

REGULATORY EXPERTS AT THE FOREFRONT

THE CURRENT (AND COMPLEX) REGULATORY CONTEXT HAS DETERMINED THE RAISE OF A MULTITUDE OF DEMANDS ADDRESSED TO THE REGULATORY EXPERTS. THEIR TRADE IS TO HELP THE INDUSTRIALISTS “DRAFT” THEIR ALLEGATION FILES AND FIND THEIR WAY THROUGH THE LABYRINTH OF NATIONAL AND COMMUNITARIAN LEGISLATIONS. BUT NOT ONLY. SOMETIMES, THEY ARE ALSO SCIENTIFIC EXPERTS, AND PROVIDE STRATEGIC CONSULTANCY TO THE COMPANIES. WELL KNOWN AGENCIES OR MONO-ENTERPRISES, THESE EXPERTS BACK UP FROM THE BRANDS OR MANUFACTURERS FOR WHICH THEY DEVELOP ACTIVITIES. LET US DIVE INTO THE UNIVERSE OF A STRATEGIC BUSINESS AT THE CORE OF FUTURE DEVELOPMENT THANKS TO FIVE QUESTIONS THEY HAVE ANSWERED.

▶ CAN YOU DESCRIBE YOUR BUSINESS ACTIVITY IN A FEW WORDS? DOES IT IMPLY ONLY REGULATORY ACTIVITIES OR OTHER TYPES OF SERVICES TOO (TECHNOLOGICAL WATCH AND/OR INGREDIENTS)?

de Vecchy Conseil : Our purpose is to provide the industry with technological and regulatory support so as to help them develop dietary supplements and health-oriented products which comply with the regulations while also being innovative. For me, this technical and regulatory responsibility is important as it allows us to participate in the process of validation and authorization of innovative ingredients at a very early phase of the chain. In my opinion, in the absence of technical skills, it is difficult to provide support in the case of complex files such as those pertaining to plant extracts for instance. Hence, the need to double my training, as a pharmacist and legal adviser.

EAS: EAS is specialized in the regulation on foodstuffs and so-called nutritional products, at a European and international level. We provide regulatory and strategic consultancy to the companies, enabling them to better succeed in marketing their products. With the help of a team comprising legal advisers, political science experts and nutritional and biological engineers, we are fully aware of the specific needs of the companies acting in the food-processing industry and of the needs of the authorities which seek the support of experts coming from different professional and cultural horizons. Over the last 16 years, EAS has focused on the watch and analysis of regulatory and political updates. We have also supported the

companies to develop new products and to successfully launch them on an increasingly global market. We have also helped the governments analyze regulatory trends and the impact of regulatory changes. Our services include: regulatory and strategic consultancy adapted to the development and marketing of nutritional/functional products, dietary supplements, ingredients intended for nutritional or physiological purposes, plant-based products and health foods in over 40 countries on an international scale; analysis reports drafted by experts with a view to reviewing regulatory trends and assess the impact of regulations on the food-processing sector and the governments; training workshops in the field of food-processing and regulatory authorities focusing on the key issues affecting this sector; the assessment of active ingredients, of their intake, of their complete composition formulas and labeling; a complete and detailed analysis of the latest developments affecting foodstuff nutritional policies.

MS Conseil : We have developed two types of services: regulatory services but also services focusing on product development. This double activity enables us to go to the upstream, to quickly advance in our development projects and obtain the regulatory validation of active ingredients and additives. In other words, our aim is to validate the formulas developed by important players but also to work with smaller-size companies and to validate their labeling projects, for instance.

Our activities also include the drafting of files for Fraud Control. We have also developed projects for the validation of dietary supplements, beforehand or afterwards their distribution.

Naturalpha: Naturalpha is a consultancy company and an R & D specializing in healthy nutrition. Developing activities that pertain to the food-processing and medical universe, Naturalpha's mission is to provide evidence on the health benefits of drugs, dietary supplements, functional ingredients and foodstuffs. The team, made up of doctors, researchers, nutritional engineers, dietitians/nutritionists and clinical study experts, supports our partners through three types of activities: consultancy (regulatory and scientific watch and consultancy), laboratories (laboratory validation of the health effects via in vitro and in vivo tests) and clinical trials (the design and management of clinical trials).

