

Supporting the Accession Process of the Candidate Countries  
Table of Concordance, Year 10

COUNCIL AND EUROPEAN PARLIAMENT DIRECTIVE 98/8/EC  
of 16 February 1998  
concerning the placing of biocidal products on the market, as amended by Regulation (EC) 1882/2003 and Directive 2006/50/EC

<b>Country:</b>	<b>Turkey</b>	Date Table Completed:
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Total no. of points if full transposition:	490 (98 x 5)	Total no. of points for current status of transposition:

Please see the information given in the 'Important Notice' for the stage of transposition

Article	EU Obligation	Existing national law <sup>1</sup> (give relevant law or regulation & no. of article)	Fully in accord? (No/no)	If not, how will transpos'n occur? (L, GO, MO)	If draft, give no. of article transposing EU obligation <sup>1</sup>	Status of transposition (5-0 accdg to lawmaking stage)	Planned year for full transpos'n
Art. 1	[This Dir. does not apply to products defined or within the scope of a number of specified Dir.s including, <i>inter alia</i> , certain medicinal products, food additives, cosmetic products, and plant protection products. It does apply to certain other specified Dir.s concerning dangerous substances, protection of workers and misleading advertising.] <sup>2</sup>	Not to be scored				-	
Art. 2.1	Definitions: (a) Biocidal products[Annex V provides exhaustive list of 23 product types]	<ul style="list-style-type: none"> <li>By-Law on Biocidal Products based on</li> <li>Public Hygiene Law No. 1593</li> </ul> <p>- Definitions are laid down in Art. 4 of the By-Law for Biocidal Products, - Definition for 'Biocidal products': Art. 4 (1) ç - List of product types: Annex V to the By-Law</p>	Yes			5	
	(b) Low-risk biocidal products	Art. 4 (1) e	Yes			5	
	(c) Basic substance	Art. 4 (1) f	Yes			5	
	(d) Active substance ("AS")	Art. 4 (1) g	Yes			5	

<sup>1</sup> Attach English translations of existing legislation and proposed legislation.

<sup>2</sup> See also Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Art. 16.2 of this Dir.

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	(e) Substance of concern	Art. 4 (1) ġ	Yes			5	
	(f) Harmful organism	Art. 4 (1) h	Yes			5	
	(g) Residues	Art. 4 (1) i	Yes			5	
	(h) Placing on the market	Art. 4 (1) i	Yes			5	
	(i) Authorisation	Art. 4 (1) j	Yes			5	
	(j) Frame-formulation	Art. 4 (1) k	Yes			5	
	(k) Registration	Art. 4 (1) l	Yes			5	
	(l) Letter of access	Art. 4 (1) m	Yes			5	
Art. 2.2	For the purposes of this Dir. definitions for: "substance", "preparation", "scientific research & development", & "process-oriented research & development", laid down in Art. 2 of Dir. 67/548/EEC shall apply.	MO (quoted), MO for chemicals (issued by the Min. for Environment), Art. 4 (2)	Yes			5	
Art. 3.1	MS shall prescribe that a biocidal product shall not be placed on the market & used in their territory unless it is authorised in accordance with this Dir..	Art. 5 and 6	Yes			5	
Art. 3.2	By way of derogation from Art. 3.1: (i) MS shall, subject to registration, allow the placing on the market & use of a low-risk biocidal product, provided that a dossier in accordance with Art. 8.3 has been submitted & verified by CAs. Unless otherwise specified, all provisions relating to authorisation under this Dir. shall also apply to registration.	Art. 5 and 6, Art. 8 to 10, Art. 13	Yes			5	
	By way of derogation from Art. 3.1: (ii) MS shall allow the placing on the market & use of commodity substances for biocidal purposes once they have been entered in Annex IB.	Art. 5 (1) b and Art. 7 g	Yes			5	

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Art. 3.3	(i) Every authorisation application shall be decided without delay.  (ii) For applications for biocidal products that require registration, CA shall take decision within 60 days.	(i) Art. 18 and 20 (ii) 18 and 20 (1) b	Yes			5	
Art. 3.4	MS shall, on request, or on own initiative establish a frame-formulation & communicate it to applicant when issuing authorisation for particular biocidal product. Without prejudice to Arts. 8-12 & providing that applicant has right of access to the frame-formulation in form of a letter of access, when a subsequent application for authorisation for a new biocidal product is based on this frame-formulation, CA shall take decision with regard to this application within 60 days.	Art. 8 (2) d, Art. 16, Art. 20 (1) d, (2)	Yes			5	
Art. 3.5	MS shall prescribe that biocidal products are to be classified, packaged & labelled in accordance with this Dir..	Art. 5 (1) a	Yes			5	
Art. 3.6	Without prejudice to Art. 7.1, authorisations shall be granted for maximum 10 years from date of first or renewed inclusion of the AS in Annex I or IA for the product type, without exceeding deadline specified for the AS in Annex I or IA.	Art. 9 (1)	Yes			5	
	Applications may be renewed after verification that conditions imposed in Arts. 5.1 & 5.2 are satisfied. Renewal may be granted only for period necessary to allow CAs to make verification, where application for renewal has been made.	Art. 26	Yes			5	

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Art. 3.7	MS shall prescribe that biocidal products are properly used. Proper use shall include compliance with conditions laid down in Art. 5 & the labelling provisions of this Dir. Proper use shall involve rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to necessary minimum. Where biocidal products are used at work, use shall be in accordance with requirements of Dirs. for protection of workers.	Art. 7	Yes			5	
Art. 4.1	Without prejudice to Art. 12, a biocidal product already authorised or registered in one MS shall be authorised or registered in another MS within 120 days, or 60 days respectively, of an application being received by the other MS, provided that the AS of the biocidal product is included in Annex I or I A & conforms to the requirements thereof. For mutual recognition of authorisations, application shall include summary of dossier as required in Art. 8.2 (a) & Annex II B, Section X & certified copy of the first authorisation granted. For mutual recognition of registration of low-risk biocidal products, application shall include data requirements of Art. 8.3, except for efficacy data for which a summary shall suffice.	By-Law, but at a later stage (possible only from the date of accession onwards)	No			2	2010
	[Authorisation may be subject to provisions resulting from implementation of other measures in accordance with EC law, relating to conditions for distribution & use of biocidal products intended to protect health of distributors, users & workers concerned.]	Not to be scored-discretionary provision				-	

