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Directive 2010/63/EU adopted

The clock is ticking...





The clock is ticking...

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After more than 10 years of discussion, the European Parliament gave a first reading to the Directive 86/609 on 5 May 2009 and thereby cleared an important hurdle in the EU legislative process.

The Parliament approved the proposed amendments to the original proposal of November 2008 with a large majority, paving the way for the next steps along the way to a new directive (s. box).

EU Directive vs. Regulations

While EU regulations are the actual laws of the Community that directly apply for Member States, the EU directives only stipulate binding standards. Before the directives can be legally enforced in the Member States, they must be implemented and passed by the respective State's legislative body as law or regulation. Each Member State has the right to make the directive's standards stricter.

On 22 September 2010 the new Directive 2010/63/EU finally was adopted and so updates and replaces the 1986 Directive 86/609. Each Member State is now required to incorporate the Directive into national law.

One thing is certain: the clock is ticking!

All EU Member States will have to comply with the provisions from 1st January 2013.

Directive 2010/63/EU

The Directive is based on the principles of the Three Rs, to replace, reduce and refine the use of animals used for scientific purposes. Its aim is to strengthen legislation, and improve the welfare of the animals. The scope is now wider and includes e.g. fetuses in their last trimester of development as well as animals used for the purposes of basic research. Furthermore it lays down minimum standards for housing and care, regulates the use of animals regarding pain, suffering distress or lasting harm caused to the animals. The development, validation and implementation of alternative methods also belongs the requirements of the Directive.

For more information about the Directive, visit:
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>

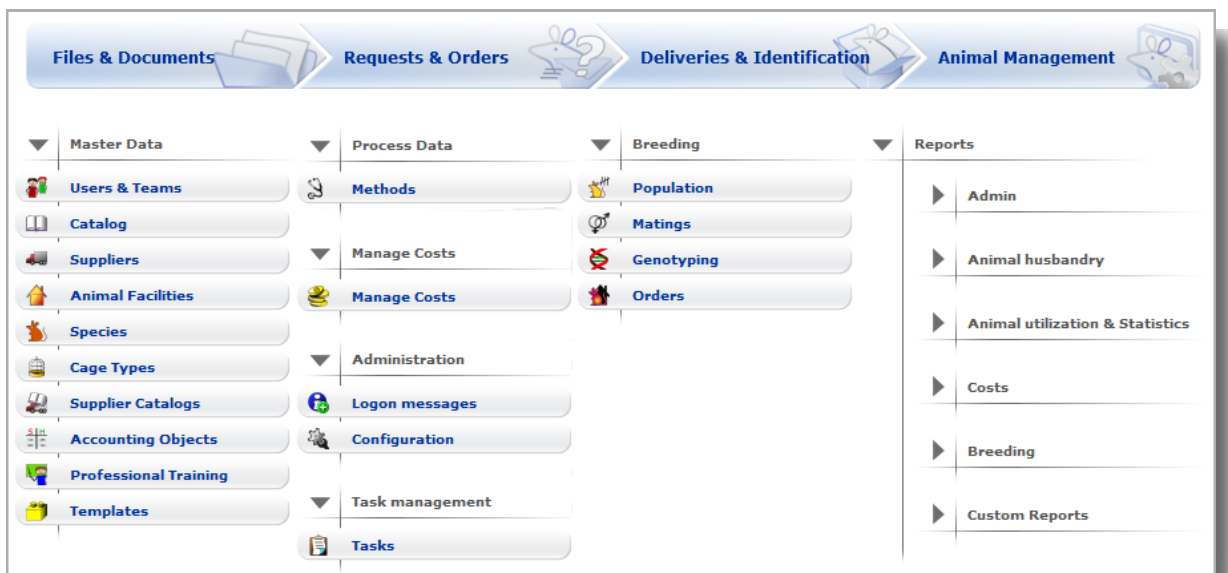


The clock is ticking...

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It is certain that the adoption of the Directive poses major challenges, for both facilities that perform animal experiments and the supervisory authorities in the EU Member States. This applies even more, of course, to States whose current regulations and laws up to now only used the EU Directive 86/609 for orientation and did not go beyond it, as is the case with Germany.

a-tune software ag is a provider of solutions to scientific research institutes, facilities and companies. Its product tick@lab assists reputable clients in Europe and the US for the optimisation of processes, compliance with laws and regulations as well as the fulfilment of documentation requirements.



