

TAXES SUBJECT TO PAYMENT OF A REGISTRATION FEE

COLLECTION OF TAXES IN 2012

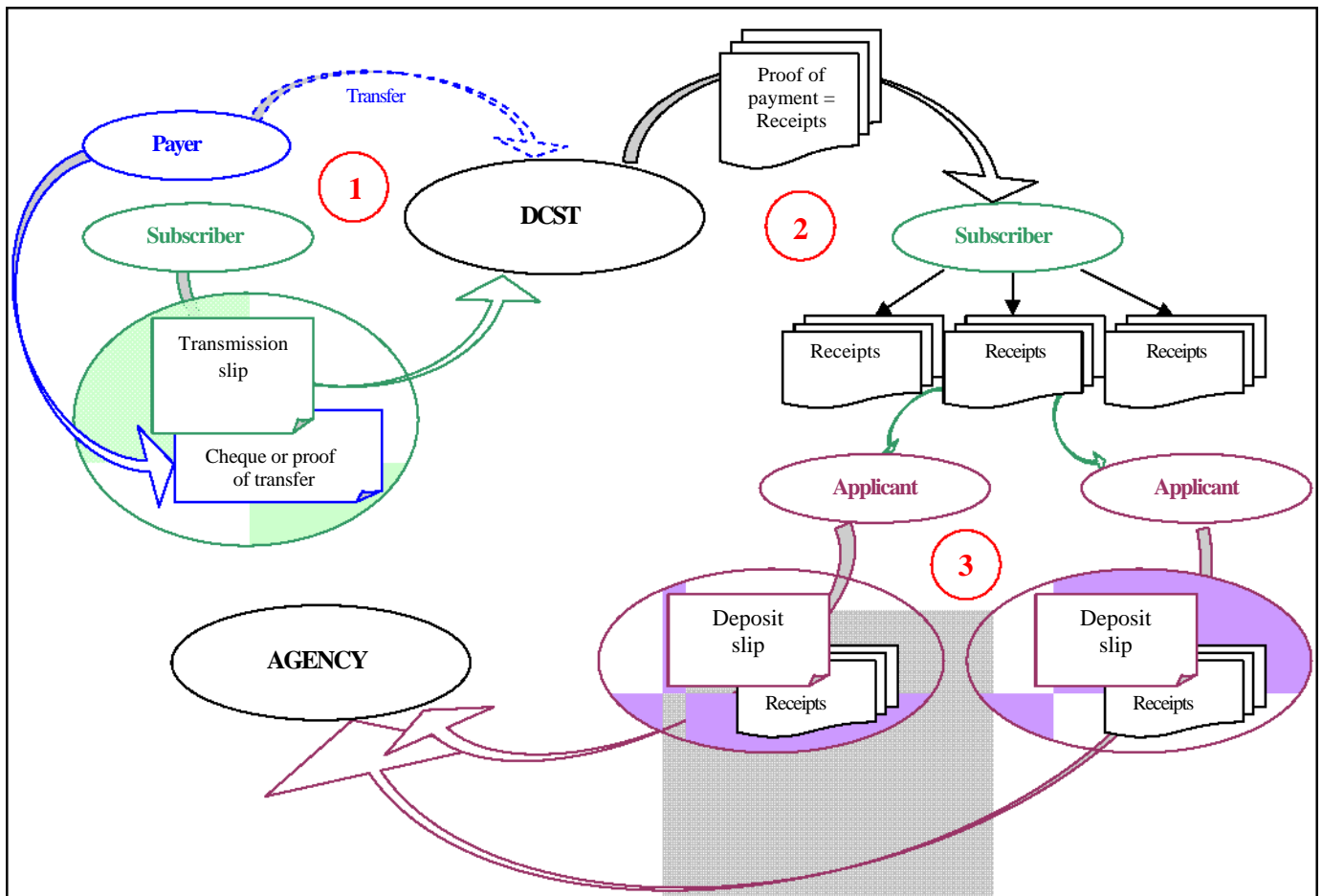
Legal source

Article 26 of the French Social Security Finance Act for 2012
creating Article 1635 bis AE of the French General Tax Code.

