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I

(Legislative acts)

DIRECTIVES

COUNCIL DIRECTIVE 2011/16/EU

of 15 February 2011

on administrative cooperation in the field of taxation and repealing Directive 77/799/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 113 and 115 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Acting in accordance with a special legislative procedure,

Whereas:

(1) The Member States' need for mutual assistance in the field of taxation is growing rapidly in a globalised era. There is a tremendous development of the mobility of taxpayers, of the number of cross-border transactions and of the internationalisation of financial instruments, which makes it difficult for Member States to assess taxes due properly. This increasing difficulty affects the functioning of taxation systems and entails double taxation, which itself incites tax fraud and tax evasion, while the powers of controls remain at national level. It thus jeopardises the functioning of the internal market.

(2) Therefore, a single Member State cannot manage its internal taxation system, especially as regards direct taxation, without receiving information from other Member States. In order to overcome the negative effects of this phenomenon, it is indispensable to develop new administrative cooperation between the

Member States' tax administrations. There is a need for instruments likely to create confidence between Member States, by setting up the same rules, obligations and rights for all Member States.

(3) Therefore, a completely new approach should be taken by creating a new text to give Member States the power to efficiently cooperate at international level to overcome the negative effects of an ever-increasing globalisation on the internal market.

(4) In such a context, the existing Council Directive 77/799/EEC of 19 December 1977 concerning mutual assistance by the competent authorities of the Member States in the field of direct taxation and taxation of insurance premiums ⁽³⁾ no longer provides for appropriate measures. Its deep weaknesses have been looked into by the Ad hoc Council Working Party on Tax Fraud in its report of 22 May 2000 and more recently by the Commission Communication on Preventing and Combating Corporate and Financial Malpractice of 27 September 2004 and the Commission Communication concerning the need to develop a coordinated strategy to improve the fight against fiscal fraud of 31 May 2006.

(5) Directive 77/799/EEC, even with its later amendments, was designed in a different context to current internal market requirements and is no longer able to meet the new requirements of administrative cooperation.

(6) Due to the number and the importance of adaptations to be made to Directive 77/799/EEC, a mere amendment thereof would not be sufficient to fulfil the objectives described above. Directive 77/799/EEC should therefore be repealed and replaced by a new legal instrument. That instrument should apply to direct taxes and indirect taxes that are not yet covered by other Union legislation. To this end, this new Directive is considered to be the proper instrument in terms of effective administrative cooperation.

⁽¹⁾ Opinion of 10 February 2010 (not yet published in the Official Journal).

⁽²⁾ Opinion of 16 July 2009 (not yet published in the Official Journal).

⁽³⁾ OJ L 336, 27.12.1977, p. 15.

- (7) This Directive builds on the achievements of Directive 77/799/EEC but provides for clearer and more precise rules governing administrative cooperation between Member States where necessary, in order to establish, especially as regards the exchange of information, a wider scope of administrative cooperation between Member States. Clearer rules should also make it possible in particular to cover all legal and natural persons in the Union, taking into account the ever-increasing range of legal arrangements, including not only traditional arrangements such as trusts, foundations and investment funds, but any new instrument which may be set up by taxpayers in the Member States.
- (8) There should be more direct contact between Member States' local or national offices in charge of administrative cooperation, with communication between central liaison offices being the rule. The lack of direct contacts leads to inefficiency, under-use of the arrangements for administrative cooperation and delays in communication. Provision should therefore be made to bring about more direct contacts between services with a view to making cooperation more efficient and faster. The assignment of competences to the liaison departments should be deferred to the national provisions of each Member State.
- (9) Member States should exchange information concerning particular cases where requested by another Member State and should make the necessary enquiries to obtain such information. The standard of 'foreseeable relevance' is intended to provide for exchange of information in tax matters to the widest possible extent and, at the same time, to clarify that Member States are not at liberty to engage in 'fishing expeditions' or to request information that is unlikely to be relevant to the tax affairs of a given taxpayer. While Article 20 of this Directive contains procedural requirements, those provisions need to be interpreted liberally in order not to frustrate the effective exchange of information.
- (10) It is recognised that the mandatory automatic exchange of information without preconditions is the most effective means of enhancing the correct assessment of taxes in cross-border situations and of fighting fraud. To that end, a step-by-step approach should therefore be followed starting with the automatic exchange of available information on five categories and reviewing the relevant provisions after a report by the Commission.
- (11) The spontaneous exchange of information between Member States should also be strengthened and encouraged.
- (12) Time limits for the provision of information under this Directive should be laid down in order to ensure that the information exchange is timely and thus effective.
- (13) It is important that officials of the tax administration of one Member State are allowed to be present in the territory of another Member State.
- (14) Since the tax situation of one or more persons liable to tax established in several Member States is often of common or complementary interest, it should be made possible for simultaneous controls to be carried out on such persons by two or more Member States, by mutual agreement and on a voluntary basis.
- (15) In view of the legal requirement in certain Member States that a taxpayer be notified of decisions and instruments concerning his tax liability and of the ensuing difficulties for the tax authorities, including cases where the taxpayer has relocated to another Member State, it is desirable that, in such circumstances, the tax authorities should be able to call upon the cooperation of the competent authorities of the Member State to which the taxpayer has relocated.
- (16) Feedback on information sent will encourage administrative cooperation between Member States.
- (17) Collaboration between the Member States and the Commission is necessary for the permanent study of cooperation procedures and the sharing of experience and best practices in the fields considered.
- (18) It is important for the efficiency of administrative cooperation that information and documents obtained under this Directive could, subject to the restrictions laid down in this Directive, be used by the Member State that received them also for other purposes. It is also important that Member States could transmit that information to a third country, under certain conditions.
- (19) The situations in which a requested Member State may refuse to provide information should be clearly defined and limited, taking into account certain private interests which should be protected as well as the public interest.
- (20) However, a Member State should not refuse to transmit information because it has no domestic interest or because the information is held by a bank, other financial institution, nominee or person acting in an agency or fiduciary capacity or because it relates to ownership interests in a person.
- (21) This Directive contains minimum rules and should therefore not affect Member States' right to enter into wider cooperation with other Member States under their national legislation or in the framework of bilateral or multilateral agreements concluded with other Member States.

- (22) It should also be made clear that where a Member State provides a wider cooperation to a third country than is provided for under this Directive, it should not refuse to provide such wider cooperation to other Member States wishing to enter into such mutual wider cooperation.
- (23) The exchange of information should be made through standardised forms, formats and channels of communication.
- (24) An evaluation of the effectiveness of administrative cooperation should be made, especially on the basis of statistics.
- (25) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.
- (26) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.
- (27) All exchange of information referred to in this Directive is subject to the provisions implementing Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽²⁾ and to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ⁽³⁾. However, it is appropriate to consider limitations of certain rights and obligations laid down by Directive 95/46/EC in order to safeguard the interests referred to in Article 13(1)(e) of that Directive. Such limitations are necessary and proportionate in view of the potential loss of revenue for Member States and the crucial importance of information covered by this Directive for the effectiveness of the fight against fraud.
- (28) This Directive respects the fundamental rights and observes the principles which are recognised in particular by the Charter of Fundamental Rights of the European Union.
- (29) Since the objective of this Directive, namely the efficient administrative cooperation between Member States to

overcome the negative effects of the increasing globalisation on the internal market, cannot be sufficiently achieved by the Member States and can therefore, by reason of the uniformity and effectiveness required, be better achieved at the level of the Union, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. This Directive lays down the rules and procedures under which the Member States shall cooperate with each other with a view to exchanging information that is foreseeably relevant to the administration and enforcement of the domestic laws of the Member States concerning the taxes referred to in Article 2.

2. This Directive also lays down provisions for the exchange of information referred to in paragraph 1 by electronic means, as well as rules and procedures under which the Member States and the Commission are to cooperate on matters concerning coordination and evaluation.

