SENATO DELLA REPUBBLICA

XVII LEGISLATURA

N. 353

ATTO DEL GOVERNO
SOTTOPOSTO A PARERE PARLAMENTARE

Schema di decreto legislativo recante disciplina sanzionatoria per la violazione delle disposizioni di cui al regolamento (CE) n. 767/2009 sull'immissione sul mercato e sull'uso dei mangimi

(Parere ai sensi dell'articolo 2 della legge 7 ottobre 2014, n. 154)

(Trasmesso alla Presidenza del Senato il 28 ottobre 2016)

La Ministra
per le riforme costituzionali
e i rapporti con il Parlamento

DRP/II/XVII/D233/16

Roma, 28 ottobre 2016

Gentile Presidente,

trasmetto, al fine dell'espressione dei pareri da parte delle competenti Commissioni parlamentari, lo schema di decreto legislativo recante "Disciplina sanzionatoria per le violazioni delle disposizioni di cui al regolamento (CE) n. 767/2009 del 13 luglio 2009 sull'immissione sul mercato e sull'uso dei mangimi", approvato in via preliminare dal Consiglio dei Ministri l'11 ottobre 2016.

In considerazione dell'imminente scadenza della delega, Le segnalo, a nome del Governo, l'urgenza dell'esame del provvedimento da parte delle competenti Commissioni parlamentari pur se privo del parere della Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e di Bolzano, che mi riservo di trasmettere non appena sarà acquisito.

Cordialità

Maria Elena Boschi

Sen. Pietro GRASSO
Presidente del Senato della Repubblica
ROMA

RELAZIONE ILLUSTRATIVA

Il presente schema di decreto legislativo, recante la disciplina sanzionatoria per le violazioni delle disposizioni di cui al regolamento (CE) n. 767/2009 del 13 luglio 2009 sull'immissione sul mercato e sull'uso dei mangimi, che modifica il regolamento (CE) n. 1831/2003 e che abroga le direttive 79/373/CEE del Consiglio, 80/511/CEE della Commissione, 82/471/CEE del Consiglio, 83/228/CEE del Consiglio, 93/74/CEE del Consiglio, 93/113/CE del Consiglio e 96/25/CE del Consiglio e la decisione 2004/217/CE della Commissione, mira a disciplinare le sanzioni da applicare in caso di violazione delle prescrizioni stabilite dal medesimo regolamento (CE) n. 767/2009, in adempimento di quanto stabilito dall'articolo 31 "Sanzioni", che prevede che *"Gli Stati membri stabiliscono le sanzioni applicabili in caso di violazione delle disposizioni del presente regolamento e adottano le misure necessarie ad assicurare che esse siano applicate. Le sanzioni previste devono essere efficaci, proporzionate e dissuasive"*.

Sino ad ora, infatti, tale materia è stata disciplinata dalla legge 15 febbraio 1963, n. 281 *"Disciplina della preparazione e del commercio dei mangimi"* e dal decreto legislativo 24 febbraio 1997, n. 45 *"Attuazione delle direttive 93/74/CEE, 94/39/CE, 95/9/CE e 95/10/CE in materia di alimenti dietetici per animali"*, che già prevedono la disciplina sanzionatoria in materia di etichettatura, ma essa risulta troppo generica e non adeguata alla materia che, con il regolamento (CE) n. 767/2009, è stata modernizzata e razionalizzata.

Le sanzioni sono applicate, sulla base delle condotte punibili e dell'autore della violazione, al responsabile di etichettatura o all'operatore del settore dei mangimi.

Sono previste sanzioni specifiche per l'uso ingannevole di *claims* e dell'etichettatura facoltativa in genere.

Sono, inoltre, modulate le sanzioni per il mancato rispetto delle tolleranze di etichettatura, a seconda che si tratti di una discrepanza dei tenori analitici (ceneri, fibra etc.) o dei livelli di additivi.

Vengono, infine, previste sanzioni più gravi per le condotte che compromettono la sicurezza dei mangimi, quali l'immissione sul mercato di mangimi contaminati senza le indicazioni di etichettatura previste o di materiali soggetti a divieto di utilizzo nei mangimi.

Di seguito, si elencano le previsioni dei singoli articoli del decreto.

L'articolo 1 descrive le finalità del provvedimento, che consistono nel prevedere una apposita disciplina sanzionatoria per le violazioni delle prescrizioni contenute nel regolamento (CE) 767/2009 al fine di garantire l'etichettatura corretta dei mangimi e la conformità alla nuova normativa in materia di mangimi e di alimenti per la tutela della salute e sul benessere degli animali, in modo da realizzare un quadro normativo certo, esaustivo, adeguato e in continuità e coerenza con il quadro sanzionatorio vigente.

L'applicazione del Regolamento (CE) 767/2009, da parte degli operatori del settore dei mangimi, ed, in particolare, da parte dei responsabili di etichettatura, garantisce l'immissione sul mercato di mangimi correttamente etichettati, che forniscono all'utilizzatore finale (allevatori di animali da reddito e proprietari di animali da compagnia), un'informazione trasparente e non ingannevole. Grazie a tali informazioni viene assicurato un uso appropriato dei mangimi. Infatti, un'etichettatura non conforme, può rendere i mangimi presenti sul mercato a rischio per gli animali e le persone (ad esempio, dosaggio non corretto degli additivi, mangimi non conformi per i livelli di sostanze indesiderabili non etichettati, mangimi che simulano in maniera ingannevole la funzione di un farmaco o mancata indicazione delle istruzioni di uso).

Inoltre, l'applicazione del regolamento, da parte degli Stati Membri dell'UE, è fondamentale al fine di garantire la correttezza delle prassi commerciali nel libero scambio dei mangimi sul territorio dell'Unione.

L'**articolo 2** detta disposizioni in materia di Autorità competenti all'accertamento ed all'irrogazione delle sanzioni, stabilendo che all'accertamento e all'irrogazione delle sanzioni previste dal decreto provvedono le strutture competenti del Ministero della salute, del Ministero delle politiche agricole, alimentari e forestali, ai sensi del decreto legislativo n. 223 del 2003, del Ministero dello sviluppo economico, delle regioni, delle province autonome e delle aziende unità sanitarie locali secondo gli ambiti di rispettiva competenza.

Gli **articoli da 3 a 17** recano disposizioni concernenti le sanzioni applicabili, in particolare, sanzioni per le violazioni riguardanti le prescrizioni in materia di sicurezza e di commercializzazione, di responsabilità e di obblighi delle imprese nel settore dei mangimi, di restrizioni e divieti, di tenore di additivi, di commercializzazione di mangimi destinati a particolari fini nutrizionali, di principi per l'etichettatura e la presentazione, di prescrizioni obbligatorie aggiuntive e di etichettatura di mangimi non conformi, di confezionamento e di codici comunitari di buona pratica ed in materia di etichettatura.

L'**articolo 18** detta disposizioni in materia di sanzioni accessorie, prevedendo che, nel caso in cui vengano violate norme in materia di sicurezza e di commercializzazione sui mangimi e di indicazione di prescrizioni obbligatorie sull'etichetta, gli organi preposti al controllo possono proporre all'Autorità competente l'adozione di un provvedimento di sospensione dell'attività da tre giorni a tre mesi; in presenza di gravi violazioni nei casi sopra esposti, l'Autorità competente può disporre la revoca della registrazione o del riconoscimento ai sensi degli artt. 9 e 10 del regolamento (CE) n. 183 del 2005.

L'**articolo 19** prevede che dalla data di entrata in vigore del decreto siano abrogati gli articoli 6, comma 3 e 7 del decreto legislativo n. 45 del 1997, recante attuazione delle direttive 93/74/CEE, 94/39/CE, 95/9/CE e 95/10/CE in materia di alimenti dietetici per animali, i quali prevedono, rispettivamente, che il responsabile dell'immissione in commercio degli alimenti dietetici è tenuto, su richiesta delle Autorità competenti al controllo, a presentare i dati e le informazioni comprovanti la conformità degli stessi alle disposizioni del

decreto (articolo 6, comma 3) nonché le sanzioni per chi viola disposizioni inerenti la regolamentazione degli alimenti dietetici per animali (articolo 7).

L'**articolo 20** detta disposizioni in materia di invarianza finanziaria.

L'**articolo 21** detta norme in materia di destinazione dei proventi delle sanzioni amministrative pecuniarie di spettanza statale, stabilendo la devoluzione dei proventi per le sanzioni di nuova istituzione riassegnate alle Autorità statali che effettuano controlli per il miglioramento delle attività di controllo previste dal decreto in esame.

Infine, l'**articolo 22** prevede che le disposizioni del presente decreto e le eventuali successive modifiche siano notificate ai sensi dell'articolo 31 del Regolamento n. 767/2009 alla Commissione Europea.

RELAZIONE TECNICO-FINANZIARIA

Il presente schema di decreto legislativo, recante la disciplina sanzionatoria per le violazioni delle disposizioni di cui al Regolamento (CE) n. 767/2009 del 13 luglio 2009 sull'immissione sul mercato e sull'uso dei mangimi, che modifica il Regolamento (CE) n. 1831/2003 e che abroga le direttive 79/373/CEE del Consiglio, 80/511/CEE della Commissione, 82/471/CEE del Consiglio, 83/228/CEE del Consiglio, 93/74/CEE del Consiglio, 93/113/CE del Consiglio e 96/25/CE del Consiglio e la decisione 2004/217/CE della Commissione, mira a disciplinare le sanzioni da applicare in caso di violazione delle prescrizioni stabilite dal medesimo Reg. CE n. 767/2009, in adempimento di quanto stabilito dall'art. 31 "Sanzioni", che prevede che *"Gli Stati membri stabiliscono le sanzioni applicabili in caso di violazione delle disposizioni del presente regolamento e adottano le misure necessarie ad assicurare che esse siano applicate. Le sanzioni previste devono essere efficaci, proporzionate e dissuasive"*.

I proventi derivanti dalla riscossione delle sanzioni amministrative pecuniarie di spettanza statale comminate per le violazioni di cui agli articoli 4, 6, 13, 16 e 17 sono versati ad apposito capitolo di entrata del bilancio statale, per essere successivamente riassegnati in favore dei Ministeri di cui all'articolo 2 del decreto, per il miglioramento delle attività di controllo previste dal presente decreto. Da tale destinazione a finalità di spesa non derivano oneri a carico della finanza pubblica, in quanto trattasi di proventi riferiti a fattispecie sanzionatorie di nuova istituzione.

Le attività di accertamento e irrogazione delle sanzioni poste in capo al Dipartimento dell'Ispettorato centrale della tutela della qualità e delle repressione frodi dei prodotti agroalimentari del Ministero delle politiche agricole alimentari e forestali non comportano nuovi o maggiori oneri per la finanza pubblica e verranno svolte con le risorse umane, strumentali e finanziarie disponibili a legislazione vigente. Le spese per le attività di controllo ispettive ed analitiche istituzionali svolte dal Dipartimento dell'Ispettorato centrale della tutela della qualità e delle repressione frodi dei prodotti agroalimentari del Ministero delle politiche agricole alimentari e forestali gravano sul capitolo 2460 "Spese per acquisti di beni e servizi", sui pertinenti piani gestionali".

Le attività di controllo, ricadenti in capo al Ministero della salute, sono quelle svolte dagli uffici periferici della Direzione Generale della sanità animale e dei farmaci veterinari, le cui spese gravano sui capitoli di bilancio relativi al costo del personale (capp. 5001, 5003, 5005 e 5022) e al funzionamento (5100).

Le disposizioni in questione non comportano oneri aggiuntivi per il Ministero dello sviluppo economico in quanto le risorse che dovessero affluire saranno versate al capitolo 3600 del

bilancio dello Stato assegnato al suddetto Ministero ed utilizzate per l'attività ispettiva da svolgere tramite apposita convenzione con gli enti già competenti a legislazione vigente o con il Corpo della Guardia di finanza.

Relativamente agli aspetti operativi ed economico-finanziari di tale intervento, si precisa che l'adempimento dei compiti derivanti dall'attuazione del decreto legislativo verrà realizzato con le risorse umane, strumentali e finanziarie disponibili a legislazione vigente e non comporterà oneri per la finanza pubblica, ma potrà determinare, invece, possibili entrate.

La verifica della presente relazione tecnica, effettuata ai sensi e per gli effetti dell'art. 17, comma 3, della legge 31 dicembre 2009, n. 196 ha avuto esito:

[X] POSITIVO [ ] NEGATIVO

20 OTT. 2016

Il Ragioniere Generale dello Stato

ANALISI TECNICO-NORMATIVA

Amministrazione proponente:
Ministero della salute

Titolo: SCHEMA DI DECRETO LEGISLATIVO RECANTE DISCIPLINA SANZIONATORIA PER LE VIOLAZIONI DELLE DISPOSIZIONI DI CUI AL REGOLAMENTO (CE) N. 767/2009 DEL 13 LUGLIO 2009 SULL'IMMISSIONE SUL MERCATO E SULL'USO DEI MANGIMI.

Referenti: Dott.ssa Marina Bellucci (Ufficio I) – Dott. Carmelo Cicero (Ufficio VII)

PARTE I. ASPETTI TECNICO-NORMATIVI DI DIRITTO INTERNO

1) *Obiettivi e necessità dell'intervento normativo. Coerenza con il programma di governo.*

Gli obiettivi perseguiti mediante l'intervento normativo proposto consistono nella determinazione delle sanzioni da applicare in caso di violazione delle prescrizioni stabilite dal Regolamento CE n. 767 del 13 luglio 2009, in adempimento di quanto stabilito dall'art. 31 "Sanzioni", che prevede che *"Gli Stati membri stabiliscono le sanzioni applicabili in caso di violazione delle disposizioni del presente regolamento e adottano le misure necessarie ad assicurare che esse siano applicate. Le sanzioni previste devono essere efficaci, proporzionate e dissuasive"*. Tali sanzioni saranno applicate, sulla base delle condotte punibili e dell'autore della violazione, al responsabile di etichettatura o all'operatore del settore dei mangimi. Saranno previste sanzioni specifiche per l'uso ingannevole di claims e dell'etichettatura facoltativa in genere. Saranno, inoltre, modulate le sanzioni per il mancato rispetto delle tolleranze di etichettatura, a seconda che si tratti di una discrepanza dei tenori analitici (ceneri, fibra etc.) o dei livelli di additivi. Verranno poi previste sanzioni più pesanti per le condotte che compromettono la sicurezza dei mangimi, quali l'immissione sul mercato di mangimi contaminati senza le indicazioni di etichettatura previste o di materiali soggetti a divieto di utilizzo nei mangimi. Ciò in coerenza con la missione e con gli obiettivi di prevenzione e di tutela della salute dell'uomo e degli animali.

