Regulation on Genetically Modified Animals: Proposed and Its Possible Application in Indonesia

(Regulasi Tentang Ternak Termodifikasi Genetik: Usulan dan Kemungkinan Penerapannya di Indonesia)

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ABSTRACT

The government is responsible for fulfil the needs of safe, healthy and halal food for all its people in a sustainable manner. The world population will increase from 7 to 9 billion people in 2050. While the availability of land may not increase in the future, it may even not be used for agriculture. Scientists are trying to overcome this problem by creating technologies that can increase livestock productivity, one of which is through a genetically modified process. Genetically modified animals are animals that have been genetically modified for many purposes including yields and disease resistance. Although genetically modified animals are at the last stage of research and the possibility to entering Indonesia remains small, but government should prepare a regulation related to it. European countries and USA have regulations to control genetically modified animals. Malaysia also has applied a similar regulation since 2007. Currently, Indonesia has formed an authority that oversees the genetically modified product, namely Biosafety Commission (*Komisi Keamanan Hayati*) on genetically modified products. However, this commission only supervises genetically modified organism in food and feed. This paper is aimed to propose the regulation for genetically modified animal that may be entering Indonesia and or be researched by Indonesian scientists.

Key words: Regulation, genetically modified organism, animal

ABSTRAK

Pemerintah mempunyai tanggung jawab untuk memenuhi kebutuhan pangan aman sehat dan halal bagi seluruh penduduknya. Pada tahun 2050 diperkirakan populasi manusia akan bertambah dari 7 milar menjadi 9 milyar orang, dipihak lain, ketersediaan lahan boleh jadi tidak akan bertambah. Seandainya pun tersedia, akan banyak terjadi alih fungsi lahan sehingga peruntukan bagi kegiatan pertanian kemungkinan berkurang. Para peneliti mencoba mengatasi hal ini melalui penciptaan teknologi yang akan meningkatkan produktivitas ternak, diantaranya melalui proses modifikasi genetik (GM). Ternak yang termodifikasi gen nya dapat dipergunakan untuk berbagai kepentingan, misalnya peningkatan produksi dan meningkatkan ketahanan terhadap penyakit. Walaupun saat ini, penelitian ternak GM ada yang sudah masuk dalam fase akhir riset dan belum akan memasuki wilayah Indonesia, akan tetapi pemerintah harus mempersiapkan regulasi terkait. Negara Uni Eropa dan Amerika Serikat telah mempunyai regulasi tentang GM ternak, hal serupa telah dimiliki negara Malaysia sejak tahun 2007. Saat ini, pemerintah Indonesia telah mempunyai Komisi Keamanan Hayati Produk Rekayasa Genetik. Tetapi komisi ini hanya menangani produk GM pangan dan pakan. Makalah ini menyampaikan usulan regulasi untuk GM ternak yang kemungkinan akan memasuki wilayah Indonesia maupun GM ternak hasil penelitian dalam negeri.

Kata kunci: Peraturan, modifikasi genetik, ternak

INTRODUCTION

World population will rise from 7 to 9 billion people in 2050 (OECD 2012). According to United Nations Millennium Goals, the targets include reduce by half the share of the global population suffering from hunger. However, the goal is not easy to be reached. Food insecurity is both an immediate tragedy and threat to longer-term well-being. Families tend to reduce higher-quality food intake, such as meat or vegetables (Dewbre 2010). Land, water and biological resources are declining at an alarming rate, this loss has significant negative impacts on the production of food and forests (Crist et al. 2017).

Agriculture sector plays an important role in low-income countries because they have high economic dependency on that sector (Brools 2012). In Indonesia, agricultural sector remains important factor, comprising 13.45% of the country's aggregate Gross Domestic Product (GDP) or the second largest after

industrial sector (19.62%) in Quarter 3 (Q3) 2019 (BPS 2019). The Indonesian government organized many programs for the realization of food security, although many obstacles in their implementation (Andoko et al. 2018). Increasing food production is important for all countries including Indonesia, but several countries are not self-sufficient and depend on imports from other regions (D'Odorico et al. 2014).

Animal agriculture also needs to increase its production. In the future, demand for animal food products will increase, mostly in developing countries. The global livestock sector is rapidly changing in response to globalization and growing demand for animal-source foods, driven by population growth and increasing wealth in much of the developing world. The rapid rate of urbanization seen in many countries is not only linked to growing affluence but also gives rise to changes in people's food preferences, usually tending towards greater convenience and higher standards of safety (Robinson et al. 2011).

