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Transgenic animals also fulfill increasingly important roles in other fields, like livestock production or in biopharming. In the framework of the European Commission's Biotechnology Programme, a workshop has been organized at Utrecht University (30 October, 1995) with leading experts in the field of animal transgenesis and animal welfare as presenting authors.

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Specific welfare aspects have to be taken into consideration with transgenic animals. They include: the extent of discomfort experienced by the parents during the experimental procedures; the effect of the expression of the transgene (the modified gene inserted) on the created transgenic animal; and the effects on their progeny.

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Transgenic technology has been used to produce animals as suitable in vivo systems to study human disease, mammalian gene expression and regulation, as well as finding applications in zootechnology, pharmacology and medicine. The past few years have seen a rapid proliferation in the creation of genetically engineered mice as animal models of human diseases, representing an unique and valuable genetic resource.

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v Preface The quality of animal models used in biomedical research has increased substantially since the first successful microinjection of foreign DNA fragments into a mouse zygote in the early 1980s. New well-defined animal models, developed either by microinjection techniques or by homologous recombination in embryonic stem (ES) cells, have become widely available and several classical animal models have now been replaced by these transgenic models. Transgenic animals also fulfill increasingly important roles in other fields, like livestock production or in biopharming. The potential

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benefits of this technology are overwhelming. It is not surprising that many research groups have rushed to jump on this wagon of scientific progress. However, no matter how important these developments are, they can not relieve us of the moral obligations towards the animals. It is generally recognized that animal use is allowed only if the harmful effects are out weighed by the potential benefits of the experimental results. But what are the harmful effects? What is the impact of trans genesis on the well-being of animals? In order to gain more insight into this aspect of trans genesis the European Commission (DGXII) has funded a 12-month project with the aim of col lecting information on the production and use of transgenic animals in EU Member States and, more specifically, to obtain information as to what extent specific welfare problems may arise and whether or not studies are being performed

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Genetic-based animal biotechnology has produced new food and pharmaceutical products and promises many more advances to benefit humankind. These exciting prospects are accompanied by considerable unease, however, about matters such as safety and ethics. This book identifies science-based and policy-related concerns about animal biotechnologyâkey issues that must be resolved before the new breakthroughs can reach their potential. The book includes a short history of the field and provides understandable definitions of terms like cloning. Looking at technologies on the near horizon, the authors discuss what we know and what we fear about their effectsâthe inadvertent release of dangerous microorganisms, the safety of products derived from biotechnology, the impact of genetically engineered animals on

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their environment. In addition to these concerns, the book explores animal welfare concerns, and our societal and institutional capacity to manage and regulate the technology and its products. This accessible volume will be important to everyone interested in the implications of the use of animal biotechnology.

This book provides background knowledge in one of the most controversial and exciting areas in science today: the genetic engineering of animals. All students and professionals involved in biotechnology - whether they are chemists, biologists or engineers - should be aware of the power behind this technique. And why? Methods of introducing transgenes into fertilized eggs and animal cells have been considerably improved. Transgenic animals, for example, can now produce therapeutic proteins in grams per liter



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milk. The range of applications is, quite simply, mind-boggling. The topics covered in this volume present a thorough and fascinating introduction to the methods, potentials and limitations of the genetic engineering of animals. Written by leading experts in the field, they include Cloning Vectors Gene Transfer Techniques Expression of Foreign Genes Transgenic Animals. The articles in this book have been excerpted from the internationally renowned VCH multi-volume series *2Biotechnology2*. They give students and professionals direct access to recent developments in genetic engineering.

Upcoming applications of genetic engineering in farm animals include higher yields, leaner meat, or disease resistance. The proceedings cover an analysis of the state of the art of the

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technology and its applications, an introduction to the specific application zoopharming (a method to produce biopharmaceuticals in transgenic livestock), including an analysis of the market for biopharmaceuticals. In addition an assessment of ethical aspects of livestock biotechnology and considerations regarding animal welfare implications are covered. The study is addressed to science, industry and politics.

Transgenic animal technologies and the ability to introduce functional genes into animals have revolutionized our ability to

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address complex biomedical and biological questions. This well-illustrated handbook covers the technical aspects of gene transfer from molecular methods to whole animal considerations for important laboratory and domestic animal species. It describes methodologies as employed by leading laboratories and is a key resource for researchers, as well as a tool for training technicians and students. This second edition incorporates updates on a variety of genetic engineering technologies ranging from microinjection and ES cell transfer to nuclear transfer in a broad range of animal modeling systems. Contains a comprehensive collection of transgenic animal and gene transfer methods Discusses background and introduction to techniques and animal systems Teaches practical step-by-step protocols Fully revised with updates to reflect state-of-the-art technology and associated changes to date

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This document provides guidance for the risk assessment of food and feed containing, consisting of or produced from genetically modified (GM) animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The assessment strategy seeks to deploy appropriate approaches to compare GM animals and derived food and feed with their respective comparators. The health status of a food/feed producing animal has traditionally been considered as an important indicator of the safety of derived foods/feed and therefore comparative analysis of the phenotypic characteristics of the GM animal with the traditionally-bred animal, including health and physiological parameters, is considered an important component in the risk assessment. The document

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addresses the molecular characterisation, which provides information on the structure and expression of the insert(s) and on the stability of the intended trait(s); the toxicological assessment, which addresses the possible impact of biologically relevant change(s) in the GM animal and/or derived food and feed, the allergenicity assessment of the novel protein(s), as well as of the whole food derived from the GM animal; and the nutritional assessment to evaluate whether food and feed derived from a GM animal is as nutritious to humans and/or animals as food and feed derived from traditionally-bred animals. This guidance document also addresses the scientific requirements for the assessment of health and welfare of GM animals bred for food and feed use. The assessment is made in terms of the effective functioning of their body systems in a given environment. The document does not cover

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the environmental risk assessment of GM animals, which will be addressed in stand-alone guidance under development by the EFSA GMO Panel.

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