2) *Analisi del quadro normativo nazionale.*

L'attuale quadro normativo contempla la legge 15/02/1963 n. 281 *"Disciplina della preparazione e del commercio dei mangimi"* ed il decreto legislativo 24/02/1997 n. 45 *"Attuazione delle direttive 93/74/CEE, 94/39/CE, 95/9/CE e 95/10/CE in materia di alimenti dietetici per animali"*, che già prevedono la disciplina sanzionatoria in materia di etichettatura, ma essa risulta troppo generica e non adeguata per la materia che, con il Regolamento CE n. 767/2009, è stata modernizzata e razionalizzata.

3) ***Incidenza delle norme proposte sulle leggi e i regolamenti vigenti.***

Lo schema di provvedimento in esame disciplina la materia in modo organico, con norme di rango primario, stabilendo le sanzioni da applicare in caso di violazione delle disposizioni previste nel Reg. CE n. 767/2009.

4) ***Analisi della compatibilità dell'intervento con i principi costituzionali.***

Tenuto conto che lo schema di decreto legislativo stabilisce le sanzioni da applicare in caso di violazione delle disposizioni previste nel Reg. CE n. 767/2009, in adempimento dell'art. 31 del medesimo Reg., non si rilevano profili di incompatibilità con i principi costituzionali.

5) ***Analisi delle compatibilità dell'intervento con le competenze e le funzioni delle regioni ordinarie e a statuto speciale nonché degli enti locali.***

Valgono le valutazioni del punto precedente.

6) ***Verifica della compatibilità con i principi di sussidiarietà, differenziazione ed adeguatezza sanciti dall'articolo 118, primo comma, della Costituzione.***

Tenuto conto che lo schema di decreto legislativo stabilisce le sanzioni da applicare in caso di violazione delle disposizioni previste nel Reg. CE n. 767/2009, in adempimento dell'art. 31 del medesimo Reg., non si rilevano profili di incompatibilità con le competenze e le funzioni delle regioni ordinarie e a statuto speciale nonché degli enti locali, né di incompatibilità con i principi di sussidiarietà, di differenziazione e di adeguatezza sanciti dall'articolo 118, primo comma, della Costituzione.

7) ***Verifica dell'assenza di rilegificazioni e della piena utilizzazione delle possibilità di delegificazione e degli strumenti di semplificazione normativa.***

Non sono previste rilegificazioni di norme delegificate.

8) ***Verifica dell'esistenza di progetti di legge vertenti su materia analoga all'esame del Parlamento e relativo stato dell'iter.***

Non sussistono progetti di legge vertenti su materia analoga all'esame del Parlamento.

9) ***Indicazioni delle linee prevalenti della giurisprudenza ovvero della pendenza di giudizi di costituzionalità sul medesimo o analogo oggetto.***

Non sono pendenti giudizi di costituzionalità sul medesimo o analogo oggetto.

PARTE II. CONTESTO NORMATIVO COMUNITARIO E INTERNAZIONALE

10) ***Analisi della compatibilità dell'intervento con l'ordinamento comunitario.***

Il provvedimento legislativo in esame non presenta profili di incompatibilità con l'ordinamento comunitario.

11) ***Verifica dell'esistenza di procedure di infrazione da parte della Commissione Europea sul medesimo o analogo oggetto.***

Non sono state aperte procedure di infrazione nei confronti dell'Italia nella materia in esame.

12) ***Analisi della compatibilità dell'intervento con gli obblighi internazionali.***

Il provvedimento legislativo in esame non presenta profili di incompatibilità con gli obblighi internazionali.

13) ***Indicazioni delle linee prevalenti della giurisprudenza ovvero della pendenza di giudizi innanzi alla Corte di Giustizia delle Comunità Europee sul medesimo o analogo oggetto.***

Non sono pendenti giudizi, innanzi alla Corte di Giustizia delle Comunità europee, sul medesimo o analogo oggetto.

14) ***Indicazioni delle linee prevalenti della giurisprudenza ovvero della pendenza di giudizi innanzi alla Corte Europea dei Diritti dell'uomo sul medesimo o analogo oggetto.***

Non sono pendenti giudizi, innanzi alla Corte europea dei diritti dell'uomo, sul medesimo o analogo oggetto.

15) ***Eventuali indicazioni sulle linee prevalenti della regolamentazione sul medesimo oggetto da parte di altri Stati membri dell'Unione Europea.***

Non si è, ad oggi, a conoscenza di eventuali analoghe iniziative nell'ambito dell'Unione Europea.

PARTE III. ELEMENTI DI QUALITÀ SISTEMATICA E REDAZIONALE DEL TESTO

1) Individuazione delle nuove definizioni normative introdotte dal testo, della loro necessità, della coerenza con quelle già in uso.

Il provvedimento in esame non introduce nuove definizioni.

2) ***Verifica della correttezza dei riferimenti normativi contenuti nel progetto, con particolare riguardo alle successive modificazioni ed integrazioni subite dai medesimi.***

I riferimenti normativi contenuti nel provvedimento in esame sono corretti.

3) ***Ricorso alla tecnica della novella legislativa per introdurre modificazioni ed integrazioni a disposizioni vigenti.***

Il provvedimento all'esame è stato redatto secondo la tecnica della novella legislativa, stabilendo le sanzioni da applicare in caso di violazione delle disposizioni del Reg CE n. 767/2009.

4) ***Individuazione di disposizioni dell'atto normativo aventi effetto retroattivo o di reviviscenza di norme precedentemente abrogate o di interpretazione autentica o derogatorie rispetto alla normativa vigente.***

Il provvedimento in esame non contiene disposizioni aventi effetto retroattivo o di reviviscenza di norme precedentemente abrogate o di interpretazione autentica.

5) ***Verifica della presenza di deleghe aperte sul medesimo oggetto, anche a carattere integrativo o correttivo.***

Non risultano altre deleghe aperte sul medesimo oggetto, anche a carattere integrativo o correttivo.

6) ***Indicazione degli eventuali atti successivi attuativi; verifica della congruenza dei termini previsti per la loro adozione.***

Non è necessaria l'emanazione di successivi atti attuativi.

7) ***Verifica della piena utilizzazione e dell'aggiornamento di dati e di riferimenti statistici attinenti alla materia oggetto del provvedimento, ovvero indicazione della necessità di commissionare all'Istituto nazionale di statistica apposite elaborazioni statistiche con correlata indicazione nella relazione economico-finanziaria della sostenibilità dei relativi costi.***

Non sono state utilizzate statistiche a livello nazionale.

ANALISI DI IMPATTO DELLA REGOLAMENTAZIONE (A.I.R.)
(all. "A" alla Direttiva P.C.M. 16 gennaio 2013)

Referente dell'Amministrazione proponente: Dott.ssa Marina Bellucci (Ufficio I DGSAF) – Dott. Carmelo Cicero (Ufficio VII DGSAF)

Allegato doc. Impact Assessment.

Sezione 1 - Contesto e obiettivi dell'intervento di regolamentazione:

A) la rappresentazione del problema da risolvere e le criticità constatate, anche con riferimento al contesto internazionale ed europeo, nonché delle esigenze sociali ed economiche considerate.

A) la rappresentazione del problema da risolvere e le criticità constatate, anche con riferimento al contesto internazionale ed europeo, nonché delle esigenze sociali ed economiche considerate.

Il quadro normativo vigente, in termini di legislazione sulla disciplina della preparazione e del commercio dei mangimi, va individuato, preliminarmente, nella disciplina generale contenuta nella legge 281, del 1963 e sue successive modifiche, che detta, appunto, regole per la produzione e l'immissione in commercio dei prodotti destinati all'alimentazione degli animali (in particolare, gli articoli 20, 21, 22 e 23 della legge citata delineano il quadro sanzionatorio) e nella disciplina correlata, contenuta nel decreto legislativo n. 45 del 1997, recante "attuazione delle direttive 93/74/CEE, 94/39/CE, 95/9/CE e 95/10/CE in materia di alimenti dietetici per animali" (in particolare, l'articolo 7 del provvedimento prevede sanzioni a carico di chi produce, confeziona, detiene per vendere alimenti dietetici per animali non conformi allo stesso provvedimento e a carico di chi viola le disposizioni previste per l'etichettatura degli stessi prodotti), nonché nella disciplina dettata dal decreto legislativo n. 149 del 2004, recante "attuazione della direttiva 2001/102/CE della direttiva 2001/32/CE, della direttiva 2003/57/CE e della direttiva 2003/100/CE, relative alle sostanze ed ai prodotti indesiderabili nell'alimentazione degli animali".

Tutte le condotte, descritte dal d.lgs. n. 45 del 1997, sono ora disciplinate dal Regolamento (CE) 767/2009 (in particolare, gli obblighi imposti per la commercializzazione di mangimi destinati a particolari fini nutrizionali, le condizioni per l'etichettatura degli alimenti dietetici destinati all'alimentazione animale e le indicazioni che il responsabile dell'immissione in commercio dei prodotti dietetici deve presentare su richiesta dell'autorità competente in merito agli stessi alimenti dietetici).

Pertanto, con il presente decreto, ai fini di una razionalizzazione del quadro normativo, si è ritenuto opportuno abrogare il d.lgs. n. 45 del 1997.

Le sanzioni previste dal presente decreto, per le violazioni in materia di etichettatura dei mangimi dietetici, corrispondono a quelle già previste dal d.lgs. n. 45 del 1997 che si intende abrogare.

In merito alle sanzioni stabilite dalla legge n. 281 del 1963, si rappresenta che, poiché il regolamento (CE) in questione non disciplina l'etichettatura di additivi per mangimi e premiscele, ma soltanto l'etichettatura delle materie prime per mangimi e dei mangimi composti, detta legge rimane in vigore per le sanzioni relative alle violazioni degli obblighi previsti in materia di etichettatura di additivi per mangimi e premiscele.

In materia di etichettatura delle materie prime per mangimi e dei mangimi composti, d'altro canto, il presente decreto, nella maggior parte dei casi, dettaglia le condotte, già individuate, in modo generico, dalla legge n. 281 del 1963, al fine di adeguare le sanzioni per la violazione delle stesse alle fattispecie descritte nel Regolamento (CE) 767/09.

Ad esempio, l'art. 10 del presente decreto sanziona, in maniera specifica, l'uso ingannevole delle allegazioni, una particolare forma di indicazioni facoltative di etichettaturadisciplinata dall'art. 13, del Reg.(CE) 767/09, mentre per l'uso ingannevole di tali indicazioni l'art. 22, comma 3, della legge n. 281/63 sanziona genericamente colui che etichetta con "*indicazioni, dichiarazioni tali da trarre hi inganno l'acquirente* ".

Sempre a titolo di esempio, le sanzioni previste dall'art. 8, commi 3 e 4, della bozza di decreto, riprendono invece sanzioni già stabilite all'art. 22, comma 1, della legge n. 281/63, relative a non conformità di mangimi, accertate a seguito di analisi ufficiali, rispetto alle dichiarazioni ed indicazioni di etichettatura.

Le sanzioni, previste dagli artt. 4, 6, 13, 16, 17, del presente decreto sono introdotte per la prima volta in quanto non previste dalla normativa vigente.

Ad esempio, l'art 13 introduce per la prima *volta* una sanzione per chi etichetta materiali non conformi in violazione dell'art. 20 del Regolamento.

Anche gli artt. 16 e 17, che prevedono sanzioni per un uso non conforme del Catalogo comunitario delle materie prime per mangimi e dei codici Comunitari di buona etichettatura, non erano previste nella norma precedente, poiché sia il Catalogo che i Codici sono strumenti introdotti per la prima volta dal Regolamento.

L'adozione dell'intervento regolatorio risponde all'obbligo, imposto dalla norma comunitaria, di regolamentare, con un atto normativo primario, le sanzioni da applicare in caso di violazione delle prescrizioni stabilite dal Reg. CE n. 767/2009, in adempimento di quanto stabilito dall'art. 31 "Sanzioni", che prevede che "*Gli Stati membri stabiliscono le sanzioni applicabili in caso di violazione delle disposizioni del presente regolamento e adottano le misure necessarie ad assicurare che esse siano applicate. Le sanzioni previste devono essere efficaci, proporzionate e dissuasive*".

L'applicazione del Reg (CE) 767/2009, da parte degli operatori del settore dei mangimi, ed, in particolare, da parte dei responsabili di etichettatura, garantisce

l'immissione sul mercato di mangimi correttamente etichettati, che forniscono all'utilizzatore finale (allevatori di animali da reddito e proprietari di animali da compagnia), un'informazione trasparente e non ingannevole.
Solo grazie a tali informazioni viene assicurato un uso appropriato dei mangimi.

Infatti, un'etichettatura non conforme, può rendere i mangimi, presenti sul mercato, a rischio per gli animali e le persone (ad esempio, dosaggio non corretto degli additivi, mangimi non conformi per i livelli di sostanze indesiderabili non etichettati, mangimi che simulano in maniera ingannevole la funzione di un farmaco o mancata indicazione delle istruzioni di uso).

Inoltre, l'applicazione del regolamento, da parte degli Stati Membri dell'UE, è fondamentale al fine di garantire la correttezza delle prassi commerciali nel libero scambio dei mangimi sul territorio dell'Unione.

Il Regolamento 767/2009 ha quindi razionalizzato e semplificato la normativa comunitaria di etichettatura dei mangimi e, di conseguenza, la disciplina sanzionatoria prevista dalla normativa nazionale deve essere adeguata alle previsioni del Reg.(CE) 767/09, in applicazione dell'art. 31 del suddetto.