List of taxes concerned by this collection method

- Application for registration mentioned in Articles L. 5121-13 and L. 5121-14 of this Code, and each application for renewal or modification of such registration;
- Application for registration mentioned in Article L. 5121-14-1 of this Code, and each application for renewal or modification of such registration;
- Application for authorisation for marketing, mentioned in Article L. 5121-8 of this Code, and each renewal application or each application or notification of a change of this authorisation;
- Application for recognition by at least one other Member State of the European Union or State in the European Economic Area of an authorisation for marketing, delivered by the director general of the agency mentioned in Article L. 5311-1, as mentioned in Article L. 5121-8 of this Code and each application for modification of this authorisation;
- Application for a parallel import license, pursuant to Article L. 5124-13 of this Code, and each request for modification or renewal of this authorisation;
- Application for authorisation, or renewal of authorisation, to advertise, as mentioned in Articles L. 5122-8 and L. 5122-14 of this Code;
- Filing of advertising, as mentioned in Articles L. 5122-9 and L. 5122-14 of this Code.

General overview of terms for 2012



Definition of players

- **Industrial groups**

Subscriber: The legal entity or natural person requesting receipt(s) from the DCST

Payer: The legal entity or natural person paying the DCST the amount equivalent to the receipts subscribed to in the transmission slip.

Applicant: The legal entity or natural person which is the correspondent of the Agency for a business application (Marketing authorisation, advertising authorisation, etc.).

Beneficiary of application: The legal entity or natural person which holds, or which in future will hold, the authorisation, registration or advertising that the request contained in the business application conducted at the Agency pertains to.



These four parties can potentially be identified in a single application process. This faculty, which is not obligatory, keeps the procedure used previously for making applications to the Agency.

- **Public entities**

DCST : Directorate of Special Treasury Receivables located at Châtellerault. State Service which receives requests for receipts, collects fees and issues receipts, which are proof of payment.

Agency: Afssaps, then the National Agency of Medicine and Health Product Safety. A public institution that receives authorisation requests, authorisation registration or filing requests, and which processes these requests.

General principles

- Any filing of requests (Marketing authorisations, advertising authorisations, etc.) sent to the Agency must include evidence of payment of requests filed. There is no exception to the rule of prior payment.
- Any filings (Marketing authorisations, advertising authorisations, etc.) sent to the Agency will lead to full payment of requests contained in the application. In the event of the withdrawal of an application, the payment remains due for the entire amount of the requests contained in the application.
- Proof of payment provided by the DCST is called "receipt". Each receipt corresponds to a request sent to the Agency. A filing with the Agency shall contain as many receipts as applications. Une quittance n'est pas remboursable.
 - A receipt is not refundable.
 - A receipt may be used indefinitely.

The collection circuit and filing of application(s)

How to pay fees? (First step)

1. Formalisation of requests

- 1.1. The subscriber who wishes to obtain the receipts that are necessary for a filing of requests at the Agency shall consult the fee schedule that is presented on the website of the Directorate General of Public Finance "impôts.gouv.fr" in order to select applications.
- 1.2. The subscriber completes a transmission slip (downloadable from the website impôts.gouv.fr), listing all the desired applications and determining the amount payable.



The transmission slip may contain applications, the communication of which to the Agency has not yet been considered. The content of a transmission slip does not strictly have to correspond to one single future application at the Agency. The statement enables the obtaining of evidence

of payment (receipts) corresponding to applications that may be sent to the Agency through various filings.

2. Payment of applications

2.1. The payer (subscriber or other entity):

- Solution 1: sends a transfer of the amount due (total of transmission slip) to the DCST, whose bank account details are indicated on the transmission slip, keeping proof of the associated transfer. The references of the transfer must include the details set out below in point 3 for a proper reconciliation between the transmission slip and the transfer.
- Solution 2: issues a cheque for the amount of the sum due (total of the transmission slip) payable to the Treasury.

2.2. The payer (subscriber or other entity):

- Solution 1: attaches evidence of transfer to the transmission slip.
- Solution 2: attaches the cheque to the transmission slip.

3. Requests for receipts

The subscriber submits its entire receipt requests (transmission slip + cheque or proof of bank transfer) to the DCST at the addresses provided in the section of the transmission slip entitled "Our address":

- By mail when paying by cheque,
- By mail, fax or email for payments by bank transfer.

Each transmission slip contains a reference number of its own. This reference number is determined by the subscriber and must start with the first 3 letters of his name followed by 5 digits.

When paying by bank transfer, this number should be entered on the section for the reason for the transfer, with the intra-community VAT number, or, failing this, the name of the subscriber.