Relying on scientific and regulatory skills, expertise enables us to support the industrialists through each stage of their development. On the one hand, by possessing a thorough knowledge of the regulatory framework (horizontal and vertical legislations) and controlling its impact on upstream activities and on all the stages of product development until its launch on the market. On the other hand, by adding scientific methodology and rigor to the management of the laboratory studies and trials conducted on humans in order to backup the health benefits of the tested products.

Nutratche Conseil: We are a consultant company with competencies mainly in industrial field, because of our training background as food engineers. We work with companies with a R&D and innovation ap-

proach. For this purpose, we prefer a global approach of the projects and we try to bring our expertise on different points : marketing, market and of course regulatory. Our expertise lies mainly on nutritional or health ingredient and on its application in dietary supplements, PARNUTS, energy products, etc. but also in health food products, more traditional, or in feed products, which are facing the same problems.

Our scientific approach allows us to give comments on a project possibility, thanks to our internal resources. In few words, we build a scientific state-of-the art. Finally we bring also our skills in term of technology: we are sometimes contacted to organize technical assays in extraction, drying, ingredients in powder form production. The regulatory aspects are integrated in this global approach of the projects.

Nutraveris Conseils: We are a Scientific and Regulatory Consultancy Agency that accompanies manufacturers in the development of scientific innovations, formulations and argumentations, as well as in the regulatory validation of their products (composition and allegations) in France and abroad. We meet our clients' demands thanks to our 2 established departments. Nutraveris Legis is the regulatory department (regulatory expertise and validation). It serves three purposes: it finds solutions for the validation of developments at an international level, it supports the clients in notifying their products and obtaining the mutual recognition of their products from the European administrations, and at an international level, it



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drafts and submits files with the EC to obtain EFSA's validation for the products falling under the scope of Article 13.5 and 14 of Regulation 1924/2006 (we are a leader agency in this field).

Nutraveris'Iris is the scientific department. We have created the Nutraveris'on-line database, a unique tool in Europe dedicated to the formulation and development of dietary supplements and fortified foods which lists and analyses on a week basis the relevance of all types of information: regulatory information (ingredient marketing authorization and claims for allegations submitted to the EC (European Commission), claims under assessment or which have already been assessed by the EFSA (European Food Safety Agency); scientific information pertaining to the efficiency and safety of over 1200 ingredients authorized in Europe within 132 segments belonging to different markets. One click and the database enables you to search by segment, ingredient, key-word... whether an ingredient is authorized, whether claims have been submitted for it, and which are the published scientific studies that might support you in the development of new products and rapid drafting of files that back up the allegations. We are also specialized in drafting files for DGCCRF's subsequent controls, allegation backup files and technical-commercial argumentations. We also help our customers to develop formulations: to choose the active ingredients, to justify their doses, to validate their choice of raw material suppliers, to conduct galenic developments and clinical and toxicological trials.

Pharmanager Development : *Pharmanager Development is a specialized company developing scientific and regulatory activities in the field of cosmetics, food-processing and pharmacy. It is important to offer a global perspective to our clients insofar we are no longer dealing with scientific or regulatory issues, but rather with a whole. The clinical support of health allegations and the European regulation governing is such an example. Technological watch, regardless of its type, is one of the main missions of Pharmanager Development and we have developed a structure and tools (mainly pharmanager-ingrédients website) specifically adapted to these stakes.*

RNI : *RNI Conseil is a regulatory and legal advisory agency specialized in all types of dietary products (dietary supplements, dietary products, dietary foods for special medical purposes, fortified foods...). Our global services include three key stages in the life of a product: the validation of its formulation (active ingredients, additives, Novel Food files), the validation of its claims (labeling, communication, claim file), its registration with the authorities (statement, notification, registration). These services are available in all*

the countries: RNI Conseil aims to be a bridge that enables and supports the circulation of products and clients from one state to another, from one continent to another. Our services are technical-regulatory oriented as they also include a scientific aspect such as the drafting of Novel Food and novel additive marketing authorization files, novel claim files and dietary food for special medical purposes files under regulation 1924/2006. Our team is made up of scientific and legal experts.