Tale disciplina sanzionatoria avrà effetto di deterrenza dal commettere infrazioni al regolamento (CE) 767/2009, evitando che vengano immessi sul mercato mangimi non correttamente etichettati, che possano, pertanto, comportare un rischio per gli animali e per le persone.
Infatti, si. ritiene che il mercato,, per le peculiari caratteristiche di eterogeneità e di vastità, non consenta fenomeni di autoregolamentazione.

Le sanzioni, irrogate ai sensi della legge n. 281/63, riguardano prevalentemente la presenza di sostanze non dichiarate in etichetta o risultanti all'analisi in quantità differenti da quanto dichiarato o la presenza di indicazioni di etichettatura non conformi.

In minima parte vengono sanzionate condotte relative alla vendita o alla preparazione, anche per conto di terzi di materiali vietati per l'alimentazione animale.

I servizi veterinari delle ASL applicano, le sanzioni previste dalla legge n. 281/63, in particolare, in caso di inesattezza o mancanza di indicazioni obbligatorie o quando, dall'analisi ufficiale prevista dal PNAA (piano nazionale di controllo ufficiale sull'alimentazione animale), si rileva una sostanza non dichiarata in etichetta o presente in quantità differenti dal dichiarato (additivi, farmaci, materie prime non dichiarate).
I servizi veterinari delle AA.SS.LL elevano circa 100-120 sanzioni annue per non conformità in etichettatura.
A queste vanno aggiunte quelle elevate dai N.A.S. e dall'ICQRF del MIPAAF, che riguardano prevalentemente non conformità qualitative o di "cartellino", ovvero

presenza di sostanze in quantità differenti dal dichiarato in etichetta (fibre grezze, proteina grezza, oligoelementi, ceneri, *etc.).*

B) l'indicazione degli obiettivi (di breve, medio o lungo periodo) perseguiti con l'intervento normativo,

L'obiettivo, che si persegue con l'intervento regolatorio, considerata la particolarità della materia, è rappresentato nel breve, medio e lungo periodo, dalla necessità di garantire l'etichettatura corretta dei mangimi e di punire comportamenti non coerenti con la nuova disciplina dei mangimi, introdotta dal regolamento (CE) 767/2009; si potrà quindi realizzare un quadro normativo certo, esaustivo,, adeguato e in continuità e coerenza con il quadro sanzionatolo vigente, al fine di garantire la conformità alla normativa in materia di mangimi e di alimenti e alle norme sulla salute e sul benessere degli animali.
L'altro obiettivo che, in coerenza con quanto sopra esposto, si intende perseguire è la tutela della salute del consumatore.
Con l'intervento regolatorio all'esame sarà possibile, per gli operatori pubblici del settore (addetti al controllo ed organi di polizia giudiziaria), irrogare sanzioni specifiche per le fattispecie riscontrate.

Alla luce della funzione di deterrenza, svolta dalle sanzioni pecuniarie, nel lungo periodo si ritiene di giungere ad uno spontaneo rispetto delle norme e ad una consequenziale riduzione dei casi d' irrogazione delle sanzioni

Gli obiettivi perseguiti con l'intervento regolatorio all'esame, sono sia di natura formale, quale l'adeguamento del diritto nazionale agli atti normativi dell'Unione europea, sia di tipo sostanziale quale l'assicurare, con ogni mezzo praticabile, un elevato livello di protezione della salute degli animali e dei consumatori.

In particolare, gli obiettivi che si intendono perseguire sono:
(1) assicurare un livello elevato di protezione della salute degli animali;
(2) ridurre il numero dei sequestri dei prodotti non conformi;
(3) contrastare il commercio illegale.

C) la descrizione degli indicatori che consentiranno di verificare il grado di raggiungimento degli obiettivi indicati e di monitorare l'attuazione dell'intervento
nell'ambito della V'IR.
L'indicatore che consentirà di verificare gli obiettivi prefissati e di monitorare l'intervento regolatolo è rappresentato dalla attesa e progressiva riduzione delle infrazioni che verranno elevate per non conformità.

Il grado di raggiungimento degli obiettivi sarà riscontrato attraverso rilevazioni sia delle non conformità rilevate dagli organi di controllo sia delle sanzioni irrogate.

Considerato che il decreto stabilisce alcune sanzioni prima non previste, è plausibile un iniziale aumento del numero delle sanzioni irrogate.

Nel tempo, si auspica, grazie all'effetto dissuasivo delle sanzioni stesse, una loro progressiva riduzione e, di conseguenza, una miglioramento del livello di conformità dei mangimi nazionali alle previsioni della normativa in materia.

D) l'indicazione delle categorie dei soggetti, pubblici e privati, destinatari dei principali effetti dell'intervengo regolatorio.

Destinatari diretti dell'intervento sono, in particolare:

1. I Ministeri della salute e delle politiche agricole alimentari e forestali;
2. le regioni e le province autonome;
3. le aziende sanitarie locali;
4. le persone responsabili dell'etichettatura dei mangimi, come definite dall'articolo 3, comma 2, lett. a), del regolamento (CE) 767/2009 (persona fisica o giuridica responsabile del rispetto delle disposizioni del presente regolamento nell'impresa nel settore dei mangimi posta sotto il suo controllo);
5. gli operatori del settore dei mangimi;
6. i detentori ed i proprietari di animali da reddito e di animali da compagnia;
7. gli animali e i consumatori, come beneficiari dell'intervento.

Il decreto ha una portata diretta sul settore mangimistico privato, sulle autorità competenti responsabili del controllo ufficiale dei mangimi, sugli allevatori di animali da reddito, sui proprietari di animali da compagnia ed un effetto indiretto sui consumatori di alimenti di origine animale.

Le aziende, che operano nel settore dei mangimi, appartengono a diverse categorie: allevatori, mangimifici, distributori, trasportatori, consorzi, agricoltori, che coltivano materie prime, industrie del settore alimentare che destinano prodotti al settore dei mangimi.

Nel complesso si tratta di circa 350.000 operatori del settore dei mangimi (OSM), registrati o riconosciuti ai sensi col Reg.(CL) 183/2005 sull'igiene dei mangimi.

Tra questi, oltre 120, sono mangimifici industriali iscritti all'Associazione dei produttori di mangimi per animali zootecnici e 32 sono produttori di pet food, iscritti all'Associazione dei produttori di mangimi per animali da compagna.

Questi OSM detengono la maggior parte della produzione industriale di mangimi composti.

Dai dati ISTAT 2011, si rileva che, in Italia, esistono circa 209.000 allevatori di animali produttori di alimenti, che somministrano ai propri animali, sia mangimi acquistati dall'esterno che mangimi autoprodotti in azienda (insilati, foraggi e granelle).

Nel 2012, il comparto mangimistico, costituito dai prodotti completi e complementari, registra una diminuzione dei quantitativi distribuiti, ma anche di quelli prodotti.

La produzione totale dei mangimi completi e complementari risulta pari a 139,4 milioni di quintali.

Dei 93,5 milioni di quintali, corrispondenti al totale dei mangimi completi, prodotti in Italia, 87,9 milioni circa sono prodotti dall'industria e 5,6 da allevatori (i quali producono principalmente per autoconsumo).

La produzione totale dei mangimi complementari, è pari a 45,9 milioni di quintali, di cui 43,3 milioni sono prodotti dall'industria e 2,6 dagli allevatori.

Per quanto riguarda la distribuzione, nel 2012 risultano distribuiti, da industrie e allevatori ,141.8 milioni di quintali di mangimi.

Dei 94,4 milioni di quintali di mangimi completi distribuiti, 88, sono stati distribuiti dall'industria.

Per quanto concerne i mangimi complementari, dei 47,5 milioni di quintali, l'industria ne ha distribuiti 44,8 milioni.

Sotto il profilo territoriale, sia la produzione che la distribuzione dei mangimi si accentra al Nord.

Con riferimento alla produzione, l'84,4 per cento di quella di mangimi completi e il 75,8 dei complementari avviene nel Nord, mentre la distribuzione si concentra al Nord per il 77,9 per cento dei completi e per il 74,4 per cento dei complementari.

Inoltre, in Italia sono presenti circa 60.5 milioni di animali da compagnia, tra cui 7 milioni di cani e 7, 5 milioni di gatti.

Sezione 2 - Procedure di consultazione precedenti l'intervento:

Lo schema di disegno di legge è stato predisposto con il coinvolgimento del Ministero delle politiche agricole alimentari e forestali, del NAS e delle principali Associazioni di categoria. A tal fine, è stata convocata apposita riunione presso il Ministero della Salute in data 23 marzo 2015.

Tutte le Amministrazioni ed Enti coinvolti si sono mostrati favorevoli al decreto, e hanno fornito elementi per una semplificazione e razionalizzazione del testo, oltre che in merito alla proporzionalità degli importi previsti con quelli di sanzioni similari.

Le Associazioni di categoria, che coprono circa l'80% della produzione nazionale di mangimi industriali per animali da compagnia e da reddito, hanno, inoltre, fornito, a seguito della suddetta riunione, 2 documenti contenenti osservazioni alla bozza di decreto sanzionatorio.

Tali osservazioni sono state valutate dagli uffici competenti del Ministero della Salute ed accolte parzialmente o totalmente, ove rispondenti agli obiettivi del decreto.

In particolare, è stata modulata l'entità delle sanzioni, aumentando l'importo di quelle relative a condotte che hanno un impatto diretto sulla sicurezza dei mangimi, quali quelle degli artt. 5 e 13 del provvedimento.

Inoltre, le sanzioni introdotte risultano rispondenti a criteri di stretta analogia, a quanto già previsto per violazioni simili.

In tal senso, si riporta un'apposita tabella di corrispondenza da cui si evince che tutte le norme trovano ispirazione in norme già precedentemente esistenti:

Fattispecie legge 281 del 1963- fattispecie d.lgs. n. 45 del 1997	*Sanzione ex legge 281/63- sanzione ex d.lgs. n. 45 del 1997*	*Fattispecie Regolamento CE n. 767/2009*	*Sanzione ex Decreto legislativo*
Articolo 3, comma 1, d.lgs. n. 45 del 1997	*Art. 7, comma 1, d.lgs. n. 45/1997 (da lire 1.000.000 a lire 6.000.000)*	*Articolo 9*	*Art. 7 (da € 500 a € 3.000)*
Articolo 5, d.lgs. n. 45 del 1997	*Art. 7, comma 2, d.lgs. n. 45/1997 (da lire 500.000 a lire 3.000.000)*	*Articoli 9 e 13*	*Art. 10, comma 1 (da € 1.000 a € 6.000)* *Art. 10, comma 2 (da € 2.000 a € 12.000)*
Articolo 7, comma 3, d.lgs. n. 45 del 1997	*Art. 6, comma 3, d.lgs. n. 45/1997 (da lire 2.000.000 a lire 12.000.000)*	*Questa fattispecie non è prevista dal Reg. CE 767/2009*	
Articolo 21 L. 281/1963	*Articolo 21 L. 281/1963 (da lire 150.000 a lire 1.500.000)*	*Articoli da 15 a 19, 22 e Allegati 2, 5, 6, 7*	*Art. 12 (da € 1.000 a € 6.000)* *Art. 15 (da € 1.000 a € 6.000)*
Articolo 22, comma 1, L. 281/1963, come modificato dalla L. 4/2011	*Articolo 22, comma 1, L. 281/1963 (da € 1.500 a € 15.000)*	*Articolo 11, par. 5 e Allegato IV*	*Articolo 8, commi 3 (da € 500 a € 3.000), 4 (da € 1.000 a € 6.000), 5 (da € 1.500 a € 10.000)*
Articolo 22, comma 2, L. 281/1963, come modificato dalla L. 4/2011	*Articolo 22, comma 2, L. 281/1963 (da € 8.000 a € 30.000)*	*Articolo 6, par. 1 e Allegato III*	*Articolo 5 (da € 5.000 a € 30.000)*
Articolo 22, comma 3, L. 281/1963, come modificato dalla L. 4/2011	*Articolo 22, comma 3, L. 281/1963 (da € 20.000 a € 66.000)*	*Articoli 9, 11, par. 1, e 13*	*Articolo 8, comma 1 (da € 3.000 a € 12.000);* *Art. 10, comma 1 (da € 1.000 a € 6.000)* *Art. 10, comma 2 (da € 2.000 a € 12.000)*
Articolo 22, comma 4 L. 281/1963, come modificato dalla L. 4/2011	*Articolo 22, comma 2, L. 281/1963 (da € 8.000 a € 30.000); Articolo 22, comma 3, L. 281/1963 (da € 20.000 a € 66.000)*	*Questa fattispecie non è prevista dal Reg. CE 767/2009*	
Articolo 23, commi 1 e 2, L. 281/1963, come modificato dalla L. 4/2011	*Articolo 23, commi 1 e 2, L. 281/1963 (Sospensione o chiusura dell'esercizio)*	*In caso di reiterazione e particolare gravità delle condotte previste da tutto il Reg. CE*	*Articolo 18 (Sospensione o revoca della registrazione o del riconoscimento*

Peraltro, per quanto concerne i destinatari pubblici, la consultazione dei medesimi avverrà a livello regionale mediante valutazione in sede di Conferenza Stato-Regioni.

Sezione 3 - Valutazione dell'opzione di non intervento di regolamentazione (opzione zero)

L'opzione di non intervento è stata valutata ed esclusa. Tale opzione di non intervento determinerebbe innanzitutto una procedura di infrazione, ai sensi dell'art. 258 del Trattato di funzionamento dell'Unione europea (già art. 226 TCE); inoltre, tale opzione rischierebbe di vanificare il sistema di sicurezza dei mangimi con conseguente rischio per la tutela della salute pubblica.

In particolare, la tutela specifica precedentemente garantita dalla legge 281/63 e dal d.lgs. n. 45 del 1997, risulta in parte compromessa dalla disapplicazione, per incompatibilità sopravvenuta, di molte disposizioni sanzionatorie della legge medesima. Dall'esame di quest'ultima emerge quanto segue:

1) Le sanzioni previste dall'art. 7 del d.lgs. n. 45/1997 devono ritenersi espressamente abrogate, in quanto superate dall'attuale normativa comunitaria.