Not only does tick@lab meet existing requirements, e.g. in accordance with German animal protection legislation and the American IACUC processes, but it also already has all the capabilities necessary to master the challenges that come with the revised European Directive. Here are just a few examples:

NOTE: If not otherwise indicated, the information on the articles or capitals of the Directive refers to the version from 22 September 2010.



Authorization of Persons

Art. 28ff

Article 28ff of the submitted Directive requires authorization and authorization renewal every 5 years for persons involved with the keeping of animals for experimental purposes or use of animals in experiments. In addition, there are requirements to verify and document qualification, training for the handling of the specific species used and the applied methods as well as ongoing training and education.

Especially in large facilities or institutes with high personnel turnover, these requirements represent a major challenge to the organization and the documentation process.

tick@lab makes it easy for organizations to comply with legal regulations:

- tick@lab's user administration function collects all of the relevant qualification, training and certification information as well as experimental animal data and past and current project information.

Field	Value
Salutation	Dr.
First name*	Verena
Last name*	Winter
User name*	VWI
E-mail	vwinter@a-tune.de

- tick@lab documents and tracks training measures for the handling of animals as well as for specific procedures and methods.

Status Functional Area	Certificator	Cert. Date (MM/DD/YYYY)	Exp. Date (MM/DD/YYYY)
✓ Dog	Vanderwal, Tom(tva)	11/09/2008	11/08/2011
✗ Guinea pig	Ende, Mona(MEN)	11/09/2006	11/09/2008
✓ Hamster	Ende, Mona(MEN)	11/09/2008	11/09/2011

Status Functional Area	Technique	Certificator	Cert. Date (MM/DD/YYYY)	Exp. Date (MM/DD/YYYY)
✓ Dog	Sample surgical procedure	Vanderwal, Tom(tva)	11/09/2008	11/09/2009
✓ Mouse	Sample surgical procedure	Vanderwal, Tom(tva)	11/09/2008	11/09/2009



Authorization of Persons

- Licences and approvals from authorities (e.g. special personal permit as per German animal protection act) can be directly submitted via the system and are added to the qualification profile.
- Resubmission functions ensure that the participants will be reminded in time to act before a special permit expires or in time to participate in upcoming training.
- Verification functions certify the applicant attempting to register for a project is sufficiently and suitably qualified to work with the specific animal species for the specified project.

Name	1.	2.	3.
Liebermann, Dirk Mr.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Winter, Verena Dr.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Staubi, Andreas	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Vanderwal, Tom Dr.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



Projects, Reviews, Ethic Committees

Approval of Projects, Reviews and Internal Ethic Committees

Art. 25, 31, 35, 37, 38, 40, etc.

The clear structure, access to key master data, verification functions and contextual help texts simplify for the laboratory supervisor the generation of consistent and valid submissions for approval.

The templates required for this can adapt to meet the content requirements of the respective approving agency. In addition, several types of application (e.g. different templates for full or simplified application procedures) are possible.

The screenshot displays the 'a-tune Lasw-A0802 (0.0.1), tick@lab IACUC example' interface. The left sidebar contains a navigation menu with items like 'General Information', 'Legal Basis', 'Investigators', 'Study Location & Contact', 'Species', 'Experiment Parts', 'Number of Animals', 'Methods & Procedures', 'Anesthesia', 'Analgesia', 'In-Life Staff', 'Animal Housing & Welfare', 'Adverse Reactions', 'Safety & Hazards', 'Literature Search', 'Annual Review', 'Workflow History', and 'IACUC Review'. The main content area is titled '1. Experiment part 1 (e.g.)' and shows a table for 'Number of Animals'. The table is organized by species: 'Dog' and 'Mouse,Rat'. Each species section includes a table with columns for 'Min', 'Max', and 'Factor', and rows for 'Treatment Groups', 'Control Groups', 'Substances', 'Animals/Group', 'Animals', and 'Experiments'. There are also 'Edit calculation' and 'Delete calculation' buttons for each species section. The 'Dog' section shows a total of 750 animals, and the 'Mouse,Rat' section shows a total of 60 animals. The interface also features 'Review' and 'Action' buttons at the top and bottom of the table area.

