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Contents



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[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.

EN

[1] Text with EEA relevance

II

*(Non-legislative acts)*

# INTERNATIONAL AGREEMENTS

**Notice concerning the provisional application of Part IV (trade matters) of the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America on the other (Guatemala)**

Pending the completion of the procedures for the conclusion of the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America on the other, signed at Tegucigalpa on 29 June 2012, Part IV thereof concerning trade matters shall, in accordance with its Article 353(4), be applied on a provisional basis between the European Union and Guatemala as from 1 December 2013. By virtue of Article 3(1) of the Council Decision 2012/734/EU [1] on the signing and provisional application of the Agreement, Article 271 shall not be provisionally applied.

[1] Council Decision 2012/734/EU of 25 June 2012 on the signing, on behalf of the European Union, of the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America on the other, and the provisional application of Part IV thereof concerning trade matters (OJ L 346, 15.12.2012, p. 1).

# REGULATIONS

## COUNCIL IMPLEMENTING REGULATION (EU) No 1194/2013

**of 19 November 2013**

**imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of biodiesel originating in Argentina and Indonesia**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community [1] ('the basic Regulation'), and in particular Article 9 thereof,

Having regard to the proposal submitted by the European Commission after having consulted the Advisory Committee,

Whereas:

### A. PROCEDURE

#### 1. Provisional measures

(1) On 27 May 2013, the European Commission ('the Commission') decided to impose a provisional anti-dumping duty on imports of biodiesel originating in Argentina and Indonesia ('the countries concerned') by Regulation (EU) No 490/2013 [2] ('the provisional Regulation').

(2) The proceeding was initiated on 29 August 2012 [3] following a complaint lodged on behalf of Union producers ('the complainants'), representing more than 60 % of the total Union production of biodiesel.

(3) As set out in recital 5 of the provisional Regulation, the investigation of dumping and injury covered the period from 1 July 2011 to 30 June 2012 ('the investigation period' or 'IP'). The examination of trends relevant for the assessment of injury covered the period from 1 January 2009 to the end of the IP ('the period considered').

#### 2. Subsequent procedure

(4) Subsequent to the disclosure of the essential facts and considerations on the basis of which it was decided to impose a provisional anti-dumping duty ('provisional disclosure'), several interested parties made written submissions making known their views on the provisional findings. The parties who so requested were granted an opportunity to be heard.

(5) The Commission continued to seek and verify all information it deemed necessary for its definitive findings. The oral and written comments submitted by the interested parties were considered and, where appropriate, the provisional findings were modified accordingly.

(6) Subsequently, all parties were informed of the essential facts and considerations on the basis of which it was intended to recommend the imposition of a definitive anti-dumping duty on imports of biodiesel originating in Argentina and Indonesia and the definitive collection of the amounts secured by way of provisional duty ('the definitive disclosure'). All parties were granted a period within which they could make comments on the final disclosure.

(7) The comments submitted by the interested parties were considered and taken into account where appropriate.

### B. SAMPLING

(8) In the absence of comments concerning the sampling of exporting producers in Argentina and Indonesia the provisional findings in recitals 10 to 14 and 16 to 20 of the provisional Regulation are hereby confirmed.

[1] OJ L 343, 22.12.2009, p. 51.
[2] OJ L 141, 28.5.2013, p. 6.
[3] OJ C 260, 29.8.2012, p. 8.

(9) One interested party requested further information on the representativity of the sample of Union producers, both at the stage of provisional selection as set out in recital 23 of the provisional Regulation and at the stage of final selection as set out in recital 83 of the provisional Regulation.

(10) The sample of Union producers provisionally selected consisted of 32,5 % of the production of biodiesel in the Union during the IP. Following the changes explained in recital 24 of the provisional Regulation the final sample consisted of eight companies covering 27 % of Union production. The sample was therefore considered to be representative of the Union industry.

(11) One interested party claimed that two Union producers that were sampled should be removed from the sample due to their relationship with Argentine exporting producers. The alleged relationship was examined prior to the imposition of provisional measures and the Commission's conclusions already published in recital 82 of the provisional Regulation.

(12) All of the alleged links between Argentine exporting producers and the two sampled companies referred to above were examined again, and no direct link between them was found such that either Union producer should be removed from the sample. The sample therefore remained unchanged.

(13) Another interested party claimed that the Commission's procedure for selecting a sample of Union producers was flawed, as the Commission proposed a sample prior to initiation of the investigation.

(14) That claim is rejected. The Commission did not select the final sample until after the initiation of the investigation and entirely in line with the provisions of the basic Regulation.

(15) In the absence of any other claim or comments, the content of recitals 22 to 25 of the provisional Regulation is confirmed.

## C. PRODUCT CONCERNED AND LIKE PRODUCT

### 1. Introduction

(16) As set out in recital 29 of the provisional Regulation, the product concerned as provisionally defined is fatty-acid mono-alkyl esters and/or paraffinic gasoils obtained from synthesis and/or hydro-treatment, of non-fossil origin, in pure form or as included in a blend originating in Argentina and Indonesia, currently falling within CN codes ex 1516 20 98, ex 1518 00 91, ex 1518 00 95, ex 1518 00 99, ex 2710 19 43, ex 2710 19 46, ex 2710 19 47, 2710 20 11, 2710 20 15, 2710 20 17, ex 3824 90 97, 3826 00 10 and ex 3826 00 90 ('the product concerned', commonly referred to as 'biodiesel').

### 2. Claims

(17) One Indonesian exporting producer claimed that contrary to what was stated in recital 34 of the provisional Regulation, palm methyl ester (PME) produced in Indonesia was not a like product to rapeseed methyl ester (RME) and other biodiesels produced in the Union, or soybean methyl ester (SME) produced in Argentina because of the much higher CFPP of PME which means that it must be blended before use in the Union.

(18) This claim is rejected. PME produced in Indonesia is in competition with biodiesel produced in the Union, which is not just RME but also biodiesel made from palm oil and other feedstocks. PME can be used throughout the Union throughout the year, by blending with other biodiesels before use, in the same way as RME and SME. PME is therefore interchangeable with biodiesel made in the Union and therefore is a like product.

(19) Recital 35 of the provisional Regulation states the claim of one Indonesian producer that fractionated methyl esters should be excluded from the product scope of this proceeding. The same producer maintained this request in its comments on provisional disclosure restating their argument from prior to provisional disclosure.

(20) The Union industry however disputed this claim stating that fractionated methyl esters were biodiesel and should remain within the product scope.

(21) Following comments received after provisional stage, the decision of the Commission in recital 36 of the provisional Regulation is confirmed. Regardless of the fact that various fatty acid methyl esters have different Chemical Abstracts Service ('CAS') numbers; that different processes are used to produce those esters; and that they have possible different uses, fractionated methyl esters are still fatty acid methyl esters and can still be used for fuel use. Given the difficulties of distinguishing one fatty acid methyl ester from another without chemical analysis at the point of importation, and the possibility of circumvention of the duties as a result, with PME biodiesel being declared as fractionated methyl ester made from palm oil, the claim remains rejected.

(22) In recital 37 of the provisional Regulation it is mentioned that one European importer of palm kernel oil fatty acid methyl ester ('PKE') requested that imports of this product be subject to End Use Relief, or otherwise be excluded from the product scope of this proceeding.

(23) The Union industry commented after provisional disclosure on the use of end use relief for imports of PKE and the possibility of circumvention of the duties proposed. They opposed the Commission's authorisation to use such a scheme for relief of anti-dumping duties due to the fungible nature of biodiesel; biodiesel declared for non-fuel use could be used for fuel as it has the same physical properties. PKE can be used for fuel use; the unsaturated fatty alcohol that is made out of PKE can also be further processed into biodiesel; and the control that Customs can apply on imports under End Use Relief is limited and the economic burden resulting from the use of this scheme remains significant.

(24) Following consultations on this issue and in view of the fact that biodiesel declared as for non-fuel use has the same physical properties as biodiesel for fuel use, it is not appropriate to allow End Use Relief for imports of PKE in the present case.

(25) One German importer repeated their request for product exclusion and/or End Use Relief for a particular fatty acid methyl ester manufactured from palm kernel oil (PKE) which was destined for use other than fuel in the EU. The comments made restated their position which had been rejected at provisional stage and no new evidence was provided that would change the conclusion that End Use Relief should not be granted and that PKE should remain within the product scope.

(26) One Indonesian exporting producer also referred to their claim for End Use Relief for fractionated methyl esters and requested End Use Relief for these imports for the manufacture of saturated fatty alcohol. As set out above, all requests for End Use Relief have been denied and the arguments set out by this interested party did not change that conclusion.

### 3. **Conclusion**

(27) In the absence of other comments regarding the product concerned and the like product, recitals 29 to 39 of the provisional Regulation are hereby confirmed.

## D. **DUMPING**

### 1. **Introductory remarks**

(28) Recitals 44 and 64 of the provisional Regulation explained that both the Argentine and the Indonesian biodiesel markets are heavily regulated by the State and thus domestic sales were not considered as being made in the ordinary course of trade. As a consequence, the normal value of the like product had to be constructed pursuant to Article 2(3) and (6) of the basic Regulation. That finding was not contested by any interested party and is therefore confirmed.

(29) For both Argentina and Indonesia the constructed normal value at provisional stage was calculated on the basis of the companies' own actual (and recorded) production costs during the IP, selling, general and administrative expenses ('SG&A') incurred and a reasonable profit margin. Recitals 45 and 63 of the provisional Regulation noted in particular that the Commission would further examine the claim that the Differential Export Tax systems ('DET') in Argentina and Indonesia distort raw material prices and that, therefore, the recorded costs of production did not reasonably reflect the costs associated with the production of the product concerned.

(30) The further investigation has demonstrated that indeed the DET systems depressed the domestic prices of the main raw material input in both Argentina and Indonesia to an artificially low level, as explained below in recitals 35 onwards for Argentina and recital 66 for Indonesia and, as a consequence, affect the costs of the biodiesel producers in both countries concerned. In view of this finding it is considered appropriate that this cost distortion of the main raw materials should be taken into account in establishing the normal values in both countries, given the particular market situation prevailing both in Argentina and Indonesia.

(31) The General Court has confirmed [1] that when the prices of raw materials are regulated in such a way that they are artificially low on the domestic market, it may be presumed that the cost of producing the product concerned is affected by a distortion. The General Court considered that under such circumstances, the Union institutions are entitled to conclude that one of the items in the records cannot be regarded as reasonable and that, consequently, such item can be adjusted.

[1] See for instance judgment T-235/08 of 7 February 2013 (Acron OAO and Dorogobuzh OAO against the Council).

(32) The General Court also concluded that it is apparent from the first subparagraph of Article 2(5) of the basic Regulation that the records of the party concerned do not serve as a basis for calculating normal value if the costs associated with the production of the product under investigation are not reasonably reflected in those records. In that case, the second sentence of the first subparagraph provides that the costs are to be adjusted or established on the basis of sources of information other than those records. That information may be taken from the costs incurred by other producers or exporters or, when that information is not available or cannot be used, any other reasonable source of information, including information from other representative markets.

(33) In the provisional calculations, the actual domestic purchase price of soya beans and the actual booked cost for crude palm oil was used when computing the costs of production for respectively Argentine and Indonesian producing exporters.

(34) Given that certain costs of production, and namely the costs of the main raw material and (soybean oil and soya beans in Argentina and crude palm oil in Indonesia), were found to be distorted, they were established on the basis of reference prices published by the relevant authorities of the countries concerned. Those prices reflect the level of international prices.

## 2. **Argentina**

### 2.1. *Normal Value*

(35) As mentioned above, the Commission has now reached the conclusion that the DET system in Argentina distorts the costs of production for biodiesel producers in that country. The investigation established that during the IP export taxes on raw material (35 % on soya beans and 32 % on soybean oil) were significantly higher than the export taxes on the finished product (nominal rate of 20 % on biodiesel, with an effective rate of 14,58 % taking into account a tax rebate). As a matter of fact, the difference between the export tax on soya beans and biodiesel was 20,42 percentage points, and between soya bean oil and biodiesel was 17,42 percentage points during the IP.

(36) To determine the level of the export tax for soya beans and soya bean oil, the Argentine Ministry of Agriculture, Livestock and Fisheries publishes on a daily basis the FOB price for soya beans and soya bean oil — 'the reference price' ([1]). This reference price reflects the level of international prices ([2]) and is used to calculate the amount of the export tax to be paid to the tax authorities.

(37) The domestic prices follow the trends of the international prices. The investigation established that the difference between the international and the domestic price of soya beans and soya bean oil is the export tax on the product and other expenses incurred for exporting it. The domestic reference prices of soya beans and soya bean oil are also published by the Argentine Ministry of Agriculture as the 'FAS theoretical price' ([3]). The producers of soya beans and soya bean oil therefore obtain the same net price no matter whether they sell for export or domestically.

(38) In conclusion, the domestic prices of the main raw material used by biodiesel producers in Argentina were found to be artificially lower than the international prices due to the distortion created by the Argentine export tax system and, consequently, the costs of the main raw material were not reasonably reflected in the records kept by the Argentinean producers under investigation in the meaning of Article 2(5) of the basic Regulation as interpreted by the General Court as explained above.

(39) The Commission has therefore decided to revise recital 63 of the provisional Regulation and disregard the actual costs of soya beans (the main raw material purchased and used in the production of biodiesel) as recorded by the companies concerned in their accounts and to replace them with the price at which those companies would have purchased the soya beans in the absence of such a distortion.

(40) In order to establish the cost at which companies concerned would have purchased the soya beans in the absence of such a distortion, the Commission took the average of the reference prices of soya beans published by the Argentine Ministry of Agriculture for export FOB Argentina during the IP ([4]).

(41) The association of Argentine exporting producers (CARBIO) and the Argentine authorities claimed that an adjustment to the costs borne by the companies under Article 2(5) of the basic Regulation is only possible when the records, and not the costs incurred by the companies, do not reasonably reflect the costs associated with the production and sale of the product concerned. They stated that in practice the Commission added the export taxes to the price paid by the companies when purchasing soya beans, thus including in the costs of productions an item which is not associated with the production or sale of the product concerned. They

([1]) Resolution 331/2001 of the Ministry of Agriculture, Livestock and Fisheries.

([2]) The main market which is considered to determine the level of the international price of soya beans and soya bean oil is Chicago Board of Trade.

([3]) The FAS theoretical value is calculated by discounting from the official FOB value all costs included in the export process.

([4]) http://64.76.123.202/site/agricultura/precios_fob_-_exportaciones/index.php

added that the General Court's ruling 'Acron' quoted in the disclosure document ([1]) is based on a wrong interpretation of Article 2.2.1.1 of the WTO Anti-Dumping Agreement (ADA), it is currently being appealed before the Court of Justice and in any event the factual considerations are different from those in the present case, since raw material prices in Argentina are not 'regulated' as it is the gas price in Russia and are not distorted but determined freely without any State intervention and therefore there is not a particular market situation in Argentina that would allow the Commission to apply Article 2(5) of the basic Regulation. They declared that the DET system in Argentina is not inconsistent with any trade rules. In addition, CARBIO claimed that, since export taxes were not taken into account when establishing the export price, the Commission did not make a fair comparison between constructed normal value (which takes into account export taxes) and export price (which does not take into account export taxes).

Moreover, they claimed that by referring to the international prices of soya beans as established in the Chicago Board of Trade (CBOT) when constructing normal value, but disregarding the gains or losses linked to the hedging activities at the CBOT when establishing the export price (see below), again the Commission did not make a fair comparison between normal value and export price. Furthermore CARBIO claimed that by mere replacing the costs recorded by the companies under investigation with an international price, the Commission did not take into account the natural competitive advantage of the Argentine producers. Finally, CARBIO complained that the Commission did not take into account the fact that in the absence of the DET in Argentina, the CBOT prices of soya beans would have been much lower.

(42) These claims must be rejected. Even if the facts of the 'Acron' case are not the same as the facts in the present case, the General Court has nevertheless established the principle of law that if the costs associated with the production of the product under investigation are not reasonably reflected in the records of the companies, they do not serve as a basis for calculating normal value. In the 'Acron' case the costs were not reasonably reflected in the records of the company concerned because the gas price was regulated. In the present case it was established that the costs associated with the production of the product concerned are not reasonably reflected in the records of the companies concerned as they are artificially low due to the distortion caused by the Argentine DET system. This holds true regardless of whether or not DET systems in general may be as such contrary to the WTO Agreement. Furthermore, the Commission considers that the General Court based itself on a correct interpretation of the ADA. In fact, in China — Broilers ([2]), the panel found that although Article 2.2.1.1 of the ADA sets up a presumption that the books and records of the respondent shall normally be used to calculate the cost of production, the investigating authority retains the right to decline to use such books if it determines that they are either (i) inconsistent with GAAP or, (ii) do not reasonably reflect the costs associated with the production and sale of the product under consideration. However, when making such a determination to derogate from the norm, the investigating authority must set forth its reasons for doing so. Consistent with this interpretation, in view of the distortion created by the DET system, which creates a particular market situation, the Commission replaced the costs recorded by the companies concerned for the purchase of the main raw material in Argentina with the price that would have been paid in the absence of the established distortion. The fact that from a pure numerical point of view the result is similar does not mean that the methodology applied by the Commission consisted in simply adding the export taxes to the costs of the raw material. International prices of commodities are set based on supply and demand and there is no evidence that the DET system in Argentina affects the CBOT prices. Therefore, all claims and allegations that by using an international price the Commission did not make a fair comparison between normal value and export price are unfounded. The same applies to the claim that the Commission did not take into account the natural competitive advantage of the Argentine producers, because the replacement of the costs recorded by the companies was due to the abnormally low price of raw material in the domestic market, rather than to a comparative advantage.

(43) In recital 45 of the provisional Regulation, it was explained that since domestic sales were not considered as being made in the ordinary course of trade, normal value had to be constructed using a reasonable amount for profit of 15 % pursuant to Article 2(6)(c) of the basic Regulation. Some exporting producers claimed that the percentage used by the Commission as a reasonable profit (15 %) when constructing normal value was unrealistically high and a radical change in the established practice in a number of other investigations in similar commodity-related markets (i.e. where the profit used was about 5 %).

([1]) Judgment T-235/08 of 7 February 2013 (Acron OAO and Dorogobuzh OAO against the Council).

([2]) Panel Report, China — Anti-Dumping and Countervailing Duty Measures on Broiler Products from the United States (WT/DS427/R, adopted 25 September 2013), para. 7.164.

(44) This claim must be rejected. First of all, it is incorrect that the Commission uses systematically a 5 % profit margin when constructing normal value. Every situation is assessed on its own merits taking into account the specific circumstances of the case. For example, in the 2009 biodiesel case against the United States, various different profit levels were used with the weighted average profit being well above 15 %. Second, the Commission looked also at the short and medium term borrowing rate in Argentina which is around 14 % according to the World Bank data. It certainly seems reasonable to expect a higher profit margin to be obtained when doing business in the domestic biodiesel markets than the borrowing cost of capital. Furthermore, this profit is even lower than the profit realised during the IP by the producers of the product concerned, albeit that level results from distortions in costs brought about by the DET and domestic biodiesel prices regulated by the State. Therefore, and for the reasons explained above, it is maintained that 15 % profit is a reasonable amount that can be achieved by a relatively new, capital-intensive industry in Argentina.

(45) Following definitive disclosure, CARBIO and the Argentine authorities claimed that (i) the reference to the profit levels in the US case was unjustified; (ii) the reference of the medium-term borrowing rate lacks logic, was never used in the past and if such a benchmark is to be used, it should not be that of Argentina because investments were made in US dollars together with foreign entities; (iii) the profit actually earned by the Argentine producers could not be taken into account due to the particular market situation; and (iv) by comparison the Union industry target profit was set at 11 %.

(46) Those claims must be rejected. The Commission considered that a 15 % profit margin was reasonable for the biodiesel industry in Argentina, since in that country during the IP it was still a young and capital intensive industry. The reference to the profit margin in the US case was made to rebut the claim that the Commission uses systematically a 5 % profit margin when constructing normal value. The reference to the medium-term borrowing rate also was not meant to set a benchmark but to test the reasonableness of the margin used. The same applies to the profit actually earned by the sampled companies. On the other hand, since the purpose of constructing normal value is different from the calculation of the target profit for the Union industry in the absence of dumped imports, any comparison between the two is irrelevant. Therefore, recital 46 of the provisional Regulation is hereby confirmed.

(47) One exporting producer manufactures biodiesel partly in its own plants and partly via a tolling agreement with an independent producer. This exporting producer requested that its cost of production be recalculated using a different weighted average of its own cost of production and of the cost of production of the toller than the one used by the Commission at provisional stage. This request was analysed and found to be justified and the cost of production for the company concerned was recalculated accordingly.

(48) The Commission received other minor company-specific claims but they became moot following the change in methodology of constructing the normal value as explained above. Therefore, the findings in recitals 40 to 46 of the provisional Regulation are, with the modifications explained above, hereby confirmed.

2.2. *Export price*

(49) In recital 49 of the provisional Regulation, it was explained that when export sales were made through related trading companies located inside the Union, adjustments were made to the export price, including for the profit accruing to the related trader in accordance with Article 2(9) of the basic Regulation. For the purpose of that calculation, a level of profit of 5 % for the related trader inside the Union was considered reasonable. Two exporting producers claimed that a 5 % profit margin for the related trader within the Union was too high in the commodity trading business and that either no profit, or a lower percentage should be used (up to 2 % depending on the companies).

(50) No evidence was provided in support of this claim. In these circumstances the 5 % profit level for related traders within the EU is confirmed.

(51) Following definitive disclosure, CARBIO maintained that a profit margin of 5 % was too high in the commodity trading business and referred to a study prepared by KPMG specifically for this purpose and submitted to the Commission on 1 July 2013 following disclosure of the provisional Regulation. The Commission considered that the findings of the study could not be relied upon due to the limitations to the analysis referred to in the study itself, which led to a selection of a limited number of trading companies, half of which were not selling agricultural products. Therefore, the evidence provided is considered to be inconclusive. As a consequence, the 5 % margin of profit for the related traders in the EU is confirmed.

(52) One exporting producer complained that when establishing the export price the Commission did not take into account the so-called 'hedging results', i.e. the gain or losses incurred by the producer when selling and purchasing future contracts of soybean oil at the Chicago Board of Trade (CBOT). The company insisted that hedging is a necessary element of the biodiesel business because of the volatility of raw material price, and that the net revenue for the biodiesel seller is not only the price paid by the purchaser, but also the profit (or loss) of the underlying hedging operations.

(53) That claim must be rejected because Article 2(8) of the basic Regulation clearly provides that the export price shall be the price actually paid or payable for the product when sold for export, regardless of any separate — albeit related — gain or loss linked to hedging practices.

(54) In the absence of any further comments regarding export prices, recitals 47 to 49 of the provisional Regulation are, with the changes mentioned above, hereby confirmed.

2.3. *Comparison*

(55) In recital 53 of the provisional Regulation, it was explained that when export sales were made through related trading companies located outside the EU, the Commission examined whether the related trader should be treated as an agent working on a commission basis and, if so, an adjustment was made in accordance with Article 2(10)(i) of the basic Regulation to take account of a notional mark-up received by the trader.

(56) One company claimed that the profit margin used by the Commission for the related trader outside the EU as a notional mark-up was too high and that a lower profit margin would be more reasonable.

(57) The Commission examined carefully the arguments put forward by the exporting producer, but concluded that in light of the extensive activities carried out by the related traders, a profit margin of 5 % was considered reasonable. Therefore, that claim must be rejected.

(58) In the absence of any other comments regarding comparison, recitals 50 to 55 of the provisional Regulation are hereby confirmed.

2.4. *Dumping margins*

(59) All cooperating Argentine exporting producers requested that if an anti-dumping duty were to be imposed on imports of biodiesel from Argentina, there should be a single duty for all cooperating exporting producers, based on the weighted average of the anti-dumping duties of all exporting producers in the sample. They supported this request by claiming that all sampled producers have commercial or other links among each other, they produce, sell, loan or swap biodiesel to each other and often the product of various companies is loaded together in the same ocean vessel and shipped to the EU and it is no longer possible for customs authorities to identify and distinguish the product of different producers. These peculiar circumstances were said to render the imposition of individual duties impracticable.

(60) Notwithstanding the fact that the request comes from all exporting producers, even including those with a lower individual dumping margin than the weighted average margin, and despite the potential simplification for the customs authorities, this request should be rejected. Indeed, alleged practical difficulties should not be used as an excuse to derogate from the provisions of the basic Regulation unless it is unavoidable. In this case, the companies' practice to swap, borrow or otherwise mingle the product concerned does not in itself render the imposition of individual duties impracticable in the meaning of Article 9(6) of the basic Regulation.

(61) Three companies requested that their names be included in the list of cooperating exporting producers in order to benefit from the anti-dumping duty rate of the cooperating non-sampled companies rather than the residual duty for 'all other companies'.

(62) Two of the three companies were already manufacturing biodiesel for the domestic market or under tolling agreements for other exporting producers during the IP, but they were not themselves exporting to the Union. The third company was not producing biodiesel during the IP since its plant was still under construction at that time.