3. This Directive shall not affect the application in the Member States of the rules on mutual assistance in criminal matters. It shall also be without prejudice to the fulfilment of any obligations of the Member States in relation to wider administrative cooperation ensuing from other legal instruments, including bilateral or multilateral agreements.

Article 2

Scope

1. This Directive shall apply to all taxes of any kind levied by, or on behalf of, a Member State or the Member State's territorial or administrative subdivisions, including the local authorities.

2. Notwithstanding paragraph 1, this Directive shall not apply to value added tax and customs duties, or to excise duties covered by other Union legislation on administrative cooperation between Member States. This Directive shall also not apply to compulsory social security contributions payable to the Member State or a subdivision of the Member State or to social security institutions established under public law.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 281, 23.11.1995, p. 31.

⁽³⁾ OJ L 8, 12.1.2001, p. 1.

3. In no case shall the taxes referred to in paragraph 1 be construed as including:

- (a) fees, such as for certificates and other documents issued by public authorities; or
- (b) dues of a contractual nature, such as consideration for public utilities.

4. This Directive shall apply to the taxes referred to in paragraph 1 levied within the territory to which the Treaties apply by virtue of Article 52 of the Treaty on the European Union.

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

1. 'competent authority' of a Member State means the authority which has been designated as such by that Member State. When acting pursuant to this Directive, the central liaison office, a liaison department or a competent official shall also be deemed to be competent authorities by delegation according to Article 4;
2. 'central liaison office' means the office which has been designated as such with principal responsibility for contacts with other Member States in the field of administrative cooperation;
3. 'liaison department' means any office other than the central liaison office which has been designated as such to directly exchange information pursuant to this Directive;
4. 'competent official' means any official who is authorised to directly exchange information pursuant to this Directive;
5. 'requesting authority' means the central liaison office, a liaison department or any competent official of a Member State who makes a request for assistance on behalf of the competent authority;
6. 'requested authority' means the central liaison office, a liaison department or any competent official of a Member State who receives a request for assistance on behalf of the competent authority;
7. 'administrative enquiry' means all controls, checks and other action taken by Member States in the performance of their duties with a view to ensuring the proper application of tax legislation;
8. 'exchange of information on request' means the exchange of information based on a request made by the requesting Member State to the requested Member State in a specific case;
9. 'automatic exchange' means the systematic communication of predefined information to another Member State, without prior request, at pre-established regular intervals. In the context of Article 8, available information refers to information in the tax files of the Member State communicating the information, which is retrievable in accordance with the procedures for gathering and processing information in that Member State;
10. 'spontaneous exchange' means the non-systematic communication, at any moment and without prior request, of information to another Member State;
11. 'person' means:
 - (a) a natural person;
 - (b) a legal person;
 - (c) where the legislation in force so provides, an association of persons recognised as having the capacity to perform legal acts but lacking the status of a legal person; or
 - (d) any other legal arrangement of whatever nature and form, regardless of whether it has legal personality, owning or managing assets, which, including income derived therefrom, are subject to any of the taxes covered by this Directive;
12. 'by electronic means' means using electronic equipment for the processing, including digital compression, and storage of data, and employing wires, radio transmission, optical technologies or other electromagnetic means;
13. 'CCN network' means the common platform based on the common communication network (CCN), developed by the Union for all transmissions by electronic means between competent authorities in the area of customs and taxation.

Article 4

Organisation

1. Each Member State shall inform the Commission, within one month from 11 March 2011, of its competent authority for the purposes of this Directive and shall inform the Commission without delay of any change thereto.

The Commission shall make the information available to the other Member States and publish a list of the authorities of the Member States in the *Official Journal of the European Union*.

2. The competent authority shall designate a single central liaison office. The competent authority shall be responsible for informing the Commission and the other Member States thereof.

The central liaison office may also be designated as responsible for contacts with the Commission. The competent authority shall be responsible for informing the Commission thereof.

3. The competent authority of each Member State may designate liaison departments with the competence assigned according to its national legislation or policy. The central liaison office shall be responsible for keeping the list of liaison departments up to date and making it available to the central liaison offices of the other Member States concerned and to the Commission.

4. The competent authority of each Member State may designate competent officials. The central liaison office shall be responsible for keeping the list of competent officials up to date and making it available to the central liaison offices of the other Member States concerned and to the Commission.

5. The officials engaged in administrative cooperation pursuant to this Directive shall in any case be deemed to be competent officials for that purpose, in accordance with arrangements laid down by the competent authorities.

6. Where a liaison department or a competent official sends or receives a request or a reply to a request for cooperation, it shall inform the central liaison office of its Member State under the procedures laid down by that Member State.

7. Where a liaison department or a competent official receives a request for cooperation requiring action which falls outside the competence it is assigned according to the national legislation or policy of its Member State, it shall forward such request without delay to the central liaison office of its Member State and inform the requesting authority thereof. In such a case, the period laid down in Article 7 shall start the day after the request for cooperation is forwarded to the central liaison office.

CHAPTER II

EXCHANGE OF INFORMATION

SECTION I

Exchange of information on request

Article 5

Procedure for the exchange of information on request

At the request of the requesting authority, the requested authority shall communicate to the requesting authority any

information referred to in Article 1(1) that it has in its possession or that it obtains as a result of administrative enquiries.

Article 6

Administrative enquiries

1. The requested authority shall arrange for the carrying out of any administrative enquiries necessary to obtain the information referred to in Article 5.

2. The request referred to in Article 5 may contain a reasoned request for a specific administrative enquiry. If the requested authority takes the view that no administrative enquiry is necessary, it shall immediately inform the requesting authority of the reasons thereof.

3. In order to obtain the requested information or to conduct the administrative enquiry requested, the requested authority shall follow the same procedures as it would when acting on its own initiative or at the request of another authority in its own Member State.

4. When specifically requested by the requesting authority, the requested authority shall communicate original documents provided that this is not contrary to the provisions in force in the Member State of the requested authority.

Article 7

Time limits

1. The requested authority shall provide the information referred to in Article 5 as quickly as possible, and no later than six months from the date of receipt of the request.

However, where the requested authority is already in possession of that information, the information shall be transmitted within two months of that date.

2. In certain special cases, time limits other than those provided for in paragraph 1 may be agreed upon between the requested and the requesting authorities.

3. The requested authority shall confirm immediately and in any event no later than seven working days from receipt, if possible by electronic means, receipt of a request to the requesting authority.

4. Within one month of receipt of the request, the requested authority shall notify the requesting authority of any deficiencies in the request and of the need for any additional background information. In such a case, the time limits provided for in paragraph 1 shall start the day after the requested authority has received the additional information needed.

5. Where the requested authority is unable to respond to the request by the relevant time limit, it shall inform the requesting authority immediately and in any event within three months of the receipt of the request, of the reasons for its failure to do so, and the date by which it considers it might be able to respond.

6. Where the requested authority is not in possession of the requested information and is unable to respond to the request for information or refuses to do so on the grounds provided for in Article 17, it shall inform the requesting authority of the reasons thereof immediately and in any event within one month of receipt of the request.

SECTION II

Mandatory automatic exchange of information

Article 8

Scope and conditions of mandatory automatic exchange of information

1. The competent authority of each Member State shall, by automatic exchange, communicate to the competent authority of any other Member State, information regarding taxable periods as from 1 January 2014 that is available concerning residents in that other Member State, on the following specific categories of income and capital as they are to be understood under the national legislation of the Member State which communicates the information:

- (a) income from employment;
- (b) director's fees;
- (c) life insurance products not covered by other Union legal instruments on exchange of information and other similar measures;
- (d) pensions;
- (e) ownership of and income from immovable property.

2. Before 1 January 2014, Member States shall inform the Commission of the categories listed in paragraph 1 in respect of which they have information available. They shall inform the Commission of any subsequent changes thereto.