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Art. 4.2	[If, in accordance with Art. 5, a MS establishes that: (a) the target species is not present in harmful quantities, (b) unacceptable tolerance or resistance of target organism to the biocidal product is demonstrated, or (c) relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the MS where the biocidal product was first authorised, & an unchanged authorisation may therefore present unacceptable risks to humans or the environment. the MS may request that certain conditions referred to in Arts. 20.3 (e), (f), (h), (j) & (l) be adjusted so that conditions for issue of an authorisation laid down in Art. 5 are satisfied.]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score				-	
Art. 4.3	[If a MS believes that a low-risk biocidal product registered by another MS does not comply with the Art. 2.1 (b) definition, it may provisionally refuse registration thereof & shall immediately communicate its concerns to CA responsible for verification of the dossier. If, within 90 days, agreement is not reached between authorities concerned, the matter will be forwarded to the Comm'n for decision in accordance with procedure laid down in Art. 4.4.]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score				-	
Art. 4.4	Notwithstanding Art. 4.2 & 4.3, if a MS believes a biocidal product authorised by another MS cannot meet the conditions set out in Art. 5.1 & consequently proposes to refuse the authorisation or registration or to restrict the authorisation under certain conditions, it shall notify Comm'n, other MS & the applicant & shall provide them with explanatory document containing the product's name & its specification & setting out grounds for the proposed refusal or authorisation restriction.	[to be scored] By-Law, but at a later stage (possible only from the date of accession onwards)	No			2	2010

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Art. 4.5	If Art. 4.4 procedure leads to confirmation of a refusal of a second or subsequent registration by a MS, the MS that previously registered the low-risk biocidal product shall, where deemed appropriate by the Standing Committee, take this refusal into consideration & review its registration according to Art. 6. If the Art. 4.4 procedure confirms initial registration, MS having introduced the procedure shall register the low-risk biocidal product concerned.	[to be scored]  By-Law, but at a later stage (possible only from the date of accession onwards)	No			2	2010
Art. 4.6	[Derogating from Art. 4.1, MS may refuse mutual recognition of authorisations granted for product types 15, 17 & 23 of Annex V provided that such imitation can be justified & does not jeopardise the purpose of the Dir. MS shall inform each other & Comm'n of such decision & indicate the reasons therefor.]	Not to be scored- discretionary provision  Please provide details on national legislation in place but do not score				-	
Art. 5.1	MS shall authorise a biocidal product only if: (a) the AS(s) included therein are listed in Annex I or IA & any requirements laid down in these Annexes are fulfilled;	Art. 5 (1) a and Art. 10 (1)	Yes			5	

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	(a) it is established, in light of current scientific & technical knowledge, and is shown from appraisal of Art. 8 dossier, according to Annex VI common principles for evaluation of dossiers that, when used as authorised & having regard to: - all normal conditions under which the product may be used, - how the material treated with it may be used, - the consequences from use and disposal, the biocidal product: (i) is sufficiently effective, (ii) has no unacceptable effects on target organisms, (iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly ( <i>e.g</i> drinking water) or on surface water & groundwater, (iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to its fate & distribution in environment; particularly contamination of waters, and its impact on non-target organisms;	Art. 10 (1) a	Yes	MO		5	
	(c) the nature & quantity of its ASs &, where appropriate, any toxicologically or ecotoxicologically significant impurities & co-formulants, & its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB;	Art. 10 (1) b	Yes			5	
	(d) its physical & chemical properties have been determined & deemed acceptable for purposes of the appropriate use, storage & transport of the product.	Art. 10 (1) c	Yes			5	

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Art. 5.2	A biocidal product classified according to Art. 20.1 as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen, or as toxic for reproduction category 1 or 2, shall not be authorised for marketing to, or use by the general public.	Art. 5 (1) a, Art. 7 (1) f, Art. 10 (9)	Yes			5	
Art. 5.3	Authorisation may be conditional on, & must stipulate conditions relating to marketing & use necessary to ensure compliance with Art. 5.1.	Art. 10 (7)	Yes			5	
Art. 5.4	Where other EU provisions impose requirements relevant to conditions for the issue of authorisation & for use of biocidal product, & particularly where these are intended to protect health of distributors, users, workers & consumers or animal health or the environment, CA shall take these into account when issuing authorisation & where necessary shall issue authorisation subject to those requirements.	[to be scored] Art. 10 (8)	Yes			5	
Art. 6	During period for which authorisation has been granted, it may be reviewed at any time, <i>e.g.</i> following information received according to Art. 14, if there are indications that any of the conditions referred to in Art. 5 are no longer satisfied. In such instances the MS may require the authorisation holder, or the applicant to whom a modification of the authorisation has been granted in accordance with Art. 7, to submit further info necessary for the review. If need be, authorisation may be prolonged only for period necessary to complete the review, but shall be prolonged for the period necessary to provide for further information.	Art. 5 (1) d, Art. 23, 24 and 26	Yes			5	