(63) The Commission considers that the conditions for being considered a cooperating exporting producer are not met in the cases of the three companies referred to above. This applies not only to the company which was not producing biodiesel at all during the IP, but also to the companies which cooperated with the investigation by submitting a sampling form, since in their sampling reply they made it clear that they were producing for the domestic market or for third parties but they were not exporting biodiesel to the Union on their own name.

(64) This request must therefore be rejected and the 'residual' anti-dumping duty should apply to the three companies in question.

(65) Taking into account the adjustments made to the normal value and to the export price as set out above, and in the absence of any further comments, the table in recital 59 of the provisional Regulation is replaced by the following and the definitive dumping margins, expressed as a percentage of the CIF Union frontier price, duty unpaid, are as follows:

| Company | Dumping margin |
|---|---|
| Louis Dreyfus Commodities S.A. | 46,7 % |
| Group 'Renova' (Molinos Río de la Plata S.A., Oleaginosa MoreNo Hermanos S.A.F.I.C.I. y A. and Vicentin S.A.I.C.) | 49,2 % |
| Group 'T6' (Aceitera General Deheza S.A., Bunge Argentina S.A.) | 41,9 % |
| Other cooperating companies | 46,8 % |
| All other companies | 49,2 % |

### 3. **Indonesia**

#### 3.1. *Normal Value*

(66) As mentioned above in recitals 28 to 34, the Commission has now reached the conclusion that the DET system in Indonesia distorts the costs of production of biodiesel producers in that country and that therefore the costs associated with the production and sale of the product concerned are not reasonably reflected in the records kept by the Indonesian producers under investigation.

(67) The Commission has therefore decided to revise recital 63 of the provisional Regulation and disregard the actual costs of crude palm oil (CPO), the main raw material purchased and used in the production of biodiesel, as recorded by the companies concerned in their accounts and to replace them with the price at which those companies would have purchased the CPO in the absence of such a distortion.

(68) The investigation has confirmed that the price level for the domestically traded CPO is significantly depressed as compared to the 'international' reference price, the difference being very close to the export tax applied to CPO. Since the DET system limits the possibilities to export CPO, it leads to larger quantities of CPO being available on the domestic market, hence putting pressure down on the domestic CPO prices. This constitutes a particular market situation.

(69) During the IP biodiesel exports had an export tax rate between 2 and 5 %. During the same period CPO exports had an export tax rate ranging between 15-20 % while the export tax for RBDPO ranged from 5-18,5 %. The different tariff rates apply according to the corresponding range of reference prices (which follow the international market trends and have nothing to do with quality differences). The export tax for the palm fruit is set at a flat rate of 40 %.

(70) For the reasons mentioned above, recital 63 of the provisional Regulation is revised and the cost of the main raw material (CPO) recorded by the companies concerned has, pursuant to Article 2(5) of the basic Regulation, been replaced by the reference export price (HPE) ([1]) for CPO published by the Indonesian Authorities which is in turn based on published international prices (Rotterdam, Malaysia and Indonesia). This adjustment is made in respect of CPO that was purchased from both related and unrelated companies. The cost of the own produced CPO within the same legal entity is accepted given that no evidence has been found that the cost of the own produced CPO within the same legal entity is affected by the distortion.

(71) All exporting producers from Indonesia as well as the Government of Indonesia claim that the replacement of the costs for CPO, as recorded by the companies, with the Indonesian reference export price for CPO is neither permissible under WTO rules nor under Article 2(5) of the basic Regulation and is hence illegal. In this regard the Government of Indonesia claimed that the Commission wrongly treated the Republic of Indonesia as a non-market economy. The arguments put forward by the companies can be summarised as follows. Firstly, the Commission has not demonstrated any reason to depart from the actual costs recorded or that these costs do not reasonably reflect the costs associated with the production of product concerned but has simply stated that the recorded costs are artificially low compared to international prices and should therefore be replaced.

This is contrary to WTO rules according to which the test for determining whether a particular cost can be used for calculating production costs is whether that cost is associated with the production and sale of the product and not whether that cost reasonably reflect market value. Secondly, even if Article 2(5) of the basic Regulation seemingly allows for an adjustment to be made, the application of that Article would be limited to situations where the State interferes directly on the market by setting or regulating the prices at an artificially low level. However, in this particular case, the

([1]) The HPE price is monthly set by the Indonesian authorities since September 2011 and averages the price information from the previous month from three different sources (i) CIF Rotterdam, (ii) CIF Malaysia, and (iii) the Indonesian commodity exchange market. The HPE price is set on the basis of the same sources but on a FOB basis. For the part of the IP before September 2011 (July-August 2011) only the Rotterdam price was used as the benchmark to establish the HPE for CPO.

Commission alleges that the domestic price of CPO, rather than being regulated by the State, is artificially low simply due to the export tax imposed on CPO. Even if this were to be true, any effect on the domestic price can only be considered as accidental or mere side-effects of the export tax system. Thirdly, the Commission wrongly relies on the Acron judgment to justify the legality of the CPO adjustment. This judgment is currently under appeal and cannot therefore be relied upon as a precedent. In any case, the factual circumstance in Acron was different as it relates to a situation where, contrary to CPO prices in Indonesia which are set freely on the market, the gas prices had been regulated by the State. Finally, the Government of Indonesia claimed that the Article 2(5) adjustment was done solely to increase dumping margins by reason of differences in taxation.

(72) The claim that the adjustment under Article 2(5) of the basic Regulation is illegal under WTO and/or Union rules must be rejected. The basic Regulation has transposed the WTO anti-dumping agreement (ADA) and it is therefore considered that all provisions of this Regulation, including Article 2(5), are consistent with the Union's obligations under ADA. In this respect it is recalled that Article 2(5) of the basic Regulation is applicable to both market and non-market economies equally. As mentioned above (recital 42), the General Court established in the Acron case the principle of law that if the costs associated with the production of the product under investigation are not reasonably reflected in the records of the companies, they do not serve as a basis for calculating normal value and that such costs could be replaced with costs reflecting a price set by market forces pursuant to Article 2(5) of the basic Regulation. The fact that the Acron case concerned prices that were regulated by the State cannot, however, be interpreted as meaning that the Commission is precluded to apply Article 2(5) in respect to other forms of State intervention that distorts, directly or indirectly, a particular market by depressing prices to an artificially low level. The panel in China — Broilers has recently reached a similar conclusion when interpreting Article 2.2.1.1 of the ADA. In the present case the Commission has found that the costs associated with the production of the product concerned are not reasonably reflected in the records of the companies concerned because they are artificially low by virtue of the Indonesian DET system. It was therefore fully justified for the Commission to adjust the costs for COP under Article 2(5) of the basic Regulation. With regard to the claim by the Indonesian Government it is noted that that the Article 2(5) adjustment is based on the demonstrated difference between domestic and international CPO prices and not on any differences in taxation.

(73) Two exporting producers in Indonesia claimed that the Commission has failed to demonstrate that the price of Indonesian domestic CPO is distorted. They argue that Commission's basic assumption that the DET limits the possibilities to export CPO, thereby leading to larger quantities of CPO being available on the domestic market and hence depressing the domestic CPO prices is factually incorrect as CPO is exported in large quantities (70 % of all production). In any event, even if the domestic CPO market would be considered distorted by virtue of the DET, also the HPE price is equally distorted, as it is based on international export prices, which include the export tax. Therefore, the HPE price for CPO cannot be used as an appropriate benchmark price for adjusting the cost of CPO.

(74) Notwithstanding the fact that CPO is exported from Indonesia in large quantities, the investigation has revealed that the domestic price of CPO is artificially low as compared with international prices. Moreover, the price difference found is close to the export tax imposed on DET. It is therefore reasonable to conclude that the low domestic price level is a result of a distortion by virtue of the DET. In addition, international prices of commodities, including CPO, are determined based on supply and demand, reflecting the dynamics of market forces. No evidence have been adduced that would indicate those market forces have become distorted by virtue of the Indonesian DET. The claim that the HPE is an inappropriate benchmark is therefore rejected.

(75) One exporting producer, which was found not to have representative domestic sales (recital 60 of the provisional Regulation) claimed that the Commission had erroneously made the representativity test on the basis of sales by related companies individually instead of the global sales of all companies within the group. It nonetheless acknowledges that this alleged error had no impact on the provisional finding made in respect of it. It is recalled that in respect to this exporting producer all related companies failed individually the representativity test. Therefore, even if this claim was to be founded it is clear that a representativity test on the basis of the totality of domestic sales of the all related companies could not, as acknowledged by the exporting producer, have had an impact on the provisional findings. In the absence of any further comments, recitals 60 to 62 of the provisional Regulation are hereby confirmed.

(76) One party claimed that in relation to recital 63 of the provisional Regulation an overstated SG&A was used for that party. After having examined this claim, it appeared that the SG&A for both domestic and export sales was included in the construction of normal value. The necessary corrections to use the SG&A for only the domestic sales were accordingly made.

(77) One party questioned the construction of normal value and in particular the choice of methodology under Article 2(6) as stated in recital 65 of the provisional Regulation. Article 2(6) provides for three alternative methodologies to establish SG&A and profit in case the actual data of the company cannot be used. This party claimed that these three methodologies must be considered in the order in which they are presented and that therefore Article 2(6)(a) and (b) should be considered first to be applied.

(78) Whereas the provisional Regulation appeared to address only the methodology under Article 2(6)(c), the following recitals elaborate why Article 2(6)(a) and (b) are not applicable in this case.

(79) Article 2(6)(a) is not applicable given that no actual amounts for any of the sampled Indonesian (and Argentinian) companies were established given the fact that they did not have any sales in the ordinary course of trade. Therefore, no data on actual amounts of any other exporter or producer (in the sample) is available to apply Article 2(6)(a).

(80) Article 2(6)(b) is not applicable given that all Indonesian (and Argentinian) companies in the sample do not have sales of products of the same general category of products that are made in the ordinary course of trade.

(81) In relation to Article 2(6)(b), this party also argued that the Basic Regulation is inconsistent with the WTO Regulation to the extent that it contains the requirement in Article 2(6)(b) that the sales should be made in the ordinary course of trade. However, as mentioned in recital 72 above, the basic Regulation has transposed the WTO anti-dumping agreement (ADA) and it is therefore considered that all provisions of this Regulation, including Article 2(6), are consistent with the Union's obligations under ADA and that the sales in the ordinary course of trade element is fully compliant.

(82) Therefore, the choice of applying Article 2(6)(c) in using any other reasonable method to determine a profit margin is confirmed.

(83) Furthermore, several parties considered the 15 % profit margin used when constructing normal value to be excessive. They claim that the provisional Regulation does not explain how the Commission has calculated the 15 % and therefore they assume that the Commission took the 15 % from the profit margin used in the injury calculations. They claimed that in several other cases concerning commodities the Commission used profit margins in the region of 5 %. Several parties suggested using the profit margin of the bioethanol case from the United States. One party also suggested using the lower profit margin of its sales of a blend of biodiesel with mineral diesel. In addition, the Government of Indonesia claimed that it is duplicative to replace the CPO cost under Article 2(5) of the basic Regulation while using at the same time a 15 % profit margin under Article 2(6)(c) which would reflect the profit margin of an undistorted market.

(84) First, it is incorrect that the Commission systematically uses a 5 % profit margin when constructing normal value. Every situation is assessed on its own merits taking into account the specific circumstances of the case. For example, in the 2009 biodiesel proceeding against the United States, various different profit levels were used with the weighted average profit being well above 15 %. Second, given that the short and medium term borrowing rate in Indonesia is around 12 % according to World bank data, it seems reasonable to expect that the profit margin of doing business in the domestic biodiesel market would be higher than the borrowing cost of capital. The reference to the medium-term borrowing rate is not meant to set a benchmark but to test the reasonableness of the margin used. Third, whether or not the sales of a blend of biodiesel with mineral diesel fall under the same general category of products, Article 2(6)(b) of the basic Regulation states, as already mentioned in recital 80 above, that such sales should be made in the ordinary course of trade. Given that the domestic sales of biodiesel are not in the ordinary course of trade, the sales of the blend of biodiesel with mineral diesel is not, mutatis mutandis, considered to be in the ordinary course of trade. Therefore, and for the reasons explained above, 15 % profit is a reasonable amount that can be achieved by a relatively new, capital-intensive industry in Indonesia. The argument of the Government of Indonesia regarding a duplicative effect cannot be accepted since a cost adjustments under Article 2(5) and the reasonable profit under Article 2(6)(c) are two clearly distinct issues. Recital 65 of the provisional Regulation is hereby confirmed.

(85) One party claimed that since the HPE price for CPO is inclusive of international transportation costs and since the purpose of the adjustment of the domestic price of CPO to the level of the international price of CPO is to arrive at an undistorted price of domestic CPO, the HPE price for CPO should be adjusted downwards to exclude transportation costs.

(86) That claim must be rejected. The Commission was considering a number of alternatives for the selection of a most suitable price which should be used as an international reference price. It should be recalled that the Indonesian authorities themselves use the HPE price as a benchmark to calculate the monthly level of export duties. The HPE price as defined by the Indonesian authorities was therefore considered the most appropriate international reference price to be used as a benchmark for establishing the level of distortion of the costs of production of biodiesel in Indonesia.

(87) Two parties submitted that the Commission failed to take into account that they manufacture biodiesel from feedstock which is different than CPO, i.e. Palm Fatty Acid Distillate ('PFAD'), Refined Palm Oil ('RPO') or Refined Palm Stearin ('RST'). By failing to take into account the parties' usage of the actual raw material in their production of biodiesel, the CPO adjustment (as described in recital 70) was applied on the incorrect raw material used and has therefore lead to an incorrect level of the constructed normal value.

(88) Those claims must be rejected. It has to be underlined that the Commission only replaced the cost of CPO purchased, from related and unrelated suppliers, for the production of biodiesel. As regards by-products such as PFAD, RPO and RST which result from the processing of purchased CPO and which are also further processed to produce biodiesel, no adjustments were made.

(89) Three parties claimed that the Commission failed to recognise that their purchase of CPO from related companies should be treated equally to the in-house production and therefore no adjustment pursuant to Article 2(5) should apply (as explained in recital 70 above). The parties claim that transactions within the group were realised at arm's length and should therefore not be adjusted and replaced by an international price. In addition, one exporting producer claimed that the constructed normal value should be calculated on a monthly basis during the IP.

(90) As the internal transfer price cannot be considered reliable it is the Commission's standard practice to verify whether transactions between related parties are indeed made at arm's length. In order to so do, the Commission compares the price between related companies to the underlying market price. Since the underlying domestic market price is distorted the Commission cannot make such verification. Therefore, the Commission has to replace such an unreliable price with a reasonable price that would be applicable under arm's length in normal market conditions. In this case, the international price. With regard to the claim for monthly calculations for the constructed normal value, the information provided and verified did not contain sufficiently detailed information to allow such a calculation. Both claims were therefore rejected.

(91) The Union Industry claimed that the cost of the own produced CPO within the same legal entity should also be adjusted under Article 2(5) of the basic Regulation as it is also affected by the distortion which resulted from the DET.

(92) That claim must be rejected. While the raw materials are being passed along the biodiesel production process at various stages of refinery/processing, the costs of those production stages can be treated as reliable since they are being realised within the same legal entity and the issue of unreliable transfer pricing as described above does not occur.

(93) One exporting producer claimed that the Commission should have deducted so called price allowances from the constructed normal value. That claim cannot be accepted. The constructed normal value was constructed on the basis of costs. It would therefore be inappropriate to make any allowances on the basis of price considerations.

3.2. *Export price*

(94) One party questioned the establishment of the export price, claiming that both the hedging gains and losses should be taken into account and alleging an inconsistent accounting treatment of biodiesel hedging gains and losses.

(95) The claim that both the hedging gains and losses should be taken into account must be rejected. Article 2(8) of the basic Regulation clearly provides that the export price shall be the price actually paid or payable for the product when sold for export, regardless of any separate — albeit related — gain or loss linked to hedging practices. Therefore, the methodology in recitals 66 and 67 of the provisional Regulation are hereby confirmed.

(96) The Commission acknowledges that an inconsistent accounting treatment of the biodiesel hedging gains and losses of one party occurred at the provisional stage. This claim is accepted and the necessary corrections have been made.

(97) In relation to recital 68 of the provisional Regulation, one party claimed that the 5 % profit margin used for related trading companies located inside the Union results in an excessive return on capital and overstates the profit that is usually incurred on sales of biodiesel by unrelated traders. It claims that a typical return on capital corresponds to a profit margin of 1,3-1,8 %.

(98) Given the absence of cooperation by unrelated importers and given the fact that trading companies are service businesses without significant capital investments rendering the return on capital allegation above as irrelevant, the Commission rejects the above claim and considers 5 % profit margin to be reasonable in this case. Recital 68 of the provisional Regulation is therefore confirmed.

(99) In relation to recital 69 of the provisional Regulation, one party claimed that the premium for double-counting biodiesel should be added to the export price, given that this is a mere implementation of the Italian law.

(100) Even if the Commission would accept this claim and add the premiums to the export price, the premiums would have to be deducted again under Article 2(10)(k) in order to compare the export price with the same normal value with due account taken for differences that affect price comparability. Given that in Indonesia there is no premium for double counting biodiesel, the higher export price in Italy would therefore not be directly comparable. That claim is therefore rejected and recital 69 of the provisional Regulation is hereby confirmed.

(101) Following the definitive disclosure that party repeated its claim. No substantial additional arguments were however brought forward as to alter the Commission's assessment. Therefore recital 69 of the provisional Regulation remains confirmed.

(102) After the final disclosure, several exporting producers drew the Commission's attention to alleged clerical errors in the dumping calculations. Those claims were examined and, where warranted, corrections were made to the calculations.

3.3. *Comparison*

(103) In the absence of any comments regarding comparison, recitals 70 to 75 of the provisional Regulation are hereby confirmed.

3.4. *Dumping margins*

(104) Taking into account the adjustments made to the normal value and to the export price as set out in recitals above, and in the absence of any further comments, the definitive dumping margins, expressed as a percentage of the CIF Union frontier price, duty unpaid, are as follows:

| Company | Dumping margin |
|---|---|
| PT. Ciliandra Perkasa, Jakarta | 8,8 % |
| PT. Musim Mas, Medan | 18,3 % |
| PT. Pelita Agung Agrindustri, Medan | 16,8 % |
| PT. Wilmar Bioenergi Indonesia, Medan and PT. Wilmar Nabati Indonesia, Medan | 23,3 % |
| Other cooperating companies | 20,1 % |
| All other companies | 23,3 % |

## E. **INJURY**

### 1. **Union production and Union industry**

(105) The provisional Regulation, in recitals 80 to 82, defined the Union industry and confirmed that three companies were excluded from the definition of the Union industry due to their reliance on imports from the countries concerned, that is to say that they imported significantly more biodiesel from the countries concerned than they produced themselves.

(106) Two further companies were excluded from the definition of the Union industry as they had not produced biodiesel during the investigation period.

(107) Comments were received after publication of the provisional Regulation that other companies should be excluded from the definition of the Union industry for importing biodiesel from the countries concerned, and also because of their relationship to exporting producers in Argentina and Indonesia, thereby shielding themselves from the negative consequences of dumping.

(108) Those comments are rejected. After analysing the claim regarding relationships between exporting producers and the Union industry, it was found that a holding company held shares in both an Argentinian exporting producer and a Union producer.

(109) Firstly, those companies were found to be openly competing with each other for the same customers on the Union market, thereby showing that their relationship did not have any impact on the business practices of either the Argentinian exporting producer or the Union producer.

(110) Following definitive disclosure, an interested party requested information as to the Commission's conclusion that Argentinian exporters and the Union industry were competing for the same clients on the European market. The investigation of Union producers, and the investigation of Argentinian exporters, showed this fact and no evidence has been provided to substantiate any allegation that Argentinian exporters and Union producers had agreed not to compete in sales of biodiesel to end users. The number of end users is relatively small and composed in the main of the large oil refineries, which purchase both from Union producers and importers.

(111) Secondly, the main centre of interest of the Union producer referred to in recital 108 above was found to be within the Union, in particular their production and related sales activities as well as research activities. As a result, the conclusion was that the relationship was not a reason to exclude this company from the definition of the Union industry under Article 4(1)(a) of the basic Regulation.

(112) The fact that some of the Union industry has been importing biodiesel from the countries concerned is in itself not enough to change the definition of the Union industry. As explained in the provisional Regulation, the imports of the Union industry from the countries concerned were made in self-defence. Furthermore, it was found that the centre of interest of some Union producers who imported from the countries concerned remained in the Union — these companies were producing more in volume terms than they were importing and their research functions were carried out in the Union.

(113) One interested party alleged that the Union industry should also contain those companies that were purchasing biodiesel and blending it with mineral diesel, as these blends were also product concerned. This claim is rejected. The product concerned is biodiesel, in pure form or as included in a blend Therefore the producers of the product concerned are producers of biodiesel and not the companies that mix the biodiesel with the mineral diesel.

(114) The definition of the Union industry as set out in recitals 80 to 82 of the provisional Regulation is therefore confirmed, along with the volume of production for the IP as set out in recital 83 of the provisional Regulation.

### 2. **Union consumption**

(115) After provisional disclosure the Union industry made a small correction to their sales for 2009, thereby adjusting the Union consumption for that year. This correction does not change the trend or the conclusions drawn from the data in the provisional Regulation. Table 1 is corrected below. In the absence of any comments, recitals 84 to 86 of the provisional Regulation are hereby confirmed.

| Union consumption | 2009 | 2010 | 2011 | IP |
|---|---|---|---|---|
| Tonnes | 11 151 172 | 11 538 511 | 11 159 706 | 11 728 400 |
| *Index 2009 = 100* | 100 | 103 | 100 | 105 |

*Source*: Eurostat, data from the Union industry

### 3. **Cumulative assessment of the effects of the imports from the countries concerned**

(116) In recitals 88 to 90 of the provisional Regulation the Commission determined that the conditions were met for cumulative assessment of the effects of imports from Argentina and Indonesia. This was challenged by one interested party who alleged that PME from Indonesia was not competing with biodiesel made in the Union on the same basis as SME from Argentina, and that PME was cheaper than Union produced biodiesel as the raw material (or 'feedstock') was cheaper than the feedstock available in the Union.

(117) Those arguments are rejected. Both SME and PME are imported into the Union, and are also manufactured within the Union, and are blended with RME and other biodiesels manufactured within the Union before being sold or blended with mineral diesel. The blenders have the choice of purchasing biodiesel from different feedstocks and different origins to produce their final product, based on the market and the climatic conditions throughout the year. PME is sold in larger quantities during the summer months and smaller quantities during the winter months, but it is still in competition with RME and Union made biodiesel and also SME from Argentina.

(118) Recital 90 of the provisional Regulation is therefore confirmed.

### 4. **Volume, price and market share of dumped imports from the countries concerned**

(119) One interested party challenged the import data set out in Table 2 of the provisional Regulation, stating that imports from Indonesia were much lower than presented in the table. Import data in Table 2 was based on Eurostat data, which was checked carefully and found to be correct, and in line with the data collected from Indonesian exporters. Biodiesel is a relatively recent product, and the customs codes applicable to imports of biodiesel have changed over recent years. Therefore, when extracting data from Eurostat, codes applicable at the time must be used in order to ensure that the data is accurate. This explains why the interested party's extraction of data is incomplete and it shows lower imports than the full dataset presented in Table 2.

(120) Given the small change in the Union consumption in Table 1, the market share for Argentina for 2009 in Table 2 has also slightly changed, while for Indonesia there was no change. This does not change the trends of the data or the conclusions drawn from them. The market share is corrected below:

| | 2009 | 2010 | 2011 | IP |
|---|---|---|---|---|
| Imports from Argentina | | | | |
| Market share | 7,7 % | 10,2 % | 12,7 % | 10,8 % |
| *Index 2009 = 100* | 100 | 135 | 167 | 141 |

*Source*: Eurostat

5. **Price undercutting**

(121) As set out in recitals 94 to 96 of the provisional Regulation, in order to determine price undercutting, the price of imports from Argentina and Indonesia was compared to the sales price of the Union industry, using data from the sampled companies. In this comparison the biodiesel imported by the Union industry for resale was excluded from the calculations of price undercutting.

(122) Interested parties noted that the methodology used, being a comparison of the Cold Filter Plugging Point ('CFPP'), was not the same as used in a previous anti-dumping investigation involving biodiesel from the USA, where the comparison was made on feedstock.

(123) Unlike the exporting producers in Argentina and Indonesia, the Union industry does not sell biodiesel made from one feedstock, but blends several feedstocks together to produce the final biodiesel that is sold. The final customer is not aware of, nor concerned by, the composition of what they are purchasing once the product meets the required CFPP. What matters for a customer is the CFPP irrespective of which feedstock is used. In these circumstances, it was found to be appropriate in this proceeding to make the price comparison on the basis of the CFPP.

(124) For imports from Indonesia, which are at a CFPP of 13 or above, an adjustment was made, being the difference in price between the Union industry's sales of CFPP 13 and the Union industry's sales of CFPP 0, in order to compare the CFPP 13 and above from Indonesia with the CFPP 0 manufactured and blended in the Union. One Indonesian exporting producer noted that as the sales of CFPP 13 by the Union industry were made in small quantities per transaction, that these prices should be compared to similar sized transactions of CFPP 0. On inspection of transactions of CFPP 0 of a similar quantity per transaction, the difference in price found was in line with the difference using all transactions of CFPP 0, with differences in price both above and below the average price difference. As a result there was no change to the level of price undercutting found in the provisional Regulation in recital 97.