3. The competent authority of a Member State may indicate to the competent authority of any other Member State that it does not wish to receive information on the categories of income and capital referred to in paragraph 1, or that it does not wish to receive information on income or capital not exceeding a threshold amount. It shall also inform the

Commission thereof. A Member State may be considered as not wishing to receive information in accordance with paragraph 1, if it does not inform the Commission of any single category in respect of which it has information available.

4. Before 1 July 2016, Member States shall provide the Commission on an annual basis with statistics on the volume of automatic exchanges and, to the extent possible, with information on the administrative and other relevant costs and benefits relating to exchanges that have taken place and any potential changes, for both tax administrations and third parties.

5. Before 1 July 2017, the Commission shall submit a report that provides an overview and an assessment of the statistics and information received, on issues such as the administrative and other relevant costs and benefits of the automatic exchange of information, as well as practical aspects linked thereto. If appropriate, the Commission shall present a proposal to the Council regarding the categories of income and capital and/or the conditions laid down in paragraph 1, including the condition that information concerning residents in other Member States has to be available.

When examining a proposal put forward by the Commission, the Council shall assess further strengthening of the efficiency and functioning of the automatic exchange of information and raising the standard thereof, with the aim of providing that:

- (a) the competent authority of each Member State shall, by automatic exchange, communicate to the competent authority of any other Member State, information regarding taxable periods as from 1 January 2017 concerning residents in that other Member State, on at least three of the specific categories of income and capital listed in paragraph 1, as they are to be understood under the national legislation of the Member State communicating the information; and
- (b) the list of categories in paragraph 1 be extended to include dividends, capital gains and royalties.

6. The communication of information shall take place at least once a year, within six months following the end of the tax year of the Member State during which the information became available.

7. The Commission shall adopt the practical arrangements for the automatic exchange of information, in accordance with the procedure referred to in Article 26(2), before the dates referred to in Article 29(1).

8. Where Member States agree on the automatic exchange of information for additional categories of income and capital in bilateral or multilateral agreements which they conclude with other Member States, they shall communicate those agreements to the Commission which shall make those agreements available to all the other Member States

SECTION III

Spontaneous exchange of information

Article 9

Scope and conditions of spontaneous exchange of information

1. The competent authority of each Member State shall communicate the information referred to in Article 1(1) to the competent authority of any other Member State concerned, in any of the following circumstances:

- (a) the competent authority of one Member State has grounds for supposing that there may be a loss of tax in the other Member State;
- (b) a person liable to tax obtains a reduction in, or an exemption from, tax in one Member State which would give rise to an increase in tax or to liability to tax in the other Member State;
- (c) business dealings between a person liable to tax in one Member State and a person liable to tax in the other Member State are conducted through one or more countries in such a way that a saving in tax may result in one or the other Member State or in both;
- (d) the competent authority of a Member State has grounds for supposing that a saving of tax may result from artificial transfers of profits within groups of enterprises;
- (e) information forwarded to one Member State by the competent authority of the other Member State has enabled information to be obtained which may be relevant in assessing liability to tax in the latter Member State.

2. The competent authorities of each Member State may communicate, by spontaneous exchange, to the competent authorities of the other Member States any information of which they are aware and which may be useful to the competent authorities of the other Member States.

Article 10

Time limits

1. The competent authority to which information referred to in Article 9(1) becomes available, shall forward that information to the competent authority of any other Member State concerned as quickly as possible, and no later than one month after it becomes available.

2. The competent authority to which information is communicated pursuant to Article 9 shall confirm, if possible by electronic means, the receipt of the information to the competent authority which provided the information immediately and in any event no later than seven working days.

CHAPTER III

OTHER FORMS OF ADMINISTRATIVE COOPERATION

SECTION I

Presence in administrative offices and participation in administrative enquiries

Article 11

Scope and conditions

1. By agreement between the requesting authority and the requested authority and in accordance with the arrangements laid down by the latter, officials authorised by the requesting authority may, with a view to exchanging the information referred to in Article 1(1):

- (a) be present in the offices where the administrative authorities of the requested Member State carry out their duties;
- (b) be present during administrative enquiries carried out in the territory of the requested Member State.

Where the requested information is contained in documentation to which the officials of the requested authority have access, the officials of the requesting authority shall be given copies thereof.

2. In so far as this is permitted under the legislation of the requested Member State, the agreement referred to in paragraph 1 may provide that, where officials of the requesting authority are present during administrative enquiries, they may interview individuals and examine records.

Any refusal by the person under investigation to respect the inspection measures of the officials of the requesting authority shall be treated by the requested authority as if that refusal was committed against officials of the latter authority.

3. Officials authorised by the requesting Member State present in another Member State in accordance with paragraph 1 shall at all times be able to produce written authority stating their identity and their official capacity.

SECTION II

Simultaneous controls

Article 12

Simultaneous controls

1. Where two or more Member States agree to conduct simultaneous controls, in their own territory, of one or more persons of common or complementary interest to them, with a view to exchanging the information thus obtained, paragraphs 2, 3 and 4 shall apply.

2. The competent authority in each Member State shall identify independently the persons for whom it intends to propose a simultaneous control. It shall notify the competent authority of the other Member States concerned of any cases for which it proposes a simultaneous control, giving reasons for its choice.

It shall specify the period of time during which those controls are to be conducted.

3. The competent authority of each Member State concerned shall decide whether it wishes to take part in simultaneous controls. It shall confirm its agreement or communicate its reasoned refusal to the authority that proposed a simultaneous control.

4. The competent authority of each Member State concerned shall appoint a representative with responsibility for supervising and coordinating the control operation.

SECTION III

Administrative notification

Article 13

Request for notification

1. At the request of the competent authority of a Member State, the competent authority of another Member State shall, in accordance with the rules governing the notification of similar instruments in the requested Member State, notify the addressee of any instruments and decisions which emanate from the administrative authorities of the requesting Member State and concern the application in its territory of legislation on taxes covered by this Directive.

2. Requests for notification shall indicate the subject of the instrument or decision to be notified and shall specify the name and address of the addressee, together with any other information which may facilitate identification of the addressee.

3. The requested authority shall inform the requesting authority immediately of its response and, in particular, of the date of notification of the instrument or decision to the addressee.

4. The requesting authority shall only make a request for notification pursuant to this Article when it is unable to notify in accordance with the rules governing the notification of the instruments concerned in the requesting Member State, or where such notification would give rise to disproportionate difficulties. The competent authority of a Member State may notify any document by registered mail or electronically directly to a person within the territory of another Member State.

SECTION IV

Feedback

Article 14

Conditions

1. Where a competent authority provides information pursuant to Articles 5 or 9, it may request the competent authority which receives the information to send feedback thereon. If feedback is requested, the competent authority which received the information shall, without prejudice to the rules on tax secrecy and data protection applicable in its Member State, send feedback to the competent authority which provided the information as soon as possible and no later than three months after the outcome of the use of the requested information is known. The Commission shall determine the practical arrangements in accordance with the procedure referred to in Article 26(2).

2. Member States' competent authorities shall send feedback on the automatic exchange of information to the other Member States concerned once a year, in accordance with practical arrangements agreed upon bilaterally.

SECTION V

Sharing of best practices and experience

Article 15

Scope and conditions

1. Member States shall, together with the Commission, examine and evaluate administrative cooperation pursuant to this Directive and shall share their experience, with a view to improving such cooperation and, where appropriate, drawing up rules in the fields concerned.

2. Member States may, together with the Commission, produce guidelines on any aspect deemed necessary for sharing best practices and sharing experience.

CHAPTER IV

CONDITIONS GOVERNING ADMINISTRATIVE COOPERATION

Article 16

Disclosure of information and documents

1. Information communicated between Member States in any form pursuant to this Directive shall be covered by the obligation of official secrecy and enjoy the protection extended to similar information under the national law of the Member State which received it. Such information may be used for the administration and enforcement of the domestic laws of the Member States concerning the taxes referred to in Article 2.

