

## ข้อมูลเกี่ยวกับเครื่องสำอาง (PRODUCTS INFORMATION FILE : PIF)

เลขที่จดแจ้ง: 1026300003493

ชื่อทางการค้าเครื่องสำอาง: แอนนัว ANUA

ชื่อเครื่องสำอาง: ฮาร์ทลีฟ 77 เปอร์เซนต์ ชูทิ่ง โทเนอร์ HEARTLEAF 77% SOOTHING TONER

ประเภทของเครื่องสำอาง: ใช้แล้วไม่ล้างออก

วันที่จดแจ้ง: 28/1/2563

วันที่ใบอนุญาตหมดอายุ: 27/1/2569

จุดประสงค์การใช้: บำรุงผิว

ลักษณะทางกายภาพ: ผิวหน้า

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**COSMETICS EUROPE:**  
EXCHANGE OF INFORMATION BETWEEN FRAGRANCE  
SUPPLIERS AND COSMETIC MANUFACTURERS

2011

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## **GUIDELINES ON EXCHANGE OF INFORMATION BETWEEN FRAGRANCE SUPPLIERS AND COSMETIC MANUFACTURERS**

COMPLIANCE WITH THE PRODUCT INFORMATION REQUIREMENTS OF ARTICLE 7  
OF THE EC COSMETICS DIRECTIVE 76/768  
AS LAST AMENDED BY THE SEVENTH AMENDMENT (DIRECTIVE 2003/15) AND ITS  
ADAPTATIONS TO TECHNICAL PROGRESS

**EUROPEAN COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION (COLIPA)  
AND  
INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA)**

**Revised Version 2011 Final**

### **I. INTRODUCTION AND SCOPE**

These guidelines are intended for the exchange of safety related product information between fragrance suppliers and manufacturers of cosmetic products needed to meet the Cosmetics Directive requirements.

This document needs to be reviewed in accordance with the mandatory requirements of any new regulation, e.g. EU Cosmetic Regulation 1223/2009.

The guidelines consist of the following sections:

- I. Introduction
- II. An overview of the information on the fragrance compound that needs to be exchanged
- III. An explanation of the importance of a reasoned safety evaluation and the status of the safety evaluator
- IV. An explanation of the background and meaning of the IFRA Code of Practice and its safety standards for consumer exposure to certain fragrance ingredients.
- V. Further information that can be exchanged.
- VI. Appendix 1A, 1B, 1C: Examples of the product information for a fragrance compound.

The information as described in paragraph II needs to be available to the cosmetic company when a fragrance compound is selected for a cosmetic product.

The examples provided in the appendices 1A, B and C are not to be regarded as formal requirements regarding the format used for information exchange. Especially for Appendix 1A, B and C, where the information in points 1 – 5 is identical, one joint format should be able to be used to communicate the information in one document, if so agreed by the fragrance supplier and its customer.

For the purpose of this document and especially with regard to labelling requirements of the EU Cosmetics Directive a fragrance compound is a mixture of fragrance ingredients and functional components with olfactory, odour-enhancing, odour-protecting or blending properties, formulated and intentionally added to a cosmetic product to impart a scent or cover a malodour.

## II. THE INFORMATION

Confidentiality: The information provided by the fragrance supplier must be handled by the cosmetic company in a way, which respects the intellectual property of the supplier. For example, unless otherwise agreed, commercially sensitive data (e.g. quantitative formulation data) should only be available to regulatory and safety personnel for the purposes of determining the correct labelling of the final product and for meeting the requirements of the Cosmetics Directive or for other safety or regulatory purposes.

Confidentiality of the fragrance formula is implicit. The Cosmetics Directive acknowledges the confidentiality of the fragrance formula and, therefore, a full disclosure of the fragrance ingredients is not legally required. However, the fragrance compound must still be considered in the safety assessment of the finished cosmetic product, as required in *Article 7a1. (d)*.

As a minimum, the fragrance supplier must provide the following information:

- The identity of the customer
- The name and address of the supplier
- The identity of the fragrance compound with its name (if any) and code number
- The product classes, use pattern and use concentration for which the fragrance compound has been assessed. Broad and multiple product categories can be considered in one declaration, as long as the assessor is satisfied that the fragrance compound is suitable for all products, which may come under those categories, up to a maximum level considered.
- A reasoned evaluation of the safety of the fragrance compound for its intended use (see paragraph III below)
- A certificate of compliance with IFRA Standards currently in place, given the commitment of COLIPA members to adhere to these Standards. In case of an update of IFRA Standards, information about a changed status of the fragrance compound (e.g. no longer compliant) needs to be issued within the time frame as stipulated by IFRA and forwarded to the cosmetic manufacturer.
- A statement of compliance of the fragrance ingredients used in the compound with relevant EU chemical control legislation
- A Safety Data Sheet in compliance with current relevant EU regulation
- Accurate information on the presence and concentration of substances, regulated in the Annexes of the Cosmetics Directive, based on reliable sources of the fragrance compound or its ingredients
- Where appropriate, additional information (please refer to section V, Further Information)
- The date
- The name, qualification and signature of the safety evaluator

All information can be supplied either via separate documents or via aggregated documents.

## III. THE SAFETY EVALUATION AND THE ROLE OF THE SAFETY EVALUATOR

In addition to the certificate of compliance with current IFRA Standards, a reasoned evaluation of the safety of the fragrance compound for its intended use should be carried out by the fragrance supplier.