(125) One Indonesian exporting producer requested that the Commission disclose the full Product Control Number ('PCN') of the blends sold by the Union industry — the percentages of each feedstock in the sale made by the Union industry of their own production. Given that the comparison for injury purposes was made solely on the basis of the CFPP, this request was denied.

(126) One interested party claimed that there was a difference in price between biodiesel that met the criteria set out in the Renewable Energy Directive ('RED certified') and biodiesel that did not. It claimed that as imports from Indonesia were not RED certified, and that the price quoted for RED certified biodiesel was higher, an adjustment should be made.

(127) That claim was rejected. Almost all imports from Indonesia during the IP were RED certified. In any case, Member States implemented the sustainability criteria set out in the RED into their national legislation only during the course of 2012, so during most of the IP whether biodiesel was RED certified or not had no effect.

(128) Following definitive disclosure, one Indonesian exporting producer commented on the price undercutting calculations and claimed that PME imports from Indonesia should be compared to all sales of the Union industry. In fact the undercutting calculation has been to compare sales of PME from Indonesia with all sales of the Union industry at CFPP 0, by increasing the price of Indonesian PME imports by a price factor calculated by comparing the CFPP 0 sales of the Union industry with the CFPP 13 sales of the Union industry. The claim is therefore rejected. The claim of the same interested party that the injury calculations included imported product is factually incorrect and is therefore rejected. In any case, imported biodiesel and Union-produced biodiesel were blended together and sold at the same price as blends that did not include any imported biodiesel.

(129) One Indonesian exporting producer also challenged the calculation of post-importation costs. However, those costs were verified as the actual costs of importation of biodiesel minus delivery costs to the final destination and no change is necessary.

### 6. **Macroeconomic indicators**

(130) As set out in recital 101 of the provisional Regulation, the following macroeconomic indicators were analysed, based on data received covering the entire Union industry: production, production capacity, capacity utilisation, sales volume, market share, growth, employment, productivity, magnitude of the dumping margin and recovery from past dumping.

(131) Following provisional disclosure the Union industry noted that the capacity data that had been used in Table 4 of the provisional Regulation included capacity that had not been dismantled, but was not in such a state that it would have been available for use during the IP, or previous years, to manufacture biodiesel. They separately identified this capacity as 'idle capacity' which should not be counted as capacity available for use. The capacity utilisation figures in Table 4 were therefore understated. After close scrutiny of this resubmitted data, it was accepted and Table 4 is restated below. The capacity utilisation rate, which had been from 43 % to 41 % in the provisional Regulation, was now 46 % to 55 %. The Union industry also corrected the production data for 2009 to produce the table below:

| | 2009 | 2010 | 2011 | IP |
|---|---|---|---|---|
| Production capacity (tonnes) | 18 856 000 | 18 583 000 | 16 017 000 | 16 329 500 |
| *Index 2009 = 100* | 100 | 99 | 85 | 87 |
| Production volume (tonnes) | 8 729 493 | 9 367 183 | 8 536 884 | 9 052 871 |
| *Index 2009 = 100* | 100 | 107 | 98 | 104 |
| Capacity utilisation | 46 % | 50 % | 53 % | 55 % |
| *Index 2009 = 100* | 100 | 109 | 115 | 120 |

(132) Recital 103 of the provisional Regulation analysed the previous capacity utilisation data, noting that production increased while capacity remained stable. With the revised data production still increases, but useable capacity decreased during the same period. This shows that the Union industry was reducing available capacity in face of increased imports from Argentina and Indonesia and thereby reacting to market signals. This revised data is now more in line with the public statements of the Union industry and Union producers, stating that during the period under consideration production was stopped in several plants and that the capacity that had been installed was not immediately available for use, or only available for use with significant reinvestment.

(133) Several interested parties questioned the revised capacity and capacity utilisation data. However, no alternatives were provided by any interested party. The revision is based on the revised capacity data provided by the complainant, covering the entire Union industry. The revised data was cross-referenced to publicly available data concerning in particular idle capacity as well as capacity of producers that ceased operations due to financial difficulties. As explained above in Section 6, 'Macroeconomic indicators', the revised data provide a more accurate dataset of capacity available to produce biodiesel during the period under consideration than the dataset originally provided and published in the provisional Regulation.

(134) One interested party stated that the Union industry was not injured, as production volumes rose in line with consumption. This argument is rejected, as other important injury indicators clearly point to the existence of injury, in particular the loss of market share to imports from the countries concerned and the reduced profitability trend leading to losses.

(135) Another interested party argued that the Union industry was not injured if comparing trends only between 2011 and the IP as opposed to comparing the trends during the period from 1 January 2009 to the end of the IP ('the period considered'). Given that the IP covers half of 2011, a comparison between 2011 and IP is not accurate. Besides, for a comparison to be meaningful it is necessary to examine the trends relevant for the injury assessment during a period which is long enough as it was done in the present case. This claim is therefore rejected.

(136) The same interested party noted that the Commission had not published the total sales value of the Union industry in the provisional Regulation and requested that this figure be published. However, all relevant factors mentioned in Article 3(5) of the basic Regulation were examined, allowing a full assessment of injury. Sales value was collected, and verified, from sampled companies, who were representative of the Union industry as a whole.

(137) The same party also noted that the Union industry was able to increase employment and therefore there was no negative effect on the Union industry during the period of investigation.

(138) However, as explained in recital 106 of the provisional Regulation, employment in this capital intensive industry is relatively low. Therefore, small variations in the numbers can cause a large movement in the indexed data. The increase in overall employment does not negate the injury suffered by the Union industry as shown by other indicators.

(139) In the absence of any further comments, recitals 103 to 110 of the provisional Regulation are hereby confirmed.

### 7. **Microeconomic indicators**

(140) As set out in recital 102 of the provisional Regulation, the following microeconomic indicators were analysed, based on data verified at the sampled Union producers: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments and ability to raise capital.

(141) In the absence of any relevant comments, recitals 111 to 117 of the provisional Regulation are hereby confirmed.

### 8. **Conclusion on injury**

(142) Several parties contested the conclusion on injury put forward in the provisional Regulation on the basis that between the year 2011 and the IP some indicators appeared to have improved. While it is true that some indicators showed an upward trend between 2011 and the IP (e.g., production and sales), the industry was not in a position to pass on cost increases during this period as noted in recital 111 of the provisional Regulation. This resulted in a further worsening of the industry's position from losses of 0,2 % in 2011 to losses of 2,5 % in the IP. Therefore, it is considered that, even if the injury analysis were to be limited to the period 2011-IP, the industry would still be found to have suffered material injury.

(143) In the absence of other comments, recitals 118 to 120 of the provisional Regulation are hereby confirmed.

## F. **CAUSATION**

### 1. **Effect of the dumped imports**

(144) One interested party claimed that imports from Argentina could not be a cause of injury, as import volumes have remained stable from 2010 to the end of the IP, decreasing slightly from 2011 to the end of the IP.

(145) This data was taken from Table 2 of the provisional Regulation and is accurate. However the Commission's analysis runs from the start of the period considered to the end of the IP and on that basis imports have risen by 48 %, with an increase of 41 % in market share. In addition, as explained in recital 90 of the provisional Regulation, not only imports from Argentina but also imports from Indonesia were taken into account.

(146) Taking a year-on-year price comparison, the same interested party noted that prices of imports from Argentina rose at a faster pace than the sales prices of the Union industry. However, imports from Argentina still undercut those of the Union industry, which would explain why the Union prices could not rise as quickly.

(147) In the absence of any other comments as regards the effect of the dumped imports, recitals 123 to 128 of the provisional Regulation are hereby confirmed.

### 2. **Effect of other factors**

#### 2.1. *Imports from third countries other than the countries concerned*

(148) In the absence of comments, the conclusion that imports from other countries did not cause injury, as set out in recital 129 of the provisional Regulation is confirmed.

#### 2.2. *Non-dumped imports from the countries concerned*

(149) Following the application of Article 2(5) as mentioned in recitals 38 and 70 above, no non-dumped imports from the countries concerned were found. Therefore, recital 130 of the provisional Regulation is revised accordingly.

2.3. *Other Union producers*

(150) In the absence of any comments recital 131 of the provisional Regulation is hereby confirmed.

2.4. *Imports made by the Union industry*

(151) As set out in recitals 132 to 136 of the provisional Regulation, the Union industry imported significant quantities of biodiesel from the countries concerned during the period considered, up to 60 % of all imports in the IP from those countries.

(152) One interested party alleged that these imports, far from being in self-defence, were part of a 'carefully matured long-term strategy' by the Union industry to invest in, and source biodiesel from, Argentina.

(153) They also allege that there has never been an economic rationale to import soya bean oil into the Union and process it into biodiesel within the Union, and that it is only economically feasible to process the soya bean oil in Argentina and export the resulting biodiesel.

(154) These claims should be rejected. No evidence of such a 'long-term strategy' has been provided and this has been denied by the Union industry. Clearly if the strategy of the Union industry was to supplement their biodiesel production by producing in Argentina and importing the finished product, it would be nonsensical and illogical to then launch a complaint against such imports.

(155) One interested party repeated that the imports of biodiesel by the Union industry, that were made in self-defence, were in fact made as part of a long-term commercial strategy. This allegation, which was not substantiated, is rejected. No evidence beyond mere allegations has been provided of such a strategy. Also, it would seem illogical for the concerned Union producers to support the complaint and, in some cases, to have increased its capacity in the Union while at the same time have a strategy to fulfil production needs by imports.

(156) The same interested party also argued that the market share of the Union industry should be calculated by including their imports made in self-defence. This submission was rejected as market share calculations have to reflect the sales of the Union industry of goods they produced themselves and not their trading activities in the finished product made in the face of increasing volumes of dumped imports.

(157) The Union industry has also shown that in previous years the importation of soya bean oil — and palm oil — for processing into biodiesel was economically viable. No evidence of the contrary was provided by the interested party. Only with the distortive effect of the differential export tax which makes the export of biodiesel cheaper than the raw materials does import of the finished product become economically sensible.

(158) One interested party alleged that those imports were a cause of injury because only the Union industry had the capacity to blend the SME from Argentina and PME from Indonesia with Union produced biodiesel for resale to diesel refiners. That allegation is incorrect. Blending is a simple operation that many trading companies are capable of doing in their storage tanks. No evidence was provided that only the Union producers are capable of such blending, and the allegation was therefore rejected.

(159) One Indonesian exporting producer further claimed that imports by the Union industry were not made in self-defence and compared data for the calendar year 2011 with data from the IP, which contains six months of the same year. A comparison between the two is therefore not accurate without being able to split the IP into two halves. Therefore this argument is rejected.

(160) In the absence of any other comments as regards the exports by the Union industry, recitals 132 to 136 of the provisional Regulation are hereby confirmed.

2.5. *Capacity of the Union industry*

(161) Recitals 137 to 140 of the provisional Regulation noted that the capacity utilisation of the Union industry remained low throughout the period under consideration, but that the situation of the sampled companies deteriorated during the period while their capacity utilisation did not decrease by the same amount.

(162) The provisional conclusion was therefore that the low capacity utilisation rate, as a constant feature, was not responsible for the injury caused to the Union industry.

(163) One interested party commented on the data in the provisional Regulation, noting that even in the absence of any imports at all capacity utilisation of the Union industry would only have been 53 % during the IP. It also points to the increase in production capacity from 2009 to the end of the IP which has led to a reduction in capacity utilisation during the period under consideration.

(164) However, the interested party did not provide any evidence to show that this low capacity utilisation was causing injury to such an extent as to break the causal link between the dumped imports and the deterioration of the situation of the Union industry. Fixed costs represent only a small proportion (roughly 5 %) of total production costs, which shows that the low capacity utilisation was only one factor of injury, but not a decisive one. Also, one of the reasons for this low capacity utilisation rate is the fact that the Union industry, due to the particular market situation, imported the finished product itself.

(165) In addition, following the inclusion of the revised data on capacity and utilisation, the Union industry decreased capacity during the period considered, and increased capacity utilisation, from 46 % to 55 %. This shows that the capacity utilisation of the Union industry would be significantly higher in the absence of dumped imports than the 53 % mentioned above.

(166) Following definitive disclosure, several interested parties cast doubt on the conclusion that low capacity utilisation was not the decisive factor causing injury. It was alleged that fixed costs in the biodiesel industry were much higher than the small proportion given above. However they gave no evidence to support this allegation and so it is rejected. In any case fixed costs do not bear any relation to capacity utilisation rates. Verification of the sampled companies gave a fixed cost to total cost of production ratio that was between 3 % and 10 % during the IP.

(167) It was also alleged in this respect that the overcapacity of the Union industry was so high that even in the absence of imports it would not be able to be adequately profitable. No evidence was given for this allegation and the fact that the Union industry was profitable in 2009 with a low capacity utilisation suggests that in the absence of dumped imports, their profitability would be even higher.

(168) In addition it was argued that the reduction in capacity of the Union industry was in itself a cause of injury due to the costs of closure of plants and reductions in capacity of plants that continued to operate. This allegation was not substantiated and no evidence was submitted to show that the costs of reducing capacity, or of closing entire plants or companies, concerned significant amounts.

(169) Finally it was alleged with regard to the capacity that any company increasing biodiesel production capacity during the period under consideration would be making an irresponsible business decision. No evidence was provided for this allegation. In addition the fact that some companies were able to increase their capacity in the face of increasing imports of dumped biodiesel from Argentina and Indonesia shows the demand on the market for their particular products.

(170) The revised macroeconomic indicators also show that companies were during the period taking capacity out of possible use, and closer to the end of the IP were starting a process of closing plants that are no longer viable. Also increases in capacity on a company-by-company level are mainly due to the expansion of so-called 'second generation' biodiesel plants, manufacturing from waste oils or hydrogenated vegetable oil ('HVO'). Therefore the Union industry was, and is, in the process of rationalising their capacity to meet the Union's demands.

(171) In the absence of any further comments as regards the capacity of the Union industry, recitals 137 to 140 of the provisional Regulation are hereby confirmed.

2.6. *Lack of access to raw materials and vertical integration*

(172) In the absence of any new comments concerning access to raw materials, recitals 141 to 142 of the provisional Regulation are hereby confirmed.

2.7. *Double-counting*

(173) Recitals 143 to 146 of the provisional Regulation dealt with the allegation that the system of 'double-counting', where biodiesel made from waste oils counts twice towards the blending mandates in some Member States, has caused injury to the Union industry, or at least to those Union producers who manufacture biodiesel from virgin oils.

(174) One interested party mentioned a comment by one Union producer that during 2011 they lost sales to other producers who manufactured biodiesel eligible for double counting.

(175) The negative impact on this one producer was however limited, temporary and only relevant for a part of the investigation period, as the double counting scheme was adopted in the Member State in which the company is located only in September 2011. Given that the financial performance of the sampled companies declined after September 2011, and this company was included in the sample, double counting cannot be considered a source of injury.

(176) As the Union industry is composed of both companies producing biodiesel from waste oils and benefiting from double-counting in some Member States, and also of companies producing biodiesel from virgin oils, the movement in demand remains within the Union industry. Due to a finite supply of used oils which are needed for manufacturing double counting biodiesel, a large increase in production of double-counting biodiesel is difficult. Therefore, there is still a strong demand for first generation biodiesel. No significant imports of biodiesel eligible for double-counting was found during the investigation period, thereby confirming that double-counting is shifting the demand within the Union industry and not generating demand for imports. The Commission received no data from the interested party to show that double counting biodiesel had caused the price of virgin oil biodiesel to fall during the period under consideration. In fact data shows that double counting biodiesel has a small price premium over virgin biodiesel, the price of which is linked to mineral diesel.

(177) The decline in performance of the Union industry, which is composed of both types of producers, cannot be attributed to the double-counting regime in force in some Member States. In particular, the fact that companies in the sample producing double-counted biodiesel are also showing a decline in performance, as mentioned in recital 145 to the provisional Regulation, shows that injury caused by dumped imports is being suffered across the industry.

(178) Several interested parties argued after definitive disclosure that the amounts of double-counted biodiesel were underestimated. However, the amounts of double-counted biodiesel available on the Union market were limited in relation to the total sales of biodiesel during the period under investigation. Also, should a Member State have double-counting in force, the biodiesel that complies to be counted as double-counted is produced in the Union and therefore demand remains within the Union industry. No new evidence was provided that would change this conclusion.

(179) In the absence of any new comments concerning regulatory factors, recitals 143 to 146 of the provisional Regulation are hereby confirmed.

2.8. *Other regulatory factors*

(180) Recitals 147 to 153 of the provisional Regulation address allegations by interested parties that restrictions in Member States, such as quota systems and tax regimes, were designed to restrict imports from the countries concerned, meaning that any injury caused to the Union industry, in particular in some Member States, could not be due to imports.

(181) These arguments were provisionally rejected, among other things because dumped imports from countries concerned are present in most Member States. Besides, after being imported to one Member State, these imports could be transported and sold in other Member States as well.

(182) One interested party noted the small amount of Argentinian biodiesel cleared through French customs controls in 2011, and also the small amount declared as being imported into Germany in the same period.

(183) Firstly, as explained above, biodiesel cleared through customs in one Member State may well be sold in another Member State, making such data unreliable. Second, the sampled companies in France and Germany both were able to demonstrate the price competition between their production and imports from the countries concerned, and the injury that they were suffering as a result.

(184) Another interested party claimed that the withdrawal of schemes designed to benefit the biodiesel industry in many Member States lowered the revenue of biodiesel companies during the period considered, thus leading to injury. They point to in particular the gradual withdrawal of tax incentives in France, and taxes on 'green fuels' in Germany.

(185) However, there is no obvious coincidence in time between these changes and the deterioration in the financial performance of the Union industry. Many of these incentives were directed at users of biodiesel, not manufacturers, and most were still in force during the IP. No evidence has been provided to show that the changes in policy of Member States, moving as they have to mandatory blending requirements, has caused injury to the Union industry.

(186) One Indonesian exporting producer noted the ongoing DG Competition investigation into alleged submission of distorted prices by contributors to Platts oil and biofuels products assessed prices and requested that the subject this investigation be considered as a possible cause of injury. This claim was denied as the investigation is ongoing and no findings have been published.

(187) In the absence of any new comments as regards the policies of Member States, recitals 147 to 153 of the provisional Regulation are hereby confirmed.

### 3. **Conclusion on causation**

(188) Imports of product concerned from the countries concerned were dumped during the IP and undercut the sales of the Union industry. There is a clear coincidence in time between the increasing volumes of dumped imports and the deterioration of the situation of the Union industry. The dumped imports were in direct competition with the Union industry's production and as a result the Union industry lost profitability and market share during the period under consideration. Whereas it is possible that other factors mentioned above have affected the performance of the Union industry to a certain extent, the fact remains that dumped imports from the countries concerned are causing injury to the Union industry.

(189) No new evidence was provided to change that conclusion that the effect of other factors, considered individually or collectively, was not such as to break the causal link between the dumped imports and the injury suffered by the Union industry. In the absence of any other comments regarding the conclusion on causation, recitals 154 to 157 of the provisional Regulation are hereby confirmed.

## G. **UNION INTEREST**

### 1. **Interest of the Union industry**

(190) In the absence of any comments regarding the interest of the Union industry, recitals 159 to 161 of the provisional Regulation are hereby confirmed.

### 2. **Interest of unrelated importers and traders**

(191) One Indonesian exporting producer alleged that the proposed duties would have a negative impact on importers and traders, but provided no evidence for their allegation. In fact their claim stated the opposite, which was that the duty could be passed on to users and consumers in higher prices which would presumably lead in fact to no impact whatsoever on importers and traders.

(192) No comments were received from any importers or traders of biodiesel after the publication of provisional measures.

(193) In the absence of any additional new comments as regards the interest of unrelated importers/traders, recitals 162 to 163 of the provisional Regulation are hereby confirmed.

### 3. **Interest of users and consumers**

(194) One Indonesian exporting producer alleged that the proposed duties would increase the price of biodiesel, and therefore reduce the incentive for consumers to buy vehicles that operate on biofuels.

(195) That allegation is rejected. The main application of biodiesel is to be blended into mineral diesel for sale to consumers, so that they do not need to buy a special vehicle that can run on pure biofuels.

(196) Although the price of the biodiesel element would rise, if that biodiesel was imported from Argentina or Indonesia, as stated in the provisional Regulation, given that the proportion of biodiesel in the diesel sold to consumers is small, the increase in price is also small and not noticeable to the consumer.

(197) The possible effect of the measures on the final price of diesel to the consumer, which are expected to be small as set out above, will not undermine the objectives of the Renewable Energy Directive ('RED').

(198) No users or consumers, or groups or associations representing users or consumers, commented on the provisional Regulation.

(199) In the absence of any additional comments regarding the interest of consumers, recitals 164 to 166 of the provisional Regulation are hereby confirmed.

### 4. **Interest of suppliers of raw materials**

(200) In the absence of any comments regarding the interest of raw material suppliers, recitals 167 to 169 of the provisional Regulation are hereby confirmed.

### 5. **Conclusion on Union interest**

(201) No comments were received that would change the analysis of the Union interest as set out in the provisional Regulation, and therefore it is still in the Union interest that measures be imposed. Therefore, recitals 170 to 171 of the provisional Regulation are hereby confirmed.

## H. **DEFINITIVE ANTI-DUMPING MEASURES**

### 1. **Injury elimination level**

(202) Several interested parties contested the use of 15 % as the target profit for the Union industry as set out in recital 175 of the provisional Regulation, stating that this was unrealistically high for the Union biodiesel industry to expect.

(203) However most of these interested parties then suggested replacing the target profit of 15 % with other data from other time periods, or from other investigations, without explaining why one time period, or one investigation, was more appropriate than another.

(204) As explained in the provisional Regulation, the profit margin of 15 % was the profit, expressed as a percentage of turnover, that the Union industry achieved in the absence of dumped imports between 2004 and 2006. This was the last period where profit was made in the absence of dumped imports as since 2006 they have always been present on the Union market, first from the USA and then from Argentina and Indonesia.

(205) However, the Union biodiesel market has matured significantly since 2004-06 in many respects. Between 2004 and 2006, dumped imports had a negligible market share and other imports were also low. During the IP dumped imports had a market share of 19 %. During the period 2004-06 the Union industry consisted of 40 companies, and now this has expanded to over 200, which has raised the level of competition.

(206) Between 2004 and 2006 consumption rose dramatically from 2 million MT to 5 million MT, whereas in the period under consideration consumption rose only slightly, and capacity utilisation, which was 90 % between 2004 and 2006, was 55 % in the IP.

(207) As a consequence, it is considered appropriate to take into account the market developments described above and to adjust target profit accordingly as to reflect the profit that the Union industry could expect to achieve under current market conditions.

(208) Therefore rather than taking the percentage profit, the actual profit for these three years in EUR per MT sold has been calculated. For each year this has been taken to reflect 2011 prices and then averaged. Expressed as a percentage of turnover, the target profit for the Union industry in the IP is 11,0 %.

(209) The injury elimination margin has therefore been recalculated on this basis.

(210) Following definitive disclosure, with regard to the calculation of the injury margin, one interested party argued that the 5,1 % import duty to which RBD palm oil imported into the EU is subject, should be removed from the cost of production of the Union producers. This argument is rejected as this duty represents a cost for Union producers which import palm oil and should therefore be taken into account.

(211) One Indonesian exporting producer challenged the calculation of target profit of the Union industry and the use of data from 2004 to 2006 and then made a suggestion for calculation of the target profit using only the year 2004. However, the previous investigation against imports from the United States determined that an average of the three years was more accurate than using 2004 alone. No arguments were brought forward that would lead to a different conclusion.

(212) Following definitive disclosure the complainants argued that the target profit of 15 % as proposed at provisional stage should be maintained. However the arguments brought forward by the complainants do not relate to the objective for which target profit is to be established, i.e. profit that was realised by the Union industry in the absence of dumped imports. Their argument is therefore rejected.

(213) In the absence of other comments concerning the injury elimination level, the methodology described in recitals 176 to 177 of the provisional Regulation is hereby confirmed.

### 2. **Definitive measures**

(214) In view of the conclusions reached with regard to dumping, injury, causation and Union interest, and in accordance with Article 9(4) of the basic Regulation, definitive anti-dumping measures should be imposed on imports of the product concerned at the level of the lower of the dumping and the injury margins, in accordance with the lesser duty rule.