Such information may also be used for the assessment and enforcement of other taxes and duties covered by Article 2 of Council Directive 2010/24/EU of 16 March 2010 concerning mutual assistance for the recovery of claims relating to taxes, duties and other measures⁽¹⁾, or for the assessment and enforcement of compulsory social security contributions.

In addition, it may be used in connection with judicial and administrative proceedings that may involve penalties, initiated as a result of infringements of tax law, without prejudice to the general rules and provisions governing the rights of defendants and witnesses in such proceedings.

2. With the permission of the competent authority of the Member State communicating information pursuant to this Directive, and only in so far as this is allowed under the legislation of the Member State of the competent authority receiving the information, information and documents received pursuant to this Directive may be used for other purposes than those referred to in paragraph 1. Such permission shall be granted if the information can be used for similar purposes in the Member State of the competent authority communicating the information.

3. Where a competent authority of a Member State considers that information which it has received from the competent authority of another Member State is likely to be useful for the purposes referred to in paragraph 1 to the competent authority of a third Member State, it may transmit that information to the latter competent authority, provided that transmission is in accordance with the rules and procedures laid down in this Directive. It shall inform the competent authority of the Member State from which the information originates about its intention to share that information with a third Member State. The Member State of origin of the information may oppose such a sharing of information within 10 working days of receipt of the communication from the Member State wishing to share the information.

4. Permission to use information pursuant to paragraph 2, which has been transmitted pursuant to paragraph 3, may be

granted only by the competent authority of the Member State from which the information originates.

5. Information, reports, statements and any other documents, or certified true copies or extracts thereof, obtained by the requested authority and communicated to the requesting authority in accordance with this Directive may be invoked as evidence by the competent bodies of the requesting Member State on the same basis as similar information, reports, statements and any other documents provided by an authority of that Member State.

Article 17

Limits

1. A requested authority in one Member State shall provide a requesting authority in another Member State with the information referred to in Article 5 provided that the requesting authority has exhausted the usual sources of information which it could have used in the circumstances for obtaining the information requested, without running the risk of jeopardising the achievement of its objectives.

2. This Directive shall impose no obligation upon a requested Member State to carry out enquiries or to communicate information, if it would be contrary to its legislation to conduct such inquiries or to collect the information requested for its own purposes.

3. The competent authority of a requested Member State may decline to provide information where the requesting Member State is unable, for legal reasons, to provide similar information.

4. The provision of information may be refused where it would lead to the disclosure of a commercial, industrial or professional secret or of a commercial process, or of information whose disclosure would be contrary to public policy.

5. The requested authority shall inform the requesting authority of the grounds for refusing a request for information.

Article 18

Obligations

1. If information is requested by a Member State in accordance with this Directive, the requested Member State shall use its measures aimed at gathering information to obtain the requested information, even though that Member State may not need such information for its own tax purposes. That obligation is without prejudice to paragraphs 2, 3 and 4 of Article 17, the invocation of which shall in no case be construed as permitting a requested Member State to decline to supply information solely because it has no domestic interest in such information.

⁽¹⁾ OJ L 84, 31.3.2010, p. 1.

2. In no case shall Article 17(2) and (4) be construed as permitting a requested authority of a Member State to decline to supply information solely because this information is held by a bank, other financial institution, nominee or person acting in an agency or a fiduciary capacity or because it relates to ownership interests in a person.

3. Notwithstanding paragraph 2, a Member State may refuse the transmission of requested information where such information concerns taxable periods prior to 1 January 2011 and where the transmission of such information could have been refused on the basis of Article 8(1) of Directive 77/799/EEC if it had been requested before 11 March 2011.

Article 19

Extension of wider cooperation provided to a third country

Where a Member State provides a wider cooperation to a third country than that provided for under this Directive, that Member State may not refuse to provide such wider cooperation to any other Member State wishing to enter into such mutual wider cooperation with that Member State.

Article 20

Standard forms and computerised formats

1. Requests for information and for administrative enquiries pursuant to Article 5 and their replies, acknowledgements, requests for additional background information, inability or refusal pursuant to Article 7 shall, as far as possible, be sent using a standard form adopted by the Commission in accordance with the procedure referred to in Article 26(2).

The standard forms may be accompanied by reports, statements and any other documents, or certified true copies or extracts thereof.

2. The standard form referred to in paragraph 1 shall include at least the following information to be provided by the requesting authority:

- (a) the identity of the person under examination or investigation;
- (b) the tax purpose for which the information is sought.

The requesting authority may, to the extent known and in line with international developments, provide the name and address of any person believed to be in possession of the requested information as well as any element that may facilitate the collection of information by the requested authority.

3. Spontaneous information and its acknowledgement pursuant to Articles 9 and 10 respectively, requests for administrative notifications pursuant to Article 13 and feedback information pursuant to Article 14 shall be sent using the standard form adopted by the Commission in accordance with the procedure referred to in Article 26(2).

4. The automatic exchange of information pursuant to Article 8 shall be sent using a standard computerised format aimed at facilitating such automatic exchange and based on the existing computerised format pursuant to Article 9 of Council Directive 2003/48/EC of 3 June 2003 on taxation of savings income in the form of interest payments⁽¹⁾, to be used for all types of automatic exchange of information, adopted by the Commission in accordance with the procedure referred to in Article 26(2).

Article 21

Practical arrangements

1. Information communicated pursuant to this Directive shall, as far as possible, be provided by electronic means using the CCN network.

Where necessary, the Commission shall adopt practical arrangements necessary for the implementation of the first subparagraph in accordance with the procedure referred to in Article 26(2).

2. The Commission shall be responsible for whatever development of the CCN network is necessary to permit the exchange of that information between Member States.

Member States shall be responsible for whatever development of their systems is necessary to enable that information to be exchanged using the CCN network.

Member States shall waive all claims for the reimbursement of expenses incurred in applying this Directive except, where appropriate, in respect of fees paid to experts.

3. Persons duly accredited by the Security Accreditation Authority of the Commission may have access to that information only in so far as it is necessary for the care, maintenance and development of the CCN network.

4. Requests for cooperation, including requests for notification, and attached documents may be made in any language agreed between the requested and requesting authority.

Those requests shall be accompanied by a translation into the official language or one of the official languages of the Member State of the requested authority only in special cases when the requested authority states its reason for requesting a translation.

⁽¹⁾ OJ L 157, 26.6.2003, p. 38.

*Article 22***Specific obligations**

1. Member States shall take all necessary measures to:
 - (a) ensure effective internal coordination within the organisation referred to in Article 4;
 - (b) establish direct cooperation with the authorities of the other Member States referred to in Article 4;
 - (c) ensure the smooth operation of the administrative cooperation arrangements provided for in this Directive.
2. The Commission shall communicate to each Member State any general information concerning the implementation and application of this Directive which it receives and which it is able to provide.

CHAPTER V

RELATIONS WITH THE COMMISSION*Article 23***Evaluation**

1. Member States and the Commission shall examine and evaluate the functioning of the administrative cooperation provided for in this Directive.
2. Member States shall communicate to the Commission any relevant information necessary for the evaluation of the effectiveness of administrative cooperation in accordance with this Directive in combating tax evasion and tax avoidance.
3. Member States shall communicate to the Commission a yearly assessment of the effectiveness of the automatic exchange of information referred to in Article 8 as well as the practical results achieved. The form and the conditions of communication of that yearly assessment shall be adopted by the Commission in accordance with the procedure referred to in Article 26(2).
4. The Commission shall, in accordance with the procedure referred to in Article 26(2), determine a list of statistical data which shall be provided by the Member States for the purposes of evaluation of this Directive.
5. Information communicated to the Commission under paragraphs 2, 3 and 4 shall be kept confidential by the Commission in accordance with the provisions applicable to Union authorities.
6. Information communicated to the Commission by a Member State under paragraphs 2, 3 and 4, as well as any report or document produced by the Commission using such information, may be transmitted to other Member States. Such transmitted information shall be covered by the obligation of

official secrecy and enjoy the protection extended to similar information under the national law of the Member State which received it.