Growing two or more crops in the same land increased yields, especially in Asian countries (Taiz 2013). Genetic engineering reached an important progress during the 1980s which triggered the development of genetic modification (GM). At the most basic level, a genetically modified organism (GMO) is any organism whose genetic material has been altered using genetic engineering techniques (Veitenheimer 2016).

First GMO crop launched in 1994 as the "Flavr-Savr" tomato (Taiz 2013). While the discussion on the risks, the general necessity and the economically optimal levels of synthetic pesticide use has not come to an end, today GM raise concerns in many parts of civil society (Zadoks & Waibel 2000). In a traditional breeding program, a breeder selects desirable parental plant lines to cross, but the changes occurring at the genetic level are unpredictable (Veitenheimer 2016). There are also numerous benefits of GMO. The prospect of GM crops offering increased yield potential for important food crops on a per acre basis is one way to address the world's increased demand for food. Some GM crops also decrease synthetic chemical pesticide utilization and lower the environmental impact associated with such use.

Underlining those advance, fast biotechnology and the need to provide foods for the human population, this paper is aimed to propose the regulation for animal GMO that may be entering Indonesia and be researched by Indonesian scientists.

THE GLOBAL STATUS OF GM ANIMAL

Regulations on GM crops and GM animals have been issued by countries in various parts of the continent (Pasquito 2019; Viera et al. 2021; Kuiken &

Kuzma 2021). Indonesia can take lessons from the country's experience and adapt to the existing conditions.

The most frequently genetically engineered crop species are the big three of cotton, corn, and soybeans (Veitenheimer 2016). However, engineered animal species are also developing. Animal's genetic modification includes altering its genetic material by adding, changing or removing certain DNA sequences which do not occur naturally (EFSA 2012). The aims of the genetic modification are to modify specific characteristics or introduce a new trait, such as resistant to disease or increased growth. Initially, GM animals were used for laboratory purpose. Genetically defined laboratory mice have been described and incorporated into biological research; this trend has accelerated in the 21st century (Pritchett-Corning & Landel 2015). However, effort has been made to modify several aspects of farm animals to improve their cultivation (Cotter & Perls 2019; Lievens et al. 2015). Amongst the most targeted traits are: animal health (increased neonatal survival), disease resistance, growth rate, improvement of meat and milk composition. Three categories can thus be defined: GM animals for human consumption, as medical bioreactors, and as companion animal. The first GM animal that enter the food chain is salmon. United States Food and Drug Administration (FDA) has approved a new animal drug application concerning AquAdvantage Salmon, a genetically engineered Atlantic salmon. There are at least 74 (on-going) attempts at animal modification, of which about half are designed for use as livestock. Amongst the latter, at the majority are intended for direct release onto the food market (as meat or meat product) as opposed to animals for wool or milk production.

The number of GM animals for which we were able to find (partial) sequence information was approximately around 56 items. Of all the genetically modified animals listed, there is currently only AquAdvantage salmon that is actually being brought into production (Lievens et al. 2015). According to EFSA (2013), no GM animals or derived products are on the EU market, nor have any applications for GM animals been received in the EU.

Table 1 showed recent molecular research of transgenic animals with potential applications. Indonesia with 265 million population has high consumption of animal products, especially in the future. The beef cattle population in Indonesia is 17,118,650 head while the population of dairy cattle is 561,061 head (Indonesian Ministry of Agriculture, 2020). Demand of beef and milk are 686,270 tons and 1.098.125 tons, respectively, while the production of beef and milk are 490,400 tons and 996,400 tons, respectively. Beef import is around 40% of the total demand which is equivalent to 204,682.78 tons of live

cattle and processed beef products as much as 164,260.57 tons .

Milk supply is also came from abroad as much as 79% (equivalent to 455,559.47 tons) of milk and dairy products. Countries of origin are Netherlands, Australia, New Zealand, and United States. Seeing the opportunity for beef and milk demand is very high, it is necessary to anticipate with regulations if GM livestock, meat products, eggs and GM milk will enter Indonesia, especially by looking at the risks posed both in terms of the environment. There is possibility that the exporting country in the future will send GM beef or milk.

Indonesian researchers (Faculty of Fishery and Maritime at University of Pajajaran, Bandung, West Java) already carried out the insertion of growth genes in catfish, and already produced GM fish. Therefore, it is necessary to have regulatory on animal genetically modified organism. Meanwhile, research related to gene modification in other livestock, has not been recorded or carried out in Indonesia.