(215) Anti-dumping duty rates have been established by comparing the injury elimination margins and dumping margins. Consequently, the definitive anti-dumping duty rates, expressed on the CIF Union border price, customs duty unpaid, are as follows:

| Country | Company | Dumping margin | Injury margin | Anti-dumping duty rate |
|---|---|---|---|---|
| Argentina | Aceitera General Deheza S.A., General Deheza, Rosario; Bunge Argentina S.A., Buenos Aires | 41,9 % | 22,0 % | 22,0 % (EUR 216,64) |
| | Louis Dreyfus Commodities S.A., Buenos Aires | 46,7 % | 24,9 % | 24,9 % (EUR 239,35) |
| | Molinos Río de la Plata S.A., Buenos Aires; Oleaginosa MoreNo Hermanos S.A.F.I.C.I. y A., Bahia Blanca; Vicentin S.A.I.C., Avellaneda | 49,2 % | 25,7 % | 25,7 % (EUR 245,67) |
| | Other cooperating companies | 46,8 % | 24,6 % | 24,6 % (EUR 237,05) |
| | All other companies | 49,2 % | 25,7 % | 25,7 % (EUR 245,67) |
| Indonesia | PT. Ciliandra Perkasa, Jakarta | 8,8 % | 19,7 % | 8,8 % (EUR 76,94) |
| | PT. Musim Mas, Medan | 18,3 % | 16,9 % | 16,9 % (EUR 151,32) |
| | PT. Pelita Agung Agrindustri, Medan | 16,8 % | 20,5 % | 16,8 % (EUR 145,14) |
| | PT Wilmar Bioenergi Indonesia, Medan; PT Wilmar Nabati Indonesia, Medan | 23,3 % | 20,0 % | 20,0 % (EUR 174,91) |
| | Other cooperating companies | 20,1 % | 18,9 % | 18,9 % (EUR 166,95) |
| | All other companies | 23,3 % | 20,5 % | 20,5 % (EUR 178,85) |

(216) However as the anti-dumping duty will also apply to blends that include biodiesel (in proportion to their biodiesel content by weight), as well as to pure biodiesel, it will be more accurate, and more appropriate for the correct implementation of the duty by Customs authorities of the Member States, to express the duty as a fixed amount in euro per tonne net and apply this to the pure biodiesel imported, or the proportion of biodiesel in the blended product.

(217) Recital 183 of the provisional Regulation noted that imports of biodiesel from the countries concerned was subject to registration, so that if necessary duties could be collected up to 90 days prior to the imposition of provisional measures.

(218) This collection of duties on registered products is only possible if the conditions set out in Article 10(4) of the basic Regulation are met. Having checked the import statistics for imports made after registration, rather than seeing a further substantial rise in imports before the imposition of provisional measures, imports dropped significantly. The conditions are therefore not met and no duties will therefore be collected on registered imports.

(219) The individual company anti-dumping duty rates specified in this Regulation were established on the basis of the findings of the present investigation. Therefore, they reflect the situation found during that investigation with respect to those companies. These duty rates (as opposed to the country-wide duty applicable to 'all other companies') are thus exclusively applicable to imports of product concerned originating in the countries concerned and produced by the companies and thus by the specific legal entities mentioned. Imported product concerned produced by any other company not specifically mentioned in the operative part of this Regulation, including entities related to those specifically mentioned, cannot benefit from these rates and shall be subject to the duty rate applicable to 'all other companies'.

(220) Any claim requesting the application of these individual company anti-dumping duty rates (e.g. following a change in the name of the entity or following the setting-up of new production or sales entities) should be addressed to the Commission [1] forthwith with all relevant information, in particular any modification in the company's activities linked to production, domestic and export sales associated with, for example, that name change or that change in the production and sales entities. If appropriate, the Regulation will accordingly be amended by updating the list of companies benefiting from individual duty rates.

(221) All parties were informed of the essential facts and considerations on the basis of which it was intended to recommend the imposition of a definitive anti-dumping duty on imports of biodiesel originating in Argentina and Indonesia and the definitive collection of the amounts secured by way of the provisional duty (definitive disclosure). All parties were granted a period within which they could make comments on the definitive disclosure.

(222) The oral and written comments submitted by the interested parties were considered and taken into account where appropriate.

### 3. **Undertakings**

(223) Two Indonesian exporting producers offered similar price undertakings in accordance with Article 8(1) of the basic Regulation. It is noted that in view of the significant price variations of the raw material, the product is not considered suitable for a fixed price undertaking. In this context both companies proposed that the minimum import prices (MIPs) are indexed regularly in relation to the fluctuations of the prices of the crude palm oil (CPO) by applying a coefficient to this raw material cost.

(224) In relation to the offers of two exporting producers, it is noted that in order to establish a meaningfully indexed MIP, this should take into account the numerous additional parameters that play a significant role and demonstrate the volatility of the biodiesel market. Biodiesel is a highly volatile market and the biodiesel business is influenced by various additional factors such as the complexity of the biodiesel trading system, the price differential between gasoil and biodiesel, the volatility and evolution of the vegetable oil markets and the interdependence of the different types of vegetable oils as well as the evolution of the USD/EUR exchange rate. Such factors would require a very complex, multiple indexation on a daily basis for it to be suitable. Therefore the mere indexation only on CPO prices on a monthly basis, as offered, is considered inappropriate and will not achieve the desired result.

(225) In addition, important cross-compensation risks were identified with regard to these Indonesian exporters and their customers as other products besides biodiesel, are also exported to the Union as well as due to the usual practice in this business of loans and swaps of biodiesel, CPO or indeed other products between companies.

(226) Therefore the above factors render the effective implementation and monitoring of undertakings extremely burdensome if not impracticable. Consequently for the reasons stated above, these undertaking offers cannot be accepted.

### 4. **Definitive collection of provisional anti-dumping duties**

(227) Following definitive disclosure, one interested party claimed that at provisional stage some clerical mistakes occurred in the calculation of the dumping margins and that, in the absence of such mistakes, the dumping margins would have been de minimis. As a consequence, that interested party requested that no provisional anti-dumping duties should be collected. This claim must be rejected as the definitive anti-dumping duty is clearly higher than the provisional duty.

(228) In view of the dumping margins found and given the level of the injury caused to the Union industry, the amounts secured by way of the provisional anti-dumping duty, imposed by the provisional Regulation, should be definitively collected,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. A definitive anti-dumping duty is hereby imposed on imports of fatty-acid mono-alkyl esters and/or paraffinic gasoils obtained from synthesis and/or hydro-treatment, of non-fossil origin, in pure form or as included in a blend, currently falling within CN codes ex 1516 20 98 (TARIC codes 1516 20 98 21, 1516 20 98 29 and 1516 20 98 30), ex 1518 00 91 (TARIC codes 1518 00 91 21, 1518 00 91 29 and 1518 00 91 30), ex 1518 00 95 (TARIC code 1518 00 95 10), ex 1518 00 99 (TARIC codes 1518 00 99 21, 1518 00 99 29 and 1518 00 99 30), ex 2710 19 43 (TARIC codes 2710 19 43 21, 2710 19 43 29 and 2710 19 43 30), ex 2710 19 46 (TARIC codes 2710 19 46 21, 2710 19 46 29 and 2710 19 46 30), ex 2710 19 47 (TARIC codes 2710 19 47 21, 2710 19 47 29 and 2710 19 47 30), 2710 20 11, 2710 20 15, 2710 20 17, ex 3824 90 97 (TARIC codes 3824 90 97 01, 3824 90 97 03 and 3824 90 97 04), 3826 00 10 and ex 3826 00 90 (TARIC codes 3826 00 90 11, 3826 00 90 19 and 3826 00 90 30), and originating in Argentina and Indonesia.

[1] European Commission, Directorate-General for Trade, Directorate H, 1049 Brussels, Belgium.

2. The rate of the definitive anti-dumping duty applicable to the product described in paragraph 1 and produced by the companies listed below, shall be as follows:

| Country | Company | Duty rate euro per tonne net | TARIC additional code |
|---|---|---|---|
| Argentina | Aceitera General Deheza S.A., General Deheza, Rosario; Bunge Argentina S.A., Buenos Aires | 216,64 | B782 |
| | Louis Dreyfus Commodities S.A., Buenos Aires | 239,35 | B783 |
| | Molinos Río de la Plata S.A., Buenos Aires; Oleaginosa MoreNo Hermanos S.A.F.I.C.I. y A., Bahia Blanca; Vicentin S.A.I.C., Avellaneda | 245,67 | B784 |
| | Other cooperating companies: Cargill S.A.C.I., Buenos Aires; Unitec Bio S.A., Buenos Aires; Viluco S.A., Tucuman | 237,05 | B785 |
| | All other companies | 245,67 | B999 |
| Indonesia | PT Ciliandra Perkasa, Jakarta | 76,94 | B786 |
| | PT Musim Mas, Medan | 151,32 | B787 |
| | PT Pelita Agung Agrindustri, Medan | 145,14 | B788 |
| | PT Wilmar Bioenergi Indonesia, Medan; PT Wilmar Nabati Indonesia, Medan | 174,91 | B789 |
| | Other cooperating companies: PT Cermerlang Energi Perkasa, Jakarta | 166,95 | B790 |
| | All other companies | 178,85 | B999 |

3. The anti-dumping duty on blends shall be applicable in proportion in the blend, by weight, of the total content of fatty-acid mono-alkyl esters and paraffinic gasoils obtained from synthesis and/or hydro-treatment, of non-fossil origin (biodiesel content).

4. In cases where goods have been damaged before entry into free circulation and, therefore, the price actually paid or payable is apportioned for the determination of the customs value pursuant to Article 145 of Regulation (EEC) No 2454/93 [1] the amount of anti-dumping duty, calculated on the amounts set above, shall be reduced by a percentage which corresponds to the apportioning of the price actually paid or payable.

5. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

*Article 2*

The amounts secured by way of the provisional anti-dumping duties imposed by Commission Regulation (EU) No 490/2013 on imports of biodiesel originating in Argentina and Indonesia shall be definitively collected.

*Article 3*

Where any new exporting producer in Argentina or Indonesia provides sufficient evidence to the Commission that:

— it did not export to the Union the product described in Article 1(1) during the investigation period (1 July 2011 to 30 June 2012),

— it is not related to any of the exporters or producers in Argentina or Indonesia which are subject to the measures imposed by this Regulation,

— it has actually exported to the Union the product concerned after the investigation period on which the measures are based, or it has entered into an irrevocable contractual obligation to export a significant quantity to the Union,

Article 1(2) may be amended by adding the new exporting producer to the cooperating companies not included in the sample and thus subject to the weighted average duty rate of the country concerned.

[1] Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).

*Article 4*

This Regulation shall enter into force on the 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, 19 November 2013.

*For the Council*
*The President*
L. LINKEVIČIUS

# COMMISSION IMPLEMENTING REGULATION (EU) No 1195/2013

## of 22 November 2013

## approving the active substance sodium silver thiosulfate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

**(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 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 ([1]), and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For sodium silver thiosulfate, referred to in Commission Decision 2003/850/EC ([3]) as silver thiosulfate, the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by that Decision.

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 27 January 2003 an application from Enhold B.V for the inclusion of the active substance sodium silver thiosulfate in Annex I to Directive 91/414/EEC. Decision 2003/850/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 4 July 2005. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant on 1 February 2012. The evaluation of the additional data by the Netherlands was submitted in the format of an updated draft assessment report in November 2012.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance sodium silver thiosulfate ([5]) on 1 March 2013. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 3 October 2013 in the format of the Commission review report for sodium silver thiosulfate.

(5) It has appeared from the various examinations made that plant protection products containing sodium silver thiosulfate may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve sodium silver thiosulfate.

(6) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

(7) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing sodium silver thiosulfate. Member States should, as appropriate,

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([3]) Commission Decision 2003/850/EC of 4 December 2003 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of BAS 670H and silver thiosulphate in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 322, 9.12.2003, p. 28).

([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

([5]) *EFSA Journal* 2013; 11(3):3136. Available online: www.efsa.europa.eu

vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

(8) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

(9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] should be amended accordingly.

(10) 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:

*Article 1*

**Approval of active substance**

The active substance sodium silver thiosulfate, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

*Article 2*

**Re-evaluation of plant protection products**

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing sodium silver thiosulfate as an active substance by 31 October 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing sodium silver thiosulfate as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 April 2014 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing sodium silver thiosulfate as the only active substance, where necessary, amend or withdraw the authorisation by 31 October 2015 at the latest; or

(b) in the case of a product containing sodium silver thiosulfate as one of several active substances, where necessary, amend or withdraw the authorisation by 31 October 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

*Article 3*

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 4*

**Entry into force and date of application**

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

It shall apply from 1 May 2014.

[1] Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

[2] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

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

Done at Brussels, 22 November 2013.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX I*

| Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| Sodium silver thiosulfate<br>CAS No not allocated<br>CIPAC No 762 | Not applicable | ≥ 10,0 g Ag/kg<br>Expressed as silver (Ag) | 1 May 2014 | 30 April 2024 | PART A<br>Only indoor uses in non-edible crops shall be authorised.<br><br>PART B<br>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium silver thiosulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to:<br>(a) the protection of operators and workers;<br>(b) limiting the possible release of silver ions through disposal of used solutions;<br>(c) the risk to terrestric vertebrates and soil invertebrates from the use of sewage sludge in agriculture.<br>Conditions of use shall include risk mitigation measures, where appropriate. |

(1) Further details on identity and specification of active substance are provided in the review report.

*ANNEX II*

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (*) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| '63 | Sodium silver thiosulfate<br>CAS No not allocated<br>CIPAC No 762 | Not applicable | ≥ 10,0 g Ag/kg<br>Expressed as silver (Ag) | 1 May 2014 | 30 April 2024 | PART A<br>Only indoor uses in non-edible crops shall be authorised.<br>PART B<br>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium silver thiosulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to<br>(a) the protection of operators and workers;<br>(b) limiting the possible release of silver ions through disposal of used solutions;<br>(c) the risk to terrestric vertebrates and soil invertebrates from the use of sewage sludge in agriculture.<br>Conditions of use shall include risk mitigation measures, where appropriate.' |

(*) Further details on identity and specification of active substance are provided in the review report.

# COMMISSION IMPLEMENTING REGULATION (EU) No 1196/2013

## of 22 November 2013

## entering a name in the register of protected designations of origin and protected geographical indications [Stakliškės (PGI)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Lithuania's application to register the name 'Stakliškės' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

*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*.

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

Done at Brussels, 22 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 166, 12.6.2013, p. 8.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

**Class 1.8. Other products listed in Annex I to the Treaty (spices, etc.)**

LITHUANIA

Stakliškės (PGI)

# COMMISSION REGULATION (EU) No 1197/2013

## of 25 November 2013

## amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

**(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 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [1], and in particular Article 31(1) thereof,

After consulting the Scientific Committee on Consumer Safety,

Whereas:

(1) Following the publication of a scientific study in 2001, entitled 'Use of permanent hair dyes and bladder cancer risk', the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, subsequently replaced by the Scientific Committee on Consumer Products ('SCCP'), pursuant to Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment [2], concluded that the potential risks of the use of hair dyes were of concern. The SCCP, in its opinions, recommended that the Commission take further steps to control the use of hair dye substances.

(2) The SCCP further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity or mutagenicity.

(3) Following the opinions of the SCCP, the Commission agreed with Member States and stakeholders on an overall strategy to regulate substances used in hair dye products according to which the industry was required to submit files, containing updated scientific data on the safety of hair dye substances, for a risk assessment by the SCCP.

(4) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS') pursuant to Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC [3], assessed the safety of individual substances for which updated files had been submitted by the industry.

(5) As regards the evaluation of possible consumer health risks by reaction products formed by oxidative hair dye substances during the hair dyeing process, based on the data yet available, the SCCS, in its opinion of 21 September 2010, did not raise any major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the Union.

(6) In order to ensure the safety of hair dye products for human health it is appropriate to limit the maximum concentrations of 21 assessed hair dye substances and to list them in Annex III to Regulation (EC) No 1223/2009, by taking into account the final opinions given by the SCCS on their safety.

(7) Following the assessment by the SCCS concerning the substance Toluene-2,5-Diamine, listed in entry 9a of Annex III to Regulation (EC) No 1223/2009, it is appropriate to change the maximum authorised concentrations thereof in the finished cosmetic product.

(8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded its application on eyelashes. This exclusion was motivated by the fact that the level of risk is different when cosmetic products are applied on the hair on the head and on eyelashes respectively. A specific safety assessment was therefore needed for the application of hair dye substances on eyelashes.

(9) The SCCS, in its opinion on oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes of 12 October 2012, concluded that oxidative hair dye substances p-Phenylenediamine, Resorcinol, 6-Methoxy-2-Methylamino-3-Aminopyridine HCl, m-Aminophenol, 2-Methyl-5-Hydroxyethyl Aminophenol, 4-Amino-2-Hydroxytoluene, 2,4-Diaminophenoxyethanol HCl, 4-Amino-m-Cresol, 2-Amino-4-Hydroxyethylaminoanisole and 2,6-Diaminopyridine, listed in Annex III to Regulation (EC) No 1223/2009 and found safe for use in hair dye products, can be safely used by professionals in products intended for colouring eyelashes. In addition, the SCCS concluded that up to 2 % of hydrogen peroxide, which is listed under entry 12 in Annex III to Regulation (EC) No 1223/2009, can be considered safe for consumers when applied on eyelashes.

[1] OJ L 342, 22.12.2009, p. 59.
[2] OJ L 66, 4.3.2004, p. 45.
[3] OJ L 241, 10.9.2008, p. 21.

(10) On the basis of the scientific assessment of those substances their use should be allowed in products intended for colouring eyelashes in the same concentrations as in hair dye products. However, in order to avoid any risk connected with the self-application of products intended for colouring eyelashes by consumers, they should be allowed for professional use only. In order to allow professionals to inform consumers about possible adverse effects of eyelash colouring and to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.

(11) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(12) In order to avoid a disruption on the market due to the transition from Council Directive 76/768/ECC of 27 July 1976 on cosmetic products [1] to Regulation (EC) No 1223/2009, this Regulation should apply from the same date as Regulation (EC) No 1223/2009.

(13) A sufficient transition period should be granted to economic operators in order to comply with the new warnings for products intended for colouring eyelashes.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

It shall apply from 11 July 2013.

However, the following provisions in the Annex shall apply from 1 July 2014:

(a) the provisions in column 'i' of point 1 and of points 3 to 9 relating to the use of the substances in products intended for colouring eyelashes;

(b) points 2 and 10.

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

Done at Brussels, 25 November 2013.

*For the Commission*
*The President*
José Manuel BARROSO

[1] OJ L 262, 27.9.1976, p. 169.

*ANNEX*

Annex III to Regulation (EC) No 1223/2009 is amended as follows:

(1) the following entry 8b is inserted:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '8b | p-Phenylene-diamine and its salts | p-Phenylenediamine;<br><br>p-Phenylenediamine HCl;<br><br>p-Phenylenediamine Sulphate | 106-50-3 / 624-18-0 / 16245-77-5 | 203-404-7 / 210-834-9 / 240-357-1 | Products intended for colouring eyelashes | | After mixing under oxidative conditions the maximum concentration applied to eyelashes must not exceed 2 % calculated as free base<br><br>For professional use only. | To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>⚠This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them.<br><br>Contains phenylenediamines.<br><br>Wear suitable gloves." ' |

(2) entry 9a is replaced by the following:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '9a) | 1,4-Benzene-diamine, 2-methyl-<br><br>2,5-Diamino-toluene sulphate | Toluene-2,5-Diamine<br><br>Toluene-2,5-Diamine sulfate [1] | 95-70-5<br><br>615-50-9 | 202-442-1<br><br>210-431-8 | Hair dye substance in oxidative hair dye products | | (a) General use | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Contains phenylenediamines (toluenediamines).<br><br>Do not use to dye eyelashes or eyebrows." |
| | | | | | | | (b) Professional use<br><br>For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % (calculated as free base) or 3,6 % (calculated as sulfate salt) | (b) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only<br><br>⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past.<br>Contains phenylenediamines (toluenediamines).<br>Wear suitable gloves." ' |

(3) entry 12 is replaced by the following:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '12 | Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide | Hydrogen peroxide | 7722-84-1 | 231-765-0 | (a) Hair products<br>(b) Skin products<br>(c) Nail hardening products<br>(d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products | (a) 12 % of $H_2O_2$ (40 volumes), present or released<br>(b) 4 % of $H_2O_2$, present or released<br>(c) 2 % of $H_2O_2$, present or released<br>(d) ≤ 0,1 % of $H_2O_2$, present or released | | For (a) and (f): Wear suitable gloves<br>For (a) (b) (c) and (e):<br>Contains hydrogen peroxide.<br>Avoid contact with eyes.<br>Rinse immediately if product comes into contact with them. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | (e) Tooth whitening or bleaching products | (e) > 0,1 % ≤ 6 % of $H_2O_2$, present or released | (e) To be only sold to dental practitioners.<br><br>For each cycle of use, first use by dental practitioners as defined under Directive 2005/36/EC [5] or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.<br><br>Not to be used on a person under 18 years of age. | (e) Concentration of $H_2O_2$ present or released indicated in percentage.<br><br>Not to be used on a person under 18 years of age.<br><br>To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use. |
| | | | | | (f) Products intended for eyelashes | (f) 2 % of $H_2O_2$, present or released | (f) For professional use only | (f) To be printed on the label:<br><br>"For professional use only.<br><br>Avoid contact with eyes.<br><br>Rinse eyes immediately if product comes into contact with them.<br><br>Contains hydrogen peroxide." |

[5] OJ L 255, 30.9.2005, p. 22.'

(4) entry 22 is replaced by the following:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '22 | 1,3-benzenediol | Resorcinol | 108-46-3 | 203-585-2 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b):<br><br>After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,25 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Contains resorcinol.<br><br>Rinse hair well after application.<br><br>Rinse eyes immediately if product comes into contact with them.<br><br>Do not use to dye eyelashes or eyebrows." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>Contains resorcinol.<br><br>⚠This product can cause severe allergic reactions.<br><br>Read and follow instructions. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them."<br><br>(c) Contains resorcinol.' |
| | | | | | (c) Hair lotions and shampoos | (c) 0,5 % | | |

(5) entry 203 is replaced by the following:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '203 | 6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride and dihydrochloride salt ([17]) | 6-Methoxy-2-Methylamino-3-Aminopyridine HCl | 90817-34-8 / 83732-72-3 | – / 280-622-9 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (c): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 0,68 % calculated as free base (1,0 % as dihydrochloride). | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,68 % as free base (1,0 % as dihydro-chloride) | For (a) (b) and (c):<br><br>— Do not use with nitro-sating agents<br><br>— Maximum nitrosamine content: 50 µg /kg<br><br>— Keep in nitrite-free containers | (b) Can cause allergic reaction |
| | | | | | (c) Products intended for colouring eyelashes | | (c) For professional use only. | (c) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>⚠ This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

(6) entry 217 is replaced by the following:

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| '217 | m-Aminophenol and its salts | m-Aminophenol<br><br>m-Aminophenol HCl<br><br>m-Aminophenol sulfate | 591-27-5 / 51-81-0 / 68239-81-6 /38171-54-9 | 209-711-2 / 200-125-2 / 269-475-1 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,2 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy. |

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| | | | | | | | | Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br>The mixing ratio.<br>"For professional use only.<br>⚠This product can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase the risk of allergy.<br>Eyelashes shall not be coloured if the consumer:<br>— has a rash on the face or sensitive, irritated and damaged scalp,<br>— has experienced any reaction after colouring hair or eyelashes, |

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| | | | | | | | | — has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

(7) entry 229 is replaced by the following:

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| '229 | 5-[(2-Hydroxyethyl)amino]-o-cresol | 2-Methyl-5-Hydroxyethyl Aminophenol | 55302-96-0 | 259-583-7 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 %<br><br>— Do not use with nitrosating agents<br><br>— Maximum nitrosamine content: 50 µg /kg<br><br>— Keep in nitrite-free containers | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio. |

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| | | | | | | | | "For professional use only.<br><br>⚠ This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

(8) entries 241 and 242 are replaced by the following:

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| '241 | 5-Amino-o-cresol | 4-Amino-2-Hydroxy-toluene | 2835-95-2 | 220-618-6 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>" ⚠ Hair colorants can cause severe allergic reactions. |

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| | | | | | | | | Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>⚠This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp, |

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| | | | | | | | | — has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." |
| 242 | 2,4-Diaminophenoxyethanol, its hydrochloride and its sulphate | 2,4-Diaminophenoxyethanol HCl<br><br>2,4-Diaminophenoxyethanol sulfate | 70643-19-5/ 66422-95-5 / 70643-20-8 | – / 266-357-1 / 274-713-2 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 2,0 % (as hydrochloride) | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio. |

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| | | | | | | | | "For professional use only.<br><br>⚠ This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

(9) entries 244 and 245 are replaced by the following:

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| '244 | 4-Amino-m-cresol | 4-Amino-m-Cresol | 2835-99-6 | 220-621-2 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions. |

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| | | | | | | | | Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>⚠This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp, |

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| | | | | | | | | — has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." |
| 245 | 2-[(3amino-4-methoxyphenyl) amino]ethanol and its sulphate | 2-Amino-4-Hydroxyethylaminoanisole<br><br>2-Amino-4-Hydroxyethylaminoanisole sulfate | 83763-47-7 /<br><br>83763-48-8 | 280-733-2 /<br><br>280-734-8 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5 % (as sulphate)<br><br>— Do not use with nitrosating agents<br><br>— Maximum nitrosamine content: 50 µg /kg<br><br>— Keep in nitrite-free containers | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio. |

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| | | | | | | | | "For professional use only.<br><br>⚠This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

(10) the following entries 265 to 285 are added:

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| '265 | 1,4-Diaminoanthraquinone | Disperse Violet 1 | 128-95-0 | 204-922-6 | Hair dye substance in non-oxidative hair dye products | 0,5 % | Impurity of Disperse Red 15 in Disperse Violet 1 for hair dye formulations should be < 1 % (w/w) | |
| 266 | Ethanol, 2-((4-amino-2-nitrophenyl)amino)- | HC Red No 3 | 2871-01-4 | 220-701-7 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,45 % | For (a): To be printed on the label:<br><br>The mixing ratio. |

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| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 3,0 % | For (a) and (b):<br>— Do not use with nitrosating agents<br>— Maximum nitrosamine content: 50 µg/kg<br>— Keep in nitrite-free containers | For (a) and (b):<br>"⚠Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 267 | [7-Hydroxy-8-[(2-methoxyphenyl)azo]-2-naphthyl]trimethylammonium chloride | Basic Red 76 | 68391-30-0 | 269-941-4 | Hair dye substance in non-oxidative hair dye products | 2,0 % | | |
| 268 | 2-[[4-(Dimethylamino)phenyl]azo]-1,3-dimethyl-1H-imidazolium chloride | Basic Red 51 | 77061-58-6 | 278-601-4 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 % | (a) To be printed on the label:<br>The mixing ratio.<br>"⚠Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16. |

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| | | | | | | | | Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 1,0 % | | |
| 269 | Phenol, 2-Amino-5-Ethyl-, Hydrochloride | 2-Amino-5-Ethylphenol HCl | 149861-22-3 | | Hair dye substance in oxidative hair dye products | | After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % | To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair, |

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| | | | | | | | | — you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 270 | Fluorescein, 2',4',5',7'-tetra-bromo-4,5,6,7-tetrachloro-, disodium salt (CI 45410) | Acid Red 92 | 18472-87-2 | 242-355-6 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % | (a) To be printed on the label:<br>The mixing ratio.<br>"⚠Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,4 % | | |
| 271 | Mixture of (1), (2) & (3) in dispersing agent (lignosulphate):<br>(1) 9,10-Anthracenedione-1,4-bis[(2-Hydroxyethyl)amino] | Disperse Blue 377 is a mixture of three dyes:<br>(1) 1,4-bis[(2-hydroxyethyl)amino]anthra-9,10-quinone | (1) 4471-41-4 | (1) 224-743-7 | Hair dye substance in non-oxidative hair dye products | 2,0 % | | |

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| | (2) 9,10-Anthracenedione-1-[(2-Hydroxyethyl)amino]-4-[(3-Hydroxypropyl)amino] | (2) 1-[(2-hydroxyethyl)amino]-4-[(3-hydroxypropyl)amino]anthra-9,10-quinone | (2) 67674-26-4 | (2) 266-865-3 | | | | |
| | (3) 9,10-anthracenedione-1,4-bis[(3-hydroxypropyl)amino | (3) 1,4-bis[(3-hydroxypropyl)amino]anthra-9,10-quinone | (3) 67701-36-4 | (3) 266-954-7 | | | | |
| 272 | 4-Aminophenol | p-Aminophenol | 123-30-8 | 204-616-2 | Hair dye substance in oxidative hair dye products | | After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,9 % | To be printed on the label:<br>The mixing ratio.<br>"⚠ Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 273 | 4,5-Diamino-1-(2-hydroxyethyl)-1H-pyrazole sulfate (1:1) | 1-Hydroxyethyl-4,5-Diamino Pyrazole Sulfate | 155601-30-2 | 429-300-3 | Hair dye substance in oxidative hair dye products | | After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3,0 % | To be printed on the label:<br>The mixing ratio. |

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| | | | | | | | | "⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 274 | Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzene-sulfonic acid (1:1) | 4-Formyl-1-Methylquinolinium-p-Toluene-sulfonate | 223398-02-5 | 453-790-8 | Hair dye substance in oxidative hair dye products | | After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5 % | To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp, |

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| | | | | | | | | — you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 275 | Pyridinium, 1-methyl-4-[(methylphenylhydrazono)methyl]-, methyl sulfate | Basic Yellow 87 | 68259-00-7 | 269-503-2 | (a) Hair dye substance in oxidative hair dye products<br>(b) Hair dye substance in non-oxidative hair dye products | (b) 1,0 % | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % | (a) To be printed on the label:<br>The mixing ratio.<br>"⚠Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 276 | 2-[(4-Aminophenyl)azo]-1,3-dimethyl-1H-imidazolium chloride | Basic Orange 31 | 97404-02-9 | 306-764-4 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,5 % | (a) To be printed on the label:<br>The mixing ratio. |

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| | | | | | | | | "⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 1,0 % | | |
| 277 | 2,6-Pyridine-diamine, 3-(3-pyridinylazo) | 2,6-Diamino-3-((Pyridine-3-yl)azo)Pyridine | 28365-08-4 | 421-430-9 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,25 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16. |

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| | | | | | | | | Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,25 % | | |
| 278 | 4-((4-Amino-3-methylphenyl)(4-imino-3-methyl-2,5-cyclohex-adien-1-ylidene)methyl)-2-methylpheny-lamine monohy-drochloride (CI 42520) | Basic Violet 2 | 3248-91-7 | 221-831-7 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp, |

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| | | | | | | | | — you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,5 % | | |
| 279 | 2,3-Diamino-6,7-dihydro-1H,5H-pyrazolo[1,2-a] Pyrazol-1-one dimethanesulfonate | 2,3-Diaminodihydropyrazolopyrazolone Dimethosulfonate | 857035-95-1 | 469-500-8 | Hair dye substance in oxidative hair dye products | | After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0 % | To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| 280 | 2-Amino-4,6-dinitrophenol and 2-amino-4,6-dinitrophenol, sodium salt | Picramic Acid and Sodium Picramate | 96-91-3<br><br>831-52-7 | 202-544-6<br><br>212-603-8 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,6 % | (a) To be printed on the label:<br><br>The mixing ratio. |

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| | | | | | | | | "⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,6 % | | |
| 281 | 1-Methylamino-2-nitro-5-(2,3-dihydroxy-propyloxy)-benzene | 2-Nitro-5-Glyceryl Methylaniline | 80062-31-3 | 279-383-3 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,8 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16. |

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| | | | | | | | | Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 1,0 % | For (a) and (b):<br><br>— Do not use with nitrosating agents<br><br>— Maximum nitrosamine content: 50 µg/kg<br><br>— Keep in nitrite-free containers | |
| 282 | 1-Propanaminium, 3-[[9,10-dihydro-4-(methylamino)-9,10-dioxo-1-anthracenyl] amino]-N,N-dimethyl-N-propyl-, bromide | HC Blue 16 | 502453-61-4 | 481-170-7 | Hair dye substance in non-oxidative hair dye products | 3,0 % | — Do not use with nitrosating agents<br><br>— Maximum nitrosamine content: 50 µg/kg<br><br>— Keep in nitrite-free containers | |
| 283 | 3-amino-2-chlor-6-methylphenol<br><br>3-amino-4-chloro-6-methylphenol HCl | 5-Amino-6-Chloro-o-Cresol<br><br>5-Amino-6-Chloro-o-Cresol HCl | 84540-50-1<br><br>80419-48-3 | 283-144-9 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy.<br><br>Do not colour your hair if:<br><br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br><br>— you have ever experienced any reaction after colouring your hair,<br><br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 0,5 % | | |
| 284 | Phenol, 2,2'-methylenebis[4-amino-], dihydrochloride | 2,2'-Methylenebis-4-aminophenol HCl | 27311-52-0<br><br>63969-46-0 | 440-850-3 | (a) Hair dye substance in oxidative hair dye products | | (a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1,0 % | (a) To be printed on the label:<br><br>The mixing ratio.<br><br>"⚠ Hair colorants can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase your risk of allergy. |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair,<br>— you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Hair dye substance in non-oxidative hair dye products | (b) 1,0 % | | |
| 285 | Pyridine-2,6-diyldiamine | 2,6-Diaminopyridine | 141-86-6 | 205-507-2 | (a) Hair dye substance in oxidative hair dye products | | For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,15 % | (a) To be printed on the label:<br>The mixing ratio.<br>"⚠Hair colorants can cause severe allergic reactions.<br>Read and follow instructions.<br>This product is not intended for use on persons under the age of 16.<br>Temporary 'black henna' tattoos may increase your risk of allergy.<br>Do not colour your hair if:<br>— you have a rash on your face or sensitive, irritated and damaged scalp,<br>— you have ever experienced any reaction after colouring your hair, |

| a | b | c | d | e | f | g | h | i |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | — you have experienced a reaction to a temporary 'black henna' tattoo in the past." |
| | | | | | (b) Products intended for colouring eyelashes | | (b) For professional use only. | (b) To be printed on the label:<br><br>The mixing ratio.<br><br>"For professional use only.<br><br>⚠ This product can cause severe allergic reactions.<br><br>Read and follow instructions.<br><br>This product is not intended for use on persons under the age of 16.<br><br>Temporary 'black henna' tattoos may increase the risk of allergy.<br><br>Eyelashes shall not be coloured if the consumer:<br><br>— has a rash on the face or sensitive, irritated and damaged scalp,<br><br>— has experienced any reaction after colouring hair or eyelashes,<br><br>— has experienced a reaction to a temporary 'black henna' tattoo in the past.<br><br>Rinse eyes immediately if product comes into contact with them." ' |

# COMMISSION REGULATION (EU) No 1198/2013

## of 25 November 2013

## terminating the anti-subsidy proceeding concerning imports of biodiesel originating in Argentina and Indonesia and repealing Regulation (EU) No 330/2013 making such imports subject to registration

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 597/2009 of 11 June 2009 on protection against subsidised imports from countries not members of the European Community [1] ('the basic Regulation'), and in particular Article 14 and 24 thereof,

After consulting the Advisory Committee,

Whereas:

### 1. PROCEDURE

(1) On 27 September 2012, the European Commission ('the Commission') received a complaint concerning the alleged injurious subsidisation of production of biodiesel originating in Argentina and Indonesia, which was lodged pursuant to Article 10 of the basic Regulation by the European Biodiesel Board ('the complainant') on behalf of producers representing more than 25 % of the total Union production of biodiesel.

(2) The complaint contained prima facie evidence of subsidy of the said product and of material injury resulting therefrom, which was considered sufficient to justify the initiation of an investigation.

(3) On 10 November 2012, the Commission announced, by a notice published in the *Official Journal of the European Union* ('the notice of initiation'), the initiation of an anti-subsidy proceeding against imports into the Union of biodiesel originating in Argentina and Indonesia [2].

(4) The Commission officially advised the complainant, other known Union producers, the known exporting producers in Argentina and Indonesia, known importers, suppliers, distributors, users and associations known to be concerned, and the authorities of Argentina and Indonesia of the initiation of the proceeding. Interested parties were invited to make their views known in writing and to request a hearing within the time limit set in the notice of initiation.

(5) All interested parties, who so requested and showed that there were particular reasons why they should be heard, were granted a hearing.

(6) On 10 April 2013, the Commission made imports of biodiesel originating in Argentina and Indonesia subject to registration under Commission Regulation (EU) No 330/2013 [3].

### 2. WITHDRAWAL OF THE COMPLAINT AND TERMINATION OF THE PROCEEDING

(7) By a letter dated 7 October 2013 to the Commission, the complainant formally withdrew its complaint.

(8) In accordance with Article 14(1) of the basic Regulation, the proceeding may be terminated where the complaint is withdrawn, unless such termination would not be in the Union interest.

(9) The investigation had not brought to light any considerations showing that such termination would be against the Union interest. Therefore the Commission considered that the present proceeding should be terminated. Interested parties were informed accordingly and were given an opportunity to comment. However, the Commission received no comments which would lead to the conclusion that such termination would not be in the Union interest.

(10) The Commission therefore concludes that the anti-subsidy proceeding concerning imports into the Union of biodiesel originating in Argentina and Indonesia should be terminated.

(11) The registration of imports of biodiesel originating in Argentina and Indonesia, established in application of Article 1 of Regulation (EU) No 330/2013, should therefore be discontinued and the said Regulation repealed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The anti-subsidy proceeding concerning imports of fatty-acid mono-alkyl esters and/or paraffinic gasoils obtained from synthesis and/or hydro-treatment, of non-fossil origin, in pure form or as included in a blend, currently falling within CN codes ex 1516 20 98, ex 1518 00 91, ex 1518 00 95, ex 1518 00 99, ex 2710 19 43, ex 2710 19 46, ex 2710 19 47, 2710 20 11, 2710 20 15, 2710 20 17, ex 3824 90 97, 3826 00 10 and ex 3826 00 90, and originating in Argentina and Indonesia, is hereby terminated.

[1] OJ L 188, 18.7.2009, p. 93.
[2] OJ C 342, 10.11.2012, p. 12.
[3] OJ L 102, 11.4.2013, p. 13.

*Article 2*

Customs authorities are directed to discontinue the registration of imports, established in application of Article 1 of Regulation (EU) No 330/2013.

*Article 3*

Regulation (EU) No 330/2013 is repealed.

*Article 4*

This Regulation shall enter into force on the 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, 25 November 2013.

*For the Commission*
*The President*
José Manuel BARROSO

# COMMISSION IMPLEMENTING REGULATION (EU) No 1199/2013

## of 25 November 2013

## approving the active substance chlorantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

**(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 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 ([1]), and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For chlorantraniliprole the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2007/560/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC Ireland received on 2 February 2007 an application from DuPont de Nemours for the inclusion of the active substance chlorantraniliprole in Annex I to Directive 91/414/EEC. Decision 2007/560/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 17 February 2010. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant on 11 July 2011. The evaluation of the additional data by Ireland was submitted in the format of an updated draft assessment report in December 2011.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance chlorantraniliprole ([5]) on 14 March 2013. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 3 October 2013 in the format of the Commission review report for chlorantraniliprole.

(5) It has appeared from the various examinations made that plant protection products containing chlorantraniliprole may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve chlorantraniliprole.

(6) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([3]) Commission Decision 2007/560/EC of 2 August 2007 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chlorantraniliprole, heptamaloxyglucan, spirotetramat and *Helicoverpa armigera* nucleopolyhedrovirus in Annex I to Council Directive 91/414/EEC (OJ L 213, 15.8.2007, p. 29).

([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

([5]) *EFSA Journal 2013*; 11(4):3143. Available online: www.efsa.europa.eu

(8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing chlorantraniliprole. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

(9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

(10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] should be amended accordingly.

(11) 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:

*Article 1*

**Approval of active substance**

The active substance chlorantraniliprole, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

*Article 2*

**Re-evaluation of plant protection products**

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing chlorantraniliprole as an active substance by 31 October 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing chlorantraniliprole as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 April 2014 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing chlorantraniliprole as the only active substance, where necessary, amend or withdraw the authorisation by 31 October 2015 at the latest; or

(b) in the case of a product containing chlorantraniliprole as one of several active substances, where necessary, amend or withdraw the authorisation by 31 October 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

*Article 3*

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

[1] Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

[2] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

*Article 4*

**Entry into force and date of application**

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

It shall apply from 1 May 2014.

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

Done at Brussels, 25 November 2013.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX I*

| Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|
| Chlorantraniliprole<br><br>CAS No 500008-45-7<br><br>CIPAC No 794 | 3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl) pyrazole-5-carboxanilide | ≥ 950 g/kg<br><br>The following relevant impurities must not exceed a certain threshold in the technical material:<br><br>Acetonitrile: ≤ 3 g/kg<br><br>3-picoline: ≤ 3 g/kg<br><br>Methanesulfonic acid: ≤ 2 g/kg | 1 May 2014 | 30 April 2024 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorantraniliprole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macroorganisms.<br><br>Conditions of use shall include risk mitigation measures, where appropriate.<br><br>The applicant shall submit confirmatory information as regards:<br><br>(1) the risk to groundwater from the active substance and its metabolites IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one), IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one), IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-carboxamide), IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one) and IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide);<br><br>(2) the risk to aquatic organisms from the photolysis metabolites IN-LBA22 (2-{[(4Z)-2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b][1,4]oxazin-4-ylidene] amino}-5-chloro-N,3-dimethylbenzamide), IN-LBA23 (2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one) and IN-LBA24 (2-(3-bromo-1H-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3H)-one).<br><br>The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016. |

(1) Further details on identity and specification of active substance are provided in the review report.

*ANNEX II*

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (*) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|---|---|---|---|
| '62 | Chlorantraniliprole<br><br>CAS No 500008-45-7<br><br>CIPAC No 794 | 3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl) pyrazole-5-carboxanilide | ≥ 950 g/kg<br><br>The following relevant impurities must not exceed a certain threshold in the technical material:<br><br>Acetonitrile: ≤ 3 g/kg<br><br>3-picoline: ≤ 3 g/kg<br><br>Methanesulfonic acid: ≤ 2 g/kg | 1 May 2014 | 30 April 2024 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorantraniliprole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.<br><br>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macro-organisms.<br><br>Conditions of use shall include risk mitigation measures, where appropriate.<br><br>The applicant shall submit confirmatory information as regards:<br><br>(1) the risk to groundwater from the active substance and its metabolites IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one), IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one), IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-carboxamide), IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one) and IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide);<br><br>(2) the risk to aquatic organisms from the photolysis metabolites IN-LBA22 (2-{[(4Z)-2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b][1,4]oxazin-4-ylidene] amino}-5-chloro-N,3-dimethylbenzamide), IN-LBA23 (2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one) and IN-LBA24 (2-(3-bromo-1H-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3H)-one).<br><br>The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.' |

(*) Further details on identity and specification of active substance are provided in the review report.

# COMMISSION IMPLEMENTING REGULATION (EU) No 1200/2013

## of 25 November 2013

## entering a name in the register of protected designations of origin and protected geographical indications [Cozza di Scardovari (PDO)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Italy's application to register the name 'Cozza di Scardovari' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Cozza di Scardovari' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

*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*.

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

Done at Brussels, 25 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 170, 15.6.2013, p. 51.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

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

ITALY

Cozza di Scardovari (PDO)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1201/2013

## of 25 November 2013

## 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 Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors [2], and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 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 XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in 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, 25 November 2013.

*For the Commission,*
*On behalf of the President,*
Jerzy PLEWA
*Director-General for Agriculture and Rural Development*

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 157, 15.6.2011, 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 | AL | 50,7 |
| | MA | 43,6 |
| | MK | 36,9 |
| | TR | 65,0 |
| | ZZ | 49,1 |
| 0707 00 05 | AL | 41,5 |
| | TR | 87,8 |
| | ZZ | 64,7 |
| 0709 93 10 | MA | 139,9 |
| | TR | 106,8 |
| | ZZ | 123,4 |
| 0805 20 10 | MA | 80,5 |
| | TR | 76,1 |
| | ZA | 87,1 |
| | ZZ | 81,2 |
| 0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90 | PK | 59,4 |
| | SZ | 56,2 |
| | TR | 75,4 |
| | UY | 56,2 |
| | ZA | 192,9 |
| | ZZ | 88,0 |
| 0805 50 10 | TR | 71,6 |
| | ZZ | 71,6 |
| 0808 10 80 | BA | 54,0 |
| | MK | 41,5 |
| | US | 130,4 |
| | ZA | 162,0 |
| | ZZ | 97,0 |
| 0808 30 90 | TR | 123,6 |
| | ZZ | 123,6 |

(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'.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION

**of 14 October 2013**

**on a Union financial contribution towards Croatia's fisheries control programme for 2013**

*(notified under document C(2013) 6606)*

**(Only the Croatian text is authentic)**

(2013/673/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 861/2006 of 22 May 2006 establishing Community financial measures for the implementation of the common fisheries policy and in the area of the Law of the Sea [1], and in particular Article 21 thereof,

Whereas:

(1) On 1 July 2013, Croatia became a Member of the European Union.

(2) Croatia submitted to the Commission a fisheries control programme for 2013, in accordance with Article 20 of Regulation (EC) No 861/2006, inclusive of its application for a Union financial contribution towards the expenditure to be incurred in carrying out the projects contained in such programme.

(3) Applications concerning actions listed in Article 8(a) of Regulation (EC) No 861/2006 may qualify for Union funding.

(4) It is appropriate to fix the maximum amounts and the rate of the Union financial contribution within the limits set by Article 15 of Regulation (EC) No 861/2006 and to lay down the conditions under which such contribution may be granted.

(5) In conformity with Article 21(2) of Regulation (EC) No 861/2006, Croatia was invited to submit a programme related to funding in the priority areas defined by the Commission in its letter of 25 January 2013, i.e. projects aiming at the implementation of the Council Regulation (EC) No 1224/2009 [2] on control, measurement of engine power, and traceability of fishery products. Requirements to be met by operators and/or Member States carrying out investments in traceability projects were defined by the Commission in its letter of 14 May 2012.

(6) On that basis and given budgetary constraints, requests in the programs for Union funding related to non-priority actions, such as installation of Automatic Identification Systems (AIS) on board fishing vessels and those training projects having no link with improvements to be brought in the control systems of Member States, were rejected since they were not dedicated to the priority areas defined above.

(7) As to traceability projects, it is important to ensure that they are developed on the basis of internationally recognised standards, as required by Article 67(8) of Commission Implementing Regulation (EU) No 404/2011 [3].

(8) The Croatian application for Union funding has been assessed with regard to its compliance with the rules set out in Commission Regulation (EC) No 391/2007 of 11 April 2007 laying down detailed rules for the implementation of Council Regulation (EC) No 861/2006 as regards the expenditure incurred by Member States in implementing the monitoring and control systems applicable to the Common Fisheries Policy [4].

(9) In order to encourage investment in the priority actions defined by the Commission and in view of the negative impact of the financial crisis on Member States' budgets, expenditure related to the abovementioned priority areas and retained for this financing decision should benefit from a high co-financing rate, within the limits laid down in Article 15 of Regulation (EC) No 861/2006.

(10) In order to qualify for the contribution, automatic localisation devices should satisfy the requirements fixed by Implementing Regulation (EU) No 404/2011.

[1] OJ L 160, 14.6.2006, p. 1.
[2] OJ L 343, 22.12.2009, p. 1.
[3] OJ L 112, 30.4.2011, p. 1.
[4] OJ L 97, 12.4.2007, p. 30.

(11) In order to qualify for the contribution, electronic recording and reporting devices on board fishing vessels should satisfy the requirements fixed by Implementing Regulation (EU) No 404/2011.

(12) The measures provided for in this Decision are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS DECISION:

*Article 1*

**Subject matter**

This Decision provides for a Union financial contribution for 2013 towards expenditure incurred by Croatia in implementing the monitoring and control systems applicable to the common fisheries policy (CFP), as referred to in Article 8(1)(a) of Regulation (EC) No 861/2006.

*Article 2*

**Closure of outstanding commitments**

All payments in respect of which a reimbursement is claimed shall be made by Croatia by 30 June 2017. Payments made after that deadline shall not be eligible for reimbursement. The budgetary appropriations related to this Decision shall be decommitted at the latest by 31 December 2018.

*Article 3*

**New technologies and IT networks**

1. Expenditure incurred, in respect of projects referred to in Annex I, on the setting up of new technologies and IT networks in order to allow efficient and secure collection and management of data in connection with monitoring, control and surveillance of fisheries activities as well as on the verification of engine power, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

2. Project HR/13/05 referred to in Annex I, related to gauges and scales, shall qualify for a financial contribution of 50 % of the eligible expenditure, within the limits laid down in that Annex.

*Article 4*

**Automatic localisation devices**

1. Expenditure incurred, in respect of projects referred to in Annex II, on the purchase and fitting on board of fishing vessels of automatic localisation devices enabling vessels to be monitored at a distance by a fisheries monitoring centre through a vessel monitoring system (VMS) shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

2. The financial contribution referred to in paragraph 1 shall be calculated on the basis of a price capped at EUR 2 500 per vessel.

3. In order to qualify for the financial contribution referred to in paragraph 1, automatic localisation devices shall satisfy the requirements laid down in Commission Regulation (EC) No 2244/2003 [1].

*Article 5*

**Electronic recording and reporting systems**

Expenditure incurred, in respect of projects referred to in Annex III, on the development, purchase, and installation of, as well as technical assistance for, the components necessary for electronic recording and reporting systems (ERS), in order to allow efficient and secure data exchange related to monitoring, control and surveillance of fisheries activities, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

*Article 6*

**Electronic recording and reporting devices**

1. Expenditure incurred, in respect of projects referred to in Annex IV, on the purchase and fitting on board of fishing vessels of ERS devices enabling vessels to record and report electronically to a Fisheries Monitoring Centre data on fisheries activities, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

2. The financial contribution referred to in paragraph 1 shall be calculated on the basis of a price capped at EUR 3 000 per vessel.

3. In order to qualify for a financial contribution, ERS devices shall satisfy the requirements established in Implementing Regulation (EU) No 404/2011.

*Article 7*

**Total maximum Union contribution for Croatia**

The planned expenditure, the eligible share thereof, and the maximum Union contribution to Croatia is as follows:

*(EUR)*

| Member State | Expenditure planned in the national fisheries control programme | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| **Croatia** | 817 000 | 618 000 | 522 600 |
| **Total** | **817 000** | **618 000** | **522 600** |

[1] OJ L 333, 20.12.2003, p. 17.

*Article 8*

**Addressee**

This Decision is addressed to the Republic of Croatia.

Done at Brussels, 14 October 2013.