A global perspective is necessary as it provides new experiences

VDMj Conseil : *My activity does not relate only to dietary supplements as I also work with files on foodstuffs for particular nutritional uses, medical devices, OTC drugs... In order to do that, I rely on my pharmaceutical experience of more than 25 years during those I developed drugs and dietary supplements. In my opinion, it is an important aspect. But my expertise encompasses also consultancy on marketing and product positioning, quality audits and the development of innovative products. This sometimes leads me to encourage*

my clients to develop patent applications for certain products. Once again, I believe that the expertise in the field of patents associated with the development of products at an international level are two key aspects of my activity.

▶ IS IT IMPORTANT TO POSSESS NETWORKS (INCLUDING INFORMAL ONES) IN OTHER COUNTRIES (NOT ONLY IN EUROPE, BUT ALSO IN ASIA, USA, ETC.), EVEN IF THE COMPANIES FOR WHICH YOU WORK HAVE NO COMMERCIAL ACTIVITIES THERE?

de Vecchy Conseil. *Historically speaking, I have worked mainly in France and to a small extent in Belgium. When the need arises, I outsource part of the files to other consultancy colleagues. But since I am a specialist in plants and their extracts, it is rather the opposite that occurs: most frequently, it is manufacturers from abroad that want to penetrate the French market that turn to me.*

EAS. *We operate in a global scientific, regulatory and marketing environment. Understanding the European framework is essential, but a global perspective is also necessary as it provides new experiences and new ways of thinking. This is the reason why EAS has set up in Asia a second office that provides the same strategic and regulatory services as EAS Europe.*

Naturalpha: *The food-processing market is not only French but also European and even international. Insofar Europe is concerned the regulatory framework has become increasingly harmonized over the last few years with a view to facilitating cross-border exchanges;*



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however, certain legislative dispositions are still to be defined or cleared up and while waiting for a European consensus, certain national regulations are still in force. This is the case of the administrative approaches to be made with the ethics committees / competent authorities beforehand carrying out the clinical studies underlying an allegation file. These stages depend on the national legislation. In a similar way, the regulatory framework that applies to health products differs from one region to another (Europe, USA, and Japan). Because of all these, it is good to possess local networks in order to understand and facilitate the approaches with the Health Authorities. These networks can lead to the creation of partnerships with sub-contractors or experts identified by the Competent Authorities. For example, in order to facilitate the creation of contacts, we have set up an office in Cambridge (MA -USA) and we are ready to meet every customer demand regarding the FDA.

MS Conseil: We actually have contacts in Europe, Japan, Canada and the USA, players that I have personally met. However, this network is rarely activated insofar there are few demands and I have not tried to develop this activity.

Nutrarech. We work with a network composed by industrials, union organizations. We have contact lists which allow us to contact many people and in fine to find the right name. We are in a process to increase such a contact data base.

Nutraveris. We have actually set up networks in most of the countries where we conduct our development activities, offices that provide both regulatory (administrations, trade unions, lawyers...) and scientific (networks of experts, mainly EFSA and other opinion leaders) services that enable us to issue accurate and exhaustive opinions, while regularly performing updating activities although it is us who directly perform all the registrations for our clients.

Pharmanager Development : Indeed, it is impossible to possess all the details pertaining to international legislation from France. This is why it is crucial to be able to rely on a network of consultancy agents that possess a thorough knowledge of the legislation in their countries, the position of the competent national authorities and the evolution of the legislation... It is Pharmanager Network's role to develop an international network of regulatory experts in different sectors of activity and to manage the whole flow of information (www.pharmanager.com).

RNI. At RNI, the importance of networks is given by the importance of every single network. We have established networks with local authorities and national scientific experts, in Russia, Asia, Africa, and in the Middle East, we possess and we develop contacts that are essential for our regulatory files. Moreover, getting to know the international dietary regulation and the Codex Alimentarius enables our team to better understand and anticipate the evolution of the European regulation.