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Art. 7.1	Authorisation shall be cancelled if: (a) the AS is no longer included in Annex I or IA as required by Art. 5.1 (a); (b) conditions within the meaning of Art. 5.1 for obtaining authorisation are no longer satisfied; (c) it is discovered that false or misleading particulars were supplied concerning the facts on which authorisation was granted.	Art. 25 (1)	Yes			5	
Art. 7.2	Authorisation may also be cancelled if authorisation holder so requests & states reasons for the cancellation.	[to be scored] Art. 25 (2)	Yes			5	
Art. 7.3	When MS intends to cancel an authorisation, it shall inform & hear the authorisation holder.	Art. 25 (1)	Yes			5	
	[When cancelling authorisation, MS may grant period of grace for disposal or for storage, marketing & use of existing stocks, of a length in accordance with the reason for the cancellation without prejudice to period provided for by decision taken pursuant to Dir. 76/769/EEC or Art. 7.1 (a).]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score Art. 25 (2)				-	
Art. 7.4	Where MS considers it necessary, on basis of developments in scientific & technical knowledge & to protect health & the environment, it shall modify the authorisation's conditions of use &, in particular, the manner of use or amounts used.	Art. 24 (2)	Yes			5	
Art. 7.5	Authorisation may be modified if the authorisation holder requests it & states the reasons for the modification.	[to be scored] Art. 24 (1)	Yes			5	
Art. 7.6	Where a proposed modification concerns extension of uses, MS shall extend the authorisation subject to the particular conditions placed on the AS listed in Annex I or IA.	Art. 24 (3)	Yes			5	

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Art. 7.7	Where a proposed modification of an authorisation involves changes to the particular conditions placed on the AS listed in Annex I or IA, such changes can be made only after evaluation of the AS, with regard to proposed changes, in accordance with procedures laid down in Art. 11.	Art. 24 (4)	Yes			5	
Art. 7.8	Modifications shall be granted only if it is established that the conditions within the meaning of Art. 5 remain satisfied.	Art. 24 (5)	Yes			5	
Art. 8.1	Application for authorisation shall be made by, or on behalf of, the person who will be responsible for the first placing on the market of a biocidal product in a MS & shall be to CA of that MS. Every applicant shall be required to have permanent office within EU.	Art. 6 and 8 (to be adapted to EU citizens by the date of accession)	No			3	2010
Art. 8.2	Applicant for authorisation of biocidal product shall submit to CA: (a) dossier or letter of access for the biocidal product satisfying, in the light of current scientific & technical knowledge, requirements set out in Annex IIB &, where specified, relevant parts of Annex IIIB, and (b) for each AS in the biocidal product, dossier or letter of access satisfying, in the light of current scientific and technical knowledge, requirements set out in Annex IIA and, where specified, the relevant parts of Annex IIIA.	Art. 12 and 14	Yes			5	

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Art. 8.3	By way of derogating from Art. 8.2 (a), MS shall require a dossier comprising the following data for a low-risk biocidal product: (i) applicant: 1.1. name & address, 1.2. name & addresses of manufacturers of the biocidal product & the ASs, 1.3. where appropriate, a letter of access to relevant data needed, (ii) identity of the biocidal product: 2.1. trade name, 2.2. full composition of the biocidal product, 2.3. physical & chemical properties (see Art. 5.1 (d)), (iii) intended uses: 3.1. product type (Annex V) and field of use, 3.2. category of users, 3.3. method of use, (iv) efficacy data, (v) analytical methods, (vi) classification, packaging and labelling, including a draft label, according to Art. 20, (vii) safety data sheet prepared in accordance with Art. 10 of Dir. 88/379/EEC or Art. 27 of Dir. 67/548/EEC.	Art. 13	Yes			5	
Art. 8.4	Dossiers shall include detailed & full description of studies conducted & of methods used or bibliographical reference to those methods. Info in the dossiers supplied in accordance with Art. 8.2 shall be sufficient for an evaluation to be made of the effects & properties referred to in Art. 5.1 (b-d). It shall be submitted to CA in form of technical dossiers, containing info & results of studies referred to in Annexes IIA & IIB &, where specified, relevant parts of Annexes IIIA & IIIB.	Art. 11	Yes			5	

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Art. 8.5	Info not necessary due to nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply info. In such cases justification acceptable to CA must be submitted. Such justification may be the existence of frame-formulation that the applicant has right to access.	Art. 11 (3)	Yes			5	
Art. 8.6	If evaluation of dossier shows that further info, including data & results from further testing, is necessary to evaluate the risks of the biocidal product, CA shall ask the applicant to submit such info. Time period for evaluation of the dossier shall start only after the dossier is complete.	Art 18, 19 (3) and 20 (2)	Yes			5	
Art. 8.7	Name of AS must be given as registered in list contained in Annex I to Dir. 67/548/EEC or, if the name is not included therein, as given in EINECS, or, if not included therein, its International Standards Organisation (ISO) common name. If the latter is not available, the substance must be designated by its chemical designation according to International Union of Pure and Applied Chemistry (IUPAC) rules.	Art. 11 (4)	Yes			5	
Art. 8.8	As a general principle, tests must be conducted according to methods described in Annex V to Dir. 67/548/EEC. If a method is inappropriate or not described, other methods used should, whenever possible, be internationally recognised & justified. Where appropriate, tests must be conducted in accordance with provisions laid down in Dir. 86/609/EEC, (animal experiments) & Dir. 87/18/EEC (good laboratory practices).	Art. 12 (6) and (7)	Yes			5	

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Art. 8.9	Where test data exist that have been generated before the adoption of this Dir. by methods other than those laid down in Annex V to Dir. 67/548/EEC, the adequacy of such data for the purposes of this Dir. & the need to conduct new tests according to Annex V must be decided on a case-by-case basis, taking into account need to minimise testing on vertebrate animals.	Art. 12 (8) and (9)	Yes			5	
Art. 8.10	CAs shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by MS concerning the application & concerning dossiers submitted in accordance with Art. 8.2, together with summary of the latter.	Art. 21 ç	Yes			5	
	On request, MS shall make available to the other CAs & to the Comm'n files provided for in this Art.; they shall supply to them, on request, all info necessary for full comprehension of applications & shall, where requested, ensure that applicants provide copy of technical documentation laid down in Art. 8.2.	Not to be scored				-	
Art. 8.11	[MS may require that samples of preparations & its ingredients be provided.]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score Art. 19 (3)		MO		-	
Art. 8.12	[Ms may require that applications for authorisation be submitted in national or official language(s).]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score Art. 11 (1)		MO		-	