Reports and documents produced by the Commission referred to in this paragraph may only be used by the Member States for analytical purposes but shall not be published or made available to any other person or body without express agreement of the Commission.

CHAPTER VI

RELATIONS WITH THIRD COUNTRIES*Article 24***Exchange of information with third countries**

1. Where the competent authority of a Member State receives from a third country information that is foreseeably relevant to the administration and enforcement of the domestic laws of that Member State concerning the taxes referred to in Article 2, that authority may, in so far as this is allowed pursuant to an agreement with that third country, provide that information to the competent authorities of Member States for which that information might be useful and to any requesting authorities.
2. Competent authorities may communicate, in accordance with their domestic provisions on the communication of personal data to third countries, information obtained in accordance with this Directive to a third country, provided that all of the following conditions are met:
 - (a) the competent authority of the Member State from which the information originates have consented to that communication;
 - (b) the third country concerned has given an undertaking to provide the cooperation required to gather evidence of the irregular or illegal nature of transactions which appear to contravene or constitute an abuse of tax legislation.

CHAPTER VII

GENERAL AND FINAL PROVISIONS*Article 25***Data protection**

All exchange of information pursuant to this Directive shall be subject to the provisions implementing Directive 95/46/EC. However, Member States shall, for the purpose of the correct application of this Directive, restrict the scope of the obligations and rights provided for in Article 10, Article 11(1), Articles 12 and 21 of Directive 95/46/EC to the extent required in order to safeguard the interests referred to in Article 13(1)(e) of that Directive.

*Article 26***Committee**

1. The Commission shall be assisted by a committee referred to as the 'Committee on Administrative Cooperation for Taxation'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

*Article 27***Reporting**

Every five years after 1 January 2013, the Commission shall submit a report on the application of this Directive to the European Parliament and to the Council.

*Article 28***Repeal of Directive 77/799/EEC**

Directive 77/799/EEC is repealed with effect from 1 January 2013.

References made to the repealed Directive shall be construed as references to this Directive.

*Article 29***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive with effect from 1 January 2013.

However, they shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 8 of this Directive with effect from 1 January 2015.

They shall forthwith inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

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 30***Entry into force**

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

*Article 31***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 15 February 2011.

For the Council

The President

MATOLCSY Gy.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) No 233/2011

of 10 March 2011

implementing Article 16(2) of Regulation (EU) No 204/2011 concerning restrictive measures in view of the situation in Libya

THE COUNCIL OF THE EUROPEAN UNION,

persons and entities subject to restrictive measures as set out in Annex III to that Regulation,

Having regard to Council Regulation (EU) No 204/2011 of 2 March 2011 concerning restrictive measures in view of the situation in Libya ⁽¹⁾, and in particular Article 16(2) thereof,

HAS ADOPTED THIS REGULATION:

Whereas:

Article 1

- (1) On 2 March 2011, the Council adopted Regulation (EU) No 204/2011 concerning restrictive measures in view of the situation in Libya.

The persons and entities listed in the Annex to this Regulation shall be included in Annex III to Regulation (EU) No 204/2011.

Article 2

- (2) In view of the gravity of the situation in Libya, additional persons and entities should be included in the list of

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, 10 March 2011.

For the Council
The President
MARTONYI J.

⁽¹⁾ OJ L 58, 3.3.2011, p. 1.

ANNEX

Persons and entities referred to in Article 1

Persons

	Name	Identifying information	Reasons	Date of listing
1.	Mr. Mustafa Zarti	born on 29 March 1970, Austrian citizen (passport no. P1362998, valid from 6 November 2006 until 5 November 2016)	Closeness of association with regime and vice chief executive of "Libyan Investment Authority", board member of the National Oil Corporation, head of oil company "Tamoil" and vice chairman of First Energy Bank in Bahrain.	(¹)

Entities

	Name	Identifying information	Reasons	Date of listing
1.	Central Bank of Libya (CBL)		Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
2.	Libya Africa Investment Portfolio	Jamahiriya Street, LAP Building, PO Box 91330, Tripoli, Libya	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
3.	Libyan Foreign Bank		Under control of Muammar Qadhafi and his family and a potential source of funding for his regime.	(¹)
4.	Libyan Housing and Infrastructure Board (HIB)	Tajora, Tripoli, Libya Legislation number: 60/2006 by Libyan General People's Committee Tel: +218 21 369 1840, Fax: +218 21 369 6447 http://www.hib.org.ly	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
5.	Libyan Investment Authority (LIA, a.k.a. Libyan Arab Foreign Investment Company (LAFICO))	I Fateh Tower Office No.99 22nd Floor, Borgaida Street, Tripoli, 1103 Libya, Phone: 218 21 336 2091, fax: 218 21 336 2082, www.lia.ly	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)

(¹) Date of Adoption

COMMISSION REGULATION (EU) No 234/2011**of 10 March 2011****implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council
establishing a common authorisation procedure for food additives, food enzymes and food
flavourings****(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 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings⁽¹⁾, and in particular Article 9(1) thereof,

After consulting the European Food Safety Authority pursuant to Article 9(2) of Regulation (EC) No 1331/2008,

Whereas:

- (1) Regulation (EC) No 1331/2008 lays down procedural arrangements for updating the lists of substances the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽²⁾, Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes⁽³⁾ and Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods⁽⁴⁾ (hereinafter referred to as 'the sectoral food laws').
- (2) Pursuant to Article 9 of Regulation (EC) No 1331/2008 it is for the Commission to adopt the implementing measure as regards the content, drafting and presentation of applications to update the Union lists under each sectoral food law, arrangements for checking the validity of applications and the type of information that should be included in the opinion of the European Food Safety Authority (hereinafter referred to as 'the Authority').
- (3) In order to update the lists it is necessary to verify that the use of the substance complies with the general and specific conditions of use as provided for in the respective sectoral food laws.

- (4) The Authority adopted a scientific opinion on 9 July 2009 on data requirements for the evaluation of food additive applications⁽⁵⁾. This data should be provided when an application for the use of a new food additive is submitted. In case of an application for a modification of the conditions of use of an already authorised food additive or for a modification of the specifications of an already authorised food additive, the data required for risk assessment may not be required, as long as this is justified by the applicant.
- (5) The Authority adopted a scientific opinion on 23 July 2009 on data requirements for the evaluation of food enzyme applications⁽⁶⁾. This data should be provided when an application for the use of a new food enzyme is submitted. In case of an application for a modification of the conditions of use of an already authorised food enzyme or for a modification of the specifications of an already authorised food enzyme, the data required for risk assessment may not be required, as long as this is justified by the applicant.
- (6) The Authority adopted a scientific opinion on 19 May 2010 on data requirements for the risk assessment of flavourings to be used in or on foods⁽⁷⁾. This data should be provided when an application for the use of a new flavouring is submitted. In case of an application for a modification of the conditions of use of an already authorised flavouring or for a modification of the specifications of an already authorised flavouring, the data required for risk assessment may not be required, as long as this is justified by the applicant.
- (7) It is important that toxicological tests are performed to a certain standard. Therefore Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances⁽⁸⁾ should be followed. Where such tests are carried out outside the territory of the Union, they should follow 'the OECD Principles of Good Laboratory Practice' (GLP) (OECD, 1998)⁽⁹⁾.

⁽¹⁾ OJ L 354, 31.12.2008, p. 1.

⁽²⁾ OJ L 354, 31.12.2008, p. 16.