“The European Union might become a “marketing chaos” where claims worn for years might be removed”

VDMj Conseil: It is a key word for me insofar 60% of my activity is conducted abroad. I have therefore participated to the registration of products in over 30 countries. This international vision is important in the European regulatory context of dietary supplements, which will have a positive effect in term of harmonization but at the same time will penalize the products range.

The regulation evolution will involve a standardization of the composition and of the products claims. In this context, for the less innovative products, the so-called “me-too” in the pharmaceutical industry, a few companies will be advantage : those which have the highest fame, the highest communication budget and also those which are the most present in other countries policy. Some key questions then are arising, such as “ which product in my range will be promoted ?”, “how to sell it ?”, “what is its international potential ?”. This is why being based abroad and possessing a network of contacts is essential in this field.

This applies to existing products but also to new products : a product has to be developed within a logic of innovation and of internationalization – which could fit with niche products development. This can go also with the development of a licensing policy, speeding an international launching.

▶ ACCORDING TO THE FIRST OPINIONS ISSUED BY EFSA (ARTICLE 14 OR GENERIC DRUG CLAIMS), THE EXPERTS HAVE RAISED THE BAR QUITE HIGH. HOW WILL THIS AFFECT YOUR WORK?

de Vecchy Conseil. Last year, I braked heavily and I refused to submit files under Article 14. Simply because I know for example, what a drug marketing authorization file should contain. On the contrary, in the case of allegations, even if we had guidelines, we did not know which would be the level of requirements for these files. A risky situation, in my opinion. Some of the “hot-head” manufacturers took their chances

and submitted the files, with the well-known consequences. Now we know how it goes.

Moreover, let us not forget that the allegations, whether accepted or not, are published in the Register of allegations. If so (the latter), I wonder about the damages this can bring to the company, especially if it wants to engage into export activities.

One thing is sure: we have to give serious consideration to these aspects. Very often, the medium-sized companies which are actually involved into R & D do not meet the standards. Perhaps they should focus on generic allegations...

EAS. EFSA will definitely become the world reference in terms of risk assessment and scientific consultancy on foods and nutrition. From this perspective, their allegation assessments will naturally become increasingly strict and only the companies able to provide evidence for the efficacy of their products will be granted positive opinions. However, as we have stated on several occasions, EFSA should not use the same criteria in the assessment of allegations under article 13 if compared to the allegations under Article 14. The regulation makes it clear that the approaches must be different. If we do not take the appropriate measures, the European Union might become a genuine "marketing chaos" where allegations worn by foodstuffs for years or even dozens of years might be removed from the labeling and other communication supports. If this is the desire of the 27 Member States of the EU, the awakening will be difficult when the application problems related to illegal allegations will reach levels unknown before.

MS Conseil. For a consultant it is always a dilemma to propose to his client an allegation file while knowing that the risk of being rejected by the European authorities exists. Moreover, it is even less pleasant to draft the file, as the manufacturer invests important funds in the clinical studies (Editor's note: from 100 000 to 200 000 euros) which must be approved (by the Afssaps for instance).

Very familiar with the field of clinical studies, I can tell from the start which claim will be easier to prove. An important aspect: it is necessary to know what we search in order to find it.

Many files have been rejected because the cause and effect relation

was not significant for the EFSA experts. Another difficulty relies in the fact that we address to apparently healthy subjects, with no declared affections, on whom we have to prove the activity of a product.

Naturalpha. We had expected a high raise in terms of requirements, but finally, EFSA's approach is very similar to that of FFSA, which means very strict. It is quite clear that EFSA's current orientation brings closer the fields of pharmacy and nutrition in terms of scientific rigor, which might be surprising; especially insofar as the health allegations under Article 13 are concerned. However, we had anticipated this rigor and taken in-house measures - before EFSA published the guidelines on the assessment grids - to assess the quality of clinical parameters in the case of allegations. We will therefore continue on this direction and supplement EFSA's opinions with detailed analysis tools in order to identify the key aspects of any file and thus appropriately guide our clients. We have realized that many applicants neglected certain key aspects of the file requirements, "details" such as the bibliographic research of data, approaches that many of the industrialists lack experience in. We are therefore currently associating the results of scientific research with the systematic assessment criteria outlined by EFSA and the formulation of allegations, in order to assess the "weight" of the file of our clients' products, and reduce the risks of negative opinions.