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Art. 9	MS shall prescribe that where a substance is an AS for use in biocidal products it may not be placed on the market for such use unless: (a) where the AS was not on the market before 14 May 2000, a dossier has been forwarded to a MS which satisfies requirements of Art. 11.1 & is accompanied by declaration that the AS is intended for inclusion in a biocidal product. This shall not apply to substances for use pursuant to Art. 17; (b) it is classified, packaged and labelled in accordance with the provisions of Dir. 67/548/EEC.	Art. 28	Yes	MO		5	
Art. 10.1	In light of current scientific & technical knowledge, an AS shall be included in Annex I, Annex IA or IB for an initial period not exceeding 10 years if it may be expected that - biocidal products containing the AS, - low-risk biocidal products complying with Art. 2.1 (b) definition, - commodity substances complying with Art. 2.1 (c) definition, will fulfil the conditions laid down in Art. 5.1 (b-d), taking into account cumulation effects from the use of biocidal products containing same ASs.	Not to be scored				-	
	An AS cannot be included in Annex IA if it is classified according to Dir. 67/548/EEC as: - carcinogenic, - mutagenic, - toxic for reproduction, - sensitising, or - is bioaccumulative and does not readily degrade. Where appropriate, the entry of an AS in Annex IA shall refer to the concentration ranges between which the substance can be used.	Not to be scored				-	

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Art. 10.2	Inclusion of AS in Annexes I, IA or IB shall, where appropriate, be subject to the following: (i) requirements on: (a) the minimum degree of purity of the AS, (b) the nature and maximum content of certain impurities, (c) product type in which it may be used, (d) manner and area of use, (e) designation of categories of users, (f) other particular conditions from the evaluation of info which has been made available in the context of this Dir.;  (ii) the establishment of the following: (a) acceptable operator exposure level (AOEL), if necessary, (b) where relevant, an acceptable daily intake for man (ADI) & maximum residue limit (MRL), (c) fate & behaviour in environment & impact on non-target organisms.	Not to be scored				-	
Art. 10.3	Inclusion in Annex I, IA or IB of AS shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Art. 8.	Not to be scored				-	
Art. 10.4	[Inclusion of AS in Annex I, IA or IB may be renewed on one or more occasions for periods not exceeding 10 years. Initial inclusion, as well as renewed inclusion, may be reviewed if there are indications that any of the requirements referred to in Art. 10.1 are not longer satisfied. Renewal may, where necessary, be granted only for minimum period necessary to complete a review, where application has been made for such renewal, & shall be granted for period necessary to provide further info requested in according to Art. 11.2.]	Not to be scored				-	

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Art. 10.5	(i) Entry of an AS in Annex I &, where relevant, IA or IB may be refused or removed, - if evaluation of the AS in accordance with Art. 11.2 shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern, and	Not to be scored				-	
	- if there is another AS on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to environment. When such refusal or removal is considered, an assessment of an alternative AS(s) shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic & practical disadvantages for the user and & without increased risk for health or for environment. The assessment shall be circulated in accordance with Art. 11.2 procedures for decision in accordance with Arts. 27 & 28.3 procedures.	Not to be scored				-	
	(ii) Refusal or removal of Annex I & IA or IB entry shall be carried out under the following conditions: 1. chemical diversity of the ASs should be adequate to minimise occurrence of resistance in the target organism; 2. it should be applied only to ASs which, when used under normal conditions in authorised biocidal products, present a significantly different level of risk; 3. it should be applied only to ASs used in products of the same product type; 4. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available; 5. complete data dossiers of the evaluation serving or having served for entry in Annex I, IA or IB shall be put at the disposal of the Committee referred to in Art. 28.3.	Not to be scored				-	

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	iii) A decision to remove an Annex I entry shall not have immediate effect but shall be delayed for a period of up to a maximum of 4 years from the date of that decision.	Not to be scored				-	
Art. 11.1	Inclusion, or subsequent changes to the inclusion, of AS in Annex I, IA or IB shall be considered when: (a) applicant has forwarded to the CA of one of the MS: (i) a dossier for the AS satisfying Annex IVA requirements or the requirements of Annex IIA &, where specified, relevant parts of Annex IIIA; (ii) a dossier for at least one biocidal product containing the AS satisfying requirements of Art. 8, with exception of Art. 8.3; (b) the receiving CA has verified the dossiers & believes them to satisfy the Annex IVA & Annex IVB requirements or requirements of Annex IIA & Annex IIB and, where relevant, Annexes IIIA and IIIB, accepts them & agrees to the applicant forwarding a summary of the dossiers to the Comm'n and the other MS.	Art. 30	Yes			5	
Art. 11.2	The receiving CA shall, within 12 months of accepting the dossiers, carry out evaluation thereof. A copy of the evaluation shall be sent by CA to the Comm'n, other MS & to applicant, together with recommendation for inclusion, or otherwise, of the AS in Annex I, IA or IB.	Art. 30	Yes			5	
	If, when the dossiers are evaluated, it appears that further info is necessary for full evaluation to be made, receiving CA shall ask that applicant submit such info. The 12-month period shall be suspended from date of issue of the CA's request until date the info is received. CA shall inform other MS & the Comm'n of its action when it informs the applicant.	Art. 30 (4)	Yes			5	