Table 1. Overview some of the transgenic animals with potential commercial applications

Species	Category	Transgene	Origin	Effect/goal
Cattle	Livestock	Lysozyme	Human	Milk composition
		a,k-Case	Bovine	Milk composition
		Omega-3	Nematode	Milk composition
		Lysostaphin	Bacterial	Mastasis resistance
	Bioreactor	Lactoferrin	Human	Prophylactic treatment
Chicken	Livestock	alv6 envelope glycoprotein	Viral	Disease resistance
		short hairpin RNA	Viral	Disease resistance
		LacZ	Bacterial	Animal Health
	Bioreactor	a-interferon	Human	Hepatitis treatment
Carp	Livestock	Growth Hormone	Piscine	Growth rate
		Lactorferrin	Human	Disease resistanc
Catfish	Livestock	Cercopin B	Insect	Disease resistanc
Fruit Fly	Livestock	fsRIDL	Hymnopteran	Pest control
Frog	Bioreactor	GFP	Cnidarian	Water purity
Goat	Livestock	Lysozyme	Human-Bovine	Animal Health
		Monosat. fat. acid	Rat-Bovine	Mastasis resistance
		MSP(1)42	Plasmodial	Malaria vaccine
		Antithrombin III	Human	Thrombosis/embolism treatment
		Tissue plasminogen activator	Human-Mouse	Anti clotting agent
		Lactoferrin	Human	Prophylactic treatment
		Lysosomalacid b-glucosidase	Human	Gaucher disease treatment
		Human coagulation factor IX	Human	Haemophilia treatment
		Human beta-defensin 3	Human	Milk composition
Pig	Livestock	Phytase	E. coli Mouse	Feed uptake
		Growth hormone	Human-Porcine	Growth rate
		cSKI	Chicken	Muscle development
		Lysozyme	Human	Piglet survival
		Unsat. fat. acid	Spinach	Meat composition
		Omega-3	Nematode	Meat composition
		a-lactalbumin	Bovine	Piglet survival
		Mx1	Murine	influenza resistance
	Bioreactor	Factor VIII	Human	Haemophilia treatment
		CD59, DAF	Human	Human transplantation

Species	Category	Transgene	Origin	Effect/goal
		DAF	Human	Human transplantation
		hHO-1	Human	Human transplantation
		hHO-1,DAF	Human	Human transplantation
		b-D Mamose, GnTIII	Human	Human transplantation
		Fibrinogen	Human	Tissue sealant
		Haemoglobin	Human	Transfusion
		Protein C	Human	Blood coagulation
		Albumin	Human	Human transplantation
Rabbit	Bioreactor	Calcitonin	Salmon	Osteoporosis treatment
		Erythropoietin	Human	Anemia treatment
		Superoxide dismutase	Human	Blood purification
		Interleukin-2	Human	Cancer treatment
		Tissue plasmogen activator	Human	Anti Clotting Agent
		VP2, VP6	Viral	Rotavirus vaccine
		Human Factor VII	Human-Mouse-Chicken	Haemophilia treatment
		Growth Hormone	Human	HGH insufficiency treatment
		Von Willebrand factor	Human-Bovine	Haemophilia treatment
Salmon	Livestock	Growth hormone	Piscine	Growth rate
		Growth hormone	Piscine	Growth rate
		Lysozyme	Piscine	Animal health
		wflAFP-6	Piscine	Cold tolerance
Sheep	Livestock	IGF-1	Ovine	Wool growth
		CsK	Bacterial	Wool growth
		HTT	Human	Disease model
		Visna resistance	Viral	Disease resistance
	Bioreactor	Factor IX	Human	Haemophilia treatment
		Factor VIII	Human	Haemophilia treatment
		a-1-antitrypsin	Human	Cystic fibrosis treatment
Silkworm	Livestock	eGFP, DsRed, or	Cnidarian	Silk color
		$A2S8_{14}$	Arachnid	Silk strength
	Bioreactor	Fibroin	Human	Cell adhesive film
		Crp	Canine	Inflammation marker
		TRACP5B	Human	Inflammation marker
Tilapia	Bioreactor	Insulin	Human	Diabetes treatment
Trout	Livestock	Follistatin	Piscine	Muscle development
Zebrafish	Companion	GFP or RFP	Cnidarian	Fish color