This safety evaluation should be based on a thorough analysis, evaluation and interpretation of available data and conditions of exposure. To this end the cosmetic manufacturer shall communicate to the fragrance supplier adequate information on product category and use pattern for which the fragrance compound is intended.

Ideally, the development of the fragrance compound should take into account these elements from the start by a close collaboration between the safety evaluator and the perfumer.

The selection of ingredients at an adequate concentration level might be sufficient to minimize risk resulting of the presence of certain potential hazardous materials. The safety evaluation should also consider the level of purity of the ingredients.

Additional information on the nature of potential health hazard(s) of the undiluted fragrance compound, according to the rules of the Dangerous Preparations Directive (and in future the CLP) can be retrieved from the Safety Data Sheet (SDS) for the selected fragrance compound. The SDS will identify the ingredient(s) responsible for the hazard(s) and leading to the classification of the fragrance compound.

If new information comes to light, or if there are changes in IFRA Standards or in legislation, the impact on existing fragrances must be considered and, if necessary, new assessments must be issued.

The safety evaluator in charge of assessing the safety of the fragrance compound should be qualified similar to a safety assessor of a cosmetic product, i.e. holding 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 recognized as equivalent by a Member State.

The role and responsibility of the safety evaluator must be emphasised. It is in the interest of the fragrance company to select a person with appropriate expertise.

As an alternative to the above reasoned evaluation of the fragrance compound, the fragrance supplier and the cosmetic manufacturer may agree that the cosmetic manufacturer will carry out the safety evaluation at the level of the safety assessment carried out on the finished cosmetic product. In this case and under appropriate terms of confidentiality, the fragrance supplier would provide a breakdown of the fragrance compound according to agreements between the supplier and manufacturer, together with any necessary information on components.

The safety evaluator is responsible for determining:

- whether the ingredients present in the fragrance compound meet the requirements of the cosmetics and chemical legislations, the current IFRA Code of Practice as well as the current COLIPA Recommendations when applicable;
- whether the toxicological data on ingredients are relevant and sufficient;
- the safety of the fragrance compound considering the type of the product and its use conditions
- whether additional information supporting the safety (e.g. market experience) can be considered for a given ingredient or the finished fragrance compound;

The safety evaluator must:

- have recognised competence in analysis, evaluation and interpretation of toxicological data;
- have access both to the toxicological and analytical information relevant for the safety of the fragrance compound;
- consider the safety of the fragrance compound independently of commercial considerations and would generally be expected to report to the senior management of a company.

The judgement of the safety evaluator relies on:

- the knowledge of the physico-chemical properties of the ingredients and QSAR studies available;
- the knowledge and experience of toxicological properties and safety-in-use of the ingredients;
- the history of safety-in-use of fragrance compounds containing the same or similar ingredients;
- the expert assessment of the appropriate data available on a new or novel ingredient
- if necessary, the results of additional data obtained either on one or more ingredients or on the finished fragrance compound itself.

#### **IV. THE IFRA STANDARDS FOR THE SAFE USE OF FRAGRANCES**

The IFRA Code of Practice prescribes Standards for the safe use of certain fragrance ingredients in consumer products and is based on an evaluation by an independent expert panel (REXPAN) of the safety data and profiles of these fragrance ingredients.

A certificate of compliance with current IFRA Standards is an integral basic part of the safety information to be supplied by the fragrance manufacturer. However, the certificate does not replace a reasoned evaluation of the safety of the fragrance compound for its intended use.

The suppliers may either declare the IFRA compliance of the fragrance compound in the product class provided by the cosmetic manufacturer (option 1, Appendix 1A) based on the intended use concentration of the compound in the finished product or disclose the maximum limit of the fragrance compound in the product class given by the cosmetic manufacturer or disclose the maximum limit in several product classes (up to the maximal number of classes identified by IFRA – option 2, Appendix 1A).

In case of an update of IFRA Standards, information about the status of the fragrance compound with regard to the new Standard(s) needs to be issued within two months after the amendment enters into force for new creations (which generally is 4 months after the date of the letter of notification) and forwarded to the cosmetic manufacturer for inclusion in the product information.

COLIPA recognizes the IFRA/RIFM safety process, the resulting Standards and the IFRA Code of Practice as central elements in the safety assessment of a fragrance compound and strongly recommends its members to ensure IFRA compliance of all its compounds in use in marketed finished products.

## **V. FURTHER INFORMATION**

Further to the information on presence and levels of substances regulated in the Annexes to the Cosmetics Directive, information on specific ingredients that are commonly subject to enquiries may be provided with the product information at the request of the cosmetic manufacturer. This will facilitate the safety assessment of the cosmetic product and dealing with consumer concerns in the marketplace (e.g. in case of sensitisation).

There may be occasions where further information is required to aid investigation of consumer complaints or adverse effects in the marketplace (Art. 7a 1. (f)). In such cases, the fragrance supplier will collaborate in any investigations and supply, in confidence, any information necessary for the investigation. This information may be supplied as necessary to the regulatory authorities, medical personnel investigating the incident as well as to the toxicologist or equivalent safety person in the cosmetic company.

Nothing in these guidelines prevents more comprehensive exchange of information between the fragrance supplier and the customer, as part of their commercial agreement.

## Appendix 1A

### EXAMPLE OF AN IFRA CONFORMITY CERTIFICATE

1. **Identity of customer:** COLIPA Hair Company  
15 A Hermann-Debroux  
1160 Brussels
2. **Product category:** Shampoo
3. **Identity of fragrance supplier:** Company xyz  
49 Avenue de la Parfumerie  
06130 Grasse
4. **Identity of fragrance compound:** Name (if any): Amber Flower  
Code Number: ABC 6789
5. **Assessment Concentration of the fragrance compound in cosmetic product:** 0.5%

#### 6. Conformity with current IFRA Standards

1<sup>st</sup> option:

When used in a shampoo at 0.5%, Fragrance compound ABC 6789 conforms to Amendment xx, the currently applicable Standards of the International Fragrance Association (IFRA).

