



**INRA's Charter
on Intellectual Property**

**DIET
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INRA

INRA's Charter on Intellectual Property

Conscious of its research public service role, the INRA has always been looking for the good balance between free dissemination of knowledge and legal protection of the research results.

Therefore, following the advice of its Ethics and Precautionary Committee for Agricultural Science and its Applications (COMEPRA), it places its responsibility beyond the sole production of results, by wishing to get involved in the use made of its research results.

The actual debates on GMOs, genetic diversity or on the assistance to developing countries brought back to light the question of the public research result appropriation and of the relations between public research and private sector. In this context, the creation and dissemination of a "Charter on Intellectual Property" by a research organisation is an important act. In this Charter, we describe what we believe is the appropriate use of the "intellectual property" for INRA, in accordance with our main missions:

- encouraging knowledge transmission and research development,
- fighting against the risk of appropriation of common resources,
- promoting innovations,
- preserving the means of an autonomy for the public welfare.

The content of this Charter is governed by three basic principles:

- 1- In certain circumstances, the protection and preservation of common heritages in the public sector require that a public institution obtain the property rights. Thus, as underlined by the scientific council and the COMEPRA, the intellectual property protection policy, particularly patents, is not only compatible but necessary for the implementation of the Institute missions;
- 2- A common heritage - the national genetic resources - that must be protected and developed by the research public service which will control the various uses made of it.
- 3- The INRA will endeavour, under the principles and the values displayed and used within its industrial property policy, to be a force of proposition and demonstration; therefore it would have a role of pioneer, dedicated to the thinking of the legislator and the regulation official authorities.

Besides the affirmation of our values, the Charter has a practical aim. It will from now on be used as a reference text for all the Institute's researchers who, like their predecessors, are willing to share the progresses made in their research activities with society, including by working with private industries, or by contributing to the development of activities on the national territory.

This Charter is the fruit of many debates and internal consultations. It has widely called up the partnership managers of scientific departments, the whole staff of the direction for Innovation, the direction board and, beyond, the scientific council and the Board of administrators of the Institute. I would like to thank all those who participated in the creation of this document that, I am sure, will mark the history of our Institute.



Marion Guillou, director general

Inra charter on intellectual property

The French Ministry for Research has asked higher education and research Institutes to adopt their own Charter on Intellectual Property (IP).

Considering this task to be of primary importance, INRA has tried to compile a charter which places issues concerning patents in the life sciences and collaborations with industry and various partners in the agronomical sector to be at the core of its consideration and commitments for the future: far from being a formal document, it must convey common values so that it can be readily applied by the concerned scientific communities.

This Charter was approved by the INRA Administration Board on June 19, 2003.

INTRODUCTION:

- Considering that a priority should be given to public service:

In its 2001-2004 orientation document, INRA, a public research organisation, reaffirmed its aim to work for the public service, which takes precedence over all other considerations.

The statutory missions of INRA are oriented towards practical and useful research which, far from restricting itself to the sole function of producing new knowledge, includes the dissemination and the exploitation of results, as well as providing scientific expertise in support for public decisions.

With a view of encouraging the competitiveness of its industrial partners and the creation of long-term scientific and technological employment in the private sector both in France and throughout Europe, INRA strongly supports the involvement of its research teams in innovative processes. Yet INRA aims at encouraging technological innovations while remaining vigilant and responsible as to their applications, notably with respect to any aspect which involves the industrialisation in the use of living organisms.

- Considering that INRA must adopt a policy which combines the primacy of public service and support for innovation in a constantly evolving international and bio-industrial context:

Both public and private research is organised through international networks, notably those which make up the European Research Area. To face challenges such as access to genetic resources and to the results of genomic research, companies in the field of

bio-industries, both French and foreign, adopt international strategies and global approaches. They are also subject to frequent reorganisation and concentration. In this highly competitive international environment, the cost of R&D has tended to increase technological inequalities, particularly between industrialised and developing countries. Nonetheless, innovation often develops within small and medium-sized companies, which thus require help in order for them to have access to key technologies.

- Considering that collaborative partnership is increasing between public and private research in life sciences:

Within a few years, "high throughput biology" has grown from the laboratory stage to a technology which is applied and organised at an industrial scale. In the agronomical biotechnology sector, large companies and pioneering start-ups alike are carrying out research with R&D investments superior to budgets devoted by public research institutes to similar themes.