Sumber: Lievens et al. (2015)

Several types of animal that have been carried out research on genetic modified organism are cattle, goats, sheep, chickens, pigs, rabbits, carp, catfish, tilapia, fruitfly, frog, salmon, trout, zebrafish and silkworm. While the genes under studied are intended to solve problems in human health, such as for the treatment of mastasis, malaria vaccines, anti-clotting agents, haemophilia treatment, human transplantation, transfusion, anemia problems and many others (Lievens et al. 2015). For example, to help the problem of anemia in humans, the genes are taken from humans and then use rabbits as bioreactors to produce Erythropoietin. This Erythropoietin then can be utilized to help curing the anemia treatment. Cooperation can

be done between agencies or companies that have GM animal patents to enter Indonesia for futher development, as well as GM crops, which are widely imported into Indonesia recently and have been subjected to risk assessments by the Biosafety Technical Team. Certain livestock growth is not optimal because it is not resistant to parasitic attacks, while overseas research has been conducted and produced research for animals that are resistant to certain diseases. In addition, there is a tendency for children under five who are not resistant to lactic acid in cow's milk, so that in the future cow milk will be produced which is tolerant of lactic acid for infants.

NATIONAL BIOSAFETY REGULATION

The avalaible legislation

The Cartagena Protocol was a strong commitment among parties that regulates across borders of living organism that derived from genetically modified organism from modern biotechnology process either from private and or institute overseas or nationally produced. The protocol ensure reliable protection in term of transit, handling and safety utilization from cross border movement of GMO products. The protection level was conducted to avoid negative effect toward sustainable and utilization of genetic resources as well as its risks for human being. Indonesia ratified the Cartagena Protocol on August 16, 2004 by implementing Law No 21/2005 regarding the authentication of Cartagena Protocol on Biosafety to the Convention on Biologiocal Diversity. Until February 2019 at least 172 countries from 180 parties already entry into force of the Cartagena Protocol. Some of these countries have the regulations on genetically modified animals (Table 2)

Indonesian Biosafety Clearing House already established as stated in article No 20 of Cartagena Protocol to facilitate information exchange interm of scientific, technical , environment and regulation about GMO. Base on article No. 77 paragraph (1), Act No. 18/2012 about foods and state that "every human being are not allowed to produce foods derived from GMO that has not been approved on biosafety before distributed", then followed by amandmend of that regulation to No. 6/2018 of food control genetically modified organism. Based on Government Regulation No. 21/2005, Commision on Biosafety was the institution that assigned for risk assessment. To facilitate operational activities for risk assessment, the Biosafety Technical Team for Food, Feed and Environment was established. Food biosafety certificate was granted by the Director General of National Agency of Drug and Food Control, feed biosafety certificate was granted by Ministry of Agriculture and environment biosafety certificate was granted by Ministry of Environment and Forestry. Regulation related to biosafety regulation in Indonesia is shown in Table 3.

Table 2. Regulations on genetically modified animals in selected countries and regions

Countries/Regions	Regulation
European Union	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Norway	Gene Technology Act of 2 April 1993 No. 38 relating to the production and use of genetically modified organisms, etc
United States	Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs; Availability (Docket No. FDA-2008-D-0394)
Argentina	Law on the Promotion of the Development and Production of Modern Biotechnology, Law 26270, 2007
Australia	Gene Technology Act 2000, implemented by Gene Technology Regulations 2001
New Zealand	Hazardous Substances and New Organisms Act 1996
Brazil	Law No. 11.105 of 24 March 2005. Safety standards and inspection mechanisms for activities involving Genetically modified organisms – GMOs – and their derivatives, creates the National Biosecurity Council (CNBS), restructures the National Biosecurity Technical Commission (CTNBio), and rearranges the National Biosecurity Policy (PNB)
South Africa	Genetically Modified Organisms Act, 1997 (No. 15 0f 1997)
Nigeria	National Biosafety Management Agency Act, 2015
Malaysia	Biosafety Act 2007

Table 3. Biosafety Regulation in Indonesia.