This safety evaluation applies only to the use of fragrance ABC 6789 in the product stated. Use in other product types or at higher concentrations should be the subject of a separate safety evaluation by the supplier.

2<sup>nd</sup> option:

In order to be in compliance with the xx IFRA Amendment to the IFRA Code of Practice, this fragrance compound should not be used at levels exceeding the following ones per category:

Class 1: x %

Class 2: x%

.....

.....

Class 11B: x %

The presence and concentration in the fragrance compound of ingredients listed in the current IFRA Standards are as follows:

CAS	Substance	Concentration (mg/kg)
6728-263	trans-2-hexenal	200
8016-20-4	Grapefruit oil expressed	8500

**Evaluator**

**Name:**

**Qualification:**

**Signature:**

**Date:**

## Appendix 1B

### EXAMPLE OF AN EXCHANGE OF REGULATORY INFORMATION FOR A FRAGRANCE COMPOUND (IN EUROPE)

1. **Identity of customer:** COLIPA Hair Company  
15 A Hermann-Debroux  
1160 Brussels
2. **Product category:** Shampoo
3. **Identity of fragrance supplier:** Company xyz  
49 Avenue de la Parfumerie  
06130 Grasse
4. **Identity of fragrance compound:** Name (if any): Amber Flower  
Code Number: ABC 6789
5. **Assessment Concentration of the fragrance compound in cosmetic product:** 0.5%

### 6. Regulatory Information

The ingredients used in Fragrance compound ABC 6789 are in compliance with current European chemical control legislation.

Fragrance compound ABC6789 is formulated in accordance with the requirements of Annex II of Dir. 76/768/EEC (Cosmetics Directive).

The presence and concentration in the fragrance compound of ingredients listed in the Annexes III, IV, VI, VII to the Cosmetics Directive (76/768/EEC) are as follows:

For practical reasons, substances considered as "allergens" (26) within Annex III will be provided on a distinct list.

#### Annex III

The following substances considered as "allergens" in annex III are present:

CAS N°	Substance Name (e.g.: INCI)	Cosmetics Directive Annex/N°	Concentration (mg/kg) in the compound
105-13-5	Anisyl Alcohol (4-Methoxybenzyl alcohol)	III / 80	2
78-70-6	Linalool	III/ 84	30.000

The following other substances regulated in the annexes of the Cosmetics Directive are present:

CAS N°	Substance Name (e.g. : INCI)	Cosmetics Directive Annex/N°	Concentration (mg/kg) in the compound
93-89-0	Ethyl benzoate	VI/1/1	20
1506-02-1 21145-77-7	AHTN	III/182	200



## 7. Other information on specific ingredients <sup>1</sup>

The presence and concentration in the fragrance compound of the following specific ingredients are as follows

CAS	Substance	Concentration (mg/kg)
123-45-6	Material ABC	200

**Evaluator**

**Name:**

**Qualification:**

**Signature:**

**Date:**

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<sup>1</sup> To be decided by individual companies on a case-by-case basis.

## Appendix 1C

### EXAMPLE OF A SAFETY EVALUATION OF THE FRAGRANCE COMPOUND

1. **Identity of customer:** COLIPA Hair Company  
15 A Hermann-Debroux  
1160 Brussels
2. **Product category:** Shampoo
3. **Identity of fragrance supplier:** Company xyz  
49 Avenue de la Parfumerie  
06130 Grasse
4. **Identity of fragrance compound:** Name (if any): Amber Flower  
Code Number: ABC 6789
5. **Assessment Concentration of the fragrance compound in cosmetic product:** 0.5%

#### 6. Reasoned Safety Evaluation of Fragrance Compound ABC 6789

Fragrance compound ABC 6789 has been evaluated for safety when used at 0.5% in shampoo.

Company xyz only uses ingredients for which a safety clearance procedure is carried out by appropriately qualified people. The safety clearance takes into account the following information:

1. Safety data generated by RIFM, the suppliers or in the open scientific literature. This data is evaluated in accordance with the principles laid down in Appendix 5 to the IFRA Code of Practice. *Appendix 5 requires consideration of possible effects on the skin, including skin irritation and sensitisation with special attention paid to the effect of sunlight, should ingredients absorb ultra-violet radiation. Systemic toxicity should be considered in relation to the quantities of fragrance material used and likelihood of entry into the body.*
2. A history of safe-use of the ingredients at the levels proposed, taking into account in particular any reports of adverse effects reported by Dermatologists or other medical professionals.
3. Restrictions on the use of the ingredient published in the IFRA Standards.
4. In the absence of adequate data, structural relationships between the proposed ingredient and ingredients already cleared for inclusion in the product concerned or comparable product.
5. Impurities in the ingredients used, where necessary imposing purity specifications.

The creative perfumery procedures in company xyz ensure that the end use and concentration of the fragrance in the product are taken into account when deciding the concentration of each ingredient to be used. This ensures that any restrictions are not exceeded, and that there are appropriate margins of safety for each ingredient with regard to relevant toxicological endpoints.

I confirm that Fragrance compound ABC 6789 is composed only of ingredients approved by the safety clearance procedure, and that all ingredients are used within the restrictions relevant to the use of this fragrance in a shampoo at 0.5%.