Species	Min	Max	Factor	Action	
Dog	(3	3	Treatment Groups	
	+	2	2) Control Groups	
	*	10	12	Substances	
	*	5	5	Animals/Group	
	*	250	300	Animals	
	*	3	3	Experiments	
			750 900	Animals per Part	Edit calculation Delete calculation
Mouse,Rat	Min	Max	Factor		
		10	10	Groups	
	*	5	5	Animals	
	+	10	10	Extra animals	
		60	60	Animals per Part	
		750	900	Dog	
or	60	60	Mouse		
and	60	60	Rat		

tick@lab controls and logs the internal processing and approval procedures and forwards applications to, e.g. animal protection auditors and the internal ethics committee for approval or to other participants. It saves comments and records the previous statuses and makes both available to all participants.

As with new submittals, running projects can be submitted for approval annually or upon expiration of the established deadlines of the internal ethics committee or changed. Completed protocols may also be evaluated retrospectively.

tick@lab enables the documentation of these evaluations as well as the documentation of reviews and inspections for the verification of compliance with applicable laws and regulations.



Approval of Projects, Reviews and Internal Ethic Committees

Review

- General Information
- Legal Basis
- Investigators
- Study Location & Contact
- Species
- Experiment Parts
- Number of Animals

[+ Start New Topic](#)

Subject	Author	Responses	Started on	
Please check Tom's records	Vanderwal, Tom	1	11/24/2008 10:05:30 AM	Delete
Biometrical Planning?	Vanderwal, Tom	1	11/24/2008 10:05:02 AM	Delete
Sample Review Topic	Vanderwal, Tom	2	11/11/2008 3:34:36 PM	Delete

IACUC Meetings

- Planning
- Agenda
- Attendance
- Minutes
- Workflow History

[Review](#) [Action](#)

Actual Start Time: 4:00 PM Attendance: 0 of 17
Actual End Time: 6:00 PM

Attendees	Admin Unit	Membership Type	Sign-In Time	Sign-Out Time	
✓ Vanderwal, Tom	IACUC Admin	Primary	4:00 PM	6:00 PM	Add/Edit Notes
✓ Winter, Verena	IACUC Admin	Primary	4:00 PM	6:00 PM	Add/Edit Notes
✓ Liebermann, Dirk	IACUC Admin	Primary	4:00 PM	6:00 PM	Add/Edit Notes
✗ Ende, Mona			5:00 PM	5:30 PM	Add/Edit Notes

[Review](#) [Action](#)

tick@lab has all the technical and functional capabilities necessary for the reliable control of the access to confidential and private data. Thus, it is possible for external participants (e.g. external IACUC members) to participate in the processes and workflows. Interfaces with external systems are also possible (e.g. as implemented in Switzerland).



3R, Applied Methods

Art. 5, 11, 13, 38 Chapter V, etc.

The purpose of the Directive is to achieve use of the gentlest methods according to most current science and research knowledge, provided there is not an alternative method available that would enable work to be performed without the use of animals.

Of course, no software can alone guarantee the use of those methods, but tick@lab assists organisations and users to identify the standards and comply with them as they are intended in the new regulations or internal organisational directives.

A system catalogue in which, for example, the methods for euthanasia as defined by the EU Directive are stipulated and are arranged according to species may be of assistance. In addition, the catalogue could contain stipulations as to anaesthesia or analgesia, surgery and non-surgery procedures and treatments.

For a new project application, the investigator can go to the catalogue and obtain the approved procedure without manual effort.

A method database permits the filing and description of standard methods. With the catalogue, a standardisation of terminology and procedures for the specific organisation is possible, leading to increased transparency and the avoidance of misunderstanding.

An auditing workflow, in which the veterinarians or the internal ethics committee can be involved, reliably ensures the validity of the methods and guarantees, through regular re-submission, permanent comparison to the current science and research standards.

Documentation & Logging

Art. 29, 30, 31, etc.

Amongst tick@lab's standard functions, is the maintenance of a resume for each animal, making available all the important data, starting at the acquisition (purchase, breeding or transfer) and continuing up to the time when the animal leaves the facility. The system automatically compiles these data unseen and without additional effort on the part of the user from the order and administrative events.

Unambiguous numbers and the additional entry and use of tattoo or ear numbers, barcodes and transponders permit the unmistakable identification and association of the resume to the respective animal.