⁽³⁾ OJ L 354, 31.12.2008, p. 7.

⁽⁴⁾ OJ L 354, 31.12.2008, p. 34.

⁽⁵⁾ <http://www.efsa.europa.eu/en/scdocs/doc/1188.pdf>

⁽⁶⁾ <http://www.efsa.europa.eu/en/scdocs/doc/1305.pdf>

⁽⁷⁾ <http://www.efsa.europa.eu/en/scdocs/doc/1623.pdf>

⁽⁸⁾ OJ L 50, 20.2.2004, p. 44.

⁽⁹⁾ OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17.

- (8) The use of food additives and food enzymes should always be technologically justified. Applicants should also explain in case of a food additive why the technological effect cannot be achieved by any other economically and technologically practicable means.
- (9) The use of a substance should be authorised if it does not mislead the consumer. Applicants should explain that the requested uses do not mislead the consumer. The advantages and benefits for the consumer should also be explained in case of a food additive.
- (10) Without prejudice to Article 9 of Regulation (EC) No 1332/2008, Article 19 of Regulation (EC) No 1333/2008 and Article 13 of Regulation (EC) No 1334/2008, the Commission should verify the validity of the application and whether it falls within the scope of the respective sectoral food law. An advice from the Authority should be taken into account, where appropriate, on the suitability of the submitted data for risk assessment. Such verification should not delay the assessment of an application.
- (11) The information provided in the opinion of the Authority should be sufficient to ascertain whether the authorisation of the proposed use of the substance is safe for consumers. This includes conclusions on the toxicity of the substance, where appropriate, and possible establishment of an acceptable daily intake (ADI) expressed in a numerical form with details of a dietary exposure assessment for all food categories, including exposure of vulnerable consumer groups.
- (12) The applicant should also take into account detailed guidance concerning the data required for risk assessment established by the Authority (The EFSA Journal ⁽¹⁾).
- (13) This Regulation takes into account current scientific and technical knowledge. The Commission may revise this Regulation in the light of any developments in this field and the publication of any revised or additional scientific guidance by the Authority.
- (14) Practical arrangements related to an application for the authorisation of food additives, food enzymes and flavourings, such as addresses, persons to contact, transmission of documents, etc., should be made available in a separate communication of the Commission and/or the Authority.
- (15) It is necessary to provide for a time period in order to allow the applicants to comply with the provisions of this Regulation.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation shall apply to applications as referred to in Article 3(1) of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

CHAPTER II

CONTENT, DRAFTING AND PRESENTATION OF AN APPLICATION

Article 2

Content of an application

1. The application referred to in Article 1 shall consist of the following:

- (a) a letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

2. The letter referred to in paragraph 1(a) shall be drafted in accordance with the model provided in the Annex.

3. The technical dossier referred to in paragraph 1(b) shall contain:

- (a) the administrative data as provided for in Article 4;
- (b) the data required for risk assessment as provided for in Articles 5, 6, 8 and 10; and
- (c) the data required for risk management as provided for in Articles 7, 9 and 11.

4. In case of an application for a modification of the conditions of use of an already authorised food additive, food enzyme or flavouring all the data mentioned in Articles 5 to 11 may not be required. The applicant shall submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment.

5. In case of an application for a modification of the specifications of an already authorised food additive, food enzyme or flavouring:

- (a) the data may be limited to the justification of the request and the changes in the specification;

⁽¹⁾ <http://www.efsa.europa.eu/en/efsajournal.htm>

(b) the applicant shall submit a verifiable justification why the proposed changes do not affect the results of the existing risk assessment.

6. The summary of the dossier referred to in paragraph 1(c) shall include a reasoned statement that the use of the product complies with the conditions laid down in:

- (a) Article 6 of Regulation (EC) No 1332/2008; or
- (b) Articles 6, 7 and 8 of Regulation (EC) No 1333/2008; or
- (c) Article 4 of Regulation (EC) No 1334/2008.

Article 3

Drafting and presentation

1. Applications shall be sent to the Commission. The applicant shall take into account the practical guidance on the submission of applications made available by the Commission (Directorate General for Health and Consumers' ⁽¹⁾ website).

2. For the establishment of the Union list of food enzymes as referred to in Article 17 of Regulation (EC) No 1332/2008, the deadline for submitting applications shall be 24 months after the date of application of the implementing measures established by this Regulation.

Article 4

Administrative data

The administrative data as referred to in Article 2(3)(a) shall include:

- (a) name of the applicant (company, organisation, etc.), address and contact details;
- (b) name of the manufacturer(s) of the substance, if different than the applicant's, address and contact details;
- (c) name of the person responsible for the dossier, address and contact details;
- (d) date of submission of the dossier;
- (e) type of the application, i.e. concerning a food additive, a food enzyme, or a flavouring;
- (f) where applicable, chemical name according to IUPAC nomenclature;
- (g) where applicable, E-number of the additive as defined in the Union legislation on food additives;
- (h) where applicable, a reference to similar authorised food enzymes;
- (i) where applicable, the FL-number of a flavouring substance as defined in the Union legislation on flavourings;
- (j) where applicable, the information on authorisations falling within the scope of Regulation (EC) No 1829/2003 of the

European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽²⁾;

- (k) table of content of the dossier;
- (l) list of documents and other particulars; the applicant shall identify the number and titles of volumes of documentation submitted in support of the application; a detailed index with a reference to volumes and pages shall be included;
- (m) list of the parts of the dossier to be treated as confidential; applicants shall indicate what they wish to be treated as confidential and give verifiable justification in accordance with Article 12 of Regulation (EC) No 1331/2008.

Article 5

General provisions on data required for risk assessment

1. The dossier submitted in support of an application for the safety evaluation of a substance shall enable a comprehensive risk assessment of the substance and shall permit verification that the substance does not pose a safety concern to consumers within the meaning of Article 6(a) of Regulation (EC) No 1332/2008, Article 6(1)(a) of Regulation (EC) No 1333/2008 and Article 4(a) of Regulation (EC) No 1334/2008.

2. The application dossier shall include all the available data relevant for the purpose of the risk assessment (i.e. full published papers of all references cited or full copies of the original unpublished studies).

3. The applicant shall take into account the latest guidance documents adopted or endorsed by the Authority available at the time of the submission of the application (The EFSA Journal).

4. The documentation on the procedure followed when gathering the data shall be provided, including the literature search strategies (assumptions made, key words used, databases used, time period covered, limitation criteria, etc.) and a comprehensive outcome of such search.

5. The safety evaluation strategy and the corresponding testing strategy shall be described and justified with rationales for inclusion and exclusion of specific studies and/or information.

6. The individual raw data of the unpublished studies and, where possible, of the published studies as well as the individual results of examinations shall be made available on request from the Authority.

7. For each biological or toxicological study, it shall be clarified whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the substance under consideration.

⁽¹⁾ http://ec.europa.eu/dgs/health_consumer/index_en.htm

⁽²⁾ OJ L 268, 18.10.2003, p. 1.

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC of the European Parliament and of the Council or, if they are carried out outside the territory of the Union, they shall follow 'the OECD Principles of Good Laboratory Practice' (GLP). The applicant shall provide evidence to demonstrate that those requirements are complied with. For studies not conducted according to standard protocols, data interpretation, as well as a justification on their appropriateness for the risk assessment, shall be provided.

8. The applicant shall propose an overall conclusion on the safety of the proposed uses of the substance. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

Article 6

Specific data required for risk assessment of food additives

1. In addition to data to be provided pursuant to Article 5, information shall be provided on:

- (a) the identity and characterisation of the additive, including the proposed specifications and analytical data;
- (b) where applicable, the particle size, particle size distribution and other physicochemical characteristics;
- (c) the manufacturing process;
- (d) presence of impurities;
- (e) the stability, reaction and fate in foods to which the additive is added;
- (f) where applicable, the existing authorisations and risk assessments;
- (g) proposed normal and maximum use levels in the food categories mentioned in the Union list, or in a newly proposed food category, or in a more specific foodstuff belonging to one of these categories;
- (h) a dietary exposure assessment;
- (i) the biological and toxicological data.