## **Conclusion**

The conclusion of the safety evaluation is that this fragrance compound satisfies, according to the current state of knowledge, the safety requirements for the intended application under normal and reasonably foreseeable conditions of use.

**Evaluator**

**Name:**

**Qualification:**

**Signature:**

**Date:**

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## Annex II : Financial Guidelines

The purpose of this document is to enable applicants to prepare their grant applications.

Please be sure to read these guidelines carefully before replying to the current call for proposals.

### MAIN FINANCIAL AND MANAGEMENT RULES

**Disclaimer:** this document provides the applicants with a quick summary of the main legal and financial rules contained in the Financial Regulation applicable to the general budget of the European Communities<sup>1</sup> and its Implementing Rules<sup>2</sup>. The information given is not exhaustive and beneficiaries are therefore asked to carefully read the agreement sent to them, as it will constitute the legal basis for the grant.

#### 1. General principles

Grants are subject to the principles laid down in the Financial Regulation, in particular the principles of co-financing, prohibition of double financing and no-profit.

##### *Co-financing principle*

Union grants may not finance the entire cost of the action to be subsidised. The applicant must contribute to the implementation of the action either by way of own resources or by financial contribution from third parties (in the form of public or private assistance obtained elsewhere)<sup>3</sup>.

##### *No double financing rule*

Each action may give rise to the award of only one grant, there can be no duplicate Union funding of the same expenditure. The applicant must indicate the sources and amounts of any other funding received or applied for in the same financial year for the same action or for any other action and for routine activities<sup>4</sup>.

##### *No-profit rule*

The Union grant may not have the purpose or effect of producing a profit for the beneficiary. Profit is defined as a surplus of total actual receipts over the total actual costs of the action.

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<sup>1</sup> Council Regulation (EC, Euratom), n° 1605/2002 of 25.06.2002 (OJ L 248, 16.09.2002), as amended by Regulation n° 1995/2006 (OJ L 390, 30.12.2006) (<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/R/02002R1605-20070101-en.pdf>)

<sup>2</sup> Commission Regulation (EC, Euratom) n° 2342/2002 of 23.12.2002, (OJ L 357, 31.12.2002) and subsequent amendments: Commission Regulation (EC, Euratom) n° 1261/2005 of 20.07.2005 (OJ L 201, 02.08.2005), Commission Regulation (EC, Euratom) n° 1248 of 07.08.2006 (OJ L 227, 07.08.2006) and Commission Regulation n° 478/2007 (OJ L 111, 28.04.2007) (<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/R/02002R2342-20070501-en.pdf>)

<sup>3</sup> Art. 113 FR and 172 IR

<sup>4</sup> Art. 111 FR and 173(5) IR

Any income of the action must be indicated in the estimated budget and the final financial statement. The amount of the grant will be reduced by the amount of any surplus.<sup>5</sup>

## **2. Rules related to the grant requested**

- The Union grant will not exceed 80% of the total eligible costs.
  - The applicant organisation and/or other fund providers are required to make financial (cash) contribution(s) to the proposal of at least 20% of the total eligible costs.
  - The grant does not cover ineligible costs (see below for definition).
  - Contributions in kind (unpaid charity work by a private individual or corporate body, etc.) cannot be accepted.
  - Signed letters of commitment from the applicant organisation and/or other sources must be provided stating the precise amount of each financial (cash) contribution to the budget. If other institutions or organisations (partners) are involved in carrying out the action, the letter of commitment/partnership, from each of the partners, should also provide the name, address and person responsible and explain the nature of their involvement.
  - The partial or total withholding by the applicant of any information that may have an impact on the Commission's final decision concerning the application will entail the automatic disqualification of the application or, if discovered at a later stage, will entitle the Commission to impose financial and administrative penalties<sup>6</sup>.

## **3. The estimated budget of the action**

### **3.1. The budget must be detailed and balanced**

Grant applications must include a detailed estimated budget presented in Euro (see application form). Applicants established in countries outside the Euro zone must use the conversion rates published in the Official Journal of the European Union (<http://ec.europa.eu/budget/inforeuro/index.cfm?Language=en>). Applicants should be aware that they fully carry the exchange rate risk.

The budget estimate must be properly balanced: the two totals (income and expenditure) must be the same, since the available income (including the grant requested from the Commission) will have to finance the planned expenditure<sup>7</sup>. Please make sure that all the items related to the implementation of the action are included and not just those for which financing is being sought.

### **3.2. Expenditure**

Expenditure must include the estimated costs exclusively for the implementation of the action.

#### *3.2.1. General criteria for eligibility of costs*

In order to be eligible for Union-funding, costs must meet the following criteria<sup>8</sup>:

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<sup>5</sup> Art. 109(2) FR and 165(1) IR

<sup>6</sup> Art. 175 IR

<sup>7</sup> Art. 173(3) IR

<sup>8</sup> Art. 172a IR

- (a) be incurred during the duration of the action, with the exception of costs relating to final reports and audit certificates;
- (b) be indicated in the estimated overall budget of the action attached to the grant agreement;
- (c) be necessary for the implementation of the action which is the subject of the grant;
- (d) be identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the usual cost-accounting practices of the beneficiary;
- (e) comply with the requirements of applicable tax and social legislation;
- (f) be reasonable, justified, and comply with the requirements of sound financial management, in particular regarding economy and efficiency.