Nutratch Conseil. We had have integrated this parameter in our approach of the regulatory files. We all knew that the scientific level would be very high. And what is happening now concerning the published advices is what had to happen. In fact a so high scientific requirement is justified: when we want to play a game we had to follow the rules. We have always considered that the industrialists would have to follow the published guidelines.

Nutraveris. EFSA panels of experts include academic researchers, it is therefore not surprising that for a scientist the level of the submitted evidence must be statistically and clinically conclusive. Thus, the requirements regarding a file submitted to EFSA relate to evidence and scientific rigor.

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After a brief analysis of the issued opinions, thanks to our expertise we have quickly identified several flaws regarding the submitted studies or even the drafting of files. A negative opinion was to be expected in such cases. Our vision on the EFSA files and our initial strategy has been confronted for 1 year and a half with the drafting of many files and we have gained experience from our exchanges with the EFSA experts. We have therefore been able to analyze the relevance of the scientific data, the accuracy of the requested allegation messages with a view to submitting the final file. We have developed an interactive pre-diagnostic which indicates to our clients the level of acceptability of their studies for such a file and the evidence still to be collected, which also enables us to propose them supplementary protocols and clinical trials essential for the final success of their file.

Pharmanager Development : Briefly, this is what Pharmanager's customers expect from us: anticipation. Thanks to our scientific and regulatory activities, our customers had already been informed in 2006 about the allegation regulation project. In 2007, we were the first to draw the alarm in our field on the radical changes to be brought to this regulation regarding the scientific support of health allegations. Finally, by recruiting (2008 JL Berta : Expert Doctor, former human nutrition responsible within the FFSA, co-editor of the Nutrition and Health National Program. 2009 - A groubert : Pharmacist, former Pharmacopoeia expert), Pharmanager knew how to make evolve its company so as to meet the new requirements imposed to our clients.

RNI. The conditions required to obtain a new allegation authorization are high and copied from the pharmaceutical universe. The manufacturers have therefore reacted to this situation in three different manners: they have either waited for the publishing of the authorized allegation register and adapted their products and communication to those of the products that have been granted positive opinions; they have either joined a trade union in order to try to lower the level of scientific requirements and make them adapt to a "nutritional" reality; or, despite all these, they have still submitted their applications for authorization and focused their developments and files on a few flagship products of their ranges. The regulatory mission currently relates, therefore, to allegations, communication and labeling and tends to include the three strategies presented above adopted by the companies.

VDMj Conseil : It's been several months since I have noticed an evolution in the manufacturers' requests. Many of them have understood that their delivery came from developing abroad, outside Europe, and this for their existing products as well as for their new ones. This somehow "imposed" evolution (by EFSA) will enhance the demand for serious agencies and/or consultants seriously working on the development of innovating products in an international vision.

The conditions required to obtain a new allegation authorization are high and copied from the pharmaceutical universe

▶ SO FAR, THE CURRENT REGULATIONS HAVE ALLOWED YOU TO FOLLOW AN UPWARD TRAJECTORY. ARE THERE ANY CLOUDS THAT COULD DARKEN THE DEVELOPMENT OF YOUR BUSINESS?

de Vecchy Conseil : The beginning of the year was a subdued one. I felt that the companies were still in a phase of questioning regarding the claim files. But neither the general context was very favorable. The gloom seems to have ended now and companies are renewing their interest in development projects. I think that both for us and our customers, the regulatory activity will be difficult for 2 or 3 years. The transition period will surely trigger certain delays.

EAS. In our sector, we have worked a lot in order to become market leaders in regulatory consultancy and we are still working hard to maintain ourselves to the top. It is our expertise, our knowledge and broad skills that attract the clients who decide to work with us. We believe that if we continue to capitalize our efforts in this direction, we will step confidently into the future as it is the future that motivates us.