2) Le sanzioni previste dalla legge n. 281/1963 sono tuttora applicabili per gli additivi e per le premiscele di additivi, che non sono incluse nel campo di applicazione del Reg. CE 767/2009. In particolare, la sanzione di cui all'articolo 22, comma 4, della L. 281/1963, come modificato dalla L. 4/2011, continua ad essere vigente poiché è destinata in maniera specifica agli allevatori, ai quali non si applicano tutte le disposizioni del Reg. CE 767/2009.

3) L'art. 21, comma 2, della L. 281/1963 è ancora applicabile per il settore dei mangimi medicati e per la vendita di mangimi oltre la data di scadenza che non sono disciplinati dal Reg. CE 767/2009.

4) L'art. 22, comma 2, della L. 281/1963 resta valido per tutte quelle sostanze vietate, non disciplinate dall'art. 6 e dall'Allegato III del Reg. CE 767/2009.

Come è evidente, in molte ipotesi di violazione della normativa comunitaria, in assenza di un intervento si dovrebbe ricorrere a disposizioni sanzionatorie non strettamente aderenti alla fattispecie, con pericolo serio e concreto che molte condotte illegittime non siano sanzionate. *Nonostante l'attività di controllo verrebbe comunque portata avanti, senza l'adozione del provvedimento, nel caso di rilevazione di illeciti, non si potrebbero adottare sanzioni per il responsabile, bensì esclusivamente meri provvedimenti amministrativi (sequestro/ritiro).*

Sezione 4 - Opzioni alternative all'intervento regolatorio

L'amministrazione non ha valutato opzioni alternative, rispetto a quelle di non intervento, considerati gli stringenti criteri posti dal regolamento e, in ogni caso, l'intervento regolatorio rispetta, e non supera, i principi ed i livelli minimi di regolazione previsti dal

regolamento. *In tal senso, l'articolo 31 del regolamento 767/2009 prevede l'adozione di sanzioni effettive, proporzionate e dissuasive.*

Premesso che è necessaria l'adozione di atto avente forza di legge e considerato che evidenti ragioni di chiarezza e certezza del diritto impongono un unico atto che regoli l'intero ambito delle violazioni al Regolamento (CE) 767/2009, si ritiene che il decreto legislativo sia lo strumento più idoneo.

Sezione 5 - Giustificazione dell'opzione regolatoria proposta e valutazione degli oneri amministrativi e dell'impatto sulle PMI:

A) gli svantaggi e i vantaggi dell'opzione prescelta, per i destinatari diretti e indiretti, a breve e a medio-lungo termine, adeguatamente misurati e quantificati, anche con riferimento alla possibile incidenza sulla organizzazione e sulle attività delle pubbliche amministrazioni, evidenziando i relativi vantaggi collettivi netti e le relative fonti di informazione.

L'intervento non presenta svantaggi. L'opzione scelta presenta il vantaggio di perseguire efficacemente comportamenti non corretti che possono incidere sulla tutela della salute pubblica. Per le imprese che agiscono in linea con il regolamento, rappresenta il vantaggio di garantire un corretto sistema di concorrenza, evitando possibili distorsioni del mercato a favore di operatori che agiscono in maniera illecita.

Considerata l'analogia tra quanto proposto con l'intervento regolatorio e le sanzioni precedentemente applicabili, di fatto i potenziali destinatari delle sanzioni opererebbero in una situazione di continuità normativa che non andrebbe ad incidere negativamente sulle loro attività.

Per gli enti addetti al controllo ed ad irrogare sanzioni l'intervento regolatorio non muterebbe l'attuale attribuzione delle competenze e consentirebbe di mantenere la ripartizione tra delitti, contravvenzioni e sanzioni amministrative preesistente.

Non ci sono costi ulteriori per il "sistema sanzioni", in quanto le sanzioni verranno applicate dallo stesso personale attualmente operante presso le Autorità competenti ed attraverso le stesse procedure già applicate.

B) l'individuazione e la stima degli effetti dell'opzione prescelta sulle micro, piccole e medie imprese.

L'intervento regolatorio riguarda attività (sanzionatoria) che già si svolge a legislazione vigente ai sensi della legge n. 281 del 1963 e ai sensi del d.lgs. n. 45 del 1997.

Non si ravvisano costi regolatori rispetto alla precedente normativa (se non un mero adeguamento degli importi delle sanzioni economiche, ampiamente giustificato dal decorso di molti anni dalle previsioni contenute nella legge n. 281 del 1963 e nel d.lgs. n. 45 del 1997). In tal senso, è necessario sottolineare che il divieto di incorrere nelle fattispecie sanzionate non deriva dal decreto, bensì dal regolamento (CE) 767/2009: l'adeguamento

alla normativa vigente in materia di mangimi non può rappresentare un costo regolatorio, essendo un dovere.

Le sanzioni sono diversificate in base alla gravità della violazione commessa valutata sulla base del possibile impatto sulla salute pubblica e degli animali. Si ritiene di non poter diversificare le sanzioni a seconda delle dimensioni dell'impresa.

C) l'indicazione e la stima degli oneri informativi e dei relativi costi amministrativi, introdotti o eliminati a carico di cittadini e imprese. Per onere informativo si intende qualunque adempimento comportante raccolta, elaborazione, trasmissione, conservazione e produzione di informazioni e documenti alla pubblica amministrazione.

Non si introducono oneri informativi nuovi per i cittadini e le imprese considerata la tipologia di intervento sanzionatorio.

Il Regolamento 767/2009 è stato applicato a partire dal 2010, pertanto le aziende hanno già adeguato le etichette alla nuova normativa.

Inoltre, il Regolamento stesso ha previsto delle misure transitorie di adeguamento al fine di rendere questo processo meno oneroso per gli operatori.

Da questo punto di vista, il decreto non comporterà nuovi oneri per le imprese, in quanto l'etichettatura dei mangimi, che le aziende adottano, è già in linea con il Regolamento 767/09.

Anche lo stesso utilizzatore dei mangimi (allevatore o proprietario di animale da compagnia) è oramai uso ad acquistare mangimi, etichettati con le informazioni previste dal regolamento.

Si ritiene, pertanto, che non sussistano oneri informativi per le imprese e per i cittadini.

D) le condizioni e i fattori incidenti sui prevedibili effetti dell'intervento regolatorio, di cui comunque occorre tener conto per l'attuazione (misure di politica economica ed aspetti economici e finanziari suscettibili di incidere in modo significativo sull'attuazione dell'opzione regolatoria prescelta; disponibilità di adeguate risorse amministrative e gestionali; tecnologie utilizzabili, situazioni ambientali e aspetti socio-culturali da considerare per quanto concerne l'attuazione della norma prescelta, ecc.).

L'intervento regolatorio è strutturato e si inserisce nell'ambito delle disposizioni del codice penale e della legge 689/81.

Si rivolge alle imprese dei mangimi, alle ASL, ai NAS nella loro attività di vigilanza, e può essere influenzato, limitatamente alle connesse attività di vigilanza sul territorio, dalla esigenza di rispettare i vincoli di spesa.

Per le ASL l'intervento regolatorio si inserisce nell'ambito di attività già svolte e, pertanto, può darsi immediata attuazione all'intervento proposto.

In definitiva, non c'è impatto erariale negativo, atteso che il sistema dei controlli e dell'irrogazione delle sanzioni rimane invariato e non c'è alcun mutamento di competenza rispetto all'assetto normativo precedente.

Sezione 6 - Incidenza sul corretto funzionamento concorrenziale del mercato e sulla competitività del Paese:

Con l'intervento regolatorio proposto si realizza un migliore funzionamento concorrenziale del paese, anche attraverso una etichettatura che garantisca l'utilizzo corretto del mangime.

Inoltre, una corretta etichettatura del mangime garantisce la trasparenza del prodotto verso l'utilizzatore e l'ottimale funzionamento del mercato.

Sezione 7 - Modalità attuative dell'intervento di regolamentazione:

A) i soggetti responsabili dell'attuazione dell'intervento regolatorio.

I soggetti responsabili dell'intervento regolatorio sono: il Ministero della salute, il Ministero delle politiche agricole alimentari e forestali, le regioni e le province autonome e le ASL.

B) le azioni per la pubblicità e per l'informazione dell'intervento (con esclusione delle forme di pubblicità legale degli atti già previste dall'ordinamento).

E' prevista la pubblicazione sul sito web del Ministero della salute.

C) strumenti e modalità per il controllo e il monitoraggio dell'intervento regolatorio.

Gli strumenti per monitorare l'intervento sono il numero delle sanzioni elevate e il contenzioso derivante dalla contestazione delle sanzioni.

Il soggetto individuato istituzionalmente quale responsabile del controllo e del monitoraggio sulla corretta attuazione dell'intervento di regolamentazione è individuato a livello nazionale nel Ministero della salute e nel Ministero delle politiche agricole alimentari e forestali e a livello territoriale nelle Regioni.

D) i meccanismi eventualmente previsti per la revisione dell'intervento regolatorio.

Non è prevista, nell'intervento regolatorio, la possibilità di procedere con interventi correttivi.

E) gli aspetti prioritari da monitorare in fase di attuazione dell'intervento regolatorio e considerare ai fini della VIR.

Sulla base delle disposizioni contenute nel D.P.C.M. 19 novembre 2009, n. 212, recante la disciplina attuativa della verifica dell'impatto della regolamentazione (VIR), questo Ministero della salute effettuerà la verifica dopo un biennio dalla entrata in vigore dell'intervento delegato, attraverso periodici controlli sul grado di raggiungimento delle

finalità e degli effetti prodotti. Tali verifiche, che vedranno coinvolti anche i destinatari dell'intervento, prenderanno prioritariamente in esame i seguenti aspetti relativi:

- numero delle sanzioni amministrative;
- numero delle sanzioni penali;
- numero dei sequestri effettuati.

Sezione 8 - Rispetto dei livelli minimi di regolazione europea.

L'intervento posto in essere non introduce livelli di regolazione differenti o superiori a quanto già imposto dalle norme comunitarie vigenti in materia e nel rispetto dei parametri stabiliti in quanto le sanzioni previste rispondono ai criteri di effettività, proporzionalità e dissuasività di cui all'art. 31 del Regolamento. L'intervento non supera i livelli minimi di regolazione europea, in quanto attiene a sanzioni che, come noto, sono di competenza degli Stati membri e che ai sensi dell'articolo 25 della Costituzione deve avvenire necessariamente mediante atto avente forza di legge.

COUNCIL OF
THE EUROPEAN UNION

Brussels, 5 March 2008

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ADD 2

Interinstitutional File:
2008/0050 (COD)

AGRILEG 38
CODEC 327

COVER NOTE

from:	Commission
dated:	4 March 2008
Subject:	Commission Staff Working Document - Accompanying document to the Regulation of the European Parliament and of the Council on the placing on the market and use of feed - Impact assessment

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUGARNAU, Director, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: SEC(2008) 276

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 3.3.2008
SEC(2008) 276

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the placing on the market and use of feed

IMPACT ASSESSMENT

{COM(2008) 124 final}
{SEC(2008) 275}

TABLE OF CONTENTS

IMPACT ASSESSMENT

Concerning the draft proposal on the modernisation and simplification of the legislation on the circulation and use of feed

1. EXECUTIVE SUMMARY

In 2005, approximately 5 million EU-farmers raised livestock with a total value of the animal products of 129 billion €, representing 42% of the total agricultural output. Feed is for livestock farmers the most significant cost factor amounting to 47%. Next to the direct on-farm use of feed, the purchase of compound feed is the most significant one in terms of quantity. Import and export of compound feed are both below 1%. The EU-compound feed industry had a turnover of 37 billion € in 2005 and employs approximately 100,000 people directly. The European pet food industry makes a turnover of approximately 9 billion € employing 21,000 people directly in 450 establishments. The pet food is sold to 62 million households in the EU with pets, cats and dogs being the most important species with about 60 millions each.

In the late 1990s, a series of crises concerning human food and animal feed (BSE, dioxin, etc.) exposed weaknesses in the food legislation within the EU. In response, based on the "White Paper on Food Safety" of January 2000, the EU established a system for ensuring a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. In line with the new "farm to fork" approach, feed legislation has been crucial as feed is a sensitive element at the very beginning of the food chain.

Currently, the circulation of feed materials and compound feed is regulated by four main Council Directives and some 50 amending or implementing acts. Whereas the evolution of feed legislation focussing on safety has been intense, the conditions for the circulation of feed, e.g. concerning marketing conditions, labelling or advertising, have received less attention. Indeed some of the relevant legislative requirements date back more than 25 years. The developments both in the feed business and in the legislative environment around the feed sector revealed the need to modernise and simplify the current law in order to;

- achieve legal clarity and a harmonised implementation,
- facilitate smooth functioning of the internal market,
- simplify technical requirements and remove unnecessary administrative burden,
- increase competitiveness of the EU feed and farming sector and
- enable users of feed to make an informed choice without being misled and based on modern labelling principles.

The starting point for the project of revision was an external study published in June 2004 which identified various issues and different policy options to be tackled. Based on this, the Commission launched in November 2005 an Interactive Policy Making online consultation to better identify impacts on the proposed policy options and, more specifically, to gather further information on financial impacts. Expert interviews on the main issues were undertaken to better fulfil the information needs for the impact assessment. The options were constantly being refined with respect to the experience gained in the earlier steps of the project.

The general view of stakeholders during the consultation activities has been that the repeal of the current Directives, with replacement by one concise Regulation, will provide for better clarity, rationality and consistency of enforcement. Whilst there are many issues that need to be addressed, there are four areas which could have major impacts:

Listing of feed materials: The evaluation revealed the need for more feed materials being unambiguously designated and clearly described. The specific characteristics of these materials are essential to ensure the efficacy of the final product. Of most concern are the many feed materials that have emerged over the last decade e.g. the increasingly important co-products of the feed grain and food processing industry or from the bio-fuel industry.

Authorisation procedures for feed: The current legislation still requires a pre-market authorisation procedure for "bio-proteins". There is concern that the pre-market authorisation procedure for bio-proteins is disproportionate in relation to any potential safety concerns. Further, concern has been expressed that in the current legislation emerging feed materials like products from exotic plants do not require any pre-market authorisation.

Labelling of compound feed for food producing animals: On labelling of compound feed for food producing animals, the current legislation requires that feed materials used in compound feeds for animals other than pets be listed with the percentages by weight. This system has been controversial since its introduction. The specific recipe for a compound feed is seen by the industry as intellectual property and having to disclose it would lead to unfair competition.