**The successful applicant must take care to avoid any unnecessary or unnecessarily high expenditure.**

The beneficiary's internal accounting and auditing procedures must permit a direct reconciliation of the costs and revenue declared in respect of the action with the corresponding accounting statements and supporting documents.

Documentation justifying costs must be kept by the beneficiary for **five years** following final payment by the Commission.

Expenditure eligible for financing may not have been incurred before the grant application was lodged.

Extra costs associated with the participation of people with disabilities are also eligible. These costs may be required to cover the use, for example, of special means of transport, personal assistants or sign language interpreters.

### *3.2.2. Eligible direct costs*

The eligible direct costs for the action are those costs which, provided that they satisfy the criteria of eligibility set out above, are identifiable as specific costs directly linked to the performance of the action and which can therefore be booked to it directly.

In particular, the following direct costs may be considered eligible:

#### **Staff costs**

The costs of staff (permanent or temporary staff employed by the beneficiary or the partners) assigned to the implementation of the action, comprising actual salaries plus social security charges and other statutory costs included in the remuneration, are eligible. The salary costs should not exceed the average rates corresponding to the beneficiary's usual policy on remuneration. In addition, they should not be higher than the generally accepted market rates for the same kind of task.

The costs of personnel of national administrations may be considered as eligible to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the action concerned were not undertaken.

Please, fill in the form reserved for these costs in the budget estimate (see application form) indicating the persons to be remunerated (full-time/part-time), the number of days of work to be performed and the daily rate calculated on the basis of an average of 20 days per month, up to a maximum total of 220 working days per year.

When submitting the request for final payment, the beneficiary may have to provide pay slips **and timesheets** justifying the actual staff costs declared.

**Warning: the cost of any work to be performed by external experts by means of subcontracting must not be included in staff costs but under services.**

If members of the staff are recruited after the submission of the application, the beneficiary must send the names and complete CVs of these persons to the European Commission for approval as soon as possible.

### **Travel, accommodation and subsistence allowances**

Travel costs must not exceed the most reasonable rates available on the market. Accommodation and subsistence costs related to the participants to the action are eligible provided that they are in line with the beneficiary's usual practices on travel costs or do not exceed the scales approved periodically by the Commission which are set out in the table below.

Journeys must be carried out by the most direct and economic route. Economy class fares will be used as the benchmark for analysing air travel costs. Air travel is acceptable only for distances above 400 km, i.e. return flight above 800 km. For other modes of transport, the benchmark is the first-class rail fare. Car journeys: equivalent of corresponding first-class train ticket. Please bear in mind that receipts, boarding passes and used tickets must always be kept as supporting evidence of travel costs paid.

The *Daily subsistence allowances (DSA)* are paid in addition to costs for accommodation as a flat-rate amount and are considered to cover breakfast and two main meals, local transport, the cost of telecommunications and all other sundries. Daily subsistence allowances are to be calculated as follows according to the length of the mission:

- stays less or equal to 6 hours: reimbursement of actual costs (on production of supporting documents);
- more than 6 hours up to 12 hours inclusive: 0.5 DSA;
- more than 12 hours up to 24 hours inclusive: 1 DSA;
- more than 24 hours up to 36 hours inclusive: 1.5 DSA;
- more than 36 hours up to 48 hours inclusive: 2 DSA;
- more than 48 hours up to 60 hours inclusive: 2.5 DSA, etc.

The maximum amounts (in Euro per calendar day) accepted for each country are set out in the table below, and applicants are advised to adhere to these rates in their budget estimates<sup>9</sup>:

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<sup>9</sup> The daily allowance rates are subject to periodic review by the Commission.



Destinations		DSA in EUR	Maximum hotel price in EUR	Destinations		DSA in EUR	Maximum hotel price in EUR
AT	Austria	95,00	130,00	IT	Italy	95,00	135,00
BE	Belgium	92,00	140,00	LT	Lithuania	68,00	115,00
BG	Bulgaria	58,00	169,00	LU	Luxembourg	92,00	145,00
CY	Cyprus	93,00	145,00	LV	Latvia	66,00	145,00
CZ	Czech Republic	75,00	155,00	MK	F.Y.R. of Macedonia	50,00	160,00
DE	Germany	93,00	115,00	MT	Malta	90,00	115,00
DK	Denmark	120,00	150,00	NL	The Netherlands	93,00	170,00
EE	Estonia	71,00	110,00	NO	Norway	80,00	140,00
EL	Greece	82,00	140,00	PL	Poland	72,00	145,00
ES	Spain	87,00	125,00	PT	Portugal	84,00	120,00
FI	Finland	104,00	140,00	RO	Romania	52,00	170,00
FR	France	95,00	150,00	SE	Sweden	97,00	160,00
HR	Croatia	60,00	120,00	SI	Slovenia	70,00	110,00
HU	Hungary	72,00	150,00	SK	Slovakia	80,00	125,00
IC	Iceland	85,00	160,00	TR	Turkey	55,00	165,00
IE	Ireland	104,00	150,00	UK	United Kingdom	101,00	175,00
LI	Liechtenstein	80,00	95,00				
RS	Serbia	80,00	140,00				

Please note that the Commission and the other European Institutions cover the travel and subsistence costs of their own officials when they participate in an event organised by the beneficiary and these should therefore not be included in the budget estimate.

### ***Catering***

**The total amount calculated according to the above mentioned rules regarding Daily subsistence allowances shall constitute a maximum.** If catering services are provided by the organisers, the DSAs directly paid to participants must be reduced accordingly.

