



WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

GENERAL TERMS AND CONDITIONS AND USER LICENSE FOR THE DATABASE CONTAINING SUBSTANCES KNOWN BY THE COUNCIL OF EUROPE TO BE USED IN PACKAGING MATERIALS FOR FOOD AND PHARMACEUTICAL PRODUCTS

BETWEEN:

The legal person of the Institut Scientifique de Santé Publique, with its registered office located at 1050 Brussels, Rue Juliette Wytsman 14, registered in the Belgian company register/crossroad bank of undertakings [*Banque-carrefour des entreprises*] under No. 0254.014.195

Represented by Dr Johan Peeters, President of the administrative committee of the legal entity,

Hereinafter referred to as the “WIV-ISP”,

AND:

_____ (company name),
with its registered office located at _____ (address),

Represented by _____ (name), _____ (position),

Hereinafter referred to as the “Subscriber”

Both referred to as “the parties”.



Whereas the WIV-ISP is owner of a database of substances known by the Council of Europe to be used in packaging materials for food and pharmaceutical products (hereinafter referred to as the “Database”);

Whereas the creation and development of the Database by the WIV-ISP is part of the work of the Council of Europe’s Expert Committee on packaging for food and pharmaceutical products (P-SC-EMB);

Whereas the data making up the Database is provided by the Member States of the Council of Europe and the WIV-ISP, the WIV-ISP being responsible furthermore for providing the significant human, technical and financial resources required for the production, management and availability of the Database;

Whereas the WIV-ISP, as per the decision of the Council of Europe, desires to facilitate the industry and Member States’ access to this Database, in return for fair compensation;

Whereas these terms and conditions govern the contractual relations between the WIV-ISP and the Subscriber regarding access to and use of the Database, while respecting the intellectual property rights of the WIV-ISP.

THE FOLLOWING IS HEREBY AGREED

Article 1 – Scope

The WIV-ISP grants to the Subscriber, in return for payment of the user fee, a personal, temporary, non-exclusive and non-transferable license for the use of the Database, on the territory on which it is established, according to the terms and conditions and subject to the limits provided for in these terms and conditions, with any use not expressly authorised hereby being reserved.

The purchase of a user license shall not result in the transfer of any intellectual property rights to the Subscriber, nor any other right associated with the content and/or structure of the Database, which shall remain the exclusive property of the WIV-ISP or its licensors.

These terms and conditions are established in French, Dutch and English. Any translation of these terms and conditions into another language is not authoritative and shall not be effective against the WIV-ISP.

Article 2 – Access to the Database – Individuals Users

The Database is solely accessible via a secure website, at the following address <https://fcm.wiv-isp.be/>. The WIV-ISP reserves the right to modify the address of the website hosting the Database at any moment, provided that prior notice is given to the Subscriber.

The website hosting the Database is designed for access via common and regularly updated Internet browsers.

Access to the Database using the access code(s) communicated by the WIV-ISP shall only be granted and activated once the WIV-ISP has received the Subscriber’s payment of the user fee.



The user fee is for one single access code. The person holding this access code may request additional access codes for an additional cost (€100 per additional user, €250 for 5 additional users, €500 for an unlimited number of users per Subscriber). The additional access codes will expire on the same date as the first access code regardless of when they were requested during the validity of the subscription.

Access to the Database is limited to the viewing of 100 substances per week. An exception to this limit may be granted subject to the prior express authorisation of the WIV-ISP, and where applicable, with the prior payment of an additional user fee.

The Subscriber shall take all necessary measures to ensure the confidentiality and authorised use of the access code(s) granted to him by the WIV-ISP. The Subscriber is responsible for ensuring that each individual user using the Database via the Subscriber's assigned access codes complies with these terms and conditions. The Subscriber may only designate as an authorised individual user those working long-term within his company or an administrative service (including self-employed workers, employees, statutory workers, interns and temporary workers), who require access to the Database for the fulfilment of their professional missions for the Subscriber.

If the Subscriber has noticed that or has reason to believe that the access codes assigned to him may have been disclosed to, or used by, persons not authorised by him or who no longer work for his company or for him, he may request that the access code(s) in question be blocked and new access codes be assigned, by contacting the WIV-ISP. The Subscriber is responsible for the usage made of the access codes allocated to him until the time that the WIV-ISP confirms the blocking of said access code(s).

Article 3 – License Period

This license granted by the WIV-ISP is limited in time. Unless otherwise specified, and provided that the annual fee is paid, the license is granted for a period of one (1) year as from the signature of this agreement by the WIV-ISP.

Article 4 – User Fees

On the day this agreement was signed, the annual licensing fee was set at 2,490 EUROS for a large company and 990 EUROS for SMEs (as per the definition established in recommendation 2003/361 of the European Commission). The user license fee for the Database is paid on a yearly basis in advance, and is non-refundable.

Unless otherwise specified, prompt payment by the Subscriber of the first user fee invoice is a condition for the activation of the Subscriber's access to the Database. For Database access to remain activated, user fee invoices shall be paid on-time for subsequent periods.