Labelling of pet food: Concerns have been expressed that the current legislation on the labelling of pet food does not adequately address user needs. This may lead to the customer being confused or misled as to what the feed they give to their pets contains.

For each of these issues different options containing proposals for de-regulation, retaining the status quo and self-regulation have been assessed for their social, environmental and economical impacts. The different options for each policy issue have been compared to identify the preferred options.

The result is a modernisation and simplification package outlining the added value of the new Community act. The combination of the preferred options results -based on the principles of food and feed safety-in a vision for the rules on the circulation of feed that

- simplifies and harmonises the legal framework by one legally clear, stringent and consistent Regulation,
- changes the development of quality-relevant marketing provisions into co-regulation for the stakeholders to encourage entrepreneurial innovation,
- improves market transparency because there will be more feed materials uniformly and better identified in particular with respect to the current unclear situation on emerging feed materials,
- removes the burden of a pre-market authorisation procedure for the current category "bio-proteins", simultaneously highlighting the responsibility of the feed business operator for the safety of the feed in combination with the negative list of prohibited feed materials to be the preferred and proportionate approach for the legislator in his function as risk manager and for the control authorities,
- increases competitiveness and innovation in the EU-feed business because it abstains from the mandatory percentage declaration of feed materials in compound feed and
- improves the appropriateness of pet food labels so that the average pet owner can understand them better and gets the information he needs.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Study on revision of the feed labelling legislation

In 2003 the Commission assigned an external contractor, Civic Consulting, to carry out a study on a revision of certain parts of the feed legislation. The final report[1] entitled "Assessment of the possible adoption of a new proposal recasting legislation on feed labelling and amending the authorisation/withdrawal procedure for some categories of feed materials" was presented in June 2004. The study identified various issues and different policy options for each issue. It included extensive consultation with all parties who are affected by the policy or have a direct interest.

The following stakeholders were contacted in order to contribute:

- competent authorities of the Member States (MS);
- feed producers, including feed industry, traders and related industries;
- feed users;
- consumers of food of animal origin;
- consumers using pet food;
- environmental organisations.

The study was the **starting point for the project** on the revision of the feed legislation.

IPM consultation

In November 2005, the Commission launched with the general public an Interactive Policy Making (**IPM**) online consultation[2] (closing date 16/01/2006) in order to collect information and data on the possible impacts of the main issues under consideration for the revision of the current legislation. The aim of this second round of consultation was to better **identify impacts on the proposed policy options and, more specifically, to gather further information on financial impacts.** 79 responses to the questionnaire were received. From feed producing organisations and companies many responses were -except the address field- identical so they were counted in the evaluation as one in each group, resulting in 58 accounted responses (see table 1). Except for one answer from a competent authority of an EFTA country all responses originate in the EU.

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1 Civic study: http://ec.europa.eu/food/consultations/study_civic_consulting.pdf

2 Link to the explanatory document and the questionnaire: http://ec.europa.eu/food/consultations/index_en.htm

Table 1: IPM responses	N°
Total	58
Competent Authorities	14
Feed producer organisations (EU or national)	34
Feed producing companies	7
Farmer organisations (feed users)	3

Questionnaire on administrative burden

In order to gather information on the implications for MS, of some of the options for revision that had been identified, a questionnaire was sent out in February 2007 with a deadline of 16 March 2007. This focussed on issues relating to administrative costs/burdens, aiming to provide qualitative information on the possible impacts of the various options. The 19 competent authorities returning the questionnaire are listed in Annex 1.

Ad hoc Consultations

Expert interviews on the main issues were undertaken to better fulfil the information needs for the impact assessment (see list in Annex 2). This was particularly important as, in the course of time, some new **options emerged** and others became less relevant. Additionally, the **options** were constantly being **refined** with respect to the experience gained in the earlier steps of the project.

There was also a constructive exchange of views with Switzerland because of the existing agreement EU-Switzerland on trade with agricultural products.

In addition, stakeholder panel discussions on the options were held with the MS in the margins of the Standing Committee on the Food Chain and Animal Health - section animal nutrition (SCoFCAH) in January and February 2007, with the European Food Safety Authority (EFSA) and with other stakeholders (those represented in the Advisory Group on the Food Chain and Animal and Plant Health in March 2007).

Inter-Service Steering Group

A Commission **Inter-Service Steering Group** on the impact assessment was set up, with the participation of the following services: Secretariat General, Enterprise, Trade, Competition and Agriculture. The group started its work on 7 November 2006 and met five times.

General Comment on the Consultation Process

Validation and plausibility tests were undertaken in-house, in the margins of the expert interviews from the competent authorities and the stakeholders. In addition, the impact assessment results were scrutinised by the MS` experts, the experts from different Directorates General represented in the Inter-Service Group and experts from relevant stakeholder groups in the working group of the Advisory Group on the Food Chain and Animal and Plant Health.

Impact Assessment Board

The European Commission Impact Assessment Board examined the draft report on the impact assessment for the modernisation and simplification of the legislation on the circulation of feed in its board meeting on 13 June 2007 and gave its opinion on 15 June 2007. The recommendations were taken on board. The report was further developed and improved, in particular, by explaining that the simplification measures are not jeopardising feed safety and that trade obstacles on the internal market and for imports would be rather removed than added. Further, the choice of the legislative instrument was clearer deduced.

3. PROBLEM IDENTIFICATION

3.1. The European feed sector

Feed can be categorised in:

- feed materials (*direct feeding or incorporated in compound feed)*[3],
- feed additives[4],
- compound feed (*mixture of feed materials and additives)*[5] and
- medicated feed[6].

Feed materials and **compound feed** are by far the most common types of feed used.

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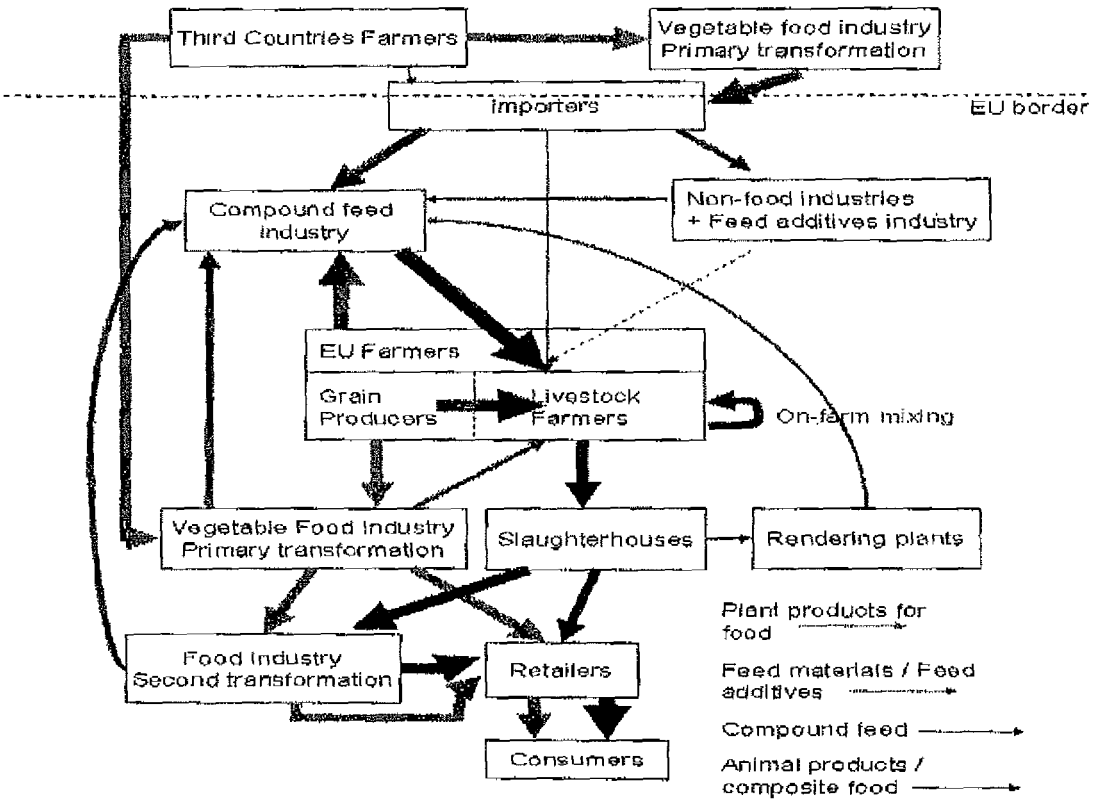
3 Current definition: various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are **intended for use in oral animal feeding either directly** as such, or after processing, in the **preparation of compound feedingstuffs or as carriers of premixtures.**

4 Substances, micro-organisms or preparations -other than feed material and premixtures- which are intentionally added to feed or water **in order to perform certain functions.**

5 Current definition: **mixtures of feed materials,** whether or not containing additives, for oral animal feeding in the form of complete or complementary feedingstuffs.

6 Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and **intended to be fed to animals without further processing,** because of its **curative or preventive properties or other properties as a medicinal product.**

Figure 1 is a flow chart explaining the complexity of the feed industry:



Whereas the general scheme is the same for the feed for farm animals and for pets, the industries are in practice so differently structured that the analysis in this report separates feed for farm animals from pet food which is overwhelmingly compound feed.

3.1.1. *Feed for farm animals*

In 2005, **5.1 million farmers** raised livestock with a total value of **129 billion €** (Table 2). It is increasingly the case that farms contain a single type of livestock and are run by professional, well qualified farmers. They are knowledgeable about feed, both in relation to the effect it has on their livestock but also the feed market and costs. This is not unexpected, as in relation to the rearing of an animal **feed is the most significant cost factor, representing 47%** of the value of EU animal products.

Table 2:[7] **Farmers with husbandry** (EU25, 2005) [Mio]	**5,1**
→ poultry holdings [Mio]	3,3
→ cattle holdings [Mio]	2,4
→ pig holdings [Mio]	1,8
Livestock production (EU25, 2005)	
Value [Mio €]	**129 000**
= Share on total agricultural output	42%
Milk [Mio t]	142
Meat [Mio t]	44,5
→ pork	21
→ poultry	11
→ beef & veal	8
Eggs [Mio t]	6,5

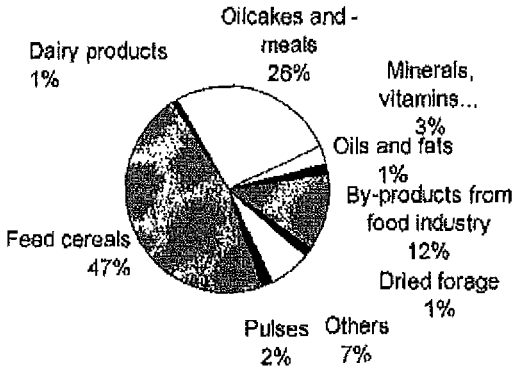
In terms of quantity, about half of the feed used is roughage produced on farm (48%), followed by **purchased compound feed (32%)**, grains produced on farm (11%) and feed materials purchased directly by farmers (9%). To put this in the context of economics, the compound feed market in the EU was worth 37 billion € in 2005 and was estimated to represent about 5% of the total turn-over of the EU food industry. After a period of steady increase, compound feed production has remained stable since the mid-1990's in the EU and currently represents about one quarter of world production. Currently, there is minimal export of compound feed from the EU (below 1 % of total production) with imports estimated to be even lower. Whether this stays the same remains to be seen, not least as whilst the overall market is still small, compound feed production is developing at a fast pace in Brazil (+10% per annum) and China (+5% per annum).

[7] Source: EUROSTAT.

The importance of **innovation** in the feed industry can be seen by the impressive improvements in the efficiency of feeding which have been made over the last decades. The interactions in different fields such as technological progress, improvements in farm management and innovation in the diverse sectors of feed industry have resulted in the feed conversion ratio (FCR) decreasing about 1 percent each year. To put it simply, each year there is a need to use 1% less feed to get the same final product. For example, in 1968 in egg production 3.1 kg of feed had to be fed to have 1 kg of egg, whilst in 2001 only 1.9 kg was necessary. For broiler production, the FCR decreased from 2.3 in 1970 to 1.6 in 2000 and for pork from 3.4 in 1974 to 2.8 in 1995[8]. The trend continues and, in addition to the **economical benefit,** there are also associated environmental benefits i.e. **less effluents** (carbon dioxide, excrements with nitrogen (nitrate/ammonia emissions), phosphorus ...) **per production unit.**

In terms of understanding the feed industry, and more specifically the compound feed industry, it is important to consider the raw materials that are used in their manufacture (Figure 2).

Figure 2: Raw materials of the compound feed industry in 2005 for EU25 (total 142 million t)[9]



Within the feed materials used by compound feed manufacturers, 47% are cereals making compound feed the largest user of home-grown cereals. Further, a significant amount of by-products from the food industry (e.g. sugar beet pulp, brewers' grains or wheat bran) are also used. The protein-rich oilcakes and –meals, representing more than one quarter of compound feed raw materials, are also of interest. Mainly as the EU is only 26% self-sufficient in protein rich feed materials[10] making these products the major portion of the imports of feed materials into the EU (Figure 3).

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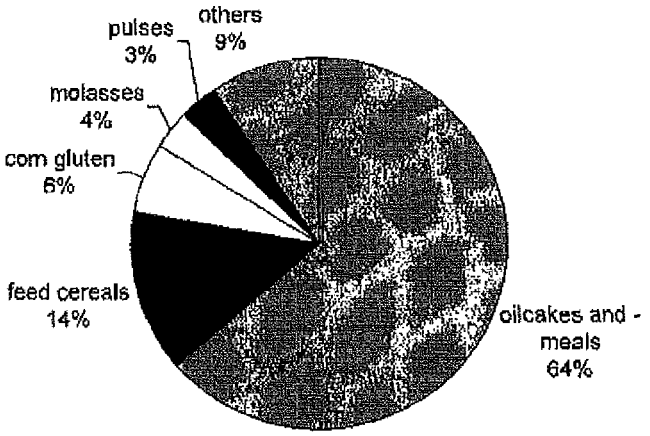
8 Sources: Jahrbuch der Gefluegelwirtschaft (different years); Close, W.H. and Cole, D.J.A. (2000); W.M. Rauw et al. (1998).

