period during which representations may be made pursuant to Article 20(5) of the basic Regulation, such offer should come at a reasonable time before the conclusion of the investigation.

(21) However, even if the offer was submitted in due time, the offer based on two average MIPs is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injurious dumping found for the exporting producer more accurately than a MIP. It also ensures that, unlike a MIP, the duty removes the injurious dumping entirely, giving immediate protection to the Union industry.

(22) Furthermore, the acceptance of the offer would be impractical. Due to the global structure and sales activities of the exporting producer, the price undertaking proposed would be impossible to be effectively monitored, offering several opportunities for price cross-compensation. The exporting producer has a number of related companies and sells also other steel products to the Union. It is thus impossible for the Commission to monitor these activities effectively.

(23) In response to the Commission's assessment, the exporting producer expressed its disagreement with the above assessment whilst emphasising the importance of its additional commitments to use only one sales channel and not to sell other products to its HRF customers.

(24) In relation to the additional commitments the Commission noted that, considering the exporting producer's global structure and the global structure of its customers, it is impossible to monitor all the available cross-compensation possibilities. For instance if the companies covered by the undertaking do not sell other products to an HRF customer in the Union, there is nothing preventing their related companies be it in the Union or outside entering into potentially cross-compensatory transactions with these customers or their related entities. Whilst the exporting producer disagreed with the assessment of the adequacy of its offer it did not put forward any additional arguments against the conclusion reached by the Commission.

2.1.5. *Novolipetsk Steel OJSC (Russia)*

(25) The exporting producer first offered several MIPs per tonne depending on a product type. Then it amended its offer, proposing one MIP per tonne for all product types with an adjustment mechanism based on the average HRF prices. In addition, the exporting producer proposed a quantitative annual ceiling and undertook to sell only to its related company in the Union and only for further processing.

(26) The offer based on one average MIP is inadequate as it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injurious dumping found for the exporting producer more accurately than a MIP. It also ensures that, unlike a MIP, the duty removes the injurious dumping entirely, giving immediate protection to the Union industry. Furthermore, the offer covers transactions between related entities. The very nature of such relations presents numerous possibilities for cross-compensation. Any other transaction, loan or grant between the two related entities could be used to offset the MIP. The Commission is unable to monitor these transactions and it lacks appropriate benchmarks that would enable it to verify whether they are genuine or compensatory.

(27) The acceptance of the offer would also be impractical. Due to the global structure and sales activities of the exporting producer, the price undertaking proposed would be impossible to be effectively monitored, offering several opportunities for price cross-compensation. Furthermore, related companies in the Union also produce and sell the like product. It is thus impossible for the Commission to monitor these activities effectively.

(28) In response to the Commission's assessment the exporting producer argued that the Commission overlooked the two key elements of its offer namely the quantitative ceiling and the end-use commitment (i.e. further processing only). According to the exporting producer these two commitments ensure that exports at dumped prices would cease as the product concerned would not be exported to the Union free market. The exporting producer then argued that in the definitive Regulation the Commission did not find injury on the captive market. Despite these arguments, in the spirit of full cooperation, the exporting producer amended its offer, offering 22 MIPs based on product types. With regard to the risk of cross-compensation the exporting producer argued that, as there will be no sales to the free market, it is in fact irrelevant at which minimum price the product concerned is sold within the group. Since such minimum price is irrelevant, the risk of cross-compensation is equally irrelevant. The exporting producer further argued that intra-group transactions are subject to group's transfer price policy and thus cannot be used for cross-compensation.

(29) The exporting producer did not sell HRF to its related entities in the Union during the investigation period. In addition, contrary to what the exporting producer suggested, intra-group sales of HRF for further processing were not excluded from the finding of injurious dumping in the definitive Regulation. These sales are currently covered by the applicable duty and this finding cannot be reversed through an undertaking. Considering that the exporting producer's argument for impossibility of cross-compensation within the group hinges on an incorrect assumption that intra-group sales for processing do not cause injurious dumping, that argument was therefore rejected. Furthermore, the group's internal transfer policy is the group's own internal decision and as such it is not a sufficient guarantee against cross-compensation. Even if it were, cross-compensation within the group could be done via other means than a sale of goods. An undertaking covering related sales may be accepted only

if the product concerned is eventually re-sold to an independent customer and the MIP, appropriately adjusted, can be applied to those transactions. This is impossible if the product concerned is transformed into another product. The offer of 22 MIPs based on groups of product types could not be accepted as its effective monitoring by customs would be impossible.