MS Conseil. I do not worry for consultancy activities as ours. I'm rather worried for the industrialists. Many of them will have to use a few generic drug claims published in 2010. Some of them will resort to the expertise of consultancy agencies; other ones, due to budgetary reasons, will only refresh their packaging.

Naturalpha. Within our activity in the field of nutrition and health we have opted, since the very beginning, for an interdisciplinary approach that combines regulatory and scientific aspects. The implementation of the European directive and mainly the drafting of the files pertaining to Article 13 have triggered a high demand for specific consultancy. However, they have also triggered a change of perspective among

manufacturers, who are questioning their strategy of development in the field of nutrition and health. We have therefore assisted to a real evolution in the demands of our clients, passing from a quantitative model that favored the submitting of allegation files in the shortest of terms, to a qualitative model that included scientific evidence. Our regulatory and R & D positioning makes us able to live at the height of the evolution of the demands, and this is the reason why we are optimistic about the future of our activity.

Nutratche Conseils. Now what is important is what will happen in a concrete way. Until the publication of the allowed claims lists in January 2010 we are in an in-between step. Then our task will be to participate to the good management of these claims. The regulatory experts had met in the past such a situation with the Novel foods legislation. There are some similar points with what happens now with the claims. In 1997 indeed the bar was raised very high also. Several industrials thought that it could have not been possible to innovate. But what do we observe? This has never stopped the new ingredients development nor their launch on the market. And if until now the will of the industrials are slightly slowed down, what will happen could be the same with the claims. Finally, concerning our consultancy activity in legislation we must not forget that there are several files in which we can collaborate with the industry. For example, food colours and additives legislation or dietetic products. These files will not be done without our help.

Nutraveris. Ever since our creation, more than 3 years ago, we have permanently anticipated the needs of the market, implemented various know-how tools and capitalized on human resources with a high level of training, experience and requirements (Doctors in pharmacy, physiology and physiopathology, food-processing engineers, masters in nutrition and health, dieticians...) that possess a wide complementary vision of any issue, enabling us to immediately treat with enthusiasm, relevance and success any such issue. We have also established partnerships with many complementary players in order to provide comprehensive services from the design of the product and until its launch on the market.

Pharmanager Development : The scientific and regulatory environment of our clients is getting increasingly complex and their expectations increasingly varied, we are therefore adapting our company to this evolution.

RNI. The EC legislation in terms of products and food-processing safety is far from being concluded. Several regulatory modifications and new texts shall be published, and they will require further juridical analyses of

the products and their adaptation. Beyond the issues related to the economical context, the Regulatory Affairs specialists, whether employed, consulting agencies or trade unions, will always be well quoted trades.

VDMj : Just as the sector of dietary supplements will undergo a real evolution, with the disappearance of laboratories which will not be able to justify their sometimes too exaggerate allegations, the sector of regulatory consultancy will undergo its own revolution, too. They were used to be regulatory consultancy agencies that kept their clients informed and made their work easier by providing them with smart tips. To my mind, such an approach will disappear. Similarly, in our primary regulatory consultancy activity, the questions pertained to the doses of vitamins or minerals to be incorporated into formulations. Henceforth, the manufacturers will be able to rely on clear and straightforward texts. And when the doses are published, everyone will be able to consult them. In fact, I think that this "primary" activity is being threatened and will increasingly lose ground. On the other hand, the consultancy activities on the development of solid products marketed at an international scale will register much progress.

▶ WILL YOUR TRADE HAVE EVOLVED WITHIN 5 YEARS' TIME? IN WHAT SENSE?

de Vecchy Conseil: If I look back over the last few years, our business has evolved. In terms of technologies, materials etc... But if we go right to the heart of the matter, we realize that we still have to meet the concerns of professionals and give them the best possible answers. And this will never change.

EAS. We have several projects in store for our business activities and we are currently developing number of them. It is clear that our activity will remain dynamic and bear its fruit, providing added value to our clients, whether they are companies, governments or associations. Any person that works at EAS and with EAS must be aware of the fact that she/he is working with a strategic player in terms of regulatory developments, solutions and actions.