### **Costs of services**

**Information dissemination, publications** costs can be taken into account provided that they are directly related to the action. Please give, for each publication and/or other materials, a description, an estimate of the number of pages and copies planned, the frequency and language of publication, an indication of the production costs per copy as well as an estimate of the distribution costs where appropriate.

**Translation** costs must include the following details: the number of languages, the number of pages to be translated, the rate applied per page. These rates may not exceed the most reasonable market rates.

**Interpretation**: the different components must be specified. In particular, the number of languages, the number of interpreters, the number of days and the daily rates must be specified. The accepted daily fee of an interpreter may not exceed 700 EURO (including VAT). Interpreters should be hired locally. For their travel and subsistence expenses to be covered by the grant, it must be impossible to hire them locally and it must be explained why this is so.

**Evaluation**: if the proposal supported requires some form of evaluation, monitoring and evaluation methods, as well as tools to assess, on an on-going basis, the progress of the action in relation to the objectives defined at the beginning and to benchmark the results, the cost of such work will be regarded as eligible expenditure.

### **Subcontracting**

Any service undertaken by an external party in connection with the implementation of the action is considered to be **subcontracting**.<sup>10</sup>

Applicants should have the operational capacity to complete the action to be supported. However, when justified and necessary, parts of the action(s) may be subcontracted to another person or organisation. In this case, the beneficiary shall ensure that some<sup>11</sup> of the terms applicable to itself under the agreement are also applicable to the subcontractors.

It must be clearly specified in the description of the project which tasks it is intended to subcontract and why this subcontracting is necessary.

#### Main rules related to subcontracting activities

When concluding external contracts in order to implement the action, the beneficiary must seek competitive tenders from potential contractors and award the contract to the bid offering **the best value for money, i.e. the best price-quality ratio**. In doing so, the beneficiary shall observe the principles of transparency and equal treatment of potential contractors and shall take care to avoid any conflict of interests.

#### Contracts as referred above may be awarded only in the following cases:

- a) They may only cover the execution of a limited part of the action;
- b) Recourse to the award of contracts must be justified having regard to the nature of the tasks necessary for the implementation of the action;
- c) The tasks to be subcontracted and the corresponding estimated costs must be set out in detail in the budget estimate;
- d) Any recourse to the award of contracts while the action is underway shall be subject to prior written authorisation by the Commission;
- e) The beneficiary shall retain sole responsibility for the implementation of the action and for compliance with the provisions of the agreement. The beneficiary must undertake the necessary arrangements to ensure that the subcontractor waives all rights in respect of the Commission under the agreement;
- f) The beneficiary must undertake to ensure that the terms, mentioned above, applicable to him under the agreement are also applicable to the subcontractor.

Where the value of the procurement contract awarded exceeds EUR 60 000, the beneficiary shall, in addition to the above general rules, apply the following procedures:

Estimated value of contract	Minimum procedure applicable
> € 60 000 but less than € 125 000	Restricted procedure following a call for expression of interest
≥ € 125 000	Open or restricted procedure

#### Administration costs

Depreciation for purchase of equipment<sup>12</sup>: the purchase cost of equipment (new or second-hand) is eligible provided that it is written off in accordance with the tax and accounting rules

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<sup>10</sup> Art. 120FR, 184 IR

<sup>11</sup> The terms related to liability, conflict of interests, confidentiality, publicity, evaluation, assignment and checks and audits

<sup>12</sup> Art. 172 IR

applicable to the beneficiary and generally accepted for items of the same kind. Only the portion of the equipment's depreciation corresponding to the period of eligibility for Union funding covered by the grant agreement and the rate of actual use for the purposes of the action may be taken into account by the Commission. A justification for the need of purchasing such equipment is to be annexed to the budget estimate.

Other eligible administrative costs are: rent of meeting rooms (coffee breaks included), rent of interpretation booths, communications' costs, charges for financial services, costs relating to a bank guarantee and to external audits, etc. Indicative amounts for rental of booths, excluding technical equipment: 750€ (excluding VAT) per day. Rental of booths with equipment and technical assistance: 1200€ (excluding VAT) per day.

### *3.2.3. Eligible indirect costs - Overheads*

Indirect costs are general administrative costs – overhead costs incurred in connection with the eligible direct costs for the action. They are limited to a maximum flat-rate of 7% of the total eligible direct costs for the action. These can include maintenance, stationery, photocopying, mailing postage, telephone and fax costs, heating, electricity or other forms of energy, water, office furniture, insurance and any other expenditure necessary for the successful completion of the action(s). Postage costs are considered as overhead costs and cannot be accepted under the headings "publications" or "administration".

If the accepted budget includes provision for flat-rate funding in respect of indirect costs, they need not to be supported by accounting documents.

Indirect costs are not eligible for an action where the beneficiary already receives an operating grant from the Union budget during the period in question.

### *3.2.4. Non-eligible costs*

The following expenses are ineligible and not accepted:

- contributions in kind: these are contributions that are not invoiced, e.g. voluntary work, equipment or premises made available free of charge;
- return on capital;
- debt and debt service charges;
- doubtful debts;
- provisions for losses or potential future liabilities;
- interest owed;
- exchange losses;
- VAT, unless the beneficiary can show that he/she is unable to recover it according to the applicable national legislation.

It should be noted that VAT paid by a public body to operators who are subject to VAT (when purchasing goods or supplying services within the framework of the implementation of the co-financed action) is not eligible. The VAT thus collected by operators liable for tax will in fact be returned to accounts of the Member State of the public body. Considering this VAT as an eligible cost would lead to double financing (by the European Union and by the fiscal revenue).