Regulation	Topic
Law No. 5 /1994	United Nation Convention on Biological Diversity (CBD)
Decree of Four Minister / 1999	Biosafety and Agriculture Genetic Modified Organism of Food Biosafety
Law No. 21/2004	Ratification of Cartagena Protocol
Government Regulation No.21/2005	Biosafety of Genetic Modified Organism
Ministry of Agriculture Decree No 37/ 2006	Testing, Reviewing and Releasing of Crop Variety
Ministry of Agriculture Decree No 67 / 2006	Conservation and Utilization of Plant Genetic Resources.
Law No. 32/2009	Environment Protection and Management
Ministry of Agriculture Decree No 36/2016	Biosafety Risk Assessment for Feed
Regulation of National Agency of Drug and Food Control No. 6/2018	Supervision on Genetically Modified Food Product
Ministry of Agriculture Decree No 38/ 2019	Testing, Reviewing and Release of Crop Variety
Ministry of Agriculture Decree No 50/ 2020	Supervision and Controlling Plant Varieties of Agricultural Genetically Modified Organisms Distributing in the Territory of the Republic of Indonesia

Table 4. GM animals and associated differences in environmental effects (EFSA, 2013)

Description	Confined GM animals	Semi-confined GM animals	Non Confined GM animals
Definition	GM animals intended to be kept under confinement	GM animals intended to be under human control but not always under confinement	GM animals directly released into specific environments
Examples for GM mammals or birds	Chicken (except free-range); pigs; fenced mammals; caged birds; companion animals held indoors	Cats; cattle or goats sometimes browsing on an unfenced pasture	Rabbits released to control wild populations
Environmental effects	Environmental effects of confined GM animals	Environmental effects during confinement periods	Environmental effects of released GM animals
		Environmental effects during non-confinement periods	
	Environmental effects of escaped GM animals	Environmental effects of escaped GM animals	

During the last 15 years after the ratification and entry into force of Cartagena protocol, the government of Indonesia already produced 41 biosafety certificates such as events of maize, soybean, canola, potato and feed additive, ice cream stabilizer and vaccines. Some events of GM maize, were imported for human consumption and feed, whereas other events will be planted for production (such as corn, sugarcane, potato and soybean). After granted the biosafety certificates of environment, food and feed, the designated varieties have to follow procedure for releasement. The Decree of Ministry of Agriculture No. 50/2020 was an expectation for GM plant varieties to be cultivated, however, those varieties require biosafety certificates of food, environment and feed.

Proposed regulation for GM animal

In a protocol published by EFSA (2013), it stated that GM animal are species of fish, bird and livestock. EFSA (2013) reported three confined facilities for GM animals, such as Confined GM animals, Semi-confined GM animals and Non Confined GM animals as shown in Table 4. If Indonesia would like to prepare and facilitate risk assessment for GM animals, therefore one needs to consider component such as GM animals for breeding stock, GM animals for food and also GM animals as bioreactor that require to be regulated.

GM animal, livestock, insect and fish are not regulated at the previous regulation schemes. To anticipate that GM livestock will enter Indonesia, there

is a need to prepare the regulation. These GM livestock could be as breed stocks or and readily consumed products or even pharmaceutical products derived from GM livestock and or animal. Nowdays, the available regulation only for environment risk assessment plants according to the Decree of Ministry of Environment and Forestry No. P.69/Menlhk/Setjen/Kum.1/8/2016 regarding testing procedure of environment biosafety of GMO at Limited Field Test. The upcoming law on Genetic Resources is expected to cover the utilization of genetic resources in Indonesia. On the other hand, regulation for GMO breed stocks has not been available yet, underlining those circumstances, procedures of GM livestock can be proposed as follows:

Breeding stock. Risk assessment needs to be conducted for genetic materials from genetic modified (GM) processes, both for incoming materials or GM animals produced in Indonesia. Frozen semen, frozen embryo, oocytes, premordial germ cell, fertilized eggs and live animals are genetic materials resulted from breeding of GM animals. The risk assessment for breeding stock that will be carried out consists of reviewing the documents submitted by the proponent, then followed by observations of the GM animals as part of the field tests. EFSA classified GM animals risk assessment according to their intended uses, within the three groups such as confined, semi-confined and non-confined GM animals (Table 4).

At the very beginning, frozen semen from GM bulls, GM embryos or GM live animals can be imported, the risk assessment conducted through reviewing the documents from the proponent. However, after the frozen embryos transfered to the recipient animals, or by conducting AI (artificial insemination) of the frozen semen, then the recipient and the offsprings required substantial risk assessment based on GM confined animals. At this point, environment technical assessment team which include member of animal aspect needed to be established. This is due to the fact that most Indonesia's environment for livestock rearing are under confinement. Therefore protocols for the environment effects and the possibilities of the environmental effects that may come from escaped GM animals must be reviewed in details.