2. As regards to the biological and toxicological data, referred to in point (i) of paragraph 1, the following core areas shall be covered:

- (a) toxicokinetics;
- (b) subchronic toxicity;
- (c) genotoxicity;
- (d) chronic toxicity/carcinogenicity;
- (e) reproductive and developmental toxicity.

Article 7

Data required for risk management of food additives

1. The dossier submitted in support of an application shall include the information necessary to verify whether there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means and whether the proposed use does not mislead the consumer within the meaning of points (b) and (c) of Article 6(1) of Regulation (EC) No 1333/2008.

2. In order to ensure the verification referred to in paragraph 1, appropriate and sufficient information shall be provided on:

- (a) the identity of the food additive, including reference to the existing specifications;
- (b) the function and technological need for the level proposed in each of the food categories or products for which authorisation is requested and an explanation that this can not be reasonably achieved by other economically and technologically practical means;
- (c) the investigations on the efficacy of the food additive for the intended effect at the use level proposed;
- (d) advantages and benefit for the consumer. The applicant shall take into account the requirements laid down in Article 6(2) of Regulation (EC) No 1333/2008;
- (e) why the use would not mislead the consumer;
- (f) proposed normal and maximum use levels in the food categories mentioned in the Union list, or in a newly proposed food category, or in a more specific foodstuff belonging to one of these categories;
- (g) the exposure assessment, based on normal and maximum intended use for each of the categories or products concerned;
- (h) the amount of the food additive present in the final food as consumed by the consumer;
- (i) analytical methods allowing the identification and quantification of the additive or its residues in food;
- (j) where applicable, the compliance with the specific conditions for sweeteners and for colours as laid down in Articles 7 and 8 of Regulation (EC) No 1333/2008.

Article 8

Specific data required for risk assessment of food enzymes

1. In addition to data to be provided pursuant to Article 5, information shall be provided on:

- (a) name(s), synonyms, abbreviations and classification(s);
- (b) Enzyme Commission Number;
- (c) the proposed specifications, including the origin;
- (d) the properties;

- (e) the reference to any similar food enzyme;
- (f) the source material;
- (g) the manufacturing process;
- (h) the stability, reaction and fate in foods in which the food enzyme is used;
- (i) where applicable the existing authorisations and evaluations;
- (j) the proposed uses in food and, where applicable, the proposed normal and maximum use levels;
- (k) the dietary exposure assessment;
- (l) the biological and toxicological data.

2. As regards to the biological and toxicological data, referred to in point (1) of paragraph 1, the following core areas shall be covered:

- (a) subchronic toxicity;
- (b) genotoxicity.

Article 9

Data required for risk management of food enzymes

1. The dossier submitted in support of an application shall include the information necessary to verify whether there is a reasonable technological need and whether the proposed use does not mislead the consumer within the meaning of points (b) and (c) of Article 6 of Regulation (EC) No 1332/2008.

2. In order to ensure the verification referred to in paragraph 1, appropriate and sufficient information shall be provided on:

- (a) the identity of the food enzyme, including reference to the specifications;
- (b) the function and technological need, including a description of the typical process(es) in which the food enzyme may be applied;
- (c) the effect of the food enzyme on the final food;
- (d) why the use would not mislead the consumer;
- (e) the proposed normal and maximum use levels where applicable;
- (f) the dietary exposure assessment, as described in the Authority's guidance document on food enzymes ⁽¹⁾.

Article 10

Specific data required for risk assessment of flavourings

1. In addition to data to be provided pursuant to Article 5, information shall be provided on:

- (a) the manufacturing process;
- (b) specifications;

⁽¹⁾ Guidance of EFSA prepared by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids on the Submission of a Dossier on Food Enzymes. *The EFSA Journal* (2009) 1305, p. 1.

- (c) where applicable, information on particle size, particle size distribution and other physicochemical characteristics;
- (d) where applicable the existing authorisations and evaluations;
- (e) the proposed uses in food and proposed normal and maximum use levels in the categories according to the Union list or in a more specified type of product within the categories;
- (f) the data on dietary sources;
- (g) the dietary exposure assessment;
- (h) the biological and toxicological data.

2. As regards to the biological and toxicological data, referred to in point (h) of paragraph 1, the following core areas shall be covered:

- (a) examination for structural/metabolic similarity to flavouring substances in an existing flavouring group evaluation (FGE);
- (b) genotoxicity;
- (c) subchronic toxicity, where applicable;
- (d) developmental toxicity, where applicable;
- (e) chronic toxicity and carcinogenicity data, where applicable.

Article 11

Data required for risk management of flavourings

The dossier submitted in support of an application shall include the following information:

- (a) the identity of the flavouring, including reference to the existing specifications;
- (b) organoleptic properties of the substance;
- (c) the proposed normal and maximum use levels in the food categories or in a more specific food belonging to one of these categories;
- (d) the exposure assessment, based on normal and maximum intended use for each of the categories or products concerned.

CHAPTER III

ARRANGEMENTS FOR CHECKING THE VALIDITY OF AN APPLICATION

Article 12

Procedures

1. On receipt of an application the Commission shall without delay verify whether the food additive, food enzyme or flavouring falls within the scope of the appropriate sectoral food law and whether the application contains all the elements required under Chapter II.

2. Where the application contains all the elements required under Chapter II, the Commission shall, where necessary, request the Authority to verify the suitability of the data for risk assessment in accordance with the scientific opinions on data requirements for the evaluation of substance applications and to prepare, if appropriate, an opinion.

3. Within 30 working days following the receipt of the Commission's request, the Authority shall inform the Commission by letter about the suitability of the data for risk assessment. If the data is considered suitable for risk assessment, the evaluation period referred to in Article 5(1) of Regulation (EC) No 1331/2008 shall begin from the date when the Authority's letter is received by the Commission.

However, in accordance with point (a) of the second subparagraph of Article 17(4) of Regulation (EC) No 1332/2008, in the case of establishment of the Union list of food enzymes, Article 5(1) of Regulation (EC) No 1331/2008 shall not apply.

4. In case of an application to update the Union list of food additives, food enzymes or flavourings, the Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information shall be provided. In the case of applications submitted in compliance with Article 17(2) of Regulation (EC) No 1332/2008, the Commission shall determine that period together with the applicant.

5. When the application does not fall within the appropriate sectoral food law or when it does not contain all the elements required under Chapter II or when the Authority considers that the data for risk assessment are not suitable, the application shall be considered as not valid. In such a case the Commission shall inform the applicant, the Member States and the Authority indicating the reasons why the application is considered not valid.

6. By way of derogation from paragraph 5, an application may be considered as valid even if it does not contain all the elements required under Chapter II, provided that the applicant has submitted verifiable justification for each missing element.

CHAPTER IV

OPINION OF THE AUTHORITY

Article 13

Information to be included in the opinion of the Authority

1. The opinion of the Authority shall include the following information:

- (a) the identity and characterisation of the food additive, food enzyme or flavouring;
- (b) the assessment of the biological and toxicological data;
- (c) a dietary exposure assessment for the European population taking into account other possible sources of dietary exposure;
- (d) an overall risk assessment establishing if possible and relevant a health-based guidance value, and highlighting uncertainties and limitations where relevant;
- (e) when the dietary exposure exceeds the health-based guidance value identified in the overall risk assessment, the dietary exposure assessment of the substance shall be detailed, providing where possible the contribution to the total exposure of each food category or foodstuff for which the use is authorised or has been requested;
- (f) conclusions.

2. The Commission may ask for more specific additional information in its request for an opinion of the Authority.

CHAPTER V

FINAL PROVISIONS

Article 14

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 11 September 2011.