9 Source: FEFAC.

10 Source: PROLEA - Filière française des huiles et protéines végétales.

Figure 3: Imports of feed materials in 2005 for EU25 (total 42.5 million t)[11]:



The European feed industry (excluding pet food) offers direct **employment for app. 100.000 people in app. 4.000 plants.** The indirect employment effects in upstream and downstream activities in the feed chain are far greater than the direct employment effects. In the EU roughly 2/3 of the companies are private and 1/3 are cooperatives.

The compound feed production is generally located close to the animal stocks, in other words the production of feed correlates with the livestock in a certain region. Hence, the establishments are often located in rural areas with limited alternative employment opportunities. In 2006, the production share of the MS in descending order was as follows: FR 15% - DE, ES 14% - UK, IT 10% - NL 9% - BE, PL, DK 4% - HU, IE 3% - others (14 MS) 10%. The most significant structural impacts resulting from the evolution in livestock density in the last two decades were a decrease in compound feed production in NL of approximately 20% whereas in ES the production rose by almost 70%.

3.1.2. Feed for pets

About 62 million EU households have pets, of which there are;

- 60 million cats,
- 59 million dogs,
- 35 million birds,

[11] Source: TOEPFER - Alfred C. Toepfer International.

- 40 million others (hamsters, rabbits etc) and
- 9 million aquaria.

Pet owners mainly buy pet food which belongs to the category of **compound feed**. With the European Pet Food Industry Federation (FEDIAF) estimating the size of the EU market at approximately **6 million tonnes of pet food,** produced by around 450 companies, and worth some **9 billion € a year.** In the last few years the market has risen up to 3% per annum. **Direct employment** is estimated to be currently **21.000 people**, and indirect 30.000 people.

The raw materials for pet food are **predominantly by-products from the food** chain which would often have **no or only limited economic value.** These amount to nearly 5 million tonnes per annum and are sourced from slaughter houses or cereal mills.

3.2. The issues

The basic principle is that feed has to be genuine, wholesome and safe according to the European Feed law. It is in the first place the responsibility of the feed business operator to assure this, e.g. by adhering to HACCP. The competent authorities control and monitor these principles. In case a risky feed material becomes obvious it is traced back and the risk is evaluated subsequently. Depending on the outcome of the assessment, the product might be added to the negative list of materials whose circulation is prohibited for animal nutrition purposes. This list was been last amended in comitology by Commission decision 2004/217/EC.

In order to allow a proper evaluation of the provisions for the circulation of feed the following box summarises the principles of labelling:

What is modern labelling about?

Labelling is an important marketing tool which should be viewed as an integral part of communication between societal players (producers to users (businesses or consumers) directly and via intermediaries, authorities to consumers, etc.). Labelling is no longer the only reliable route for communicating information to the consumer, as it once was. Before the development of an information society (internet, free-phone numbers), it was the only way to ensure information reached the consumers. However, markets, product-information gathering habits and consumer expectations have become considerably more complex and ways to communicate information to consumers more sophisticated. Full disclosure of information, even if not all via labels, may be important to allow intermediaries to play their role in the market or for minority information wishes to be addressed.

Consumers benefit from essential information (use-by dates, safety warnings, etc.) as well as from useful information (composition, using instructions, etc.) about products. As such, the label has the role of allowing the consumer to make an informed choice. **For the industry,** labelling is a **powerful tool** which, when used effectively and responsibly, not only ensures operators pass on essential information, but also enables them to highlight the benefits of their products when compared to those of their competitors. If there is additional cost in providing these benefits and an operator needs to convince the consumer to pay a higher price than for competing products on the market.

However, although labelling should be a win-win situation for both the consumer and operator, in practice there is often a market failure and many stakeholders would argue that labelling is not fulfilling its full potential. **Simply put, the effectiveness of labelling as a communication tool can be questioned not least because of legal requirements.** The reasons for this failure are varied, but perhaps start with a simple lack of consumer interest in or capability to understand the information the labels provide.

The developments of the last decades particularly in the feed sector lead to a shift of the key labelling function from protecting the consumer to buy unsafe products to a means to forward information on the quality of the product. Thus, the strategic goals for modern labelling are to

- provide consumers with **necessary** information to enable them to make the optimal choice for his needs (What does the customer want and need to know?)
- be consistent, coherent, transparent and **understandable**
- create a **pro-competitive market environment** in which dynamic, efficient, innovative operators can make full use of the power of labelling to sell their products
- create common framework and rules in order to eliminate barriers to free circulation of goods.

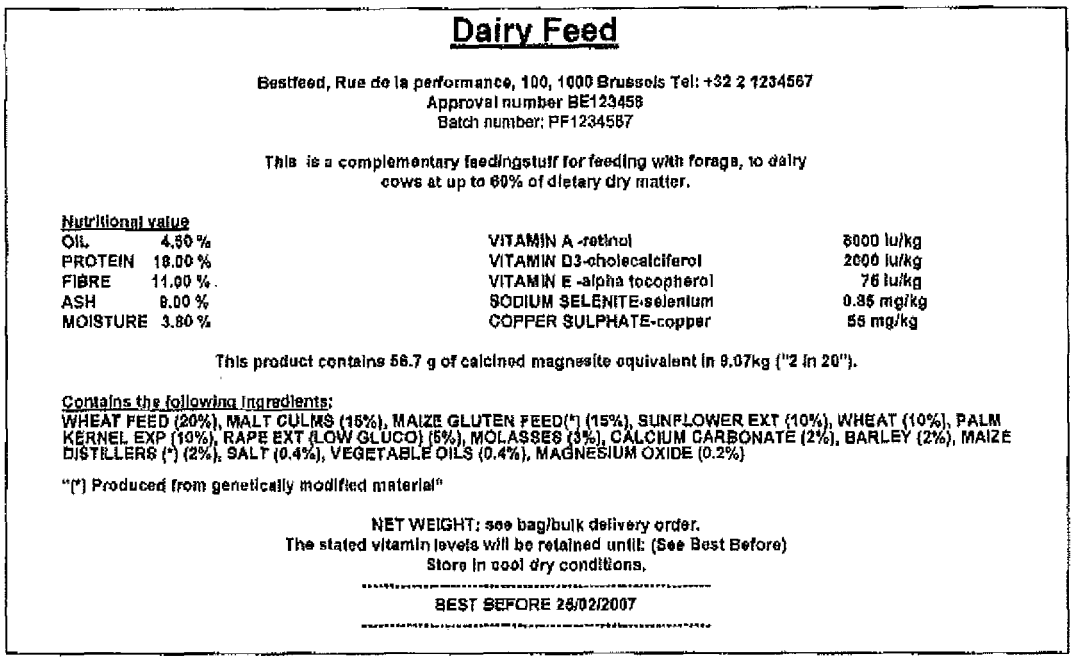
Currently, the circulation of feed materials and compound feed is regulated by a number of legal texts comprising of four main Council Directives[12], two of them dating back more than 25 years, and some 50 amending or implementing acts. Stakeholders claim, with some justification, that the situation has evolved to an extent that the legislation is now so scattered, and contains so many cross references, that it is very **difficult to understand and implement in a uniform way.** However, the issue is not simply one of consolidating current texts as experience over the last few years has identified a number of issues which may need to be amended. This would simplify the legislation, leading to better **clarity, rationality and consistency** of enforcement. In addition, it would remove obstacles and encourage intra-community trade and innovation. In fact, **only 2.6 % of the compound feed produced in the EU goes into the intra community trade.**

The picture below illustrates the current labelling of compound feed. The list "nutritional value" contains the analytical components that are currently regulated in terms of mandatory and voluntary indication but as well nutritional additives like vitamins. The list of "ingredients" indicates the feed materials.

Whilst any revision of the legislation will consider many separate issues, there are only a few for which significant impacts are envisaged. The 'major' issues subject to this impact assessment are

1. Listing of feed materials
2. Authorisation procedures for feed
3. Labelling of compound feed for food producing animals
4. Labelling of pet food.

[12] Directive 79/373/EEC: circulation of compound feedingstuffs; Directive 82/471/EEC: certain products used in animal nutrition ("bio-proteins"); Directive 93/74/EEC: feedingstuffs intended for particular nutritional purposes ("dietetics"); Directive 96/25/EC: circulation and use of feed materials.



Dairy Feed

Bestfeed, Rue de la performance, 100, 1000 Brussels Tel: +32 2 1234567
Approval number BE123456
Batch number: PF1234567

This is a complementary feedingstuff for feeding with forage, to dairy cows at up to 60% of dietary dry matter.

Nutritional value

Oil.	4.50 %	VITAMIN A -retinol	5000 iu/kg
PROTEIN	18.00 %	VITAMIN D3-cholecalciferol	2000 iu/kg
FIBRE	11.00 %	VITAMIN E -alpha tocopherol	75 iu/kg
ASH	8.00 %	SODIUM SELENITE-selenium	0.35 mg/kg
MOISTURE	3.80 %	COPPER SULPHATE-copper	55 mg/kg

This product contains 56.7 g of calcined magnesite equivalent in 9.07kg ("2 in 20").

Contains the following ingredients:
WHEAT FEED (20%), MALT CULMS (15%), MAIZE GLUTEN FEED(*) (15%), SUNFLOWER EXT (10%), WHEAT (10%), PALM KERNEL EXP (10%), RAPE EXT (LOW GLUCO) (5%), MOLASSES (3%), CALCIUM CARBONATE (2%), BARLEY (2%), MAIZE DISTILLERS (*) (2%), SALT (0.4%), VEGETABLE OILS (0.4%), MAGNESIUM OXIDE (0.2%)

"(*) Produced from genetically modified material"

NET WEIGHT: see bag/bulk delivery order.
The stated vitamin levels will be retained until: (See Best Before)
Store in cool dry conditions.

BEST BEFORE 28/02/2007

The following 'minor' issues relate to undisputed, smaller simplification projects or updating and clarifying the legal texts:

- Existing 12 derogations from the labelling requirements: Harmonised application of the legislation by maintaining the flexibility of the industry and abolishing not practice-relevant derogations.
- Basic labelling requirements for feed materials and compound feedingstuffs: Simplification by alignment of general labelling provisions.
- Borderline premixtures - complementary feed: clarification in order to assure adequate use of the products.
- Labelling of feed additives and premixtures: Revision of Art. 16 of Regulation 1831/2003 in order to allow a proper labelling of these products.
- Status of water: Legal clarification in order to harmonise implementation.
- Analytical constituents to label: Simplification and modernisation aiming to release issue into self regulation.
- Methods for the determination of analytical constituents: Harmonisation of analytical constituents labelling by inducing the elaboration of codes of conduct.

- Tolerances for values labelled: Simplification of the extremely detailed and complicated settings.

- Rules for circulation dietetic feed: Updated and streamlined in order to take into account legal developments (i.e. General Food Law Regulation 178/2002).

- Claims and advertising of feed: Enable buyers to make an informed choice without being misled, enhance fair competition.

3.2.1. Issue 1: Listing of feed materials

Summary

It is important to have **unambiguous designations and clear descriptions** for the feed materials that are used to produce compound feed or that are directly fed to animals. The specific characteristics of these materials are essential to ensure the efficacy of the final product. Whilst such designations/descriptions are available for many feed materials, the listings are by no means exhaustive. Indeed, the way that the current legislation has evolved has led to a complex situation with what many would describe as an inconsistent and incoherent approach.

Of most concern are the many feed materials that have emerged over the last decade e.g. co-products of the feed grain and food processing industry or from the bio-fuel industry. Although potentially of significant benefit to the feed users, lack of clear designations and descriptions contribute to an under-utilisation of these materials because of feed users not being willing to take the risk of inserting feed materials for which there are no clear specifications. On the other hand, the trend of an **increasing supply in co-products** for feed rations will continue due to the stronger **competition between feed, food and fuel** for the raw materials (base grains). The use of the base grains for feed has normally a low substitution value.

Background

Currently there are two lists of **feed materials with unambiguous designations and clear descriptions** (but with different provisions) in the legislation:

- **A list** of some **160 feed materials in Directive 96/25.** The list has not been updated since 1998. It is not exhaustive and consequently **other feed materials, which are not as well specified** in terms of designation and properties, **can be incorporated in feed.**

- A positive list of **bio-proteins** with **authorised products** which act as protein source and have been obtained from technological processes (e.g. inactivated yeast cultivated on substrates of vegetable origin).

The "wheat feed" e.g. indicated in the above specimen label is listed as 1.25 in the current non-exhaustive list and described as "by-product of flour manufacture, obtained from screened grains of wheat or dehusked spelt". It consists principally of fragments of the outer skins and of particles of grain from which less of the endosperm has been removed than in wheat bran. If wheat feed is placed on the market, the crude fibre content has to be labelled. Thus, it can be distinguished from wheat middlings (1.24), wheat bran (1.26) or wheat germ (1.27). Similarly, the labelled "palm kernel exp(peller)" (2.12) can be distinguished from "palm kernel, extracted" (2.13).

Thus, many feed materials that have emerged on the market over recent years are not listed and only **poorly specified.** In addition there will be more materials emerging with the continued expansion and incorporation of the **co-products** of the feed grain and food processing industry into livestock diets. The expansion and incorporation of the **co-products** of the feed grain and food processing industry into livestock diets has exhibited **huge growth** representing a top-ten-development in animal nutrition in the recent decade.[13]

The significance of co-products from biofuel production:

The production of **bioethanol** in the EU increased from 528 million litres in 2004 to 913 million litres in 2005[14]. Depending on the production procedure, producing 1 litre of bioethanol by-products about **0.7 to 1.1 kg** of dried distillers' grains with solubles (**DDGS**).

The production of **biodiesel** in the EU increased from 2004 to 2005 by 65% to reach 3.2 million tonnes[15]. For 2006 an increase of 30% is forecast. From 1 kg raw plant oil used for the biodiesel production about 0.1 kg of **glycerol** is received as by-product in addition to the expeller feed (residue of pressing the oil seed grains to obtain the oil).