Companies in these sectors thus become important partners for public research, and public funding policies tend to encourage collaborative partnerships between public and private research.

In the life sciences, these trends raise new issues, such as an increased risk of elitist appropriation of basic technologies or a reduced access to genetic resources, to which INRA must pay close attention.

- Considering that new relationships have to be built with agricultural development:

Changes which affect the image, the activities and the role of agriculture in European society have a direct impact on how innovative results arising from agricultural research are accepted by society.

Collaboration with partners involved in agricultural development ("extension services") traditionally relied on the release of results in the public domain without prior protection.

New means of collaboration with actors in agricultural development lead to the building up and funding of programmes on a joint basis, which would allow them to claim joint ownership of the results. While maintaining the diversity of its ways of partnership, INRA must take this evolving context into account and adjust its IP policy accordingly.

INRA has to develop an appropriate policy on intellectual property:

For scientists working for INRA, publication in scientific journals must remain the main pathway to international dissemi-

nation of their research results. However, by systematically publishing results that might constitute an exploitable invention, INRA would lose all rights and control over further uses.

By developing an appropriate and efficient policy on intellectual property protection, INRA expects more than just a financial gain to provide support for its efforts in favour of innovation. INRA does not aim to use its IP to secure a monopoly over exploitation of its results. Indeed INRA wants to maintain its strategic ability to choose its industrial partners and to control conditions under which inventions achieved using public funds can be exploited.

1. Principles specific to INRA concerning the implementation of Intellectual Property policy for its in-house research

The knowledge and results generated by INRA concern a wide variety of subjects and fields: genetic resources, plant varieties, software, databases, methods, industrial processes, biological materials, expert systems, etc.

Accordingly, INRA will employ all types of protection made available through regulations and legal provisions: certificates of plant variety protection (PVP), patents, confidential know-how, copyright protection, biological material transfer agreement, etc... selecting them on the basis of the nature of the results and the methods retained for their exploitation and dissemination.

1.1 Defending and extending the use of plant variety protection certificates

INRA encourages and strongly supports the protection of new plant varieties through the use of certificates of plant variety protection (PVP).

Indeed, the PVP certificate offers an excellent compromise between the property rights of inventors and the free use of improved materials to enable the invention of new varieties intended for commercial exploitation. It provides free access to plant material as a genetic resource for the breeding of new varieties, while at the same time ensuring a financial return for the creator of a new variety which complies with the DHS criteria of Distinction, Homogeneity and Stability.

This is the system of protection which INRA will continue to defend at a European level and worldwide.

1.2 Reaffirming the advantages of a patent by ensuring its correct application

Along with the ways of protecting plant varieties, INRA strongly encourages its researchers to consider patents as a satisfactory compromise which ensures both dissemination and protection of knowledge.

For INRA, patent protection permits control on the use of the results derived from its research, while making them available to the international scientific community for research purposes. It therefore limits the use of secrecy and encourages the dissemination of knowledge.

Finally, such patent protection constitutes an important tool to facilitate R&D partnership with industry, and to implement INRA's missions in favour of innovation.

The decision to patent a result must first of all be based on the three basic criteria for patentability: novelty, inventive step and industrial application. The cost of this protection requires a collective professional approach in order to evaluate the strategic and economical value of the result considered and the actual protection against counterfeit.

The decision to maintain a patent must then be based on a realistic and stringent analysis of the abilities of INRA - and its subsidiaries in charge of Technology Transfer - to identify a licensed industrial partner or to do the development work necessary for the industrial exploitation of this patent. Results which might lead to a patent application must, of course, be kept confidential until a decision has been taken as to whether such an application is appropriate. Once it has been made, the related scientific knowledge must be published as soon as possible.

Imposing highly restrictive conditions for results arising from genomic research

INRA will only apply for patents to cover gene sequences for which a definite biological function has been demonstrated experimentally.

In this respect, it will follow the advice of its Ethics and Precautionary Committee (COMEPR) and of its Scientific Board. Patents relating to products of genes will be drafted in such a way that the sequence will only be protected for a given application, corresponding to the function demonstrated. In addition, INRA claims shall be limited to practical, clearly-identified applications which are relevant to its specific missions.