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Art. 11.3	To avoid dossiers being evaluated by only few MS, evaluation can be carried out by MS other than the receiving one. Request for this shall be given when dossiers are accepted, & decision shall be taken in accordance with Art. 28.2 procedure, at the latest 1 month after receipt by the Comm'n of the request.	not to be scored				-	
Art. 12.1	MS shall not make use of info referred to in Art. 8 for benefit of second or subsequent applicant: (a) unless the second or subsequent applicant has written agreement in form of letter of access of the first applicant that use may be made of such info, or (b) in case of AS not on the market on 14 May 2000, for a period of 15 years from date of first inclusion in Annex I or IA, or (c) in case of an AS already on market on 14 May 2000: (i) for a period of 10 years from 14 May 2000 for any info submitted for the purposes of this Dir., except where such info is already protected under existing national rules relating to biocidal products. In such cases, the info shall continue to be protected in that MS until the expiry of any remaining period of data protection provided for under national rules, up to a max 10 years from 14 May 2000; (ii) for period of 10 years from the date of entry of an AS onto Annex I or IA for info submitted for the first time in support of the first inclusion in Annex I or IA of either the AS or an additional product type for that AS,	Art. 43 and 44	Yes	MO		5	

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	(d) in the case of any further info submitted for first time for any of the following: (i) variation of requirements of the entry on Annex I or IA; (ii) maintenance of entry of Annex I or IA for a period of five years from the date of decision following receipt of further info unless the 5-year period expires before period provided for in Art. 12.1 (b) & (c), in which case the 5-year period shall be extended so as to expire on same date as those periods.	Art. 43 and 44	Yes			5	
Art. 12.2	MS shall not make use of info referred to in Art. 8, for the benefit of second or subsequent applicant: (a) unless the second or subsequent applicant has written agreement in form of a letter of access of the first applicant that use may be made of such information; or (b) in case of biocidal product containing AS not on the market on 14 May 2000 for period of 10 years from date of first authorisation in any MS, or; (c) in case of biocidal product containing AS already on market on 14 May 2000; (i) for a period of 10 years from 14 May 2000 for any information submitted for purposes of this Dir., except in case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected in that MS until the expiry of any remaining period of data protection provided for under those national rules, up to a maximum of 10 years from 14 May 2000; (ii) for a period of 10 years from date of entry of AS into Annex I or IA, for info that is submitted for the first time in support of inclusion in Annex I or IA either of the AS or of additional product type for that AS;	Art. 43 and 44	Yes			5	

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	(d) in the case of any data submitted for the first time for either: (i) variation of the conditions of authorisation of a biocidal product; or (ii) submission of data necessary to maintain entry of an AS onto Annex I or IA for a period of five years from the date of first receipt of further info, unless the 5-year period expires before the period in Art. 12.2 (b) & (c), in which case the 5-year period shall be extended so as to expire on the same date as those periods.	Art. 43 and 44	Yes	MO		5	
Art. 12.3	[For decisions to be taken in accordance with Art. 10.5, info referred to in Art. 12.1 & 12.2 can be used by the Comm'n, the Scientific Committees & the MS.]	Not to be scored				-	
Art. 13.1	[For biocidal product already authorised in accordance with Arts. 3 & 5, and without prejudice to obligations imposed pursuant to Art. 12, CA may agree that second/subsequent applicant for authorisation may refer to data provided by first applicant in so far as the second/subsequent applicant can provide evidence that the biocidal product is similar and its ASs are the same as the one formerly authorised, including degree of purity and nature of impurities.]	Not to be scored- discretionary provision Please provide details on national legislation in place but do not score Art. 45				-	

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Art. 13.2	Notwithstanding Art. 8.2: (a) applicant for authorisation of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of CA of MS to which he intends making application: - whether the biocidal product for which application is to be made is similar to a biocidal product for which authorisation has been granted, and - the name & address of the holder(s) of the authorisation(s). The enquiry shall be supported by evidence that prospective applicant intends to apply for authorisation on his own behalf and that the other info specified in Art. 8.2 is available;	Art. 45	Yes			5	
	(b) CA of the MS, if satisfied that the applicant intends to apply, shall provide name & address of the holder(s) of former relevant authorisations & shall at that time inform the holders of the authorisations of the name & address of the applicant. The holder(s) of former authorisations & the applicant shall take all reasonable steps to reach agreement on info sharing, to avoid duplication of testing on vertebrate animals. CA shall encourage data-holders to cooperate in the provision of the requested data.	Art. 45	Yes			5	
	[If it is not possible for the applicant and holders of former authorisations of same product to reach agreement on data sharing, MS may introduce national measures obliging the applicant & holders of former authorisations located within their territory to share data with a view to avoiding duplicative testing on vertebrate animals & determine both procedure for utilising info, & reasonable balance of the interests of the parties.]	Not to be scored- discretionary provision Please provide details on national legislation in place but do not score Art. 45				-	

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Art. 14	MS shall prescribe that holder of authorisation for a biocidal product shall immediately notify CA of info of which he/she is, or may reasonably be, aware concerning AS or biocidal product containing it & which may affect continuing authorisation. In particular, the following shall be notified: - new knowledge or info on effects of the AS or biocidal product for humans or environment, - changes in source or composition of the AS, - changes in composition of a biocidal product, - development of resistance, - changes of administrative nature or other aspects, such as the nature of the packaging.	Art. 22	Yes			5	
Art. 14.2	[MS shall immediately notify other MS & Comm'n of any such info they receive concerning potentially harmful effects for humans or environment or new composition of a biocidal product, its ASs, impurities, co-formulants or residues.]	not to be scored				-	
Art. 15.1	[By way of derogation from Arts 3 & 5, MS may authorise temporarily for a period not exceeding 120 days, the placing on the market of biocidal products not complying with the provisions of this Dir. for limited & controlled use if such measure appears necessary because of unforeseen danger which cannot be contained by other means. In this case, MS shall immediately inform other MS & Comm'n of its action & the justification for it.]	Not to be scored- discretionary provision Please provide details on national legislation in place but do not score Art. 15				-	