Unless otherwise specified, the WIV-ISP's invoices are payable within 30 calendar days from the invoice's issue date. The total of any invoice not paid in full by the due date is increased automatically and without prior notice by a late payment interest of 1% per month, each month begun considered as a full month, in addition to a lump-sum penalty of 15% of the total amount of the unpaid invoices, with a minimum of €50.00. The WIV-ISP also reserves the right to claim reasonable costs for notices, reminders or collection actions. Should the customer fail to pay one or several invoices, the WIV-ISP reserves the right to suspend the Subscriber's access to the Database until the full payment of the outstanding amounts, including any penalties, interest and costs for reminders or collection actions.



The WIV-ISP reserves the right to modify the amount of the licensing fee and/or modify the frequency and/or method of invoicing during the agreement period. Unless otherwise specified, such modifications shall be applicable on the anniversary date of the Agreement if the Subscriber has been notified of them at least two (2) months prior to the agreement anniversary date. Should the Subscriber not accept the modifications requested by the WIV-ISP by virtue of this article, he may terminate the agreement in accordance with the provisions of this article.

Member States of the Council of Europe and the national public or semi-public institutions representing them, or also the supranational public institutions, and in particular the contributors of the data presented in the Database and updates, may address a motivated request for an exemption from payment of the Database user fee to the WIV-ISP. The WIV-ISP may grant such an exemption if it is deemed in line with the objectives of the Council of Europe and, in particular, the Expert Committee on packaging for food and pharmaceutical products of the Council of Europe (P-SC-EMB). This exemption shall not affect other provisions of the agreement. The WIV-ISP's decision of whether to grant this exemption or not is entirely discretionary and can be revoked at any moment. The WIV-ISP shall grant an exemption to public institutions of the Member States of the Council of Europe.

Article 5 – Scope and Limits of User Rights

In return for payment of the user fee by the Subscriber, the WIV-ISP grants to the Subscriber a personal, temporary, non-exclusive and non-transferable license for the use of the Database, on the territory on which it is established.

A license for non-exclusive use shall be understood as access to, consultation of, and partial and selective extraction of data from the Database for printing on paper or partial and selective export of data from the Database in electronic format in a non-permanent way and not to be placed on network(s), within the limits of normal use of the Database according to these terms and conditions, by the individual users duly authorised by the Subscriber.

As regards the purpose of use, the Subscriber agrees to use the Database and data contained therein solely for (i) internal use within the company of the Subscriber and/or (ii) illustrative purposes for teaching or scientific research, or to document on data to clients or national control authorities with regard to product compliance .

As part of authorised use, the Subscriber is authorised to:

- save information from the Database in electronic or paper form, provided that the use is compliant with the other terms and conditions described in this agreement;
- include data from the Database in a paper written for strictly scientific purposes provided that the terms “Reproduced with the consent of the WIV-ISP” and the Database name appear on these documents in a place and font making it possible for the audience to clearly see them;
- include data from the Database in a published work provided that authorisation from the WIV-ISP was sought and obtained in advance.

Any other use of the Database is strictly prohibited, unless expressly specified by the WIV-ISP, and in particular,

- the copy or reproduction by the Subscriber of the Database and/or its content, in full or in part, or the modification thereof of any kind, is prohibited;



- the Subscriber shall not propose copies of the Database or its content to any third party in any form and under any conditions whatsoever;
- the Subscriber shall not distribute the Database or its content through the sale, rental, lending, distribution or provision via a network, the Internet or any other form of provision to a third party, for whatever reason, whether commercial or not, and even free of charge;
- the Subscriber shall not communicate to any third party, even free of charge, all or part of any element that is part of the Database, if this communication would allow this third party to benefit free of charge from the benefits or the equivalent of a Database license which he does not hold;
- the Subscriber shall not use the Database to create a new catalogue, transfer data to another database, or manipulate and/or use the Database in a way that could directly or indirectly compete with the WIV-ISP;
- the Subscriber agrees to refrain from decompiling, decoding, copying, adapting or dismantling the protection system or software used in the Database.

The Subscriber also acknowledges that the Database and the data contained therein are legally protected and agrees to refrain from the extraction, reuse, storage, reproduction, representation or conservation, whether directly or indirectly, on any medium whatsoever, and by whatever method and in whatever form, in whole or a qualitatively or quantitatively substantial part of the Database, or from causing the extraction or the repetitive and systematic reuse of qualitatively and quantitatively non-substantial parts, when these operations clearly exceed the boundaries of the conditions of normal use as described, in particular, in this agreement.

This user license covers only the use of the Database according to the conditions described above and does not include any license or transfer of rights associated with the reproduction and/or reuse of any kind of the items protected by intellectual property rights of the WIV-ISP or its licensors and which are not strictly necessary for the use of the Database.

Article 6 – Scope of the WIV-ISP's commitments and liability

The WIV-ISP shall make commercially reasonable efforts to provide access to the Database on the site, 24 hours a day and 7 days a week, as well as to maintain the site and Database in operational condition, but make no guarantee in relation to this. The Subscriber acknowledges and accepts that access may be interrupted by the WIV-ISP or be temporarily unavailable, in particular for maintenance and updates, temporary technical failures, or a failure or problems with the connection between the servers hosting the Database and the computer equipment of the Subscriber, or in the case of improper setup of computer equipment, or in the event of force majeure. The WIV-ISP shall not be held liable for temporary breaks in Database access, unless this is due to gross negligence or fraud on the part of the WIV-ISP.