Furthermore, during any subsequent negotiations and exploitation, INRA shall apply in its own fields of activity the general principles which govern the granting of automatic licences on request with respect to human genes and their applications in human health.

Thus, if the holder of a patent concerning a new function of a sequence (which INRA has already protected for another application) cannot exploit it without infringing the intellectual property rights of INRA, the Institute will grant him a license so that he may exploit this dependent patent, on condition that the new invention constitutes a technical advance and is of significant economic importance.

1.3 Restricting the use of confidential know-how.

Confidential know-how has so far been the type of protection in most of the active licenses granted by INRA to pri-

vate companies. This type of protection is indeed highly appropriate for manufacturing processes, which are difficult to protect and easy to counterfeit, or for rapidly evolving techniques.

Licensed confidential know-how can also include biological material (hybridomas, plasmids, clones, vaccines, microbial strains, etc.) which may already have been mentioned in scientific articles. Indeed, publication of the creation of this material does not prohibit its exploitation through appropriate agreements.

Protection through confidential know-how has some major drawbacks: retention of information, prohibition on publication, volatility of confidentiality and weakness of protection if a third party subsequently publishes or patents the same results. INRA only recommends protection through confidential Know How for process technologies which cannot be protected by patent.

Furthermore, a license for confidential know-how should be granted only for a limited period of time, the time needed by the licensee to develop the innovation and get a reasonable return on his investment.

1.4 Dissemination of copyright-free software within the scientific community

Software benefits from protection under copyright law and must be the subject of an application to the French APP (Agence pour la Protection des Programmes, or Programs Protection Agency) to guarantee proof of the intellectual paternity of its authors and the date of its creation. It is the software itself which is protected, in the form of its original structure.

Its dissemination may be envisaged under different types of licenses.

When software programs are designed for use by scientists, INRA expresses a preference for "free" licenses, such as GPL, or General Public License, which constitutes an appropriate means of dissemination.

Software programs imply access (free of charges or in return for payment) to source code, as well as the freedom to modify and distribute the basic software and its extensions. However, such licenses may prove too restrictive, as the related conditions and prerogatives (access to source code and free use) apply to any derived work, so that their commercial distribution may then prove impossible. One should be vigilant concerning the choice and the terms of the license when a real potential for commercial distribution is identified.

In some cases, communities of informed users and researchers in the public sector may set up networks and create a scientific dynamic around simulation models associated with jointly-developed software programs. To sup-

port these collaborative efforts, it is not essential to provide access for all partners to source code, but the signature of a licensing agreement fixing joint rules is necessary.

Any work which transforms a prototype research software into a marketable, operational product does not fall within INRA's competence. In order to preserve the interests of a private partner likely to undertake this transformation, INRA recommends that free access should not be given to source code. Straightforward software user rights should then be granted to third parties, a distinction being made, depending on whether they are academics or not: the use of INRA software for public research or teaching must remain free of charge or easily accessible.

1.5 Developing and amplifying the improved used of databases

Research work carried out by INRA often requires the collection of data or the use of data collected by others. These data may be organised into databases. As for software programs, databases are covered by copyright, which protects the originality of their architecture. This copyright is supplemented by a "sui generis" right, which protects their content.

In this respect, the compiler of a database retains the exclusive right to prohibit the extraction or re-use (through its availability to the public) of its contents, either totally or partially. Being the only person able to make this data available to the public (either free of charge or in return for payment), the compiler may then impose or control the conditions of use of his results.

INRA thus encourages the submission of databases to the APP (Programs Protection Agency), a procedure which guarantees proof of paternity (as for software programs) and fixes the date of creation of the database.

Unless they have potential for industrial application or economic exploitation, data acquired by INRA are intended for widespread dissemination. Placing data on the Internet encourages the broad and rapid spread of knowledge within the international scientific community.

High throughput genomic data requires particular caution

In this case, INRA recommends delaying, for a short period necessary for their analysis, the dissemination of results in a database, if they are likely in the near future to require protection by a patent or lead to original scientific publications.

Other data should be published in appropriate databases.