The risk analysis elements of the breeding stocks (Table 5) include of hazard characterisation, exposure characterization (high, moderate, low or negligible). The component of risk assessment can be divided into 1) Molecular characterisation, 2) Compositional characterisation, 3) Phenotypic characterisation and 4) Interaction between the GM animal and its receiving environment. The molecular information include of 1) genetic information (consist of genetic element, source of the gene, transformation system, genetic stability),

2) biosafety information (substantial equivalent, toxicity (bioinformatics study, toxicity test) (EFSA 2013).

The phenotypic parameters required for risk assessment of breeding stocks include of 1) production data (body weight, growth rate, carcass percentage, egg production, milk production, milk quality, meat quality, egg quality etc according to the species being assessed) , 2) reproduction data (sperm quality, mature age, age at first mating, body weight at first mating, puberal age etc), 3) disposal from the animals (urine, manure), 4) other products (feather, leather), 5) processing of the urine and manure, 6) disease that may occur during the assessment, 7) mortality rate and 8) physiological data of the animals (rectal temperature, heart rate as well as respiration rate) (EFSA 2013).

GM Animals Products. In the future, GM Animal products possibly come into the market, eventhough the research has not been conducted in Indonesia. Products from GM animals can be as meat, milk, eggs, wool, leather, honey and bones that require risk assessed by food biosafety technical team. The GM animals products can be in a wide range such as their products and also the result from their processing. The output from processing such as from milk processing (yoghurt, cheese, kefir etc), product of egg processing (powdered eggs, albumin powder, egg yolk powder, egg yolk liquid etc) and products of meat processing (sausage, smoked beef, meatball, nuggets etc).

The risk assessment for GM Animals Products (Table 5) include of 1) Molecular characterisation and 2) Compositional characterisation. Data required for risk analysis molecular characterisation include of 1) general description of GM animal product (description of the host and its use as food; description of gene sources; description of genetic transformation methods and characterization of genetic modification); 2) food safety information which includes substantial equivalence; changes in food composition; allergenicity; toxicity; and 3) other considerations include of marking genes for antibiotic resistance; potential accumulation of substances that have a significant impact on human health The compositional characterisation include of proximate analysis, amino acid content, mineral content, secondary compund etc.

The goals of livestock GM research generally fall into three categories such as increased yield, increased the cost-effectiveness in keeping animals (e.g., certain disease resistance) and changes in the quality of nutrition for milk, meat or eggs (Cotter & Perls, 2019). Examples of genetically engineered animals in development include of super-muscle of cows, sheep and pigs. Due to many diseases problems in chicken and pigs, therefore considerable GM researches are conducted for resistant to the respiratory disease for pig and chicken. An ongoing experiment is conducted

Table 5. Proposed biosafety risk assessment of GM breedstock and product of GM livestock .

Type of product	Document assessment	Biosafety containment test	Contained field test
Breeding Stocks			
Semen (frozen and fresh)	Yes	Yes	Yes
Embryo(frozen and fresh)	Yes	Yes	Yes
Fertilized eggs	Yes	Yes	Yes
Live animal	Yes	Yes	Yes
GM Livestock Products			
Meat	Yes	No	No
Milk	Yes	No	No
Egg	Yes	No	No
Livestock Bioreactor Products			
Enzyme	Yes	No	No
Hormone	Yes	No	No
Serum	Yes	No	No

also to engineered the gene-edited chickens to potentially produce non-allergenic eggs.

GM Animal Bioreactor Products. Enzyme, hormone and serum are some bioreactor products that may be produced in the future, and will be utilized for human esthetics, pharmacy and medication. Depend on the type of research, the products can also be used for human as well as for animal needs. Data required for risk analysis of GM animals bioreactor products include of molecular characterisation and compositional characterisation. A biosafety risk assessment worksheet is shown in Table 5.

The molecular characterisation include of 1) general description of GM animal bioreactor product (description of the host; description of gene sources; description of genetic transformation methods; and characterization of genetic modification); 2) product safety information which includes substantial equivalence; changes in the composition; allergenicity; toxicity and 3) other considerations include of marking genes for antibiotic resistance; potential accumulation of substances that have a significant impact on human health.

CONCLUSION

Regulation for GM animal is required to anticipate the products that will enter the territory of Indonesia. Institution that conduct laboratory and field trial of G animal breed stocks required to be developed before the products are available in the market. Labelling for GM animal breeds and animal products is a necessity.

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