Without prejudice to the provisions of this agreement, the WIV-ISP takes on the responsibility for publishing of the Database and its update. However, despite the care taken for the publishing of the Database, its maintenance, and its updates, the WIV-ISP shall only be bound by an obligation of means when it comes to the operability of the Database and its content. In particular, the Subscriber is aware of the fact that toxicological data regarding the substances contained in the Database are essentially based on a software analysis using different toxicological analysis programs, and not on an experimental analysis of each substance. The Subscriber acknowledges and accepts that the WIV-ISP provides the Database and its contents to the Subscriber strictly for informational purposes only and that the WIV-ISP does not guarantee the scientific exactness of the data, its exhaustiveness



and/or the absence of errors and/or omissions in the Database data. The Database data, including the related toxicological analyses, shall never be considered by the Subscriber as authorising or prohibiting the use of a substance or combination of substances in packaging for food and pharmaceutical products.

The Subscriber acknowledges and accepts that, except for in the event of gross negligence or fraud on the part of the WIV-ISP, the WIV-ISP shall never be held liable for any loss or damage, direct or indirect, of any type, presumed to have been caused by errors, omissions or alteration of the Database, or more generally the use of the Database by the Subscriber. If liability on the part of the WIV-ISP can nonetheless be claimed by virtue of this article, the Subscriber acknowledges and accepts that the WIV-ISP shall never be liable for the compensation of indirect damages or losses, directly resulting or as a repercussion, suffered by the Subscriber, including but not limited to the loss of data, revenue, turnover or expected savings, fees for the purchase of replacement products or services, non-material harm such as harm to one's image or reputation, and claims or actions of a third party against the Subscriber or persons for whom he's responsible, even if the WIV-ISP was informed that these damages or losses were foreseeable.

Article 7 – Ownership

The website hosting the Database, the text, structure, formatting, graphic components, logos, software programs, source or object codes, documentation, help texts and user manuals, and all other items accessible or provided to the Subscriber under this agreement, and the use of the Database, including the Database itself and, where applicable, the data making it up, are creations that can be protected by the intellectual rights of the WIV-ISP or its licensors. These intellectual rights include but are not limited to copyrights, related rights, the sui-generis database right, trademarks, know-how, etc.

The Subscriber agrees not to infringe on the property rights or intellectual rights of the WIV-ISP, and to take all measures necessary to ensure that the persons for whom he's responsible respect the WIV-ISP's rights as well.

Article 8 – Confidentiality and Personal Data

The WIV-ISP is responsible for connections to the server containing detailed information on the Subscriber's access, including date and time of access, IP address or user name/password used by the Subscriber to access the Database and the specific type and name of file downloaded from the Database. This access information may be used by the WIV-ISP and its staff or subcontractors to provide assistance to the Subscriber for the use of the Database. The WIV-ISP will provide commercially reasonable efforts to protect confidentiality of the Subscriber's user statistics and access information from third parties.

The WIV-ISP shall comply with the requirements of the Law of 8 December 1992 on the protection of privacy when processing personal information. The processing of personal information by the WIV-ISP is strictly limited to that which is required for the performance of this agreement. Personal information collected by the WIV-ISP is not disclosed to any third parties. Each time the Database is accessed, the individual user using the access code of the Subscriber is asked to confirm his express agreement to the Privacy Terms and Conditions describing the limited possible use of his personal data by the WIV-ISP. These persons may exercise their right to access and correct their personal data, free of charge, by contacting the WIV-ISP at coe_fcm_database@wiv-isp.be.



Article 9 – License Termination

In the event of the non-renewal, termination or end-of-contract for whatever other reason, this license and the associated user rights related to the Database shall be terminated immediately.

In the case of the failure to comply with any of the provisions of this agreement, the WIV-ISP reserves the right to terminate, without notice or compensation, or any formality other than registered letter with acknowledgement of receipt, and to prohibit the use of the Database by the Subscriber, without prejudice to its right to claim damages from the Subscriber where applicable.

Article 10 – Entire Agreement

This agreement covers the entirety of the agreement between the parties. It henceforth replaces and cancels all verbal or written agreements, communications, offers, proposals or correspondence, previously exchanged or signed between the parties and related to the subject of this agreement.

Article 11 – Nullity of the Agreement

Any provision of this agreement or part of a provision declared null and void shall be considered independent of this agreement, the remaining provisions of which shall remain valid.

Article 12 – Applicable Law – Dispute Resolution

Belgian law shall be the applicable law for the enforcement, interpretation and performance of this agreement. In the event of a dispute, the courts of the judicial district of Brussels shall have exclusive jurisdiction.

Signed in Brussels on _____, in two copies. Each party confirms having received an original copy.

For the WIV-ISP
Johan Peeters
President of the Administrative Committee

For _____

_____ (name)
_____ (position)

_____ (signature)

_____ (signature)