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Art. 15.2	<p>[Derogating from Art. 5.1 (a) &amp; until AS is listed in Annex I or IA, a MS may authorise provisionally, for a period not exceeding 3 years, the placing on the market of a biocidal product containing AS not listed in Annex I or IA &amp; not yet available on the market on 14 May 2000 for purposes other than those defined in Art. 2.2 (c-d). Such authorisation may be issued only if, after dossiers have been evaluated in accordance with Art. 11, MS believes that:</p> <ul style="list-style-type: none"> <li>- AS satisfies the requirements of Art. 10 and,</li> <li>- biocidal product may be expected to satisfy Arts. 5.1(b-d) conditions,</li> </ul> <p>and no other MS, on the basis of the summary it receives, makes legitimate objection, in accordance with Art. 18.2, to the completeness of the dossiers. Where objection is made, decision on the completeness of dossiers shall be taken in accordance with the procedure laid down in Art. 28.2 without undue delay. If it is decided that the AS does not satisfy requirements specified in Art. 10, MS shall ensure that the provisional authorisation is cancelled. In cases where evaluation of dossiers for the purposes of inclusion of AS in Annex I or IA is not completed when the 3-year period expires, CA may further provisionally authorise the product for a period not exceeding 1 year, providing there are good reasons to believe the AS will satisfy requirements of Art. 10. MS shall inform other MS &amp; Comm'n of such action.]</p>	<p>Not to be scored-discretionary provision</p> <p>Please provide details on national legislation in place but do not score</p> <p>-</p>				-	
Art. 16.1	<p>[Derogating from Arts. 3.1, 5.1, 8.2 &amp; 8.4, &amp; without prejudice to Art. 16.2 &amp; 16.3, MS may until 14 May 2010 continue to apply its current system or practice of placing biocidal products on the market. It may according to its national rules, authorise the placing on the market in its territory of a biocidal product containing ASs not listed in Annex I or IA for that product type. Such ASs must be on the market on 14 May 2000 as ASs of a biocidal product for purposes other than those defined in Art. 2.2 (c-d).]</p>	<p>Not to be scored-discretionary provision</p>				-	

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Art. 16.3	Following an Art. 16.2 decision to include or not to include an AS in Annex I, IA or IB, MS shall ensure that authorisations or, where relevant, registrations for biocidal products containing the ASs & complying with the provisions of this Dir. are granted, modified or cancelled as appropriate.	Not to be scored				-	
Art. 17.1	By way of derogation from Art. 3, MS shall prescribe that any experiment or test for research or development involving the placing on the market of unauthorized biocidal product or AS intended exclusively for use in a biocidal product shall not take place unless: (a) in case of scientific research & development, persons concerned draw up & maintain written records detailing the identity of the biocidal product or AS, labelling data, quantities supplied & names & addresses of those persons receiving the biocidal product or AS & compile a dossier with all available data on possible effects on human or animal health or impact on the environment. This info shall, if requested, be made available to CA,	Art. 31 (1) and (2) a	Yes			5	
	(b) in case of process-oriented research & development, info required in (a) is notified to CA where & before placing on the market occurs and to CA of MS where the experiment/test is to be conducted.	Art. 31 (2) b	Yes			5	
Art. 17.2	MS shall prescribe that unauthorised biocidal product or AS for exclusive use in a biocidal product may not be placed on the market for the purpose of any experiment or test which may involve, or result in, release into environment unless CA has assessed available data & issued authorisation for this purpose which limits quantities to be used & areas to be treated and may impose further conditions.	Art. 32	Yes			5	

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Art. 17.3	Where any experiment/test takes place in a MS other than the MS where placing on the market occurs, the applicant shall obtain experiments/tests authorisation from CA of the MS in the territory of which the experiments/tests are to be conducted. If the proposed experiments/tests referred to in Arts. 17.1 & 17.2 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on environment, MS concerned may prohibit them or only allow them subject to conditions it considers necessary to prevent such consequences.	This provision will be inserted in Art. 32 at the date of accession	No			3	2010
Art. 17.4	Art. 17.2 shall not apply if MS has granted the person concerned the right to undertake certain experiments & tests and has determined the conditions under which the experiments and tests have to be undertaken.	This provision will be inserted in Art. 32 at the date of accession	No			3	2010
Art. 18.1	[Within a period of 1 month from end of each quarter, MS shall inform each other & the Comm'n of any biocidal products which have been authorised or registered within their territory or for which authorisation or registration has been refused, modified, renewed or cancelled, indicating at least: (a) name or business name of the applicant for, or the holder of, the authorisation or registration; (b) trade name of the biocidal product; (c) name & amount of each AS which it contains, as well as name & amount of each dangerous substance in the meaning of Article 2.2 of Dir. 67/548/EEC & their classification; (d) product-type & use(s) for which it is authorised; (e) type of formulation; (f) any proposed limits on residues; (g) authorisation conditions & where relevant, reasons for modification or cancellation of authorisation; (h) indication of whether the product is of a special type (e.g. within frame-formulation, low-risk biocidal product).]	not to be scored				-	

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Art. 18.2	Where a MS receives summary of dossiers in accordance with Arts. 11.1 (b) & 15.2 and has legitimate reason to believe the dossiers are incomplete, it shall immediately communicate its concerns to CA responsible for dossier evaluation & shall without undue delay inform the Comm'n & other MS of its concerns.	This provision will be inserted in Art. 32 at the date of accession	No			3	2010
Art. 18.3	[MS shall draw up annual list of biocidal products authorised or registered in its territory & shall communicate that list to the other MS & the Comm'n.]	not to be scored				-	
Art. 19.1	Without prejudice to Dir. 90/313/EEC on access to environmental information, applicant may indicate to CA info considered commercially sensitive & disclosure of which might harm him industrially or commercially & which he therefore wishes to be kept confidential from all persons other than the CAs & the Comm'n. Full justification will be required in each case. Without prejudice to info referred to in Art. 19.3 & provisions of Dirs. 67/548/EEC & 88/379/EEC, MS shall take necessary steps to ensure confidentiality of the full composition of product formulations if requested by the applicant.	Art. 46	Yes			5	
Art. 19.2	CA receiving application shall decide, on basis of documentary evidence produced by applicant, which info shall be confidential within terms of Art. 19.1. Info accepted as confidential by receiving CA shall be treated as confidential by other CAs, MS, & the Comm'n.	Art. 46	Yes			5	