The appearance of factories that are utilizing cereal grains and oilseeds bring with them the opportunity for abundant co-products. Ongoing research is expanding our understanding of the levels of inclusion, variation in composition, and impacts on metabolism that accompany the greater utilisation of these products will bring. Likewise, as the cost for the base grains (rapeseed, corn, soybeans) that the co-products originate from increase, producers will increasingly look to co-products to fill the void that higher priced feed grains leave. **Different substrates** e.g. sugar beet, grains or residues of the food industry with **different production processes** entail **different processing aids** with consequences for the composition of the co-product for animal nutrition.

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13 Source: M. Hersom (2007).

14 Source: European Bioethanol Fuel Association (ebio).

15 Source: European Biodiesel Board (EBB).

A further challenge created by **co-products** is that by their very nature they tend to **concentrate nutrients, particularly minerals and protein**. Mineral imbalances associated with cereal grain co-products are an important consideration when including co-products in the diets of our livestock. Increasing regulatory oversight on the application of animal manures onto land could lead to limitations on the amount and type of co-products utilised in livestock rations. Finally, the increasing availability for many of the current co-products will lead to expansion of the use of other products such as feed additives to supplement their properties.

3.2.2. *Issue 2: Authorisation procedures for feed*

Summary

Currently pre-market authorisation procedures are required for certain categories of feed – feed additives, the pharmaceutical component of medicated feed, genetically modified feed, dietetic feed and bio-proteins[16]. For the latter, the range of materials included in this category has changed with the entry into force of the Regulation on feed additives. With this change there is now concern that the **pre-market authorisation procedure for bio-proteins** is too onerous and is disproportionate in relation to any potential safety concerns. The effect of this being that the feed industry is not utilising new sources of bio-protein from within the EU because of the effort required to gain approval. Hence the current situation where there is only 26% self-sufficiency for protein rich feed materials in the EU25.

Further, concern has been expressed that in the current legislation **emerging feed materials** (e.g. products from exotic plants) **do not require any pre-market authorisation**. Whilst there is a priori no evidence that such products provide any safety concerns, they are often circulated without clear product identity. Consequently the need to consider a consistent system of authorisation/notification has been raised. Not the least as having nothing at all is seen as having legislation which is inconsistent, i.e. some materials need authorisation and some do not.

Background

The bio-protein Directive came into force in 1982 to cope with the **rising demand in protein rich feed**. Though products falling under the scope of this Directive have in several categories (yeasts, ammonium salts, by-products from amino acid production) reached some significance, the **self-sufficiency** in the EU25 **in protein rich feed materials is still only 26%** (see 3.1.1). The most significant imported protein rich feed materials are soybean meal and corn gluten which are to a large extend produced from genetically modified organisms (GMOs).

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16 Protein-rich products manufactured by certain technical processes.

In view of this 'lack' of self-sufficiency, it would have been expected that the European industry would seek to have new sources of bio-proteins authorised. However, since 1990 only four bio-proteins that meet the new definition have been authorised. Considering the increasing significance of co-products for feed use there is are potentially more bio-proteins to be incorporated in feed. Stakeholders have indicated that at least part of the problem is the current burdensome application procedure, this requiring a dossier that includes studies on laboratory and target animals which has then to be assessed by the European Food Safety Authority (EFSA). In simple terms, this system is hindering a broader use of bio-proteins. For example, currently the producer of a certain nutritional yeast, which has been used for many years as a food ingredient, intends to market it as feed material. Because of the cumbersome and expensive authorisation procedure required under the bio-protein directive the circulation is not yet authorised and therefore he can not sell it in the EU.

Another issue relating to authorisations is the request that for **some emerging feed** materials ("functional", "exotic" feed or feed produced with new technologies) a **risk assessment** should be needed. Concrete examples for "functional" feed are oligosaccharides (indigestible carbohydrates with positive regulatory effects on the gut flora) and for exotic/unconventional feed are the fruit of morinda citrifolia (Noni) or algae meals. Further the current lack of information on the production process and the properties (see 3.2.1) for some of these products, 54% of the responses in the IPM stakeholder consultation unveiled a possible **need for a kind of authorisation procedure.**

The feed material 'meat- and bone-meal' (MBM) has been banned to farm animals in the BSE-legislation. The state of play concerning a possible re-authorisation is given in the following box. The issue of a revision of the feed ban is not covered by this impact assessment.

MBM-Ban: A ban on the feeding of mammalian MBM to cattle, sheep and goats was introduced as of July 1994. This partial ban was extended to a total EU wide suspension on the use of processed animal protein in feeds for any animals farmed for the production of food on 1 January 2001 with some exceptions like the use of fish meal for non-ruminants.

The starting point when revising the current feed ban provisions should take into account the control tools. Further improvement in differentiating animal proteins specific to certain species may result in an amendment of the provisions with regard to the use in feedingstuffs of animal products, in particular non-ruminant proteins taking into account the prohibition on intra-species recycling. Differential tests are not yet practical mainly because the mandatory treatment of mammalian proteins (133°C, 3 bars during 20 min.) results in very small fragments of animal proteins.

3.2.3. *Issue 3: Labelling of compound feed for food producing animals*

Summary

The legislation currently requires that **feed materials used in compound feeds** for animals other than pets be listed, in descending order, with the percentages by weight with a tolerance of +/- 15%. This labelling requirement, the so-called "open declaration", has been a controversial measure since its introduction. The specific recipe for a compound feed is essentially seen by the industry as intellectual property and having to disclose it means that competitors (be they in the EU or elsewhere) can easily take advantage of the investment that has been made in product development. Consequently the open declaration is seen by many as a disincentive to invest in research and development of new, improved feeds.

The current labelling rules are also problematic with regards to the indication of **feed additives on the labels of compound feed**. Other than feed materials, the evolution of the legislation on additives has led to the situation where some need to be labelled and others do not. The additive labelling in compound feed is still governed by an Article in the old additive Directive which is complicated, formulated and outdated. In the authorisation act of a feed additive, particular provisions can be laid down as well for its labelling in compound feed. Thus, the principles for the general labelling provisions for additives in compound feed could be streamlined.

Background

The Commission report of 20 December 2006[17] portrayed a divergent picture on the implementation of the so called "open declaration" within the EU: the application of the percentage declaration being suspended by national court decision in several MS. In one MS, the suspension only covered companies that initiated court cases. Another group of MS had decided to be flexible when carrying out official checks and even not to impose penalties on operators in cases of infringement of the quantitative labelling obligations. The majority of these MS have transposed the open declaration as a consequence of the Court ruling of 6 December 2005. There is thus one group of MS that have transposed and enforced the provisions of the "open declaration" directly; they foresee fines if non-compliance is detected.

[17] Report from the Commission to the Council and the European Parliament on the implementation of the measures introduced by Directive 2002/2/EC amending Directive 79/373/EEC on the circulation of compound feedingstuffs (COM(2006) 839 final).

The system was introduced to increase feed safety in an era when several feed scandals (e.g. the BSE and dioxin crisis) highlighted the limitations of the old provisions which **required just indicating categories and not the exact feed materials.** However, subsequently great efforts concerning manufacture, handling, transport and storage of feed materials have been devoted to improve the safety of feed materials and food. This has to be seen in the context of the implementation of the principles in the General Food/Feed Law and in particular the feed hygiene Regulation[18]. On top of this, several farmer organisations criticise the negative effect of the percentage declaration on production costs and even deny the advantage in terms of product information. Therefore the value added of the percentage declaration taking into account the current feed safety system can be doubted.

Further, the industry complains strongly that the indication of the percentage declaration of all feed materials in a compound feed requests the disclosure of their recipes. The companies' **know how would not be protected** properly and competitors could easily take advantage of their investment in product development. Industry claims that the investment in research and development (R&D) in the EU amounts to 1-1.5 billion € per year. It has to be taken into account that this value includes next to private (industry) as well public (universities, institutes) R&D. Whilst only a part relates to the composition of the compound feed, the industry claims that this is a significant part.

According to a FEFAC-survey covering 9 compound feed companies representing 18% of the EU-production the R&D-spending for laboratory analysis, product development and employment of nutritionists varied in 2006 between 2.5 and 44 million € per company. The average of 8.4 million € per company amounts to approximately 2€ per ton (for information: in 2004 the average turn-over per ton was 255€). This would result in R&D-spending of the compound feed industry to reach 300 million € per year.

The obligation generally to indicate the percentage of all feed materials would **weaken the competitiveness of the European feed industry and hinder further research and development** in the sector. Though there is a tolerance of +/- 15% for the industry in the percentage declaration the flexibility to change the composition of the compound feed. Taking into account that the innovation in the industry according to their announcements resulted in a well filled pipeline for new products (e.g. feed that improves the nutritional value of the animal product or feed with salmonella insensitive raw materials) the disclosure of the recipes for these would heavily harm the EU industries.

Finally, the critics in the declaration of a percentage allowing a tolerance of +/-15% led to a new ECJ-case (C-421/06), explicitly attacking this as being misleading to the customer.

[18] Regulations (EC) N°178/2002 and N° 183/2005.

To conclude, considering the value added of the percentage declaration in the current regulatory environment, the adherence to the principle of proportionality could be scrutinised.

3.2.4. *Issue 4: Labelling of pet food*

Summary

Concerns have been expressed that the current legislation on the labelling of pet foods does not adequately address customer needs with respect to information on the specific components of the final product. This may lead to the customer being confused, or at worse misled, as to what the feed they give to their pets contains. Further with a focus on empowering the customer to an informed choice, the average pet owner seems to be swamped by labelling technical designations be it for feed materials or for additives. Whilst it is MS that have tended to highlight this issue, there is also evidence from the industry that this is an area where there is consumer interest and where there may be a need to reflect again on the current rules.

Background

Whereas legal provisions on circulation and labelling for feed for food producing animals have to focus in the first place on the safety of the animal products, for pet food apart from the necessity that it shall not harm to animal health the focus is to **prevent giving the consumer misleading information.** In the case of compound feedingstuffs intended for pets, the indication of the specific name of the feed material may be replaced by the name of the category to which the material belongs. So instead of e.g. **"pig lungs"** the label may show **"meat and animal derivatives".** Further, it is permitted to draw attention to one ingredient which is essential for characterising the feed. In such a case, the minimum or maximum content is expressed in terms of percentage by weight of the feed material. Frequently in practice, the minimum for an ingredient which is appreciated by the customer is indicated. A consumer wanting to buy feed for dogs, for example, **"with 4% minimum of beef"**, will know his dog food **contains some 4% of beef but will not know** that the product may contain some **30% of chicken by-products.**

Another general issue is what type of information pet food users want to see or do not want to see on labels. The labels tend to be overloaded. Further, as there is only a limited amount of space on labels the prioritisation as to what should go on a label or is better provided elsewhere (i.e. off-pack) is difficult. It has to be taken into account that there is difference between the well qualified farmer and the average **purchaser of pet food, the latter usually not being so acquainted with the technical details of animal nutrition.** Another issue is that the declaration of certain constituents, e.g. the crude ash content on dog food, confuses a considerable number of customers. On the strength of experience gained from customer hotlines of the pet food industry, and the consultations carried out, the labelling of pet food re composition (feed materials and additives) is to a certain extent seen as too complex. Put simply: too much information that is hardly understandable for the average pet owner.

Market research – customer attitudes

FEDIAF gathered data from 36 pet food manufacturers about the topics raised via the customers care hotlines. In a time span of 3 years 150000 consumer questions were analysed. The main areas of interest for the pet owners contacting the pet food industry were about general topics or marketing measures – only 4 % asked for the composition of the pet food. But this figure does not yet give a precise picture what information the average customer wants to see on the package.

Additionally, the results of a PFMA[19] (UK pet food industry) gave interesting insight in consumer issues: Irrespective the objective quality of a product, the survey unveiled for the pet food customers a clear link between familiarity with certain components and attractiveness or rejection. E.g. only 9% of the dry pet food buyers were familiar with the qualitative irreproachable feed material "decorticated rapeseed expeller" and 51% were at least quite worried about its use in pet food. Similarly only 7% of wet pet food buyers were familiar with the trace element cobaltous nitrate; consequently only 9% were happy to have it in their pet food and 45% stated concerns against it. The importance that the label must be understandable became evident for several technical designations.

Similarly, but going beyond the pure aspect of familiarity, the issue of animal by-products shows interesting facades: The pet food industry sources huge amounts of different animal parts from different species and can label them in the compound feed as "meat or animal derivatives". According to the market research, 73% of the customers are quite happy if this category is used in their wet pet food and only 22% stated worries. Hence, if confronted with the concrete products under this category many customers were worried against animal by-products such as chicken heads and feet (56%), ground pork bones (51%) or chicken viscera (48%). This can not be just explained by unfamiliarity but indicates a clear resentment against these parts of animals even if they are authorised as feedingstuffs and of good hygienic and nutritional quality.

According to the above mentioned survey only 19% of the pet food buyers think it would be important to have all additives listed on the label.

3.3. The right of the Union to act – Subsidiarity test

As the project refers to a revision of existing legislation (four Directives) the problem at issue and the objectives pursued by the Union have been already defined. Articles 37, 95 and 152 of the Treaty provide the legal basis for the EU legislative measures on feed. The core of the community action is setting the conditions for the **circulation of feed within the EU which can not be appropriately addressed by MS alone** if the common internal market shall function smoothly (n.b.: only 2.6% of the compound feed goes into intra-community trade). The Treaty confers this kind of approximation of laws to the Union, in particular Article 95. Further, the Union has the right to act in the frame of the production conditions for the European agriculture

[19] Survey of 326 nationally representative pet owners in home and 349 shoppers in the pet food aisle of supermarkets undertaken by Conquest.

(Article 37) considering that the feed is the most significant cost factor (47% of the output) in animal production which represents 42 % of the total agricultural output.

Chapter 3.2 explains to which extent the situation has changed since the establishment of the current legislation in order to detect the policy issues where community action can create added value. The project shall harmonise the regulatory framework for the circulation of feed. Under the prerequisite of ensuring feed/food safety it is scrutinised for each envisaged option if it is proportionate in comparing the expected benefit with the drawbacks. Respective added-value and boundary tests are undertaken once the options are compared in chapter 7.