With respect to gene sequences, the extensive publication of accessible annotations and information, and any foreseeable application, is encouraged by INRA: indeed, such publication forbids any third party from obtaining these sequences through a patent.

1.6 Systematic use of biological material transfer agreements.

INRA is responsible and accountable for considerable assets, built up owing to the input of public funds:

- animal, plant and microbial genetic resources, mutants, microbial strains,
- biological material: tissue and cell cultures, DNAC, BAC, YAC, irradiated hybrid and peptide banks.

INRA's mission is to ensure that the international scientific community benefits from these assets, while taking into account the increasing risks of inappropriate use if such materials are disseminated without sufficient care.

INRA therefore strongly recommends the systematic use of Material Transfer Agreements (MTA).

In addition to ensuring a satisfactory traceability of exchanges, these agreements must guarantee for INRA the confidential nature of the transfer, the preservation of its ownership of the material, its ability to control the exploitation of results obtained using transferred biological material as well as to be relieved from any liability in the event of inappropriate use.

Regarding the special case of genetic resources of foreign origin, only requests concerning materials received by INRA prior to December 1993 are concerned and are then covered by the rules described above (MTA). Requests relative to foreign material received after December 1993 are sent to the original States and owners, in accordance to the principles laid down in the Rio Convention on Biological Diversity, which gives each State responsibility to lay down rules relating to the circulation of their genetic resources.

2. Underlying principles and implementation of Intellectual Property policy with respect to research conducted in the context of collaborative research

In the case of research projects conducted with external partners, the different parties will all contribute in terms of resources: biological, technological, financial, human and intellectual.

For INRA, questions concerning the ownership, dissemination, commercial exploitation of results, which must then be covered by a contract, are not dealt similarly with public or private partners.

2.1 Managing the joint ownership of results with public partners

In the case of public partners, ownership may be predefined by framework agreements or conventions governing the creation of Joint Research Units (JRU).

The joint ownership of results (or a fair financial return on their subsequent exploitation) is proposed to the partner, if it is established that the results were obtained jointly.

The respective shares are then determined proportionally with *lato sensu* investments of each contributor: intellectual and financial investments, including the costs of personnel, functioning, equipment and equipment depreciation.

The designation of the project leader for exploitation, and his role, are set down formally in an *ad hoc* agreement (or, if relevant, in the constitutive agreement for the JRU). Project management is determined by agreement, and in principle is entrusted to that party holding a majority share in ownership, and generally the most closely concerned by the field of application of the results.

2.2. Developing and sharing results with industrial partners.

INRA always claims full ownership of its own results, i.e. those obtained during work executed on its premises, carried out and managed by its researchers.

Thus, INRA must remain the owner of results obtained, even when private sector partners participate in the funding of its research. The latter may then benefit from a prerogative of access to information or options for a license concerning the results, in compensation for its participation.

Indeed, joint ownership with an industrial partner presents the major disadvantage of submitting the dissemination and exploitation of new research results to the agreement of the partner; who may very well not have the same objectives as INRA.

However, such joint ownership may be chosen as a result of negotiations, on the explicit condition that the intellectual and financial contribution of the industrial partner fully justifies this decision.

This is particularly the case if permanent, salaried employees of the partner are working under contract and wholly carrying out their activities in an INRA laboratory. Doctorate students receiving a public grant however represent a distinct case.

In addition, joint ownership must not constitute an obstacle to the continuity of research efforts or their exploitation. Accordingly, INRA must demand the industrial partner for the granting of a free-of-charge, irrevocable license to use the common results for research purposes within its own laboratories or those of its JRU.

In addition, joint ownership of materials or knowledge must not cover research product derived from them but obtained by INRA alone.

The exclusive devolution of intellectual property to an industrial partner is not recommended by INRA. It can only be accepted under exceptional circumstances, strictly limited to applicative technologies of no generic or strategic importance to INRA.

3. Efficient exploitation and transfer of our results

3.1. Concession of exploitation rights without mortgaging the future

INRA's intellectual property policy must allow it to fulfil its mission regarding the exploitation of its research results, in accordance with the principles and values recalled in the introduction. This objective requires the granting of exploitation rights to stakeholders in the industrial and commercial sectors.

INRA must favour the granting of non-exclusive licenses, most particularly concerning patents covering a wide scope of protection.