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Art. 19.3	After authorisation has been granted, confidentiality shall not in any case apply to: (a) name & address of the applicant; (b) name & address of the biocidal product manufacturer; (c) name & address of the AS manufacturer; (d) names & content of the AS(s) in the biocidal product & name of the biocidal product; (e) names of other substances regarded as dangerous within the meaning of Dir. 67/548/EEC & contribute to the classification of the product; (f) physical & chemical data concerning the AS & biocidal product; (g) ways of rendering the AS or biocidal product harmless; (h) summary of results of Art. 8 tests to establish the substance's or product's efficacy & effects on humans, animals & environment &, where applicable, its ability to promote resistance; (i) recommended methods & precautions to reduce dangers from handling, storage, transport & use as well as from fire or other hazards; (j) safety data sheets; (k) methods of analysis referred to in Art. 5.1 (c); (l) disposal methods & its packaging; (m) procedures to be followed & measures to be taken in the case of spillage or leakage; (n) first aid & medical advice in the case of injury to persons.	Art. 47	Yes			5	
	If the applicant or manufacturer or importer of the biocidal product or AS should later disclose previously confidential information, CA shall be informed accordingly.	Art. 47 (1) b	Yes			5	
Art. 20.1	Biocidal products shall be classified in accordance with provisions relating to classification in Dir. 88/379/EEC.	Art. 33	Yes			5	

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concerning the placing of biocidal products on the market, as amended by Regulation (EC) 1882/2003 and Directive 2006/50/EC

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Art. 20.2	Biocidal products shall be packaged in accordance with Art. 6 of Dir. 88/379/EEC. In addition: (a) products which may be mistaken for food, drink or feedingstuff shall be packaged to minimize the likelihood of such a mistake being made; (b) products available to general public that may be mistaken for food, drink or feedingstuff shall contain components to discourage their consumption.	Art. 34 and 35	Yes			5	

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Art. 20.3	<p>Biocidal products shall be labelled in accordance with provisions relating to labelling in Dir. 88/379/EEC. Labels shall not be misleading or give exaggerated impression of the product &amp;, in any case, not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless' or similar indications. The label must show clearly &amp; indelibly the following:</p> <p>(a) identity of every AS &amp; its concentration in metric units;</p> <p>(b) authorisation number allocated to the biocidal product by CA;</p> <p>(c) type of preparation (e.g. liquid concentrates, granules, powders, solids, etc.);</p> <p>(d) uses for which the biocidal product is authorised (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc.);</p> <p>(e) directions for use &amp; the dose rate, expressed in metric units, for each use provided for under terms of the authorisation;</p> <p>(f) particulars of likely direct or indirect adverse side effects &amp; any directions for first aid;</p> <p>(g) if accompanied by a leaflet, the sentence 'Read attached instructions before use';</p> <p>(h) directions for safe disposal of the biocidal product &amp; its packaging, including, where relevant, any prohibition on reuse of packaging;</p> <p>(i) formulation batch number or designation &amp; expiry date relevant to normal conditions of storage;</p> <p>(j) period of time needed for the biocidal effect, interval to be observed between applications of the biocidal product or between application &amp; next use of the product treated, or the next access by man or animals to area where the biocidal product has been used, including particulars concerning decontamination means &amp; measures &amp; duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage &amp; transport (e.g. personal protective clothing and equipment...); and where applicable:</p> <p>(k) categories of users to which the biocidal product is</p>	Art. 36	Yes			5	

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	MS shall require that items (a), (b), (d) & where applicable (g) & (k) always be carried on the label of the product. MS shall permit items (c), (e), (f), (h), (i), (j) & (l) to be carried elsewhere on the packaging or on accompanying leaflet integral to the packaging.	Art. 36 ç	Yes			5	
Art. 20.4	Where a biocidal product identified as insecticide, acaricide, rodenticide, avicide or molluscicide is authorised pursuant to this Dir. & is subject to classification, packaging and labelling according to Dir. 78/631/EEC by virtue of other Community provisions, MS shall permit changes to packaging & labelling of that product which may be required as consequence of those provisions in so far as they do not conflict with conditions of authorisation issued under this Dir..	No longer valid in EU					
Art.. 20.5	[MS may require the provision of samples, models or drafts of the packaging, labelling & leaflets.]	Not to be scored-discretionary provision Please provide details on national legislation in place but do not score Art. 12 (2) c				-	
Art. 20.6	MS shall make the placing of biocidal products on the market in their territories subject to labelling in national language(s).	Art. 36 (1) c	Yes			5	

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Art. 21	MS shall take necessary measures to ensure that a system of specific info is established to enable professional & industrial users & other users of biocidal products to take necessary measures for protection of environment & health as well as health & safety at the workplace. This shall be done in form of a safety-data sheet provided by those responsible for the placing on the market of the product. The safety-data sheets shall be prepared: - for biocidal products classified as dangerous & in accordance with Art. 10 of Dir. 88/379/EEC, - for ASs used exclusively in biocidal products in accordance with Art. 27 requirements of Dir. 67/548/EEC.	Art. 37	Yes			5	
Art. 22.1	MS shall require that every advertisement for biocidal product is accompanied by sentences 'Use biocides safely. Always read the label and product information before use'. The sentences shall be clearly distinguishable in relation to the whole advertisement. MS shall prescribe that advertisers may replace the word "Biocides" with accurate description of the product-type being advertised, for example wood preservatives, disinfectants,... etc.	Art. 38 (2)	Yes			5	
Art. 22.2	MS shall require that advertisements for biocidal products do not refer to the product in a manner which is misleading in respect of the risks from the product to man or environment. Under no circumstances may the advertising of a biocidal product mention 'low-risk biocidal product', 'non-toxic', 'harmless' or any similar indications.	Art. 38 (1)	Yes			5	