2.1.6. *Metinvest Group (Ukraine)*

(30) The exporting producer proposed two scenarios in its original offer. The first scenario is based on one MIP per tonne (its average price during the investigation period, increased by the duty and adjusted for the increase of the price of the raw materials after the investigation period) and with possibility of selling below that MIP, under the duty. The second scenario is based on a lower MIP per tonne (without the adjustment for the increase of the price of the raw materials after the investigation period) and without possibility of selling below that MIP. Subsequently, the exporting producer amended its offer by adding an annual quantitative ceiling for sales under the undertaking.

(31) The Commission does not accept the so called pick-and-choose clauses whereby the exporting producer is allowed to sell within an undertaking and in parallel below the MIP under the duty, thus the only scenario open for consideration is the second one. Acceptance of such clause would allow for a cross-compensation mechanism where transactions at the MIP level could be offset by transactions at prices below MIP.

(32) Article 50 of the EU-Ukraine Association Agreement expresses a preference for undertakings, provided that the Commission receives a workable offer that is adequate and the acceptance of which is not considered impractical. In this case, for the reasons explained below, the Commission did not receive a workable undertaking offer and therefore the preference cannot be accommodated.

(33) In the Commission's assessment there are several reasons for which the offer is inadequate. It is based on one average MIP thus it will not remove the injurious effects of dumping for all product types, in particular the most expensive ones. As acknowledged in recitals 632 and 655 of the definitive Regulation, the Commission considered that a measure in the form of a company-specific fixed amount per tonne reflected the injurious dumping found for the exporting producer more accurately than a MIP. It also ensures that, unlike a MIP, the duty removes the injurious dumping entirely, giving immediate protection to the Union industry. The exporting producer did not propose an adjustment on the account of sales via its related companies. While the prices of HRF tend to vary significantly over time, the exporting producer did not propose an adjustment mechanism. Furthermore, only two out of the three production sites that exported the product concerned to the Union during the investigation period are covered by the undertaking. Finally, the exporting producer proposed that its sales to related entities in the Union would be covered by the terms of the undertaking. The very nature of such relations presents numerous possibilities for cross-compensation. Any other transaction, loan or grant between the two related entities could be used to offset the MIP. The Commission is unable to monitor these transactions and it lacks appropriate benchmarks that would enable it to verify whether they are genuine or compensatory.

(34) The acceptance of the offer would also be impractical. Due to the global structure and sales activities of the exporting producer, the price undertaking proposed would be impossible to be effectively monitored, offering several opportunities for price cross-compensation. The exporting producer has several related companies in various Member States and outside the Union, some of which produce and sell the like product. The exporting producer sells to the Union via one or more of these companies. It is thus impossible for the Commission to monitor these activities effectively.

(35) In response to the Commission's assessment, the exporting producer submitted a third version of its undertaking offer. In the new version of the offer the exporting producer proposed four different MIPs and undertook not to sell below them. According to the exporting producer this change was made despite the Commission considering a single MIP for all product types acceptable at a stage of the investigation that lead to the imposition of the duty. Furthermore, the exporting producer undertook to include the third production site in the undertaking offer; not to sell the product concerned via its related entities in the Union; to provide details of its sales in the Union of

other products to its Union HRF customers; and not to sell outside of the Union the product concerned and other products to its Union HRF customers. Finally, the exporting producer proposed a lower annual quantitative ceiling. Beyond that ceiling, the exporting producer offered to sell under the applicable anti-dumping duty.

(36) In addition to these commitments, during the consultations the Government of Ukraine proposed to provide the Commission with export statistics for the product concerned and to establish an expert group that would facilitate the exchange of statistics and other information.

(37) On 5 February 2018, the exporting producer made another amendment to its undertaking offer. The exporting producer argued that all of its sales are subject to strict price-making policy of the group and prevent cross-compensation. Furthermore, the exporting producer argued that the regular tax authorities' audits, both in the Union and in Switzerland, rigorously verify the pricing policies of the group. Despite these, the exporting producer undertook not to sell HRF produced in the Union and other products produced by its group to its HRF customers which buy the product concerned. This would apply to all of its customers except for one, who would be buying HRF from Ukraine, the Union and other products produced by the group.