- excessive or reckless expenditure;
- costs declared by the beneficiary and covered by another action or work programme receiving a grant from the European Union.

### 3.3. Income

Total income must be identical to total expenditure. The income side of the budget must show:

- The beneficiary's contribution in cash: the direct monetary (cash) contribution from the applicant's own resources and/or the contribution from any other fund providers. This means a financial flow that can be traced in the written accounts of the beneficiary.
- The revenue generated by the action: any income expected to be generated by the implementation of the action should be detailed (e.g. the yield from sales of publications or the fees charged to participants attending a conference, etc.).
- The Union grant: the grant requested from the Commission.

## 4. How the grant will be calculated ?

If the proposal is selected for a grant, the Commission will calculate the Union contribution as a percentage of the total eligible costs as shown in the estimated budget for the implementation of the action.

The Commission reserves the right to reduce the grant requested if the proposal is acceptable but considered too expensive, and to reduce individual unit costs if these are estimated to be too high.

### *Determination of the final amount of the grant*

The Union final grant is calculated on the basis of the **actual** eligible expenditure by applying the "double ceiling" rule and verifying compliance with the no-profit rule.

- Application of the "double ceiling" rule limiting the grant both to the percentage of the eligible costs and to the maximum amount mentioned in the grant agreement

The Union final grant is calculated by applying the percentage for the co-financing of the eligible costs laid down in the grant agreement to the total of the actual eligible costs. This amount must not exceed the maximum amount for the Union grant laid down in the grant agreement.

As a result, if the actual expenditure turns out to be lower than the expenditure you budgeted, the actual grant will also be reduced in application of the percentage contribution which will remain the same. If the actual expenditure turns out to be higher than the expenditure budgeted, the Union grant will not be increased. It is therefore in the applicant's interest to submit a realistic estimate of expenses.

- Verification of compliance with the **no-profit rule**

The grant may not have the purpose or effect of producing a profit for the beneficiary<sup>13</sup>. On the basis of the above rule if the total income of the action is higher than the total costs, the final grant amount will be reduced accordingly so that it will not produce a profit.

A mere forecast of expenditure does not give entitlement to a grant. This is why the final grant amount cannot be calculated until the Commission has received the final activity report and

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<sup>13</sup> Art. 109(2) FR

the final statement of expenditure. The expenditure that is committed to the implementation of the action must be justified by invoices or equivalent supporting documents, in order to be accepted as actual expenditure. It must also relate to actual rather than inputted costs.

## **5. Agreement governing the grant**

Should the Commission award a grant, a standard grant agreement for an action setting out the conditions and maximum level of funding will be concluded with the beneficiary.

Successful applicants will receive two original copies of the grant agreement for acceptance and signature. Both of these copies must be sent back to the Commission, which will then return one of them once it has been signed by both parties.

## **6. Payment procedures**

The payment arrangements will be laid down in the grant agreement.

Payment of the grant will be made in two instalments (a pre-financing payment and a final payment under the following conditions:

- A pre-financing payment of 50 % at the signature of the grant agreement.
- The balance will be paid upon acceptance by the Commission of the final technical implementation report and final financial statement.

## **7. Bank account and interest generated by pre-financing payments<sup>14</sup>**

Payment shall be made to the beneficiary's bank account or sub-account denominated in Euro. This account or sub-account indicated by the beneficiary must make it possible to identify the funds transferred by the Commission.

If the funds paid to their account yield interest or equivalent benefits under the law of the State on whose territory the account is opened, such interest or benefits, if they have been generated by pre-financing payments which remain the property of the European Union, shall not be treated as a receipt for the action.

The beneficiary shall, as specified in the grant agreement, inform the Commission of any interest or equivalent benefits yielded by pre-financing payments higher than EUR 50 000, it has received from the Commission. Notification must be made when the request is introduced for interim payment or for payment of the balance that clears the pre-financing.

Interests yielded by pre-financing payments between € 50 000 and € 750 000 will be directly deducted from payments.

Interests shall not be due to the Union for pre-financing paid to Member States, to their regional or local authorities including organisms and administrative and instrumental structures under their control or paid in the framework of joint management with international organisations.

All costs related to these requirements (such as the cost for opening and closing accounts) are eligible and may be submitted in the budget estimate.

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<sup>14</sup> Art. 5(a) FR, Art. 3, 4, 4(a) IR

## 8. Submission of reports and other documents

The final report on the implementation of the action along with a final financial statement of all actual expenditure and actual revenue are to be sent within three months from the closing date of the action.

The final report should answer at least to the following questions:

- 1) How was the action performed? Was it performed in accordance with the description of the action annexed to the grant agreement? (Describe the action, its results and methodology, planned activities, timetable, partners, participants, etc.).
- 2) To what extent did the action meet the objectives set?
- 3) What was the European added value of the implementation of the action?
- 4) How was the action presented to the public and how were the results disseminated?
- 5) What lessons have been learned from this experience?
- 6) Describe the results of the evaluation (internal/external) of the implementation of the action.

The final activity report must be completed using the template annexed to the grant agreement.

These templates will be an essential part of performance monitoring of PROGRESS which is strongly committed to results-based management, which is the continuous measurement of the programme's achievements towards its objectives, reporting and taking action to fine-tune the programme in order to improve its performance.

Please also attach to the final report a copy of the documents produced during the action (publications, press articles, manuals, leaflets, posters...).

Should the final report be deemed to be inadequate and of low quality, the Commission reserves the right to request additional information within 60 days of reception of the final report, and, if necessary, to suspend the final payment until the requested information is provided.