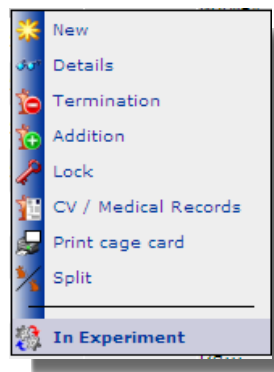
If useful and required, this information may be complemented with medical records to provide a complete picture for evaluation in respect to scientific and animal protection considerations.



Severity, Reuse and End of Procedure

Art. 14, 15, 16, etc.

tick@lab permits or requests the documentation of every experiment. Depending on the legal requirements, additional information, such as the rating of the experiment based on the level of severity, categorisation of the experiment according to specified criteria or the methods used, can be recorded or confirmed at the beginning or end of the experiment.



The system can evaluate and determine, based on various guidelines, if and for which experiments an animal may be reused or if and when a veterinarian must make a decision. The criteria may be the character of a species or breed, the number of experiments already performed or the collective burden of the experiments.

This relieves users of excessive documentation work and ensures consistent compliance to the animal protection directive.

Keeping

Art. 32, etc. Supplements

Besides multifaceted support with the management of the animals, tick@lab assists users with the management of the cages and space where they are kept. Main guidelines as to the possible type of cage, enrichments and maximum occupation for each species help users in their choice of the most appropriate accommodation and compliant care.

The preparation of space with specific accommodations, safety and capacities as well as the tracking of the past, current and future animals are of significant assistance to users in maintaining conditions that are compliant with animal protection guidelines and laws.



Keeping

The screenshot shows a software window titled 'Details: Room - R. 1-1-15'. It has three tabs: 'General', 'Capacity', and 'Attachment'. The 'General' tab is active and contains the following fields:

- Save**, **Restore**, and **Close window** buttons.
- General** section:
 - Description*: R. 1-1-15
 - Address: Building 1, 1st Floor, 1st Room, Section North
 - Contact: Winter, Verena Dr. (dropdown menu)
 - Notes: (text area)
 - Safety Level: S1 - no risk (dropdown menu)
 - Use as study location:
- Allowed Species** section:
 - Available**: Cow, Dogs, Guinea pig, Hamster, Pig, Rat, Sheep
 - Assigned**: Mouse
 - Navigation arrows: up, down, left, right

Reports & Statistics

Art. 49, etc.

tick@lab records all the relevant experimental data and the animals used at the source where the information is generated – easy, quick and reliable.

Statistics and reports can be automatically compiled at anytime from this data. As a result, the time-consuming manual collection of information from the individual laboratories, usually associated with error, becomes a thing of the past and up to date interim reports can be pulled up at any time.

Below are several examples of what is possible with tick@lab's reporting function:

- Animal acquisition according to source, species, intended use
- Experimental use and whereabouts
- User, qualification and authorisations
- Animal use according to intended experimental use, species, methods
- Distress, pain, reuse, methods and much more

Such reports may be obtained upon request and in many different layouts for further use and processing.



Questions?

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Scientific institutes that use animals in experiments control and optimise their processes and workflows with tick@lab.

a-tune software ag's clients in Germany, Europe and the USA guarantee their compliance to current laws and regulations with tick@lab.

With tick@lab, you too will be prepared for the future! The clock is ticking...

Questions? - Contact Us!

a-tune software ag

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E: sales@a-tune.de



Links

Information section of the EU pertaining to the new Directive:

http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm



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a-tune software ag

a-tune software ag is an established software house with headquarters in Darmstadt, Germany, one of the leading centres of advanced technologies on the IT market. Highly innovative, the company is rapidly growing, serving the international market from its central location in the Rhine-Main regional hub, which provides a-tune with exceptional mobility and flexibility.

Since 1998 on the market delivering sophisticated software solutions for project management, process control and optimisation, a-tune today meets the challenges of its varied clientele's needs for optimisation and support of workflows and processes.

All of the projects and solutions utilise a web technology that features lower costs, higher efficiency and state-of-the-art technology.

To maintain its edge as a medium-sized company in the face of competition from larger firms, a-tune relies on providing its clients with uncompromising **premium** product and service **quality**. **Satisfied clients** translate into a secure company **future** and constitute the basis for continuous growth.



ISV/Software Solutions