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

Done at Brussels, 10 March 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

MODEL LETTER ACCOMPANYING AN APPLICATION FOR FOOD ADDITIVES

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date:

Subject: Application for authorisation of food additive in accordance with Regulation (EC) No 1331/2008.

- ☐ Application for an authorisation of a new food additive
- ☐ Application for a modification of the conditions of use of an already authorised food additive
- ☐ Application for a modification of the specifications of an already authorised food additive

(Please indicate clearly by ticking one of the boxes).

The Applicant(s) and/or his/their Representative(s) in the European Union.

(name, address, ...)

.....

.....

.....

submit(s) the present application in order to update the EU list on food additives.

Food additive name:

.....

ELINCS or EINECS number (if attributed)

CAS No (if applicable)

Functional class(es) of food additives ⁽¹⁾:

(list)

.....

Food categories and required levels:

Food category	Normal use level	Maximum proposed use level

⁽¹⁾ The functional classes of food additives in foods and of food additives in food additives and food enzymes are listed in Annex I to Regulation (EC) No 1333/2008. If the additive does not belong to one of the mentioned classes, a new functional class name and definition can be proposed.

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential
- ☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR FOOD ENZYMES

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date:

Subject: Application for authorisation of food enzyme in accordance with Regulation (EC) No 1331/2008.

- ☐ Application for an authorisation of a new food enzyme
- ☐ Application for a modification of the conditions of use of an already authorised food enzyme
- ☐ Application for a modification of the specifications of an already authorised food enzyme

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/her Representative(s) in the European Union

(name, address, ...)

.....
.....

submit(s) the present application in order to update the EU list on food enzymes.

Food enzyme name:

.....

Enzyme Classification Number of Enzyme Commission of the IUBMB

Source material

.....
.....

Name	Specifications	Foods	Conditions of use	Restrictions on the sale of the food enzyme to the final consumer	Specific requirement in respect of labelling of food

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential
- ☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR FLAVOURINGS

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date:

Subject: Application for authorisation of food flavouring in accordance with Regulation (EC) No 1331/2008.

- ☐ Application for an authorisation of a new flavouring substance
- ☐ Application for an authorisation of a new flavouring preparation
- ☐ Application for an authorisation of a new flavour precursor
- ☐ Application for an authorisation of a new thermal process flavouring
- ☐ Application for an authorisation of a new other flavouring
- ☐ Application for an authorisation of a new source material
- ☐ Application for a modification of the conditions of use of an already authorised food flavouring
- ☐ Application for a modification of the specifications of an already authorised food flavouring

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the European Union

(name, address, ...)

.....

.....

submit(s) the present application in order to update the EU list on food flavourings.

Name of the flavouring or source material:

.....

FL-, CAS-, JECFA-, CoE-number (if attributed)

Organoleptic properties of the flavouring

.....

Food categories and required levels:

Food category	Normal use level	Maximum proposed use level

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential
- ☐ Copy of administrative data of applicant(s)

COMMISSION IMPLEMENTING REGULATION (EU) No 235/2011**of 10 March 2011****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 March 2011.

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

Done at Brussels, 10 March 2011.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	IL	122,2
	MA	55,0
	TN	115,9
	TR	82,8
	ZZ	94,0
0707 00 05	TR	166,8
	ZZ	166,8
0709 90 70	MA	43,0
	TR	137,5
	ZZ	90,3
0805 10 20	EG	56,5
	IL	70,5
	JM	51,6
	MA	49,2
	TN	56,2
	TR	69,8
	ZZ	59,0
0805 50 10	EG	42,1
	MA	42,1
	TR	48,3
	ZZ	44,2
0808 10 80	AR	99,8
	CA	101,6
	CL	119,8
	CN	101,7
	MK	52,3
	US	146,4
	ZA	67,5
	ZZ	98,4
0808 20 50	AR	89,7
	CL	103,2
	CN	53,6
	US	182,7
	ZA	88,8
	ZZ	103,6

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION IMPLEMENTING REGULATION (EU) No 236/2011**of 10 March 2011****amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EU) No 867/2010 for the 2010/11 marketing year**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ⁽²⁾, and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

- (1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups

for the 2010/11 marketing year are fixed by Commission Regulation (EU) No 867/2010 ⁽³⁾. These prices and duties have been last amended by Commission Regulation (EU) No 232/2011 ⁽⁴⁾.

- (2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EU) No 867/2010 for the 2010/11, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 11 March 2011.

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

Done at Brussels, 10 March 2011.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 259, 1.10.2010, p. 3.

⁽⁴⁾ OJ L 63, 10.3.2011, p. 15.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 11 March 2011

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 ⁽¹⁾	57,95	0,00
1701 11 90 ⁽¹⁾	57,95	0,00
1701 12 10 ⁽¹⁾	57,95	0,00
1701 12 90 ⁽¹⁾	57,95	0,00
1701 91 00 ⁽²⁾	54,91	1,00
1701 99 10 ⁽²⁾	54,91	0,00
1701 99 90 ⁽²⁾	54,91	0,00
1702 90 95 ⁽³⁾	0,55	0,19

⁽¹⁾ For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.⁽²⁾ For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.⁽³⁾ Per 1 % sucrose content.

DECISIONS

COUNCIL IMPLEMENTING DECISION 2011/156/CFSP

of 10 March 2011

implementing Decision 2011/137/CFSP concerning restrictive measures in view of the situation in Libya

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DECISION:

Having regard to Council Decision 2011/137/CFSP of 28 February 2011 concerning restrictive measures in view of the situation in Libya ⁽¹⁾, and in particular Article 8(2) thereof, in conjunction with Article 31(2) of the Treaty on European Union,

Article 1

The persons and entities listed in the Annex to this Decision shall be included in Annex IV to Decision 2011/137/CFSP.

Whereas:

Article 2

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

(1) On 28 February 2011, the Council adopted Decision 2011/137/CFSP concerning restrictive measures in view of the situation in Libya.

Done at Brussels, 10 March 2011.

(2) In view of the gravity of the situation in Libya, additional persons and entities should be included in the list of persons and entities subject to restrictive measures as set out in Annex IV to that Decision,

For the Council
The President
MARTONYI J.

⁽¹⁾ OJ L 58, 3.3.2011, p. 53.

ANNEX

Persons and entities referred to in Article 1

Persons

	Name	Identifying information	Reasons	Date of listing
1.	Mr. Mustafa Zarti	born on 29 March 1970, Austrian citizen (passport no. P1362998, valid from 6 November 2006 until 5 November 2016)	Closeness of association with regime and vice chief executive of "Libyan Investment Authority", board member of the National Oil Corporation, head of oil company "Tamoil" and vice chairman of First Energy Bank in Bahrain.	(¹)

Entities

	Name	Identifying information	Reasons	Date of listing
1.	Central Bank of Libya (CBL)		Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
2.	Libya Africa Investment Portfolio	Jamahiriya Street, LAP Building, PO Box 91330, Tripoli, Libya	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
3.	Libyan Foreign Bank		Under control of Muammar Qadhafi and his family and a potential source of funding for his regime.	(¹)
4.	Libyan Housing and Infrastructure Board (HIB)	Tajora, Tripoli, Libya Legislation number: 60/2006 by Libyan General People's Committee Tel: +218 21 369 1840, Fax: +218 21 369 6447 http://www.hib.org.ly	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)
5.	Libyan Investment Authority (LIA, a.k.a. Libyan Arab Foreign Investment Company (LAFICO))	I Fateh Tower Office No.99 22nd Floor, Borgaida Street, Tripoli, 1103 Libya, Phone: 218 21 336 2091, fax: 218 21 336 2082, www.lia.ly	Under control of Muammar Qadhafi and his family, and potential source of funding for his regime.	(¹)

(¹) Date of Adoption

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