*For the Commission*
Maria DAMANAKI
*Member of the Commission*

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*ANNEX I*

**NEW TECHNOLOGIES AND IT NETWORKS**

*(EUR)*

| Project code | Expenditure planned in the national fisheries control programme | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| HR/13/05 | 84 000 | 84 000 | 42 000 |
| HR/13/07 | 100 000 | 100 000 | 90 000 |
| **Total** | ***184 000*** | ***184 000*** | ***132 000*** |

*ANNEX II*

**AUTOMATIC LOCALISATION DEVICES**

*(EUR)*

| Project code | Expenditure planned in the national fisheries control programme | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| HR/13/01 | 192 000 | 192 000 | 172 800 |
| HR/13/02 | 192 000 | 0 | 0 |
| **Total** | ***384 000*** | ***192 000*** | ***172 800*** |

*ANNEX III*

**ELECTRONIC RECORDING AND REPORTING SYSTEMS**

*(EUR)*

| Project code | Expenditure planned in the national fisheries control programme | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| HR/13/04 | 50 000 | 50 000 | 45 000 |
| **Total** | ***50 000*** | ***50 000*** | ***45 000*** |

*ANNEX IV*

**ELECTRONIC RECORDING AND REPORTING DEVICES**

*(EUR)*

| Project code | Expenditure planned in the national fisheries control programme | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| HR/13/03 | 192 000 | 192 000 | 172 800 |
| **Total** | ***192 000*** | ***192 000*** | ***172 800*** |

*ANNEX V*

**TRAINING AND EXCHANGE PROGRAMMES**

*(EUR)*

| Project code | Expenditure planned in the national fisheries control programmes | Expenditure for projects selected under this Decision | Maximum Union contribution |
|---|---|---|---|
| HR/13/06 | 7 000 | 0 | 0 |
| **Total** | ***7 000*** | ***0*** | ***0*** |

# COMMISSION IMPLEMENTING DECISION

## of 25 November 2013

## on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

**(Text with EEA relevance)**

(2013/674/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [1], and in particular the third subparagraph of Article 10(1) thereof,

Whereas:

(1) It is essential that cosmetic products made available on the Union market be safe for human health when used under normal and reasonably foreseeable conditions of use. To that end, Regulation (EC) No 1223/2009 requires that, in order to establish that a cosmetic product is safe under those conditions, cosmetic products undergo a safety assessment.

(2) The operator designated as the responsible person in accordance with Regulation (EC) No 1223/2009 is to ensure that, for each cosmetic product which is to be placed on the Union market, a cosmetic product safety report is drawn up on the basis of the relevant information and in accordance with the requirements laid down in Annex I to Regulation (EC) No 1223/2009.

(3) In order to facilitate the understanding of the requirements of Annex I to Regulation (EC) No 1223/2009 by all undertakings, and especially small and medium-size enterprises, the Regulation requires that the Commission adopts appropriate guidelines.

(4) This Decision sets out appropriate guidelines on Annex I to Regulation (EC) No 1223/2009. They were developed with the contribution of the relevant stakeholders, including representatives of small and medium-sized enterprises.

(5) The guidelines should assist responsible persons in complying with their regulatory obligations. However, they are not meant to replace the knowledge and expertise of the qualified safety assessor, as required by Article 10(2) of Regulation (EC) No 1223/2009, who should remain the only professional allowed to carry out the cosmetic product safety assessment as described in Part B of Annex I.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DECISION:

*Article 1*

The guidelines to enable undertakings to comply with the requirements laid down in Annex I to Regulation (EC) No 1223/2009 on cosmetic products are set out in the Annex to this Decision.

*Article 2*

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

Done at Brussels, 25 November 2013.

*For the Commission*

*The President*

José Manuel BARROSO

[1] OJ L 342, 22.12.2009, p. 59.

*ANNEX*

**GUIDELINES ON ANNEX I TO REGULATION (EC) No 1223/2009 ON THE COSMETIC PRODUCT SAFETY REPORT**

1. INTRODUCTION

Article 11 of Regulation (EC) No 1223/2009 requires that a product information file is drawn up for each product before it is placed on the market. The product information file should be updated when necessary and kept readily accessible, in electronic or other format, at the address of the responsible person given on the label, to the competent authorities for market surveillance purposes for a period of 10 years following the placing on the market of the last batch of the product.

The most important element of the product information file, from a safety point of view, is the cosmetic product safety report referred to in Article 10(1). The other elements are a clear description of the cosmetic product, a description of the method of manufacturing and a statement on compliance with good manufacturing practice, the proof of the effects claimed, and data on animal testing ([1]).

Where the responsible person drawing up the cosmetic product safety report is not the manufacturer of the product, they should ensure they have access to all the technical and scientific skills necessary to obtain reliable cosmetic product safety information and an appropriate safety assessment to demonstrate that the product they are responsible for is safe, in accordance with Article 3 of Regulation (EC) No 1223/2009. They may therefore need to involve not only the safety assessor, but also the manufacturer, the suppliers of raw materials, and other technical experts.

In any case, the responsible person is to ensure that the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment; an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources; the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market ([2]).

The cosmetic product safety assessment, as set out in Part B of Annex I to Regulation (EC) No 1223/2009, is to be carried out by a qualified safety assessor. The responsible person and the safety assessor should work closely together to ensure that the safety of the product is properly assessed and documented and that the assessment is kept up to date. The responsible person and the safety assessor should gather all the necessary information as required by Part A of Annex I to Regulation (EC) No 1223/2009.

The cosmetic product safety report should be drawn up in a transparent way and should be well-argued and easily understood.

The Cosmetic Product Safety Report is an expert piece of work made up of different modules and where the information required under Part A may be stored in different databases. The report, which should contain, as a minimum, all the information indicated in Annex I to Regulation (EC) No 1223/2009, should appear under the same or similar headings for ease of reference of the competent authorities. However, it may be sufficient to provide under each heading a clear reference to a document containing the information and readily available in electronic or printed format.

2. ANNEX I TO REGULATION (EC) No 1223/2009 — COSMETIC PRODUCT SAFETY REPORT

In accordance with Annex I to Regulation (EC) No 1223/2009, the Cosmetic Product Safety Report is to contain, 'as a minimum', the information required under each of the headings of Part A and Part B.

Part A aims to gather all the data necessary for the safety assessment of the product, while Part B sets out the reasoning, starting from the data, for drawing conclusions as to the safety of the product.

([1]) Article 11(2) of Regulation (EC) No 1223/2009.
([2]) Article 10(1) of Regulation (EC) No 1223/2009.

The structure and content of the safety report should reflect the requirements of Annex I to Regulation (EC) No 1223/2009. However, if the report does not directly contain the required information, it should provide a reference to another readily available source.

The responsible person is to ensure that the Cosmetic Product Safety Report is kept up to date in the light of additional relevant information emerging after the product has been placed on the market [1].

3. PART A — COSMETIC PRODUCT SAFETY INFORMATION

**Part A of the cosmetic product safety report is intended to gather the data necessary to prove that the cosmetic product is safe. The information should enable the safety assessor to clearly identify and quantify, based on the identified hazards, the risks a cosmetic product may present to human health. A hazard may arise, for example, from the raw materials, the manufacturing process, the packaging, the conditions of use of the product, the microbiological specifications, the quantities used, the toxicological profile of the substances, etc.**

**As Part A of Annex I to Regulation (EC) No 1223/2009 requires that the data listed under its headings are provided as a minimum, any discrepancy with regards to the requirements of Part A should be justified.**

Part A of Annex I to Regulation (EC) No 1223/2009 lists the data that is to be available, '*as a minimum*', for the safety assessor to be able to carry out the safety assessment.

In addition to the minimum data listed in Part A of Annex I to Regulation (EC) No 1223/2009, the safety assessor can use any additional data, where relevant. On the other hand, they, or the responsible person, may consider that, depending on the type of product, some of the required data are not relevant or necessary to assess the safety of the product (e.g. preservation challenge test). In this case, the absence of specific data is to be clearly justified in Part A and the justification is to be repeated and validated by the safety assessor in their reasoning in Part B. The responsible person should check the presence of the required data or the justification for their absence.

The data required by Part A can be drawn from any reliable source. Examples include: data from suppliers, scientific literature, experience gained with similar or other product categories, results of studies on the product itself or on the substances it contains, available data on similar formulations, or computer models. The safety report should highlight the relevance of the data in relation to the product.

The guidance published by the EU scientific committees concerned with risk assessment [2], as well as the recommendations of national competent authorities or professional organisations, may provide further helpful support.

3.1. **Quantitative and qualitative composition of the cosmetic product**

**The aim of that section of the cosmetic product safety report is to provide the exact quantitative and qualitative composition of the finished product, starting from the raw materials. Raw materials are substances or mixtures used in the manufacturing of the cosmetic product. The intended function of each substance is to be indicated.**

The complete product composition is to be specified, stating the name and identity (qualitative) of each raw material (including chemical name, INCI, CAS, Einecs/ELINCS, where possible), and the amount of each raw material, stating the weight percentage (quantitative). Ranges should not be used, unless this can be justified (e.g. viscosity or pH adjusters). If concentration ranges are unavoidable, toxicological considerations and calculations should be based on the highest concentration figure. It may also be useful to indicate the supplier(s) of the raw materials.

[1] Article 10(1)(c) of Regulation (EC) No 1223/2009.
[2] The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, SCCS/1501/12, and its subsequent updates.

All substances entering into the composition of commercial mixtures supplied as raw materials (including directly added preservatives, antioxidants, chelators, buffering agents, solvents, other additives, etc.) are to be identified and quantified in the formula of the finished product. This also applies to all substances indirectly added to the product, such as preservatives used for preserving raw materials. The intended function of each substance is to be indicated.

When chemically well-defined substances are present, their quantity and molecular formula should be given together with their analytical specifications (degree of purity, identification of major impurities, criteria and test methods used).

When complex ingredients are present, their nature and quantity together with a clear definition of the mixture and the material(s) used should be given in order to identify the substances with regard to their composition and effects (manufacturing and purification processes, including physical, chemical, enzymatic, biotechnological and microbiological steps). The purity criteria and test methods used should be provided. Examples of complex ingredients include those of mineral, botanical, animal or biotechnological origin. The scope of the information needed on complex ingredients, depending on their nature and origin, is explicitly listed in the Scientific Committee for Consumer Safety (SCCS) Note of Guidance [1].

When a mixture of both chemically well-defined substances and complex ingredients is present, the above guidance also applies.

Where any fragrance (or flavour) compound comprising a mixture of fragrance (or flavour) ingredients and functional components with olfactory, odour-enhancing, odour-protecting or blending properties is formulated and intentionally added to a cosmetic product to impart a scent (or flavour) or to cover a malodour, its identification is to include the name and code number as well as the identity of the supplier. Qualitative and quantitative information about regulated substances in the fragrance (or flavour) compound and information relevant for a safety assessment should be disclosed to the responsible person and the safety assessor, and should be included in the safety report.

3.2. **Physical/chemical characteristics and stability of the cosmetic product**

**The aim of that section of the cosmetic product safety report is to describe the relevant physical and chemical specifications of the substances or mixtures used and the cosmetic product itself. These specifications are crucial for an appropriate safety assessment, as they may influence the safety of a cosmetic product. For example, physico-chemical properties, in combination with other information, can help the safety assessor determine the need to investigate relevant toxicological parameters.**

**In addition, the physico-chemical characteristics of the substances or mixtures and finished products set the benchmark against which the products and the raw materials can be considered acceptable from a quality point of view** [2]**.**

**That section of the cosmetic product safety report also requires an assessment of the stability of the cosmetic product, under reasonably foreseeable storage conditions. The aim is to evaluate if the stability of the cosmetic product affects the safety and quality of the product, and to use the information to determine its minimum durability and period-after-opening (PAO).**

3.2.1. *Physical/chemical characteristics of substances or mixtures*

This description is to include the most relevant physico-chemical properties of each substance and mixture contained in the product, for example: chemical identification, physical form, molecular weight, solubility, partition coefficient, substance purity, other parameters relevant for the characterisation of specific substances and mixtures, and, for polymers, the average molecular weight and range.

[1] SCCS Notes of Guidance, para. 3-6.2, pp. 35-36.

[2] This point is relevant in the context of Good Manufacturing Practices, and is explicitly addressed by the relevant standard EN ISO 22716:2007. More specifically, it matches the requirements for the release of raw materials and the finished product.

Where relevant, the particle-size distribution curve of substances should be included in the physico-chemical characteristics, especially for nanomaterials.

Cosmetics manufacturers should ensure that the specifications of raw materials are properly documented by their suppliers. Specifications should be available for each raw material actually used in the product. Based on function, additional specifications may be needed. For UV absorbers, for instance, the absorption spectra should be provided.

For each description of physico-chemical properties and specifications (for each substance and mixture contained in the product), the reference methods should be stated in the safety report.

3.2.2. *Physical/chemical characteristics of the finished cosmetic product*

This description is to contain the specifications of the finished product. Each specification should be given with relevant limits, e.g. pH between 5.5 and 6.5.

For each description of physico-chemical properties and specifications of the finished product, the reference methods should be stated in the cosmetic product safety report.

3.2.3. *Stability of the cosmetic product*

As the requirement is to assess the stability of the cosmetic product under reasonably foreseeable storage conditions, if stability is dependent on storage conditions, information about these conditions should be passed on throughout the supply chain, and, if relevant for the end user, it should be indicated on the labelling of the product.

The methodology used to determine the product's minimum durability should be described. Any specific preservation precautions should be mentioned.

All available data used to justify the indicated minimum durability should be listed in the safety report. In order to determine the coherence of the stability study conducted, and to check the relevance of the date of minimum durability chosen for the product, the description of the tests specific to the stability study and the results of those tests should be included in the cosmetic product safety report. In addition, the following should also be provided:

(1) evidence that the composition of the product used for stability testing corresponds to the product actually placed on the market;

(2) the results of the preservative efficacy study, e.g. challenge test, if applicable [1];

(3) when applicable, the period-after-opening (PAO) [2] and its justification.

The SCCS has recommended that 'relevant stability tests, adapted to the type of cosmetic product and its intended use, should be carried out. To make sure that no stability problems are induced by the type of container and packaging used, physical stability tests are currently carried out with inert containers and those intended to be used on the market.' [3]

[1] See section 3.3 on Microbiological quality.

[2] See 'Practical implementation of Article 6(1)(c) of the Cosmetics Directive (76/768/EEC): Labelling of product durability: "period of time after opening" ' (Council Directive 76/768/EEC, OJ L 262, 27.9.1976, p. 169) http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/wd-04-entr-cos_28_rev_version_adoptee20040419_en.pdf

[3] SCCS Notes of Guidance, para. 4-3.3, p. 74.

3.3. **Microbiological quality**

**The aim of that section of the cosmetic product safety report is to determine the acceptable microbiological specifications of the raw materials (substances or mixtures) and finished product from a microbiological point of view. In accordance with Annex I to Regulation (EC) No 1223/2009, particular attention is to be paid to the microbiological specifications of cosmetic products intended to be used on sensitive body parts and on specific populations. In addition, information regarding microbiological quality is essential in order to justify the effectiveness of the preservation system and justify the indicated minimum durability of the cosmetic product stored under appropriate conditions and period-after-opening (PAO)** [1] **of the finished product in terms of safety.**

The microbiological specifications of the raw materials (substances or mixtures) and cosmetic product are to form part of the safety assessment. Particular attention is to be paid to the microbiological specifications of cosmetic products intended to be used around the eyes, on mucous membranes in general, on damaged skin (e.g. skin care products suitable for atopic or irritated skin), on children under three years of age, on elderly people or on persons with compromised immune responses.

3.3.1. *Microbiological quality of substances and mixtures*

The main parameters for microbiological quality are the original level of contamination and the possibility of microbial growth. Particular attention should be paid to the raw materials (substances and mixtures) most susceptible to microbial growth (e.g. water-based mixtures, protein-rich materials, plant or animal raw materials). On the other hand, there are raw materials which do not support microbial growth, e.g. organic solvents.

3.3.2. *Microbiological quality of the finished cosmetic product*

Concerning microbiological susceptibility, there is a difference between three product categories:

(1) low microbiological risk products (e.g. products with an alcohol content > 20 %, products based on organic solvents, high/low-pH products), for which neither a preservation challenge test nor microbiological quality tests on the finished product are necessary. A scientific justification is to be provided, however;

(2) single-use products, and products which cannot be opened (e.g. for which the packaging allows dosing the product without it coming in contact with the air), for which only microbiological quality tests on the finished product are necessary. A scientific justification is to be provided, however;

(3) all other products, for which both a preservation challenge test and microbiological quality tests on the finished product are necessary.

Specific 'Guidelines on Microbiological Quality of the Finished Product' are provided in the SCCS Notes of Guidance [2].

3.4. **Impurities, traces, information about the packaging material**

**The aim of that section of the cosmetic product safety report is to assess whether the cosmetic product contains substances that have not been intentionally added to the formulation, and which may have an impact on its safety.**

**Impurities are unintended substances in raw materials.**

[1] The 'date of minimum durability' is the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain safe; the PAO is the period of time after opening for which the product can be used without any harm to the consumer. See 'Practical implementation of Article 6(1)(c) of the Cosmetics Directive (76/768/EEC): Labelling of product durability: "period of time after opening" '.

[2] SCCS Notes of Guidance, para 4-4, pp. 75–76.

**A trace is a small quantity of an unintended substance in the finished product. Traces are to be evaluated with regard to safety of the finished product. When traces of prohibited substances are present, evidence of their technical unavoidability are also to be provided.**

**Traces can originate from the following sources: impurities in the raw materials/substances; the manufacturing process; potential chemical evolution/interaction and/or migration of substances in the product that could occur under normal storage conditions and/or through contact with the packaging material.**

**Because substances may migrate from the packaging to the formulation, the relevant characteristics of the packaging material are to be considered.**

In accordance with point 4 of Annex I to Regulation (EC) No 1223/2009, the section on 'Impurities, traces, information about the packaging material' is to address three specific issues:

(a) the purity of substances and mixtures;

(b) in case of traces of prohibited substances, evidence of their technical unavoidability;

(c) the relevant characteristics of the packaging material, in particular purity and stability.

In practical terms, those elements may be interpreted as follows:

(a) precise definition of impurities and traces (see 3.4.1);

(b) evidence of technical unavoidability of prohibited substances (see 3.4.2);

(c) potential release of substances from the packaging or possible deterioration of the product in contact with the packaging (see 3.4.3).

For the analysis of impurities and packaging material, data from suppliers are of crucial importance and should be preferred.

3.4.1. *Purity of substances and mixtures*

The presence of unintended substances, such as impurities and traces, can have an impact on the safety of the finished product. The cosmetic product safety report is to include data on the purity of raw materials (substances and mixtures) and the identification of the toxicologically relevant unintended substances. These substances should be taken into account in the safety assessment of the product.

Impurities are unintended substances in raw materials.

A trace is a small quantity of an unintended substance in the finished product.

The presence of traces in the finished product can be evaluated in two ways:

(a) through the specifications/technical data for each raw material, based on knowledge of the process for manufacturing the raw material (origin of substance, production process, synthesis route, extraction process, solvent used, etc.);

(b) through a physico-chemical analysis of possible impurities in raw materials and, if necessary, in the final product (e.g. nitrosamines which are potentially generated during or after the manufacturing process).

Traces of prohibited substances are dealt with in paragraph 3.4.2 of these Guidelines.

Some traces have regulatory concentration limits. For the presence of traces of substances that are not prohibited, and for which there are no regulatory concentration limits, but which could be expected to impact consumer safety, the safety assessment needs to be carried out by the safety assessor.

3.4.2. *Evidence of the technical unavoidability of traces of prohibited substances*

While the procedure outlined in paragraph 3.4.1 should be followed for all known impurities and traces to evaluate their toxicological impact, further investigation is required for prohibited substances present as traces in the finished product ([1]).

When such presence is technically unavoidable, the cosmetics manufacturers are required to provide evidence of the technical unavoidability. That means they have to justify the presence of those traces by all necessary means. The presence of traces of prohibited substances should be kept as low as is reasonably achievable under good manufacturing practices. In addition, the safety assessor has to decide whether their levels are toxicologically acceptable and whether the product is still safe.

Especially in the case of non-threshold genotoxic and carcinogenic substances ([2]), the cosmetic industry should keep improving its best practices in order to eliminate these substances (ALARA principle ([3])) in the finished cosmetic product. The main concern is to ensure the protection of human health, as required by Article 3 of Regulation (EC) No 1223/2009.

Traces generated by the degradation of substances within the final product (stability issues), by preservation or transport problems, or by the interaction of raw materials should be avoided through good manufacturing practices, or possibly through re-formulation of the product.

3.4.3. *The relevant characteristics of packaging material*

Packaging material means the container (or primary packaging) that is in direct contact with the formulation. The relevant characteristics of packaging materials in direct contact with the final product are important for the safety of the cosmetic product. Reference to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]) could be useful.

Experience with similar formulation/packaging combinations already on the market provides useful indications. Materials that have been developed for food packaging have often already been tested, so relevant information on stability and migration may be available. Additional testing may not be required. However, more evaluation may be needed for new or novel packaging.

The combination of packaging material, formulation of the cosmetic product and contact with the external environment may have an impact on the safety of the finished product, due to the following factors:

(a) interaction between the product and the packaging material;

(b) barrier properties of the packaging material;

(c) substance migration from/to the packaging material.

The information on relevant characteristics of the packaging materials in direct contact with the product should allow an estimation of potential risks. Relevant characteristics could include, for example, the following:

(a) composition of the packaging material, including technical substances such as additives;

(b) technically unavoidable impurities;

(c) possible migration from the packaging.

([1]) Article 17 of Regulation (EC) No 1223/2009 establishes that traces of prohibited substances are only permitted if they are technically unavoidable and if they have no impact on the safety of the cosmetic products.
([2]) The 'non-threshold genotoxic and carcinogenic substances' are the genotoxic and carcinogenic substances without a threshold for the carcinogenic-genotoxic effects.
([3]) Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances Which are both Genotoxic and Carcinogenic, the *EFSA Journal* (2005) 282, pp. 1-31.
([4]) OJ L 338, 13.11.2004, p. 4.

This information only indicates the hazard. It is up to the safety assessor to evaluate the risk ([1]).

Studies on interactions/suitability between formulation and packaging allow testing of the potential migration of small amounts of substances from the primary packaging material to the product. These tests are performed under specific and relevant test conditions. There are, however, no standard procedures for cosmetic products. An appropriate assessment may be made based on knowledge of the formulation and primary packaging materials and experienced expert judgment.

If migration is dependent on storage conditions, the correct conditions should be indicated on the product labelling. If the formulation is sensitive to light or air, and would degrade in a way that impacts product safety or product efficacy, appropriate packaging should be used.

3.5. **Normal and reasonably foreseeable use**

**The section on normal and reasonably foreseeable use of the product is essential for the safety assessor to be able to determine a relevant exposure scenario. The intended use should be appropriately communicated to the consumer in order to avoid misuse of the product.**

**In addition, warnings and other explanations on the labelling should be consistent with the identified normal and reasonably foreseeable use, and the reasoning justifying their inclusion is to be given.**

A clear explanation of the normal intended use and the reasonably foreseeable use should be provided. For instance, in the case of a shampoo, the normal intended use would be to use it on the scalp; an (unintended) reasonably foreseeable use would be for it to be used as a shower gel. Ingestion would be a clear misuse.

To this end, a practical approach may be useful. For example, one could include a photo of the packaging or the artwork in the cosmetic product safety report to show the presentation of the product and its intended use. It would also be useful to make the link with the warnings and labelling, as highlighted by Annex I to Regulation (EC) No 1223/2009 on this point.

3.6. **Exposure to the cosmetic product**

**The exposure assessment is an essential element of risk assessment. The aim of this section is to quantify the amount of cosmetic product coming into contact with the external parts of the human body or the teeth and the mucous membranes of the oral cavity under normal or reasonably foreseeable use for each use and the frequency of use.**

The assessment of exposure to the cosmetic product shall take into consideration the findings regarding 'normal and reasonably foreseeable use' under section 5 of Annex I to Regulation (EC) No 1223/2009 in relation to a set of elements that are explicitly listed in section 6. Secondary exposure routes should also be taken into consideration, where appropriate.

The description of concrete conditions of use for the purpose of exposure analysis should also take the following parameters into account:

(a) product type (e.g. leave-on, rinse-off);

(b) area of application (e.g. whole body, eyes, mouth cavity);

(c) amount per application in the case of normal and reasonably foreseeable use, e.g. including when a shampoo is used as shower gel;

(d) duration and frequency;

(e) possible (foreseeable) routes of exposure (e.g. oral for lipstick and toothpaste, or inhalation for aerosols and solvents);

([1]) To evaluate the risk, one needs to consider the hazard together with the exposure, and this is the duty of the safety assessor.

(f) target group for use (e.g. children under the age of three years, adults);

(g) impact of particle size on exposure.

The SCCS Notes of Guidance provide useful information on exposure calculations and particularly relevant tables ([1]).

However, as the tables may not contain the daily exposure values for specific cosmetic products, other ways of calculating exposure may be used. Several alternatives are possible. For instance, calculations could be performed based on either skin surface data or user experience data.

If the available data are considered insufficient, it is recommended to assume a worse-case exposure taking into account the foreseeable conditions of use.