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Art. 23	MS shall appoint body(ies) responsible for receiving info on biocidal products placed on market, including info on chemical composition of the products, & for making the info available in cases where suspected poisoning arises from biocidal products. Such info may only be used to meet medical demand by formulating preventive & curative measures, in particular in emergencies. MS shall ensure that info is not used for other purposes. MS shall take necessary steps to ensure that appointed bodies provide all requisite guarantees for maintaining confidentiality of info received.	Art. 48	Yes			5	
	MS shall take necessary steps to ensure that appointed bodies have at their disposal all info required to carry out the tasks for which they are responsible from manufacturers or persons responsible for marketing.	Art. 48	Yes			5	
	For biocidal products already on market on 14 May 2000, MS shall take measures to comply with this Art. by 14 May 2003.	Art. 48	Yes			5	
Art. 24	MS shall take necessary arrangements for biocidal products placed on market to be monitored to establish whether they comply with requirements of this Dir.	Art. 49 to 58	Yes			5	
	[Every 3 years after 14 May 2000, MS shall forward to Comm'n by 30 Nov. of the third year a report on their action in these matters together with info on poisonings involving biocidal products.]	Not to be scored				-	
Art. 25	MS shall establish systems obliging those having placed or seeking to place biocidal products on the market & those supporting entries for ASs on Annexes I, IA or IB to pay charges, corresponding to their costs in carrying out the procedures associated with this Dir..	Art. 59	Yes			5	
Art. 26.1	MS shall designate CA(s) responsible for carrying out the duties imposed on MS pursuant to this Dir..	Art. 17 und 49	Yes			5	

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Art. 26.2	MS shall inform Comm'n of the identity of their CA(s), not later than 14 May 2000.	Not to be scored				-	
Art. 27	[Commission procedures]	Not to be scored				-	
Art. 28	[Committees & procedures]	Not to be scored				-	
Art. 29	[Adaptation to technical progress]	Not to be scored				-	
Art. 30	[Modification or adaptation of Annexes V & VI]	Not to be scored				-	
Art. 31	Granting of authorisation & other measures in conformity with this Dir. shall be without prejudice to general civil & criminal liability in the MS of the manufacturer & of the person responsible for placing the biocidal product on market or using it.	Art. 58	Yes			5	
Art. 32	[Where MS has valid reasons to consider that a biocidal product which it has authorised, registered or is bound to authorise or register pursuant to Arts. 3 or 4, constitutes unacceptable risk to human or animal health or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. It shall immediately inform Comm'n and the other MS of such action and give reasons for its decision].	Not to be scored-discretionary provision				-	
Art. 34.1	MS shall bring into force the laws, regulations & administrative provisions necessary to comply with this Dir. not later than 14 May 2000 and forthwith inform the Comm'n thereof.	Not to be scored				-	
Art. 34.2	National measures shall contain reference to this Dir. or shall be accompanied by such reference on the occasion of their official publication. Methods of making reference shall be laid down by the MS.	Not to be scored				-	
Art. 34.3	MS shall communicate to Comm'n texts of provisions of national law which they adopt in field covered by this Dir..	Not to be scored				-	
Annex I	List of active substances with requirements agreed at community level for inclusion in biocidal products	Annex I to the By-Law	Yes			5	

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Annex IA	List of active substances with requirements agreed at community level for inclusion in low-risk biocidal products	Annex IA	Yes			5	
Annex IB	List of basic substances with requirements agreed at community level	Annex IB	Yes			5	
Annex IIA	Common core data set for active substances	Annex IIA	Yes			5	
Annex IIB	Common core data set for biocidal products	Annex IIB	Yes			5	
Annex IIIA	Additional data set for active substances	Annex IIA	Yes			5	
Annex IIIB	Additional data set for biocidal products	Annex IIIB	Yes			5	
<u>Annex IVA</u>	Data set for active substances	Annex IV A	Yes			5	
<u>Annex IVB</u>	Data set for biocidal products	Annex IV B	Yes			5	
Annex V	Biocidal product-types and their descriptions as referred to in article 2.1 (a) of this Dir.	Annex V	Yes			5	
Annex VI	Common principles for the evaluation of dossiers for biocidal products	Annex VI	Yes			5	

**Important Notice:** MOH was carrying out a project on biocidal products. In the context of this project (TR/2004/IB/EN/03) the harmonisation and implementation of biocidal products legislation and administration was in principle achieved. The project aimed at developing national legislation transposing the Directive 98/8/EC and at installing a national competent authority for biocidal products. Additionally, the National Inventory of Marketed Biocidal Products was developed in the scope of the Twinning Project. The project was finalised in March 2008. The workplan of the respective Project is attached to this Table of Concordance as Annex 1 for follow up of the activities regarding transposition.

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**ANNEX 1**

**ARTICLE 5. SCHEDULE**

Project Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
<b>RTA, RTA Assistant and Language Assistant</b>																								
<b>Component 0 Inception Phase / Starting Meeting</b>																								
0.1 Establishment of working groups		B0.1																						
0.2 Kick-off meeting			B0.2																					
0.3 Joint Assessment meeting			B0.3																					
0.4 Technical Assistance to BC Public Information Services			B0.4																					
<b>Component 1 Inventory of biocidal products on the Turkish market</b>																								
1.1 Status and needs assessment				B1.1																				
1.2 Development of the concept for information retrieval						B1.2																		
1.3 Compilation of the inventory													B1.3-1	B1.3-2										
1.4 Inventory report															B1.4									
<b>Component 2 Establishment of the Competent Authority(ies), handbook</b>																								
2.1 Assessment of the legislative and institutional situation				B2.1																				
2.2 BPD scope conference				B2.2																				
2.3 Institution building framework						B2.3-1	B2.3-2																	
2.4 Responsibilities and tasks, drafting the handbook												B2.4-1	B2.4-2											
<b>Component 3 Preparation of a detailed Action Plan</b>																								
3.1 Analysis of preconditions								B3.1																
3.2 Drafting of action plan																	B3.2							
3.3 Action plan workshop																		B3.3	B3.3					



