f_OXYDE
make_chem happen

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Not exactly new.

FXD has gained regulatory experience with biocidal actives and products since more than 10 years. FXD´s staff started off with a Dutch authorisation for both substance and product (with basically the same data requirements than under BPR), followed by an active and template product application within the scope of the BPD 98/8/EC review programme, the preparation of an US-EPA / FIFRA Act authorisation as well as numerous national and company registration.

Predictable.

The long-lasting experience in this field and the associated, intense and sometimes even friendly contacts to consulting agencies, universities, competent authorities or certified laboratories put FXD in the unique position to offer regulatory projects within the scope of the BPR (EU) 528/2012 as a prime-contractor (flat-rate).
If working on a regulatory project based on a flat-rate it is an absolute requirement, predominantly at the beginning of the project, to co-operate very intensively with the applicant, according to FXD´s sub-claim *„make_chem happen“*, which also could read as *„make ´em happen“*.

„If you can´t beat them - join them.“

Previous experience with product authorisations within the scope of the BPD have revealed that the by far largest portion of companies takes the route of the (primary) least resistance, in some cases these strategies are even recommended by assigned consulting agencies. Currently a disproportional share of biocidal product applications (first authorisations) are filed with the HSE / UK.
Problems are foreseeable and arise later on, during mutual recognition applications in other EU member countries: „Opinion-leader“ competent authorities like The Netherlands (Ctgb), Austria (BMLFUW) or Germany (BAUA, BfR) have already rejected applications (or have asked for additional data packages, significantly delaying the process) where deficits of the granted first authorisation with respect to comprehensiveness of data submitted or evaluation quality are obvious.

In order to rule out these cumbersome issues, FXD will work with the Austrian BMLFUW exclusively for flat-rate assigned first authorisations, since authorisation granted by this authority will certainly be accepted by all other EU member states.

The Austrian BMLFUW was one of the key players during development / establishment of the BPD and continued to play this important role in final formulation and implementation of the BPR.
FXD has a particularly personal and intensive contact to decision-makers at the Viennese BMLFUW.

Negotiating instead of gambling.

Other than most consulting agencies FXD will not eagerly wait for the most recent "readings" and subtle wording of proposed legal texts in order to prophesy possible changes from a mere draft.
More than 10 years with the BPD have shown that (even the passed) legal text of the directive and the subsequent revisions indeed have very little in common with the established frame-documentation ("jurisdiction"; e.g. ESDs, MoD, TNsG) that will be decisive for a successful authorisation application and procedure.

Particularly within the scope of FXD´s flat-rate assignments it is crucial to negotiate and receive a notice of acceptability from the competent authority prior to assignment of studies or actual dossier preparation. A respective agreement has been reached with the Austrian BMLFUW.

In time.

FXD´s previous experience with active substance application within the scope of the BPD has shown that an early project start will leave much more room for the establishment and reassuring authority commenting of cost-saving alternative regulatory strategies.
This is particularly true for flat-rate assignments, where FXD has to insist on an early project commencement, since (avoidable) time-pressure will inevitably lead to increased cost.

Moreover, the Commissions present numbers and prospects regarding biocidal products first authorisation applications (2009: ca. 3,000 FAs, 2012 / 2013: ca. 20,000 FAs) suggest an extreme shortage in, even by now already exploited, future resources in consulting professionals and laboratory capacities, making a significant increase in lab or consulting cost very likely, if not unavoidable.

(A partner consulting agency has already started to refuse regulatory projects due to the impossibility of hiring adequate professionals, even when looking at the entire European labour market.)

„Darf´s ein bisschen mehr sein? *“ *("May I give you a little bit more?")*

* This Austrian colloquialism can be frequently heard in delicatessen stores, when a shop assistant has cut e.g. 128 grams of ham instead of the requested 100 grams.

FXD does not really have a self-perception of being a conventional regulatory consulting agency. This would not do justice to our long-lasting experience in managing and senior scientific position within research and development (chemical´s industry) as well as intellectual property:

Consultancy for sustainability of regulatory projects:

For FXD formulations do not only consist of CAS numbers and percentages that are taken for granted. FXD´s background in R&D has resulted in the insight that a product most likely is only the incarnation of the present state of development and consequently is subject to permanent changes / improvements. This is applicable for the long-term availability of, frequently proprietary, co-formulant raw materials as well, that can be taken from the market by the manufacturer / supplier without prior notice or suitable replacement offered. FXD´s consulting advice regarding the selection and inclusion of potential alternative raw materials into submitted product families (PFs) is a fundamental aspect of the final definition / acceptability approval of PFs.

Pre-testing, where reasonable:

Studies that have been carried out by certified (e.g. GLP, GMP) labs have to be stringently included into the product dossier, even if their outcome reduces the chances of authorisation grant or will at least cause limitations regarding application possibilities / required safety precautions.
Therefore FXD will evaluate products and data requirements with respect to possible risk studies („unexpected results“) prior to study assignment and will suggest respective pre-tests in order to anticipate the results of a comparable GLP study, if reasonable. FXD is able to conduct a large portion of these pre-tests or otherwise will take care of external assignment and evaluation of results.

Support and supervision national registrations / authorisations:

In order to secure an uninterrupted marketability, biocidal products have to be legally correct (which means: under observation of all national registration or authorisation requirements) on all individual European markets prior to the inclusion of an active substance into the Annex of the BPD.
Regarding compliance even larger companies exhibit surprising deficits that might have to be compensated for under serious time-pressure. If desired - or required, FXD could lead superordinate project management and project supervision.

Open for „Private Labels“:

The considerable cost of product authorisations within the scope of BPR exceed the financial possibilities of numerous smaller companies operating in this field of business. Nevertheless, for the primary applicant / manufacturer these smaller businesses might still cover a considerable and interesting portion of biocidal product sales. The current scenarios and authority requirements for „Private Labels“, „Marketing Licenses“ oder „Authorisation Assignments“ are nationally completely inconsistent. FXD acknowledges the necessity of these co-operative efforts, is prepared for inclusion of "Private Label" customers and will (in case of future requirement for a full „Authorisation Assignment“) handle disclosed formulations and other business-critical information of all involved parties based on the principle of administrative trust.

Imbedded in our network.

Based on a long-time co-operation with authorities, laboratories, consultants or universities (one of the FXD partners is a permanent lecturer at the University of Vienna, Faculty of Nature Sciences) FXD has access to unparalleled opportunities regarding availability, quality, pricing and technological coverage of third-party services that are required for successful and timely processing of biocidal product submissions.

Reinsured.

The long standing, amicable relationship of FXD with one of Europe´s leading consulting agencies in the field of chemicals offers the unique opportunity to secure our all-in regulatory projects in so far, that - independently from their future work-load - this agency guarantees the timely finalisation of FXD projects in case of total disability of FXD´s responsible scientific staff.
(In return, FXD assigns this agency exclusively with the preparation of the particularly critical dossier sections Doc IIB, IIC and Doc IIIB 7.9.)

Secure.

FXD acknowledges the economical value of intellectual property and available studies. For security reasons FXD works on highly encrypted MacIntosh clients / servers only, uses the recent possibilities of encrypted Cloud-backups and does not store any hardcopies of business-critical client information.