(38) Concerning the comment that the Commission considered a single MIP for all product types acceptable at a stage of the investigation, the Commission noted that ultimately that solution was rejected. The reasons for this rejection were given in, among others, recitals 632 and 655 of the definitive Regulation, which are summarised in recital 33 above.

(39) The offer remains inadequate for several reasons. Out of the four MIP groups proposed there were barely any sales in one of them, there is a price variant in another and significant price variants in the remaining two groups. The MIPs, being based on the average prices in each group will therefore not remove the injurious effects of dumping for all product types, in particular the most expensive ones in each group. Furthermore, the levels of four MIPs were set in a completely arbitrary fashion. The Commission was presented with no data justifying the difference between the MIPs. Finally, whilst HRF prices tend to vary significantly over time, the exporting producer still did not propose an adjustment mechanism.

(40) The acceptance of the undertaking offer remains impractical. The exporting producer undertook not to sell any products to its Union customers' entities based outside of the Union. However, this undertaking covers only the three producing companies and omits dozens of its related companies including the Swiss trader. Even if all these companies were covered by the undertaking, considering the size of the exporting producer's group and that of their customer base, such commitment would be impossible to monitor. Furthermore, the exporting producer proposed to report on sales of other products to its HRF customers in the Union. However the Commission would not have the appropriate benchmarks in order to verify whether these transactions are of a compensatory nature. Whilst the exporting producer undertook not to sell via its related entities in the Union, these entities sell the like product on the Union market. Whilst these transactions may concern the same customers and thus can be used for compensation, they are completely outside of the scope of the undertaking.

(41) The amendment to the undertaking offer proposed on 5 February 2018 (i.e. to sell only the product concerned to all of its HRF customers in the Union, except for one), does not remove the abovementioned concern for the excluded customer. For the other customers, considering the size of the exporting producer's group, it would be impossible to monitor whether any of the companies related to the exporting producer sell other products to the Union HRF customers or their related entities. The internal pricing policies of the exporting producer and the customer it intends to sell to are not a sufficient guaranty against cross-compensation. Furthermore, the exporting producer failed to explain how tax authorities' audits in the Union and in Switzerland would detect cross-compensatory prices. Agreeing to sell a product at a price lower than otherwise would be demanded is not necessary an offence against a tax law. It is part of day-to-day price negotiations.

(42) Finally, the sales beyond the annual ceiling under the applicable anti-dumping duty cannot be accepted as they could be used for compensation. This is basically a variation of the pick-and-choose clauses described in recital 31 above, postponed in time. Therefore, by lowering the ceiling well below the historical annual export quantities, this new offer increases the risk of cross-compensation.

(43) Despite the preference for undertakings expressed in Article 50 of the EU-Ukraine Association Agreement, the offer cannot be accepted as it is inadequate. Had it been adequate, for the reasons outlined above, its acceptance would still be impractical. None of the concerns listed above would have been sufficiently addressed by the exchange of statistics and the creation of the expert group proposed by the Government of Ukraine during the consultation.

2.2. **Conclusion**

(44) For the reasons set out above the Commission cannot accept any of these undertaking offers.

2.3. **Comments of parties and rejection of the undertaking offers**

(45) The interested parties have been informed of the reasons underlying this decision and were given an opportunity to comment and to be heard. The Government of Ukraine was also offered consultation in accordance with Article 50 *bis* of the EU-Ukraine Association Agreement. Consultations took place with the Ukrainian authorities on 26 January 2018, with the Government of Ukraine providing written comments on 31 January 2018. In addition, a number of hearings with the exporting producers concerned and Eurofer, representing the Union industry, took place. All comments received throughout this process were addressed above. Neither the comments provided by interested parties, nor the consultations with the Government of Ukraine, led to a different conclusion than the rejection of the undertaking offers,

HAS ADOPTED THIS DECISION:

Article 1

The undertakings offered by the exporting producers in connection with the anti-dumping proceeding concerning imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Brazil, Iran, Russia and Ukraine, are hereby rejected.

Article 2

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

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