How to obtain receipts? (2nd step)

4. Obtaining receipts

After confirmation of the payment, the DCST sends one or more receipts, copies of which will have been provided to the subscriber by email (subject to it providing an email address on the transmission slip).



In the event the amount of the payment is less than the sum of the fees due for each application indicated in the transmission slip, no receipt of applications included in the transmission slip will be issued. In this case, the DCST will notify the subscriber that it will have to rectify the situation. To do this, the payer will have to complete its payment, the cheque or proof of bank transfer being communicated to the DCST via the subscriber, stating:

- In the event of payment by cheque, the reference number of the transmission slip to which the payment relates.
- In the event of payment by bank transfer, this number should always be entered in the section for the reason for the payment with the intra-community VAT number, or failing this, the name of the subscriber.

When the payment supplement is validated by the DCST, it will issue the corresponding receipts.

How to file applications with the Agency? (Third step)

5. Establishment of a file of applications

The applicant forms a file of applications to send to the Agency according to the same terms as in the past. In addition to this, there is another criterion of admissibility: the presence in the application of proofs of payment (receipts) corresponding to the requests in the application.



Each receipt enables the processing of the application stated on the receipt. However, in the event of error by the applicant: if the nature of an application mentioned on the receipt does not match that identified in the application, provided that the amount of the receipt is at least equal to that of the application, the receipt may be accepted.



If a receipt is not reassigned to a file, it may be "stored" by the applicant, pending its future use.

- 5.1. The applicant selects the appropriate receipts for the requests that it wishes to file with the Agency.
- 5.2. The applicant completes the application slip, listing the receipts attached to the file to be completed at the Agency. This slip may be downloaded from the Agency's website.
- 5.3. The applicant shall provide the Agency with its applications in the usual way, which remains unchanged, supplemented by the appropriate receipts in paper form and the associated application slip in paper form.

The rules for admissibility of an application with the Agency

The rules for admissibility of an application are not changed in the "business" section. However, there is an additional study of admissibility of the application in light of the evidence of payments (receipts) attached to the application.

General principles

- An application for receipts will be considered valid (full) when it consists of an amount of receipts that is at least equal to the amount due for the entire application to which the receipts are associated.
- Each receipt entitles the application mentioned on the receipt to be processed. Each application must strictly be associated to the receipts identifying the requests contained in the application. However, tolerance may be granted in the event of the applicant's failure; if the nature of an application stated on the receipt does not match that identified in the application, but the amount of the receipt is at least equal to that of the application, the receipt may be accepted.
- If the total amount of receipts associated with an application is not at least equal to the amount due for this application, its processing will be suspended entirely. None of the application requests will be processed until the situation is settled.

The consequences of insufficient receipts in an application

The Agency will inform the applicant by mail that its application has been declared incomplete and unprocessed and will ask it to complete its application by additional receipts. In this mail, the Agency will specify the information identifying the application, data that will facilitate the attachment of the receipts to receive for the appropriate application. The absence of these identifiers in the applicant's reply will *de facto* result in a continued suspension of the application, since the attachment would be impossible.



This suspension may occur immediately upon receipt of the application, or during the processing of requests. This latter case corresponds to an error by the applicant in the very nature of his request. The reclassification of the request by the Agency's scientific services may lead to the identification of a higher rate than that paid. In this case, the entire application shall be suspended until the situation is settled.



Additional receipts of a variable amount (other than those of the rates set by decree) may be obtained from the DCST. Therefore, if the shortfall does not strictly correspond to one of the tariffs provided, the payer will not have to pay a higher amount than that which is just due for the application.

The consequences of an excessive amount of receipts in an application

In the event of detection of an excessive amount of receipts, the application will be declared complete and its processing can begin.

Case 1: it is possible not to validate one or more receipts without lowering the amount of other receipts deposited below the amount due for the application.

The Agency will inform the applicant by mail that one or more receipts have not been used and may be represented in a future application.

Case 2: the failure to validate one or more receipts reduces the amount of other receipts transmitted below the amount due for the business application.

The Agency will inform the applicant by mail that one or more receipts are awaiting settlement. The Agency will specify in this mail the information identifying the application, data that will enable the receipts to be received to be attached to the appropriate application.

The applicant will then have 15 days to transmit the appropriate receipts to the Agency; failing this, the receipts that were initially transmitted will be finally validated.

None of these cases suspends the processing of the application requests.