## 9. Publicity

Beneficiaries of the grant are required to mention clearly the fact that they have received funding from the Union in any publication and/or in other materials, or in the occasion of activities (conferences or seminars, etc.), for which the grant is used, using the following wording: "**With support from the European Union**". The logo of the EU, given at the following web address: <http://europa.eu/abc/symbols/emblem/> and the logo of the "For Diversity. Against discrimination campaign" should also be visible.

Any communication or publication by the beneficiary, in any form and medium, including the Internet, shall indicate that sole responsibility lies with the author and that the Commission is not responsible for any use that may be made of the information contained therein.

In addition to these minimum requirements, references specified in the text of the call for proposals must also be indicated (see Point 17 of the guidelines).

All grants awarded in the course of a financial year shall be published on the Internet site of the Union institutions during the first half of the year following the closure of the budget year in respect of which they were awarded.

By signing the grant agreement for an action, the beneficiary authorises the Commission to publish the following information in any form and medium, including via the Internet site of the Union<sup>15</sup>:

- the beneficiary's name and the address
- the subject of the grant,
- the amount awarded and the rate of funding of the costs of the action.

Upon a duly substantiated request by the beneficiary, publication of this data can be waived if it threatens the safety of the beneficiary or harms his business interests.

### **Publication of information related to partner(s) in PROGRESS-funded projects**

In order to increase the visibility of transnational partnerships established under PROGRESS and to facilitate networking between organisations involved in actions covered by PROGRESS grants, the Commission intends to publish the name and address of partners in PROGRESS-funded projects together with the name and address of the beneficiary, the reference of the call for proposals and the title and description of the project. To that purpose, the Beneficiary will be asked to seek the partners' agreement to authorise the Commission to publish this data. This written agreement should be included in the letters of commitment sent to the Commission with the application form.

## **10. Evaluation**

If the proposal should include a specific evaluation component for ongoing monitoring and final evaluation of the action, these costs can be taken into account as eligible in the budget estimate.

Successful proposals could be the subject of an ongoing and ex-post evaluation led by the Commission and/or by independent experts selected by the European Commission. Therefore, the beneficiaries of the grant undertake to make available to the Commission and/or persons authorised by it, all such documents or information as will allow the evaluation to be successfully completed and give them the rights of access required.

## **11. CHECKS AND AUDITS**

The beneficiary undertakes to provide any detailed information requested by the Commission or by another qualified outside body chosen by the Commission for the purposes of checking that the action and the provisions of the agreement are being properly implemented. The beneficiary must enable the Commission and/or the Court of Auditors to verify the organisation's accounting documents, if they deem this appropriate. To this end, documentation justifying items of expenditure must be retained by the applicant's organisation for five years following final payment by the Commission.

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<sup>15</sup> Art. 110(2) FR, 169(2) IR

## **12. Procedure: Electronic means of submission - SWIM**

The Internet Web application called "SWIM" (SAGA Web Input Module) allows applicants/beneficiaries to introduce, edit, validate, print and submit grant applications, request for payments and request for modifications on the budget estimate. SWIM can be accessed in the following web address<sup>16</sup>: <https://webgate.ec.europa.eu/swim>.

### **12.1. Introduction of grant applications**

The grant application form has to be electronically filled in as follows: first, access the system at the address mentioned above and click on the link "New grant application", then, select the number of the call for proposals you wish to apply for and, eventually, fill in your application. Once your application is completed, click on the "submission" button in order to finalise the submission procedure.

Please note that after having submitted your application form electronically no changes to the application are possible.

After being submitted electronically, the application form must also be printed out, signed by the legal representative of the organization submitting the proposal and sent by post to the responsible Unit, as specified in the text of the call for proposals.

Failure to respect this procedure will render the application ineligible.

### **12.2. Requests for payments and budgetary modifications**

In addition to the documents specified in the grant agreement, financial documents required in support for payment of the balance, as well as requests for modifications of the budget estimate to be made by addendum must also be electronically submitted using SWIM.

To be allowed to log on into SWIM and access its grant file, the beneficiary will be asked to enter on the login page the same file number and Access code assigned by the system to the grant application when it was created.

## **13. Data Protection**

The grant application will be processed by computer. All personal data (such as names, addresses, CVs, etc.) will be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>17</sup>. Replies to the questions in the application form are necessary in order to assess the grant application and they will be processed solely for that purpose by the department responsible for the Union grant programme concerned. On request, applicants may be sent personal data and correct or complete them. For any question relating to these data, please contact the Commission department to which the form must be returned. Beneficiaries may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time.

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<sup>16</sup> For more technical details on SWIM utilisation, a user's manual is available on line

<sup>17</sup> Official Journal L 8, 12.1.2001.



#### **14. WARNING SYSTEM AND CENTRAL EXCLUSION DATABASE**

Grant applicants and, if they are legal entities, persons who have powers of representation, decision-making or control over them, are informed that, should they be in one of the situations mentioned in:

- the Commission Decision of 16.12.2008 on the Early Warning System (EWS) for the use of authorising officers of the Commission and the executive agencies (OJ, L 344, 20.12.2008, p. 125), or
- the Commission Regulation of 17.12.2008 on the Central Exclusion Database – CED (OJ L 344, 20.12.2008, p. 12),

their personal details (name, given name if natural person, address, legal form and name and given name of the persons with powers of representation, decision-making or control, if legal person) may be registered in the EWS only or both in the EWS and CED, and communicated to the persons and entities listed in the above-mentioned Decision and Regulation, in relation to the award or the execution of a procurement contract or a grant agreement or decision.