Indeed, the granting of exclusive rights constitutes a major obstacle to any subsequent development of a partnership with a third party in the same field.

Exclusive exploitation rights will only be granted in exceptional cases to a partner, once an analysis has been made of its strengths and assets, its capacity and will to develop an innovative product or process, its leadership in the concerned field, and the specificities of the technological innovation and market.

In all cases, an exclusive license shall be restricted in terms of its duration, **territorial validity** and limited to a clearly-defined area of application.

Such granting of rights should first of all benefit French and European agriculture and the biotechnological or traditional industries closely linked to farming: within this context, INRA wishes to favour companies long-established in France or Europe, so that these territories may benefit from the introduction of its innovations.

Indeed, INRA considers it will exert maximum leverage by focusing its actions and demands on the research strategies of its partners. Thus INRA will prefer research and exploitation partnerships which are likely to create jobs for the research in France, and build up partnership networks which will generate long-term scientific collaboration.

The financial products arising from industrial exploitation will benefit the research organisations and original inventors of the results exploited, in accordance with INRA memorandum relative to profit-sharing by researchers (implemented by the Institute in 2002).

3.2 Encouraging the creation of innovative start-up companies

Innovative start-ups deserve particular attention, if their scientific investment and professionalism are to make them truly active partners in exploiting the knowledge portfolio held by the Institute.

INRA will adapt the founding principles of its intellectual property policy to the specific case of innovative start-up companies, so as to guarantee their development, notably during critical phases of their growth.

A distinction must be made between:

- ownership of the results of research already carried out by INRA: this must remain the property of INRA which may concede an exclusive operating license to the start-up;
- research results obtained in the context of a collaborative agreement with the start-up, which may then be the subject of joint ownership.

3.3 Strict limitation and control of recourse to service provisions

Recourse to service provisions by INRA's research units must remain a marginal practice.

Service provision contracts conferring the ownership of results on the sponsoring partner must never replace research agreements, as this partnership arrangement does not allow satisfactory control of the transfer of knowledge: it must therefore be avoided whenever original results, know-how or innovative technologies are liable to be produced.

4. Implementation of the Charter

4.1 Implementation of the Charter by research departments

Decisions concerning patent applications, extensions or withdraw are under the responsibility of research departments. Operational management of the industrial IP portfolio is centralised: it is entrusted to the Direction of Innovation which is in charge for the IP budget.

INRA's IP policy is achieved in practice through a transversal network comprising partnership managers, legal and IP experts, and managers responsible for the commercial exploitation of INRA transfer subsidiaries. An "IP committee" has been set up to carry out a monthly examination of invention disclosures, to monitor applications, extensions, delivery, withdrawal and to decide of a market clearance opinion work. It plays a key, if consultative, role of coordination of Intellectual Property policy for INRA.

4.2 Sustained efforts to raise awareness

At an individual level, the awareness of INRA researchers to intellectual property issues will be the subject of specific measures and regular reminders: vademecum on legal matters, regional conferences, widespread circulation of this Charter, annual research training course devoted to patent policy in the life sciences.

At the level of research units, the use of lab data book, a practice already well mastered by numerous teams, will be encouraged at all times in the context of our Quality policy.

4.3 Two European initiatives

At the national and European levels, INRA will participate actively in two strategic initiatives.

The first concerns the defence of its patents: the credibility of an intellectual property policy relies on the institution's ability to conduct and succeed in litigation procedures. These extremely costly operations, which cannot be covered by the budget of a single establishment, require the pooling of national and European public efforts. For this reason, INRA is in favour of the creation of a mutual fund for patent defence.

The second initiative aims to achieve concerted management at a European level of patent portfolio owned by pub-

lic research organisations relevant to the agronomical and biotechnological domains. Inspired by the American Federal initiative (the Clearing House), this project for centralised exchanges will be aided and encouraged by INRA in close coordination with other public research institutes (CIRAD, IRD, CNRS) and its principal European scientific partners.

<p>The present INRA Charter on Intellectual Property will be supplemented by guidelines on Good Practices In Partnership. It will be updated on a regular basis so as to take account of the rapidly evolving legal and technological contexts concerning applications in the field of life sciences.</p>



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