The specific target population and the populations otherwise exposed to the product should be kept in mind. For example, in the case of products for professional use, there will be different exposure scenarios for the targeted consumers and the exposed professionals in terms of exposure frequency, exposure duration and size of exposed skin area, possible exposure through inhalation (for example, in the case of shampoos, when assessing the risk for consumers, exposure of the scalp with a frequency of approximately once a day should be considered, whereas for hair dressers exposure of the hands several times a day should be considered).

3.7. **Exposure to the substances**

**The assessment of the exposure to each of the substances contained in the cosmetic product is necessary in order to assess the risk associated with each individual substance. The objective of that section of the cosmetic product safety report is to determine the amount of each substance coming into contact with the external parts of the human body or the teeth and the mucous membranes of the oral cavity under normal or reasonably foreseeable use, for each use.**

**Exposure to each of the substances in the cosmetic product is calculated from the exposure to the final product and the concentration of the individual substances in the final product. It is necessary to calculate this exposure in order to assess the potential risk from each substance.**

Exposure to individual substances is calculated from the quantitative composition of the product. Where substances are generated or released during the use of the product, the exposure should be estimated and taken into account in the safety assessment.

The exposure conditions to each individual substance are determined by those for the finished cosmetic product under 3.6.

3.8. **Toxicological profile of the substances**

**The aim of this section of the cosmetic product safety report is to describe the toxicological hazard of each of the substances in the finished product, determine the potential exposure, and draw up a risk characterisation. These aspects are of crucial importance in order to perform the risk assessment, as they are the three essential steps of the risk assessment process** ([2])**.**

**The endpoints to be considered, as well as the necessary data, depend on a number of factors, including the routes of exposure, the conditions of use of the product, the physico/chemical characteristics and the possible absorption of the substance. The choice of relevant endpoints should be the responsibility of the safety assessor, who should justify their decisions.**

([1]) SCCS Notes of Guidance, para 4, p. 66 *et seq*.
([2]) M. Pauwels, V. Rogiers, Human Health Safety Evaluation of Cosmetics in the EU: A Legally Imposed Challenge to Science, *Toxicology and Applied Pharmacology*, 243 (2010), p. 261.

**The safety assessor should ensure that the experimental data comply with the requirements of Article 18 of Regulation (EC) No 1223/2009 concerning animal testing. Such requirements are clarified in the Commission Communication on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics** [1]**.**

Point 8 of Part A of Annex I to Regulation (EC) No 1223/2009 establishes the key requirements for the cosmetic product safety report as far as the toxicological profile of substances is concerned.

3.8.1. *General considerations concerning the toxicological profile as part of the safety assessment*

The relevant elements of the toxicological profile of each substance or mixture should be described in detail in the cosmetic product safety information (Part A) and assessed in the safety assessment (Part B), bearing in mind the exposure situation, the intrinsic toxicity (or hazard) of each substance, and the specific conditions of use of the product.

Human experiences, animal studies or alternative methods to animal testing are helpful in understanding the health risk for humans exposed to dangerous substances. For the toxicological profiles, toxicological studies are used to identify the hazards which could be associated with a risk to humans. It is essential to consider the quality and limitations of the studies that have been performed. The validity of a study should be taken into consideration in determining whether there is a need for new information to understand the risk to human health [2]. Studies conducted in accordance with international guidelines are the most useful, but unfortunately not all studies meet these standards. Thus, the limitations of such studies should be considered in assessing the toxicological profile for each substance.

The safety assessor should ensure that the experimental data comply with the requirements of Article 18 of Regulation (EC) No 1223/2009 concerning animal testing. The Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics outlines the Commission's interpretation of those requirements [3].

3.8.2. *Toxicological profile of substances for all the relevant toxicological endpoints*

The toxicological profile for each substance is determined by the hazard identification and the dose-response characterisation.

The first essential step in developing the toxicological profile is to gather all the relevant information about the intrinsic properties of the substance. Such information should include the following:

(1) as the most valuable toxicity information, actual test data from *in vivo* or *in vitro* studies obtained in accordance with Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [4], recognised international guidelines, or standards (e.g. OECD Test Guidelines), and performed in accordance with good laboratory practice principles;

(2) existing test data that have not been obtained in accordance with the latest adopted/accepted version of a test guideline or with good laboratory practice standards, but which are considered valid;

(3) *in vitro* data or alternative data from valid test systems, to be used as a screening study to predict toxicity;

[1] Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics, COM(2013) 135 final.
[2] H.J. Klimisch, E. Andreae and U. Tillmann (1997), *A systematic approach for evaluating the quality of experimental and ecotoxicological data*. Regul Toxicol Pharmacol 25:1-5.
[3] See in particular point 3.1 of the Communication.
[4] OJ L 142, 31.5.2008, p. 1.

(4) human data and/or experience. It is in general not acceptable to perform human toxicology studies for hazard identification, but, if data or experience exist, they should be included in the final assessment;

(5) human (clinical) data, including data from clinical trials and applications in other industries such as food and medicinal products;

(6) data gathered from post-marketing surveillance;

(7) human volunteer compatibility studies, which should only be used to confirm safe levels of use for a relevant target population ([1]);

(8) read-across ([2]) approaches, based on the chemical structure and properties of related substances in order to predict the toxicity of the ingredient, grouping of substances, and non-testing data from QSAR model outputs.

Based on data obtained from all available sources, and taking into account the quality of the data, the safety assessor can evaluate the likelihood of adverse effects in humans through the 'weight of evidence' approach ([3]).

A prerequisite for a proper risk assessment is the availability of adequate data. For additional support on this matter, one may consult the guidance for the preparation of safety dossiers for submission to the Scientific Committee for Consumers Safety (SCCS), set out by the Committee itself in its Notes of Guidance. Though these Notes of Guidance are provided for substances where an authorisation is needed, i.e. for colorants, preservatives and UV filters, or which otherwise raise concern, the requirements they set out may be helpful for the safety assessment of all substances used in cosmetic products. In addition, a section of the most recent Notes of Guidance focuses on the safety assessment of finished cosmetic products ([4]).

The toxicological profile may address a number of different endpoints. A final decision about which endpoints are relevant is made by the safety assessor on a case-by-case basis, taking into account exposure, use of the product, the physico-chemical characteristics of the substances, experience with the substances, etc. ([5]). Attention should also be paid to local effects (e.g. irritation and photo-toxicity), when relevant. Where a certain endpoint is considered to be not relevant, this should be justified.

Endpoints that may be relevant for the toxicological profile are:

(1) acute toxicity via relevant routes of exposure;

(2) irritation and corrosivity;

(3) skin irritation and skin corrosivity;

(4) mucous membrane irritation (eye irritation);

(5) skin sensitisation;

([1]) SCCS Notes of Guidance, para. 3.4.11. Also cf. opinions SCCNFP/0068/98, an earlier version of the Notes of Guidance, and SCCNFP/0245/99 on Basic Criteria of the Protocols for the Skin Compatibility Testing of Potentially Cutaneous Irritant Cosmetic Ingredients or Mixtures of Ingredients on Human Volunteers.

([2]) Read-across is a technique for data gap filling in which information for one or more source chemicals is used to make a prediction for a target chemical, which is considered to be similar in some way. From ECHA, 'Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information', December 2011, p. 12. http://echa.europa.eu/documents/10162/17235/information_requirements_r4_en.pdf

([3]) One definition for weight of evidence is: 'the process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning a property of the substance.' From ECHA, 'Practical guide 2: How to report weight of evidence', 2010, p. 2, http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf

([4]) Cfr. SCCS Notes of Guidance, Section 3-6 Basic Requirements for Cosmetic Substances Present in Finished Cosmetic Products (which are to be evaluated by individual safety assessors).

([5]) The SCCS Notes of Guidance clearly address this issue in para. 3-6.1 General toxicological requirements.

(6) dermal/percutaneous absorption;

(7) repeated dose toxicity (normally 28- or 90-day studies) [1];

(8) mutagenicity/genotoxicity;

(9) carcinogenicity;

(10) reproduction toxicity;

(11) toxicokinetics (ADME studies);

(12) photo-induced toxicity;

For the appropriate endpoints, the most relevant concentrations or No Observed Adverse Effect Levels (NOAEL) or Lowest Observed Adverse Effect Levels (LOAEL) should be identified for further use in the risk characterisation process.

Additional information regarding endpoint specific data and their interpretation can be found in the endpoint specific guidance [2] prepared by the European Chemical Agency (ECHA) for the implementation of Regulation (EC) No 1907/2006 of the European Parliament and of the Council [3] on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

For some cosmetic ingredients e.g. of mineral, animal, botanical and biotechnological origin (see also Substances of Unknown or Variable composition, Complex reaction products or Biological materials or 'UVCB substances' under REACH) [4], their identification should carefully address source, process, organisms involved, etc., in order to evaluate their toxicological profile.

If certain hazards cannot be sufficiently addressed, or if doubts remain regarding the robustness of the data, additional uncertainty factors may be introduced or additional data may need to be generated.

3.8.3. *Consideration of all the significant routes of absorption*

Dermal, oral and inhalation routes of exposure are potentially relevant for human exposure to cosmetic products. It is essential to calculate the systemic exposure in order to compare it with the relevant NOAEL. The ratio between these two is defined as the margin of safety, which is an indicator of whether the product can be considered safe or not (see also section 3.8.4 and following).

Absorption is linked to the bioavailability of a substance, and is essential for calculating the margin of safety. Systemic exposure can be calculated as:

$$\text{Systemic exposure dose [5] (SED)} = \text{External exposure} \times \text{absorption}$$

Absorption can occur through several external routes: dermal, oral and inhalation.

[1] According to the SCCS's Notes of Guidance (para. 3-4.5), priority should be given to the NOAEL as regards sub-chronic toxicity (90 day study). Only if such values are not available should results relating to sub-acute toxicity (28-day study) be used.
[2] ECHA, Guidance on information requirements and chemical safety assessment — Chapter R.7a: Endpoint specific guidance, May 2008.
[3] OJ L 396, 30.12.2006, p. 1.
[4] Cfr. ECHA, Guidance for identification and naming of substances under REACH and CLP, November 2011, p. 29. http://echa.europa.eu/documents/10162/17235/substance_id_en.pdf
[5] *I.e.* 'the systemically available dose that passes the relevant physical barriers (gastro-intestinal, skin or lung structures) and becomes available in the blood stream for subsequent distribution to tissues and organs', ref. M. Pauwels, V. Rogiers, p. 262.

If the intended exposure for the cosmetic product is not in line with the route of exposure in the safety data, route-to-route extrapolation should be considered.

(a) Absorption after dermal exposure

The dermal absorption ([1]) of a substance in a product is dependent on both intrinsic factors (e.g. LogPow, molecular weight) and its behaviour in the vehicle. Dermal *in vivo* human absorption of a substance can be estimated using the data from existing *in vivo* animal studies and *in vitro* studies on animal and human skin. When no measurement data are available and no absorption rate can be determined using a scientifically valid *in silico* method or default absorption rates, a worst case value of 100 % should be used for calculation of the systemic exposure ([2]). In case MW > 500 Da and log Pow is smaller than – 1 or higher than 4, a value of 10 % dermal absorption can be considered.

(b) Absorption after oral exposure

When a reasonably foreseeable use can entail ingestion, the oral route should be included in the exposure scenarios.

(c) Absorption after inhalation

For all substances used in spray applications and some powders, the inhalation route is to be taken into consideration in determining the systemic exposure.

In addition, there may also be a possibility of secondary inhalation exposure where cosmetic products contain volatile substances which can be inhaled unintentionally in the case of direct use, e.g. toluene in nail polish, various substances contained in nail modelling gels, etc.

3.8.4. *Consideration of systemic effects and calculation of the margin of safety*

The safety assessment of a product for systemic toxicity is highly dependent on data on each substance, since there will be no data on systemic toxicity for the finished cosmetic product.

Risk characterisation usually involves an expert evaluation of the potential non-quantifiable adverse effects, followed by calculation of an uncertainty factor or margin of safety ([3]). This calculation depends on the systemic exposure to the substance and its toxicological parameters.

In accordance with Point 8 part A of Annex I to Regulation (EC) No 1223/2009, systemic effects and margin of safety are to be considered in Part A of the safety report. As they are mandatory, the omission of these steps is to be duly justified. An example where this could apply would be the presence of a substance in the cosmetic product at a low level, with the expected (worst case) exposure levels being below the appropriate threshold of toxicological concern (TTC) values ([4]). Another example could be the inclusion of food materials for which a much higher innocuous ingestion level is known.

When the requirement to calculate the margin of safety cannot be met, a different way of expressing the safe dose for each substance may be appropriate, where justified. When a NOAEL is not available, other reference toxicology values such as No Observed Effect Level (NOEL), LOAEL, Lowest Observed Effect Level (LOEL), can be used to calculate the margin of safety; Benchmark Dose (BMD) or Virtually Safe Dose (VSD), used to qualify and quantify a risk in other fields, may be used in the context of cosmetic products safety assessment, provided a relationship with exposure is established, by comparing the exposure from cosmetics and these reference doses.

([1]) Basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients (SCCS/1358/10).
([2]) SCCS Notes of Guidance, para 3-7.2, p. 49.
([3]) M. Pauwels, V. Rogiers, p. 262.
([4]) SCCS, SCHER and SCENIHR, Opinion on Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, SCCP/1171/08.

Otherwise, the safety of a particular substance in a particular product cannot be demonstrated.

According to the procedures described in the SCCS Notes of Guidance [1], the margin of safety (MoS) for a specific route of exposure can be calculated using the following formula:

MoS = No-Observed-Adverse-Effect Level (NOAEL)/Systemic Exposure Dose (SED)

where the Systemic Exposure Dose (SED) is obtained by combining the external exposure (mg/kg bw/day) with the absorption rate (typically expressed in % or $\mu g/cm^2$), frequency and retention factors.

It is generally accepted that the margin of safety should be at least 100 to declare a substance safe for use in a finished product.

In the case of route-to-route extrapolation, the respective bioavailability via each route should ideally be taken into consideration. The assumption of 100 % oral bioavailability might overestimate the systemic exposure in a toxicity study via the oral route. Therefore, in the absence of data, it should be assumed that not more than 50 % of an orally administered dose is systemically available. If there is evidence to suggest poor oral bioavailability, for example if the substance is a poorly soluble particulate, it may be more appropriate to assume that only 10 % of the administered dose is systemically available [2]. Whenever oral absorption data are available, these should be included in the calculations.

The NOAEL chosen for calculating the margin of safety is taken from long-term repeated dose toxicity studies (sub-acute, sub-chronic, and/or chronic toxicity tests, carcinogenesis tests, teratogenesis tests, reproduction toxicity, etc.).

The value used will be the lowest NOAEL obtained by the most pertinent study with respect to the conditions of use of the substance, to species sensitivity, etc.

From the complete toxicological profile, a NOAEL should be determined for the systemic effects. In general, the lowest relevant NOAEL of the most relevant endpoint is selected for calculating the margin of safety.

The calculation of the margin of safety based only on Median Lethal Dose (LD50) data derived from single dose tests (instead of a NOAEL from at least sub-acute tests) cannot be used to justify safe use.

When the absence of bioavailability can be clearly demonstrated, the calculation of the margin of safety is not necessary. In these cases the possible local effects on skin or mucous membranes should still be considered.

3.8.5. *Impact on the toxicological profile of certain characteristics of the substances or the product*

(a) Particle size

The particle size and its distribution curve can have an influence on the toxicity of a substance. When it cannot be excluded that they have an impact on the safety of the finished product, they should be included among its physico-chemical characteristics, and be taken into account during the safety assessment. The most recent scientific opinions on the subject should be followed (SCENIHR, SCCS) [3].

[1] SCCS Note of Guidance, para 3-7, p. 46.
[2] IGHRC, Guidelines on route-to-route extrapolation of toxicity data when assessing health risks of chemicals. The Interdepartmental Group on Health Risks from Chemicals (2006), http://www.silsoe.cranfield.ac.uk/ieh/ighrc/ighrc.html
[3] See for example: SCCS (Scientific Committee on Consumer Safety), Guidance on safety assessment of nanomaterials in cosmetics, SCCS/1484/12; SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Opinion on the scientific basis for the definition of the term 'nanomaterial', 8 December 2010.

(b) Impurities in the substances and raw materials

Impurities can have a major impact on the overall toxicity of any substance. It is important to check the impurities profile of a substance to avoid, or at least assess, any additional risk from the impurities. In the absence of safety data from toxicological studies, the threshold of toxicological concern (TTC) ([1]) might be a useful tool for assessing the safety of certain impurities.

When toxicological studies are used to characterise the toxicological profile of a substance, the purity and impurities profile of the substance used in the toxicological studies should be described. If the batches actually used in the formulation of the cosmetic product do not have a comparable impurity profile, the differences need to be assessed.

3.8.6. *Use of read-across should be substantiated and justified*

Several approaches exist for the read-across technique. The use of this technique should be substantiated and justified.

3.8.7. *Identification of the sources of information*

The determination of the toxicological profile requires a minimum of information on the substance to be evaluated.

This information can be collected from toxicological studies. If data from human experience exist, they should be taken into account.

Other tools such as quantitative structure-activity relationship (QSAR) or bridging approaches are only estimations of toxicity, and the weight of evidence should be substantiated and justified.

The following sources of data should be taken into consideration:

(a) Safety and quality data which may be on file with the respective suppliers of the raw materials in the formulation, and which the supplier should share with the manufacturer of the cosmetic product. This is an important element in considering the availability of relevant data to demonstrate the safety of each cosmetic ingredient in the final product formulation;

(b) If an opinion of the SCCS exists, the NOAEL used in the opinion should be used. The safety assessor should take into account the most up-to-date scientific opinion;

(c) If an opinion of another authoritative scientific committee exists, the NOAEL used in the opinion could be used, provided that the conclusions and limitations are applicable to the expected use (the use taken into account for calculating the margin of safety can be different). The safety assessor should take into account the most up-to-date scientific opinion;

(d) If no scientific opinion exists, it will be necessary to provide information to characterise the toxicological profile of each substance. The data can be obtained from several databases or literature (see the Appendix) ([2]);

(e) Classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]);

(f) Studies performed or obtained by the manufacturer of the product;

(g) *In silico* prediction (QSAR);

([1]) R. Kroes, A. G. Renwick, V. Feron, C. L. Galli, M. Gibney, H. Greim, R. H. Guy, J. C. Lhuguenot, J. J. M. van de Sandt, *Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients,* Food and Chemical Toxicology 45 (2007), pp. 2533–2562.

([2]) Several publicly available databases containing toxicological data on substances used in cosmetics exist, and are listed in the Appendix to this Guideline.

([3]) OJ L 353, 31.12.2008, p. 1, and ECHA's registration website: http://apps.echa.europa.eu/registered/registered-sub.aspx

(h) Bridging approach;

(i) Assessments of non-cosmetic uses of the substance (foodstuffs, food additive, food contact materials, biocides, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)…) may also be used in order to complete information on the toxicological profile of the substance.

(j) When available, the CSR (Chemical Safety Report) or the robust study summaries submitted pursuant to Regulation (EC) No 1907/2006 (REACH).

A number of substances and/or mixtures have not been studied sufficiently to determine all the pertinent toxicological parameters. For these missing parameters, or where the risk characterisation is based on an approach using toxicological data acquired for other substances (for example similar structures) or for uses other than cosmetics (food, biocides, pharmaceutical products, *etc.*), justifications should be included in the report.

3.9. **Undesirable effects and serious undesirable effects**

**The aim of that section of the cosmetic product safety report is to monitor the safety of the product after it has been placed on the market and to take corrective action, where necessary. To this end, the responsible person (in collaboration with the distributors) is required to set up a system to collect, document, establish the causality of and manage the undesirable effects caused by the product after its use in the Union** [1]. **When the undesirable effects are serious, the responsible person (and the distributors) are to notify the competent authority of the Member State where the effects occurred** [2].

**Information on undesirable effects and serious undesirable effects is to be included in the cosmetic product safety report, kept up-to-date and made available to the safety assessor, who may revise their assessment or take the information into account when assessing similar products.**

The cosmetic product safety report is to include all the available data, including statistical data, on the undesirable effects and serious undesirable effects of the cosmetic product or, where relevant, other cosmetic products.

In particular, information on **undesirable effects** which, according to the causality assessment, are found to be very likely, likely, not clearly attributable or unlikely to be attributable [3] to the cosmetic product in question are to be included in the safety report.

Data on undesirable effects may be included in this part of the safety report in the form of statistical data such as the number and type of undesirable effects per year.

Information on **serious undesirable effects** which, according to the causality assessment, are found to be very likely, likely, not clearly attributable or unlikely to be attributable to the cosmetic product in question are to be included in the safety report in accordance with section 9 of Part A of Annex I to Regulation (EC) No 1223/2009, and notified to the national competent authorities, in accordance with Article 23 of the same Regulation [4]. The notification forms sent to the competent authorities are therefore to be attached to the cosmetic product safety report.

The responsible person's reaction to and handling of the reported serious undesirable effects is to be stated. The corrective and preventive measures taken, if any, should be described.

[1] This is a consequence of the requirement of Article 23 of Regulation (EC) No 1223/2009, which establishes the obligation for responsible persons to notify serious undesirable effects to competent authorities in the EU Member States.
[2] Article 23 of Regulation (EC) No 1223/2009.
[3] For undesirable effects that are very likely or likely to be attributable to the cosmetic product, Article 21 of Regulation (EC) No 1223/2009, 'Access to information for the public', applies.
[4] European Commission, Serious Undesirable Effects (SUE) Reporting Guidelines, http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/sue_reporting_guidelines_en.pdf

The information on undesirable effects is to be kept up-to-date and regularly made available to the safety assessor [1], who may consider it necessary to revise the safety assessment, suggest improvements to the formulation or use the information to establish the safety assessment for similar products.

Additional cosmetovigilance data, such as serious undesirable effects of a non-intended use may also provide helpful information that the safety assessor should consider.

3.10. **Information on the cosmetic product**

**That section of the cosmetic product safety report allows the inclusion of any additional information which is not covered under the other headings of Part A of Annex I to Regulation (EC) No 1223/2009, but is considered relevant in order to carry out the safety assessment of the product.**

This section of the cosmetic product safety report should contain other relevant information, either relating to the product or similar formulations, such as existing studies on human volunteers, or relating to specific substances, such as the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

This section could be used to refer to information on substances or mixtures also used in other kinds of products, such as food and pharmaceuticals.

4. PART B OF ANNEX I TO REGULATION (EC) No 1223/2009 — COSMETIC PRODUCT SAFETY ASSESSMENT

**Part B of the report is the actual assessment of the safety of the product. In their reasoning, the safety assessor is required to take into account all the hazards identified for the product and the exposure to it.**

Part B of the cosmetic product safety report comprises:

(1) The assessment conclusion;

(2) The labelled warnings and instructions of use;

(3) The reasoning;

(4) The credentials of the safety assessor and their final approval.

4.1. **Assessment conclusion**

**The assessment conclusion is a statement on the safety of the cosmetic product in relation to the safety requirement of Article 3 of Regulation (EC) No 1223/2009.**

The conclusion should state whether the product is safe, safe with restrictions or not safe for human health when used under normal or reasonably foreseeable conditions of use.

The legal framework for the assessment should be explicitly mentioned, in particular Regulation (EC) No 1223/2009 on cosmetic products.

If the product has been assessed as not safe, it cannot be considered to comply with Regulation (EC) No 1223/2009 and therefore is not to be placed on the market.

4.2. **Labelled warnings and instructions of use**

**The aim of that section of the cosmetic product safety report is to explicitly list the particular precautions to be observed in use, including at least those listed in Annexes III to VI to Regulation (EC) No 1223/2009 and any special precautionary information on cosmetic products for professional use, which should appear on the labelling.**

[1] This is an obligation of the responsible person according to article 10(1)(c) of Regulation (EC) No 1223/2009.

In accordance with Annex I to Regulation (EC) No 1223/2009, this section is to be a statement regarding the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d) of Regulation (EC) No 1223/2009.

It is the task of the safety assessor to determine which warnings or instructions of use, in addition to those listed in Annexes III to VI, need to be labelled to ensure the safe use of the product.

The safety assessor should decide what is to appear on the labelling on a case-by-case basis, taking into account the legal obligations deriving from Article 19 and the Annexes to Regulation (EC) No 1223/2009 and, where relevant, instruments such as Commission Recommendation 2006/647/EC [1] and other guidelines published by the Commission such as those on the 'period of time after opening' labelling [2] and the labelling of ingredients under Directive 76/768/EEC [3].

4.3. **Reasoning**

**The reasoning is the core of the safety assessment, as its aim is to clearly and accurately explain how the safety assessor reaches his or her conclusions on the safety of the cosmetic product from the data gathered under Part A of Annex I to Regulation (EC) No 1223/2009.**

**The safety assessment is to be performed on a case-by-case basis for each individual cosmetic product and be the result of an expert evaluation of the available data. The safety assessor should ensure that all the information (s)he needs to carry out a safety assessment is available; (s)he should check the relevance of the data provided on the product to be assessed; and (s)he should justify the absence of data required under Part A, when (s)he considers they are not relevant or necessary.**

**In order to draw conclusions on the safety of a cosmetic product, the safety assessor is required to evaluate the safety of the individual substances or mixtures present in the formulation and the safety of the finished product. His/her conclusions are to be based on a body of evidence showing that, for all the hazards identified, the product can be considered safe in terms of human health.**

**The safety assessor may accept, reject, or accept under specific conditions the formulation under consideration. A product that does not comply with Regulation (EC) No 1223/2009 is to be rejected and not marketed.**

The reasoning for the safety assessment sets out the considerations that lead the safety assessor, based on all available safety-related information, to an overall conclusion on the safety of a product.