MS Conseil: Yes, certainly because we can imagine a decrease of the number of dietary supplements laboratories without a decrease in the market. Therefore it will not be enough work left for all the consultants presents in this market. The evolution could also trend to an internationalization of this activity.

Naturalpha. The regulation on health allegation continues to evolve, if taking into consideration only the publishing of the authorized allegations under Article



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13, the nutritional profiles... Other directives or regulations are under development or shall be modified, i.e. novel foods, dietary supplements.... These different texts will set the limits of the regulatory framework and precisely define the necessary prerequisites for the development and valorization of different foodstuffs. Thus, once the regulatory framework will have been set, the industrialists will be able to implement product development strategies in line with the standards, such as the ones already implemented in the case of OTC drugs and products. Within this context, the scientific file underlying the beneficial effects of the products will represent once again the core of our trade. The major stakes of the evolution of our activity will be, within the context of accompanying the drafting of regulatory files, to own and enhance this double scientific and regulatory expertise.

Nutratche Conseils : Just on this claims subject, it is clear that we will have things to do and to say. What is preparing on the European level is going in the direction of a needed clarification concerning the products claims. This will contribute to clean up in some industrial areas. For us, as well as for the industrialists with whom we are working for, it will be important to follow the line.

Nutraveris. The regulation is permanently evolving, the scientific affairs less, but they have to adapt to the needs and limits of the former, and our advantage relies in our two departments that stimulate the exchange of information in order to better meet any needs and constrains.

Pharmanager Development : Yes, our multidisciplinary team (cosmetics, food-processing, dietary supplements, pharmaceuticals) is currently comprising 9 persons (health engineers, pharmacists, doctors) and through our watch activities we are able to anticipate the future regulations and already prepare (as we have made in the case of the allegation re-

gulation) our future expert recruitment. For us, as well as for our clients, "forecasting is being able to outline the future and prepare it; forecasting is taking action". [Henri Fayol].

RNI. A regulatory expert must always be in line with the regulatory evolutions but especially with the manufacturers' evolution. RNI Conseil's competency and services have evolved for several years according to two parameters: scientific skills for allegation

files, technical skills for Novel Food files, skills in International & Comparative Law for export activities. Regarding the new regulatory texts and the future objectives of the European Commission or the European Council objectives (such as the safety of plants and of their mixtures), the demands will focus around two supplementary directions: the toxicity and safety of products. At the time being, Europe is one of the last continents that do not require explicit evidence for the harmlessness of the mixtures at the registration of products, an element which is essential in many other countries. RNI Conseil has already anticipated this trend and has already established relations with well-known toxicological experts. Finally, the allegation

regulation and the problems related to mutual recognition in Europe will spur the industrialists to collaborate more closely with their in-house or external regulatory experts and their marketing and R & D teams. The development of nutrition products will turn to enhanced collaboration and the organization of the different services within an enterprise. The regulatory expert will become increasingly involved earlier and more in the upstream into product development.

VDMj : I think that we will witness a serious evolution of the companies. Major groups will be formed but also very innovating small-sized companies will develop. The universe of regulatory consultancy will follow a similar evolution and will experience a symmetric revolution through the set up of powerful agencies based in several countries. At their side, smaller structures able to provide an innovating insight and a tailor made answer will continue to exist.

Regulatory experts / De Vecchy Conseils.
Hélène de Vecchy / EAS. Estelle Marais / MS
Conseil. Michel de Sarrieu / Nutratche. Rodolphe
Merlet / Nutraveris. Cédric Bourges / RNI
Conseil. Violaine Chaumont / VDMj. Jacques
Vandermander

Europe does not require, for the moment, explicit evidence for the harmlessness of the mixtures



REGULATION AND SCIENCE

Launching a product on the market depends on 2 crucial questions that require 2 inseparable types of expertise. Regulatory: what can we do? And scientific: what should we do?

In fact, a formula depends on the choice of authorized ingredients and doses that justify the claimed health benefit for the target population. Thus, it is obvious that within the industrial framework of health nutrition, regulatory expertise cannot be separated from scientific expertise (source Nutraveris).

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