In their reasoning, the safety assessor is required to take into account all the hazards identified, the intended and reasonably foreseeable exposure conditions of the individual substances or mixtures present in the formulation and of the finished cosmetic product.

Analysis and evaluation of the validity/reliability of all existing information is the task of the safety assessor. By conducting this analysis, the safety assessor is able to decide whether the available data are sufficient to perform a safety assessment or whether additional data need to be obtained on an individual substance or the finished cosmetic product.

The reasoning is based on the data compiled in Part A of the cosmetic product safety report and takes into account the safety evaluation of substances and mixtures, carried out by the Scientific Committee for Consumer Safety when the substances appear in the Annexes to Regulation (EC) No 1223/2009, by other competent scientific committees or panels, or by the safety assessor him/herself, and the safety evaluation of the cosmetic product.

(1) OJ L 265, 26.9.2006, p. 39.
(2) Available on http://ec.europa.eu/consumers/sectors/cosmetics/documents/guidelines/labelling/index_en.htm
(3) Available on http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guide_labelling200802_en.pdf

4.3.1. *Safety Evaluation of Substances and/or Mixtures*

The safety evaluation of substances and/or mixtures consists of three main steps:

(1) hazard characterisation of substances and mixtures;

(2) assessment of the local and systemic exposure (considering absorption data);

(3) risk assessment of systemic effects (calculation of margin of safety) and risk assessment of local effects (such as skin allergy, skin irritation).

For fragrance and flavour compounds, where information on their composition is confidential, a safety assessment may be provided to the responsible person for the finished cosmetic product by the manufacturer of that mixture. Taking into account the concentration in the final cosmetic product and its exposure pattern, the safety assessment of the fragrance and flavour compound should be prepared following the principles described in Annex I to Regulation (EC) No 1223/2009 and these guidelines. An appropriate document demonstrating the safety of the fragrance or flavour compound should be provided by the supplier to the responsible person for the finished cosmetic product.

4.3.2. *Safety Evaluation of the Cosmetic Product*

The safety evaluation of the cosmetic product covers three main aspects:

(1) summary of the risk assessment based on the local and systemic effects of all individual substances/mixtures ([1]);

(2) additional assessment of the safety of the formulated product, which cannot be assessed by assessing the substances/mixtures separately. This could for instance be the formulation's skin compatibility, assessment of possible combination effects, such as one ingredient that can increase the absorption rate of another ingredient, possible effects that could arise from interaction with packaging material, or possible effects due to chemical reactions between the individual substances/mixtures in the formulated product ([2]);

(3) other factors that influence the safety assessment, such as stability, microbiological quality, packaging, and labelling, including use instructions and precautions for use.

The specific assessment for cosmetic products intended for use on children under the age of three which is required in accordance with Regulation (EC) No 1223/2009 should take into account the specific recommendations in the SCCS Notes of Guidance ([3]).

In the specific assessment required in accordance with Regulation (EC) No 1223/2009 for cosmetic products intended exclusively for use in external intimate hygiene, the particular characteristics of the application site also are to be taken into account.

The safety assessor may accept, reject, or accept under specific conditions the formulation under consideration. A product that does not comply with Regulation (EC) No 1223/2009 is to be rejected and is not be marketed. Recommendations by the safety assessor regarding the safe use of the product should be followed.

In order to ensure that the cosmetic product safety report is kept up to date as required by Article 10(1)(c) of Regulation (EC) No 1223/2009, the safety of the finished product should be reassessed regularly.

([1]) For products in the same range, where the only difference among different products is the colouring agent, and that has no impact on safety, e.g. for lipsticks or other colour make-up, a combined product safety report may be considered, but is to be justified.
([2]) SCCS, SCHER, SCENIHR, Toxicity and Assessment of Chemical Mixtures, 2012 http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf
([3]) SCCS Notes of Guidance, para 3-7.3, p. 51.

When changes in the legal requirements occur (e.g. restrictions of one of the substances included in the formulation), it should be checked, amongst others (e.g. labelling), whether the formulation still complies with the law, and the safety assessment should be reviewed and, if necessary, updated.

The safety assessment should also be reviewed and, if necessary, updated, where one or more of the following circumstances apply:

(a) new scientific findings and toxicological data on the substances are available which could modify the result of the existing safety assessment;

(b) changes occurring in the formulation or specifications of raw materials;

(c) changes occurring in the conditions of use;

(d) a rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse [1].

Structures and processes should be established to ensure that the information relevant for the update of the cosmetic product safety report is efficiently exchanged between the responsible person and the safety assessor, and that the safety assessor is in a position to intervene where an update is necessary.

4.4. **Assessor's credentials and approval of Part B**

**The safety assessor is to be a professional with the necessary knowledge and expertise to draw up an accurate safety assessment, as indicated by the qualification requirements in Article 10(2) of Regulation (EC) No 1223/2009. That section of the cosmetic product safety report aims at ensuring that this requirement is met and that the necessary evidence is provided.**

That section of the safety report is required to list the name and address of the safety assessor and to be dated and signed.

The result of the safety assessment is to be signed stating the date of preparation or be issued based on an electronic release establishing a clear relationship between the assessor, the formulation and the date of assessment. The electronic version should be protected from abuse by unauthorised persons.

In accordance with Article 10(2) of Regulation (EC) No 1223/2009, the safety assessor is required to be 'a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline or a course recognised as equivalent by a Member State'.

A person who has obtained qualifications in a third country may act as a safety assessor if they have completed 'a course recognised as equivalent [to a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline] by a Member State'.

Proof is to be provided of the safety assessor's qualification (i.e. copy of the diploma and, where needed, proof of equivalence) laid down in Article 10 of Regulation (EC) No 1223/2009.

[1] European Commission, Serious Undesirable Effects (SUE) Reporting Guidelines, http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/sue_reporting_guidelines_en.pdf

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*Appendix*

**Known Databases Containing Toxicological Data on Substances Used in Cosmetics**

ChemIDPlus Light — http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

ChemIDPlus Advanced — http://chem.sis.nlm.nih.gov/chemidplus/

Cosmetics Europe Recommendations — https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/recommendations.html

IPCS Inchem — http://www.inchem.org/pages/jecfa.html

PubMed — http://www.ncbi.nlm.nih.gov/pubmed

ToxNet — http://toxnet.nlm.nih.gov/

# ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

## DECISION No 2/2013 OF THE EU-EFTA JOINT COMMITTEE ON COMMON TRANSIT

**of 7 November 2013**

**amending the Convention of 20 May 1987 on a common transit procedure**

(2013/675/EU)

THE EU-EFTA JOINT COMMITTEE,

Having regard to the Convention of 20 May 1987 on a common transit procedure [1], and in particular Article 15(3)(a) thereof,

Whereas:

(1) The Recommendation of 26 June 2009 of the Customs Cooperation Council amended the Harmonised System nomenclature. As a consequence, on 1 January 2012, Commission Implementing Regulation (EU) No 1006/2011 [2] entered into force and replaced HS code 1701 11 by two new HS codes, namely 1701 13 and 1701 14, and HS code 2403 10 by two new HS codes, namely 2403 11 and 2403 19.

(2) Consequently, the corresponding HS codes specified in the list of goods involving higher risk of fraud of Annex I to Appendix I to the Convention of 20 May 1987 on a common transit procedure (the 'Convention') should be amended accordingly.

(3) Due to a new revision of Recommendation 21 of the United Nations Economic Commission for Europe, revision 8.1, on, *inter alia*, package codes, it is appropriate to adapt Annex A2 to Appendix III to the Convention accordingly.

(4) As the package codes format has changed from alphabetical2 (a2) to alphanumeric2 (an2) codes, the Type/Length of the kind of packages (box 31) in Annex A1 to Appendix III to the Convention should be amended accordingly.

(5) The proposed amendments lead to an alignment of provisions on common transit with the EU provisions on transit.

(6) Therefore the Convention should be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1*

The Convention of 20 May 1987 on a common transit procedure shall be amended as set out in the Appendix to this Decision.

*Article 2*

The amendments set out in point 1 of the Appendix to this Decision shall apply from 1 January 2012.

The amendments set out in points 2 and 3 of the Appendix to this Decision shall apply from 1 January 2013.

Done at Reykjavik, 7 November 2013.

*For the EU-EFTA*
*Joint Committee on common transit*
*The President*
Karl F. GARÐARSSON

[1] OJ L 226, 13.8.1987, p. 2.
[2] Commission Implementing Regulation (EU) No 1006/2011 of 27 September 2011 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 282, 28.10.2011, p. 1).

*Appendix*

1. Annex I to Appendix I to the Convention is amended as follows:

(i) the row for HS codes '1701 11, 1701 12, 1701 91, 1701 99' is replaced by the following:

| | | | | |
|---|---|---|---|---|
| '1701 12<br>1701 13<br>1701 14<br>1701 91<br>1701 99 | Cane or beet sugar and chemically pure sucrose, in solid form | 7 000 kg | | —<br>—<br>—<br>—' |

(ii) the row for HS code '2403 10' is replaced by the following:

| | | | | |
|---|---|---|---|---|
| '2403 11<br>2403 19 | Smoking tobacco, whether or not containing tobacco substitutes in any proportion | 35 kg | | —' |

2. The entry 'Kind of packages (box 31) Type/Length a2 The packaging codes presented in Annex A2 shall be used.' in Annex A1 to Appendix III to the Convention is replaced by the following:

'Kind of packages (box 31)

Type/Length: an2

The package codes referred to in Annex A2 shall be used.'.

3. Point 5 of Annex A2 to Appendix III to the Convention is replaced by the following:

'PACKAGE CODE

(UN/ECE Recommendation No 21/Rev.8.1 of 12 July 2010)

| | |
|---|---|
| Aerosol | AE |
| Ampoule, non-protected | AM |
| Ampoule, protected | AP |
| Atomizer | AT |
| Bag | BG |
| Bag, flexible container | FX |
| Bag, gunny | GY |
| Bag, jumbo | JB |
| Bag, large | ZB |
| Bag, multiply | MB |
| Bag, paper | 5M |
| Bag, paper, multi-wall | XJ |
| Bag, paper, multi-wall, water resistant | XK |
| Bag, plastic | EC |
| Bag, plastics film | XD |
| Bag, polybag | 44 |
| Bag, super bulk | 43 |
| Bag, textile | 5L |

| | |
|---|---|
| Bag, textile, sift proof | XG |
| Bag, textile, water resistant | XH |
| Bag, textile, without inner coat/liner | XF |
| Bag, tote | TT |
| Bag, woven plastic | 5H |
| Bag, woven plastic, sift proof | XB |
| Bag, woven plastic, water resistant | XC |
| Bag, woven plastic, without inner coat/liner | XA |
| Bale, compressed | BL |
| Bale, non-compressed | BN |
| Ball | AL |
| Balloon, non-protected | BF |
| Balloon, protected | BP |
| Bar | BR |
| Barrel | BA |
| Barrel, wooden | 2C |
| Barrel, wooden, bung type | QH |
| Barrel, wooden, removable head | QJ |
| Bars, in bundle/bunch/truss | BZ |
| Basin | BM |
| Basket | BK |
| Basket, with handle, cardboard | HC |
| Basket, with handle, plastic | HA |
| Basket, with handle, wooden | HB |
| Belt | B4 |
| Bin | BI |
| Block | OK |
| Board | BD |
| Board, in bundle/bunch/truss | BY |
| Bobbin | BB |

| | |
|---|---|
| Bolt | BT |
| Bottle, gas | GB |
| Bottle, non-protected, bulbous | BS |
| Bottle, non-protected, cylindrical | BO |
| Bottle, protected bulbous | BV |
| Bottle, protected cylindrical | BQ |
| Bottlecrate/bottlerack | BC |
| Box | BX |
| Box, aluminium | 4B |
| Box, Commonwealth Handling Equipment Pool (CHEP), Eurobox | DH |
| Box, fibreboard | 4G |
| Box, for liquids | BW |
| Box, natural wood | 4C |
| Box, plastic | 4H |
| Box, plastic, expanded | QR |
| Box, plastic, solid | QS |
| Box, plywood | 4D |
| Box, reconstituted wood | 4F |
| Box, steel | 4A |
| Box, wooden, natural wood, ordinary | QP |
| Box, wooden, natural wood, with sift proof walls | QQ |
| Bucket | BJ |
| Bulk, gas (at 1 031 mbar and 15 °C) | VG |
| Bulk, liquefied gas (at abnormal temperature/pressure) | VQ |
| Bulk, liquid | VL |
| Bulk, scrap metal | VS |
| Bulk, solid, fine particles (“powders”) | VY |
| Bulk, solid, granular particles (“grains”) | VR |
| Bulk, solid, large particles (“nodules”) | VO |
| Bunch | BH |
| Bundle | BE |
| Bundle, wooden | 8C |
| Butt | BU |

| | |
|---|---|
| Cage | CG |
| Cage, Commonwealth Handling Equipment Pool (CHEP) | DG |
| Cage, roll | CW |
| Can, cylindrical | CX |
| Can, rectangular | CA |
| Can, with handle and spout | CD |
| Canister | CI |
| Canvas | CZ |
| Capsule | AV |
| Carboy, non-protected | CO |
| Carboy, protected | CP |
| Card | CM |
| Cart, flatbed | FW |
| Carton | CT |
| Cartridge | CQ |
| Case | CS |
| Case, car | 7A |
| Case, isothermic | EI |
| Case, skeleton | SK |
| Case, steel | SS |
| Case, with pallet base | ED |
| Case, with pallet base, cardboard | EF |
| Case, with pallet base, metal | EH |
| Case, with pallet base, plastic | EG |
| Case, with pallet base, wooden | EE |
| Case, wooden | 7B |
| Cask | CK |
| Chest | CH |
| Churn | CC |
| Clamshell | AI |
| Coffer | CF |
| Coffin | CJ |
| Coil | CL |
| Composite packaging, glass receptacle | 6P |

| | |
|---|---|
| Composite packaging, glass receptacle in aluminium crate | YR |
| Composite packaging, glass receptacle in aluminium drum | YQ |
| Composite packaging, glass receptacle in expandable plastic pack | YY |
| Composite packaging, glass receptacle in fibre drum | YW |
| Composite packaging, glass receptacle in fibreboard box | YX |
| Composite packaging, glass receptacle in plywood drum | YT |
| Composite packaging, glass receptacle in solid plastic pack | YZ |
| Composite packaging, glass receptacle in steel crate box | YP |
| Composite packaging, glass receptacle in steel drum | YN |
| Composite packaging, glass receptacle in wickerwork hamper | YV |
| Composite packaging, glass receptacle in wooden box | YS |
| Composite packaging, plastic receptacle | 6H |
| Composite packaging, plastic receptacle in aluminium crate | YD |
| Composite packaging, plastic receptacle in aluminium drum | YC |
| Composite packaging, plastic receptacle in fibre drum | YJ |
| Composite packaging, plastic receptacle in fibreboard box | YK |
| Composite packaging, plastic receptacle in plastic drum | YL |
| Composite packaging, plastic receptacle in plywood box | YH |
| Composite packaging, plastic receptacle in plywood drum | YG |
| Composite packaging, plastic receptacle in solid plastic box | YM |
| Composite packaging, plastic receptacle in steel crate box | YB |
| Composite packaging, plastic receptacle in steel drum | YA |
| Composite packaging, plastic receptacle in wooden box | YF |
| Cone | AJ |
| Container, flexible | 1F |
| Container, gallon | GL |
| Container, metal | ME |
| Container, not otherwise specified as transport equipment | CN |
| Container, outer | OU |
| Cover | CV |
| Crate | CR |

| | |
|---|---|
| Crate, beer | CB |
| Crate, bulk, cardboard | DK |
| Crate, bulk, plastic | DL |
| Crate, bulk, wooden | DM |
| Crate, framed | FD |
| Crate, fruit | FC |
| Crate, metal | MA |
| Crate, milk | MC |
| Crate, multiple layer, cardboard | DC |
| Crate, multiple layer, plastic | DA |
| Crate, multiple layer, wooden | DB |
| Crate, shallow | SC |
| Crate, wooden | 8B |
| Creel | CE |
| Cup | CU |
| Cylinder | CY |
| Demijohn, non-protected | DJ |
| Demijohn, protected | DP |
| Dispenser | DN |
| Drum | DR |
| Drum, aluminium | 1B |
| Drum, aluminium, non-removable head | QC |
| Drum, aluminium, removable head | QD |
| Drum, fibre | 1G |
| Drum, iron | DI |
| Drum, plastic | IH |
| Drum, plastic, non-removable head | QF |
| Drum, plastic, removable head | QG |
| Drum, plywood | 1D |
| Drum, steel | 1A |
| Drum, steel, non-removable head | QA |
| Drum, steel, removable head | QB |

| | |
|---|---|
| Drum, wooden | 1W |
| Envelope | EN |
| Envelope, steel | SV |
| Filmpack | FP |
| Firkin | FI |
| Flask | FL |
| Flexibag | FB |
| Flexitank | FE |
| Foodtainer | FT |
| Footlocker | FO |
| Frame | FR |
| Girder | GI |
| Girders, in bundle/bunch/truss | GZ |
| Hamper | HR |
| Hanger | HN |
| Hogshead | HG |
| Ingot | IN |
| Ingots, in bundle/bunch/truss | IZ |
| Intermediate bulk container | WA |
| Intermediate bulk container, aluminium | WD |
| Intermediate bulk container, aluminium, liquid | WL |
| Intermediate bulk container, aluminium, pressurised > 10 kPa | WH |
| Intermediate bulk container, composite | ZS |
| Intermediate bulk container, composite, flexible plastic, liquids | ZR |
| Intermediate bulk container, composite, flexible plastic, pressurised | ZP |
| Intermediate bulk container, composite, flexible plastic, solids | ZM |
| Intermediate bulk container, composite, rigid plastic, liquids | ZQ |
| Intermediate bulk container, composite, rigid plastic, pressurised | ZN |
| Intermediate bulk container, composite, rigid plastic, solids | PLN |
| Intermediate bulk container, fibreboard | ZT |
| Intermediate bulk container, flexible | ZU |
| Intermediate bulk container, metal | WF |
| Intermediate bulk container, metal, liquid | WM |

| | |
|---|---|
| Intermediate bulk container, metal, other than steel | ZV |
| Intermediate bulk container, metal, pressure 10 kPa | WJ |
| Intermediate bulk container, natural wood | ZW |
| Intermediate bulk container, natural wood, with inner liner | WU |
| Intermediate bulk container, paper, multi-wall | ZA |
| Intermediate bulk container, paper, multi-wall, water resistant | ZC |
| Intermediate bulk container, plastic film | WS |
| Intermediate bulk container, plywood | ZX |
| Intermediate bulk container, plywood, with inner liner | WY |
| Intermediate bulk container, reconstituted wood | ZY |
| Intermediate bulk container, reconstituted wood, with inner liner | WZ |
| Intermediate bulk container, rigid plastic | AA |
| Intermediate bulk container, rigid plastic, freestanding, liquids | ZK |
| Intermediate bulk container, rigid plastic, freestanding, pressurised | ZH |
| Intermediate bulk container, rigid plastic, freestanding, solids | ZF |
| Intermediate bulk container, rigid plastic, with structural equipment, liquids | ZJ |
| Intermediate bulk container, rigid plastic, with structural equipment, pressurised | ZG |
| Intermediate bulk container, rigid plastic, with structural equipment, solids | ZD |
| Intermediate bulk container, steel | WC |
| Intermediate bulk container, steel, liquid | WK |
| Intermediate bulk container, steel, pressurised > 10 kPa | WG |
| Intermediate bulk container, textile without coat/liner | WT |
| Intermediate bulk container, textile, coated | WV |
| Intermediate bulk container, textile, coated and liner | WX |
| Intermediate bulk container, textile, with liner | WW |
| Intermediate bulk container, woven plastic, coated | WP |
| Intermediate bulk container, woven plastic, coated and liner | WR |
| Intermediate bulk container, woven plastic, with liner | WQ |
| Intermediate bulk container, woven plastic, without coat/liner | WN |
| Jar | JR |
| Jerrican, cylindrical | JY |
| Jerrican, plastic | 3H |
| Jerrican, plastic, non-removable head | QM |

| | |
|---|---|
| Jerrican, plastic, removable head | QN |
| Jerrican, rectangular | JC |
| Jerrican, steel | 3A |
| Jerrican, steel, non-removable head | QK |
| Jerrican, steel, removable head | QL |
| Jug | JG |
| Jutebag | JT |
| Keg | KG |
| Kit | KI |
| Liftvan | LV |
| Log | LG |
| Logs, in bundle/bunch/truss | LZ |
| Lot | LT |
| Lug | LU |
| Luggage | LE |
| Mat | MT |
| Matchbox | MX |
| Mutually defined | ZZ |
| Nest | NS |
| Net | NT |
| Net, tube, plastic | NU |
| Net, tube, textile | NV |
| Not available | NA |
| Octabin | OT |
| Package | PK |
| Package, cardboard, with bottle grip-holes | IK |
| Package, display, cardboard | IB |
| Package, display, metal | ID |
| Package, display, plastic | IC |
| Package, display, wooden | IA |
| Package, flow | IF |
| Package, paper wrapped | IG |
| Package, show | IE |
| Packet | PA |

| | |
|---|---|
| Pail | PL |
| Pallet | PX |
| Pallet, 100 cm × 110 cm | AH |
| Pallet, AS 4068-1993 | OD |
| Pallet, box Combined open-ended box and pallet | PB |
| Pallet, CHEP 100 cm × 120 cm | OC |
| Pallet, CHEP 40 cm × 60 cm | OA |
| Pallet, CHEP 80 cm × 120 cm | OB |
| Pallet, ISO T11 | OE |
| Pallet, modular, collars 80 cm × 100 cm | PD |
| Pallet, modular, collars 80 cm × 120 cm | PE |
| Pallet, modular, collars 80 cm × 60 cm | AF |
| Pallet, shrinkwrapped | AG |
| Pallet, triwall | TW |
| Pallet, wooden | 8A |
| Pan | P2 |
| Parcel | PC |
| Pen | PF |
| Piece | PP |
| Pipe | PI |
| Pipes, in bundle/bunch/truss | PV |
| Pitcher | PH |
| Plank | PN |
| Planks, in bundle/bunch/truss | PZ |
| Plate | PG |
| Plates, in bundle/bunch/truss | PY |
| Platform, unspecified weight or dimension | OF |
| Pot | PT |
| Pouch | PO |
| Punnet | PJ |
| Rack | RK |
| Rack, clothing hanger | RJ |
| Receptacle, fibre | AB |
| Receptacle, glass | GR |

| | |
|---|---|
| Receptacle, metal | MR |
| Receptacle, paper | AC |
| Receptacle, plastic | PR |
| Receptacle, plastic wrapped | MW |
| Receptacle, wooden | AD |
| Rednet | RT |
| Reel | RL |
| Ring | RG |
| Rod | RD |
| Rods, in bundle/bunch/truss | RZ |
| Roll | RO |
| Sachet | SH |
| Sack | SA |
| Sack, multi-wall | MS |
| Sea-chest | SE |
| Set | SX |
| Sheet | ST |
| Sheet, plastic wrapping | SP |
| Sheetmetal | SM |
| Sheets, in bundle/bunch/truss | SZ |
| Shrinkwrapped | SW |
| Skid | SI |
| Slab | SB |
| Sleeve | SY |
| Slipsheet | SL |
| Spindle | SD |
| Spool | SO |
| Suitcase | SU |
| Tablet | T1 |
| Tank container, generic | TG |
| Tank, cylindrical | TY |
| Tank, rectangular | TK |
| Tea-chest | TC |

| | |
|---|---|
| Tierce | TI |
| Tin | TN |
| Tray | PU |
| Tray, containing horizontally stacked flat items | GU |
| Tray, one layer no cover, cardboard | DV |
| Tray, one layer no cover, plastic | DS |
| Tray, one layer no cover, polystyrene | DU |
| Tray, one layer no cover, wooden | DT |
| Tray, rigid, lidded stackable (CEN TS 14482:2002) | IL |
| Tray, two layers no cover, cardboard | DY |
| Tray, two layers no cover, plastic tray | DW |
| Tray, two layers no cover, wooden | DX |
| Trunk | TR |
| Truss | TS |
| Tub | TB |
| Tub, with lid | TL |
| Tube | TU |
| Tube, collapsible | TD |
| Tube, with nozzle | TV |
| Tubes, in bundle/bunch/truss | TZ |
| Tun | TO |
| Tyre | TE |
| Uncaged | UC |
| Unit | UN |
| Unpacked or unpackaged | NE |
| Unpacked or unpackaged, multiple units | NG |
| Unpacked or unpackaged, single unit | NF |
| Vacuum-packed | VP |
| Vanpack | VK |
| Vat | VA |
| Vehicle | VN |
| Vial | VI |
| Wickerbottle | WB’ |

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