A fully harmonised legislation on the circulation of feed will ease the feed recalls after detection of a risk. To date e.g. the recall due to hormone-contaminated feed (sugar syrup contaminated with Medroxy-Progesteron Acetate) in 2002 caused only in the Netherlands being the most affected country direct costs of 43 million €, 44% of which represents the value of destroyed food and feed and 31% the cost of destruction.

In light of the different elements outlined in chapter 3, EU action is justified as experience shows that MS can not achieve particularly a harmonised common market satisfactorily and that the **EU can do better and more efficiently** for the competitiveness of the European feed business and livestock farming.

4. OBJECTIVES

The project is included in the rolling programme of simplification. Thus, the objectives are linked to the Commission's strategic objectives and the initiative Better Regulation for improving the implementation of legislation, facilitating innovation, fostering entrepreneurship and investments especially in relation to small and medium sized enterprises (SMEs)[20,21]. Therefore, the **general objectives** are to consolidate, revise and modernise the Directives on the circulation and labelling of feed materials and compound feed in order to:

- achieve legal clarity and a harmonised implementation,
- facilitate smooth functioning of the internal market,
- simplify technical requirements and remove unnecessary administrative burden,
- increase competitiveness of the EU feed and farming sector and
- enable users of feed to make an informed choice without being misled via modern labelling.

The **operational objectives** focussing on the issues raised in Chapter 3 are

- for listing feed materials: the smooth functioning of the internal market by clear designations and proper information of the customer;
- concerning authorisation procedures: ensuring procedures are proportionate to risk and to assure that emerging feed materials are safe and adequately specified for a proper use;
- for compound farm animal feed labelling: Increase innovation and competitiveness by reducing unnecessary labelling requirements and further to update the labelling of feed additives, modernise the labelling framework;
- for pet food labelling: Improve the appropriateness of the pet food labels and modernise the provisions to enable the purchaser of the pet food to an informed choice and to prevent misleading labelling.

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20 Strategic objectives 2005-2009, Europe 2010: A Partnership for European Renewal; Prosperity, Solidarity and Security; Communication from the President in agreement with Vice-President Wallström; COM (2005) 12 final.

21 First progress report on the strategy for the simplification of the regulatory environment (COM (2006) 690 final); A follow-up to the October 2005 Communication COM (2005) 535 "Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment" and a complement to the Communication on the "Strategic review of Better Regulation in the European Union".

Aiming at simplification embedded in the Better Regulation strategy, self-regulation and de-regulation should be envisaged. There is a consensus that self-regulation on provisions for circulation (labelling, advertising) can only maximise its potential in a clear legislative framework which allows self-regulation sufficient scope to operate.

The label serves on the one hand for enforcement, traceability and control purposes and on the other hand to pass information to the user. Being the crucial mean of communication between vender and purchaser labelling should be as simple and clear as possible. The mandatory requirements should be checked against what is necessary to enable the average user to an informed choice. Hence, the concrete options shall consider the level of education of the purchaser to guarantee he understands the information given on the label. As users` demands change the measures should foresee flexibility for the vender to adapt accordingly the labels not being forced to wait for an update of the legislation.

5. MAJOR POLICY ISSUES

The **baseline** of doing nothing would maintain the current situation with complex and scattered legislation perpetuating the following negative effects:

- Heterogeneous and suboptimal product identification for a significant amount of feed materials resulting in different labelling for compound feed throughout the MS hampering the smooth functioning of the internal market because of the (n.b. that only 2,6% of the compound feed production goes into intra-community trade).
- Suboptimal use of new feedingstuffs e.g. co-products from the bio-fuel industry because of missing product identification.
- Unnecessary administrative burden for the industry e.g. for the authorisation of certain feed materials like inactivated yeasts.
- No good information to the pet food user because they can usually not understand the currently mandatory technical designations e.g. for the content of retinol (= vitamin A for which a maximum level has to be respected).

This outlook confirms the justification of EU-action mentioned in the chapter on subsidiarity (3.3).

The proposal for the new legislation is intended to amend and replace provisions already in place under the current four main Directives. For the following reasons, the impact assessment resulted in choosing as a legal act **one single Regulation**:

1. *Scattered legislation*

   Over time, the Community has developed extensive requirements relating to the circulation of feed with many cross references within each other. However, the requirements were either adopted as a scattered response to the needs of the Internal Market or the Communities objective to increase feed and food safety. This has resulted in a series of different regimes, which can only be justified for historical reasons.

2. *No uniform classification of products*

   Further, the national implementation of the Directives lead and is still leading to disharmonised marketing conditions resulting in barriers in internal EU-trade as proved by several ECJ-cases (see example down below). Concerning "complementary feedingstuffs" the definition in Directive 79/373/EEC gave rise to application problems in various MS. A more precise, directly applicable definition laid down in a Regulation would help a uniform application of the legislation within the MS.

Case 145/02:

Two MS (NL and DE) applied the Directive differently as regards the permitted level of vitamin D3 in complementary feedingstuffs which gave rise to obstacles to the free circulation. The Court ruled (13/1/2005) that Art. 12 and 19 of Dir. 70/524/EEC preclude the adoption by MS of a national measure prohibiting the marketing within its territory of a supplementary feedingstuff lawfully manufactured in another MS in accordance with Art.12(1) of Dir. 70/524 on grounds of its vitamin D level.

The issue of different qualifications of certain feed with significant implications on the rules for circulation is chronically and emergently preoccupying businesses, national and EU-authorities including the Courts. Some recent examples are the phytosterols, glycosamine and chrondroitin regarded in some MS as feed and in others as additives or veterinary drugs thus hampering the free circulation within the EU. A uniform classification is hindered as long as the Community rules are laid down in Directives. E.g. in the Case 211/03, the ECJ ruled that a MS is free to qualify a product as a drug even if another MS classifies it as food.

3. *Clear request in consultation for Regulation*

According to the Commission simplification communication (COM(2005)535) the use of Regulations supports generally to simplify because it guarantees that all actors have to follow at the same time the same rules. This notice was reflected in concrete in the consultation process by vast majority of stakeholders, explicitly in the CIVIC study[22] and the IPM[23].

4. *Call for harmonisation concerning national derogations*

Directives 79/373/EEC and 96/25/EC contain 12 derogations from the general labelling requirements which are not applied in the same way by all the MS (see box below). In addition to problems to the free circulation (different labelling requirements from one MS to another one), this causes also lack of transparency throughout the whole feed chain.

[22] About 3/4 of the feed users stated one Regulation to be "very or fairly beneficial". 2/3 of the competent authorities rated in the same way and the support from the feed producers was even 94%.

[23] The stakeholders stated one Regulation to be very or fairly beneficial in terms of fair competition (82%) and of food and feed safety (64%).

Art 5(4) of Dir 79/373: MS may, for feedingstuffs produced and marketed in their territories:
(a) permit the particulars specified in paragraph 1 (b) to (f) and (h) (species for which is intended, directions of proper use, declaration of feed materials, analytical constituents, compulsory declarations) to be shown only in an accompanying document; (b) prescribe an official code number enabling the manufacturer to be identified where the latter is not responsible for the labelling particulars.

5. *Delay in transposition of MS*

The authorisation acts for bio-proteins or dietetics are Commission Directives with the problem of delayed transpositions by MS and consequent infringement procedures to launch by Commission to assure the free circulation of goods.

6. *Move in feed law to Regulations*

The various amendments made in the past years to the Directives concerned were actually drafted in such a way that no real "marge de manoeuvre" was left to the Member States for the transposition (e.g. Directive 2002/2/EC), thus being more "Regulation-like" than in the spirit of Directives. The aim was precisely to avoid divergences in the application by MS. For several years, Community legislation in the field of animal nutrition is drafted in this way, responding to the need of legal certainty wanted by the operators and also by MS (e.g. Regulations (EC) Numbers 1831/2003, 882/2004 or 183/2005).

To resume, a new comprehensive Regulation would introduce consistency and clarity throughout the EU feed sector.

Scrutinised against the principle of subsidiarity, community action in this field is seen to be crucial for the smooth functioning of the internal market and to boost competitiveness of the sector. Thus, the modernisation elements of the project should improve the market conditions for feed whereas the simplification focuses on removal of disproportionate requirements and the legal clarity, rationality and consistency.

The following major policy issues were the subject for the impact assessment:

1. Listing of feed materials.
2. Authorisation procedures for feed.
3. Labelling of compound feed for food producing animals.
4. Labelling of pet food.

5.1. **Policy issue 1 - Listing of feed materials**

Option 1: Deletion of the non-exclusive list of feed materials (de-regulation):

As the current EU legislation allows the incorporation in compound feed of feed materials not listed the value of conserving this list can be questioned. The legislator would maintain a right to act on a case by case decision for products with a possible safety risk by means of the negative list with forbidden products.

Option 2: Retention of the *status quo*:

The current list with some 160 feed materials will be transferred to any new legislation.

Option 3: Extending the current non-exclusive list of feed materials:

The current list will be transferred to any new legislation but new feed materials will be added using the comitology procedure on the basis of notifications by the MS and stakeholders.

Option 4: Elaboration of an EU-list of feed materials by stakeholders (self-regulation)

The current lists are retained in form of an Annex until the industry produces its own comprehensive, voluntary list comprising designation, description including production procedure if appropriate and analytical constituents to be labelled.

5.2. **Policy issue 2 – Authorisation procedures for feed**

5.2.1. Sub-options on bio-proteins:

Option 1-1: Abandon the pre-market authorisation procedure for bio-proteins (de-regulation):

The products listed as bio-proteins are included in the list of feed materials (see chapter 5.1). Bio-proteins would become normal feed materials.

Option 1-2: Retention of the *status quo* for bio-proteins:

Requirement of a pre-authorisation procedure would remain.

Option 1-3: Alleviated authorisation procedure for bio-proteins:

Lessen the burden for the applicant e.g. by using the qualified presumption of safety-approach (QPS) or by abstaining from the requirement to prove efficacy of the products in order to make the assessment to be done by EFSA leaner.

5.2.2. Sub-options on emerging feed:

Option 2-1: Retention of the *status quo* for emerging feed

No pre-market authorisation procedure for emerging feed materials

Option 2-2: Request for emerging feed materials a pre-market authorisation procedure

As for bio-proteins, emerging feed materials would have to undergo a risk assessment followed by an authorisation act before circulation in the EU.

5.3. Policy issue 3 - Labelling of compound feed labelling for food producing animals

5.3.1. Sub-options on feed material declaration:

Option 1-1: Retention of the *status quo* on feed material declaration:

The mandatory percentages declaration of the feed materials is retained.

Option 1-2: Indication of all feed materials in descending order of weight[24]:

The manufacturer would have the option to label the percentage of all feed materials on a voluntary basis if deemed to be advantageous for him. The producer would be required to disclose the composition to the competent authority for control reasons.

5.3.2. Sub-options on feed additive declaration:

Option 2-1: Retention of *status quo* on the declaration of feed additives:

The compulsory declaration of name and level of the additives in compound feed is limited to certain groups of additives that may pose a higher risk.[25]

Option 2-2: Mandatory declaration of the names of all additives incorporated:

Similar to the feed material labelling, all feed additives would have to be indicated at least with their name.

5.4. Policy issue 4 - Labelling of pet food

Option 1: Retention of the status quo and update additive labelling:

Retain the provisions i.e. category labelling of feed materials, possibility to highlight one ingredient and mandatory labelling only of certain feed additives. In updating the additive labelling not only the risk approach but as well the understandability for the average pet owner will be considered.

Option 2: Indication of all the feed materials in descending order of weight and name all feed additives:

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[24] The indication of the feed materials in percentage ranges (banding) and the option to solely indicate the percentage of feed materials if they are incorporated above a de-minimis threshold have not been further addressed because this would be another special legislation for feed that is difficult to control and the benefits against the to options assessed is marginal.

[25] Currently: coccidiostats, enzymes, micro-organisms, vitamins A, D, E and copper. For colorants, antioxidants and preservatives only the declaration of the name is mandatory. The modernisation of this risk based approach could be done using the new systematic of the feed additive Regulation i.e. zootechnical additives, coccidiostats/ histomonostats and additives with maximum levels must be labelled in compound feed. For the rest of the additives there would be an optional labelling.

Like in option 1-2 for farm animals (see chapter 5.3) all feed materials would have to be labelled by their specific name. Similarly, the names of all feed additives incorporated would have to be indicated.

Option 3: Provide additional information by means of a code of good practice (self-regulation):

The status quo (option 1) would be maintained and the stakeholders elaborate a Code for the labelling of the products incorporated in their feed. On additives similarly to option 1 the updating of the provisions would focus on the understandability for the average pet owner.

6. ANALYSIS OF IMPACTS

This Impact Assessment combines **quantitative and qualitative** approaches to ensure that adequate consideration is given to a broader range of direct and indirect as well as social, environmental and economic impacts.

Data limitations: The stakeholder consultation of January 2006 delivered very poor information on financial impacts, though in the questionnaire it was asked to indicate administrative, packaging, labelling and other costs resulting from the different options. Though there was proper advance notice for the stakeholders and they were notified about the information need concerning the nature of the respective administrative obligations. Further, on the first page of the questionnaire the importance to provide detailed explanations of their main arguments on financial implications were highlighted supplemented by and example for the steps to calculate the costs.

Probable reasons for non-delivery: A common hindrance for a broader information sourcing was that the companies did not want to disclose their financial calculation neither on an anonymous basis to the Commission nor to their own industry organisation. Another point is that the feed sector is generally dominated by SME. Usually these companies do not dispose of serious calculations about costs of these options. Finally, for many options it is not possible to link them with costs because the variable for the calculations are hardly to detect. In case variables have been identified for very concrete options, the series of variables where assumptions would have to be made is so long that the accuracy of the calculation is very poor. The sensibility of would be easily to be contested and the figures would probably not stand a plausibility test. These problems have been evident in as well in the focused expert interviews after the IPM consultation.

Based on these data limitations and according to the proportionality principle, the assessment of the options has not been undertaking using the **Standard Cost Model**. Consequently in order to quantify the impacts, calculations for concrete options have been based on assumptions where appropriate.

Finally it has to be stated that -considering the reflux of the consultations including the Civic study- none of them can be regarded as **representative survey**.

6.1. Policy issue 1 - Listing of feed materials

Option 1: Deletion of the non-exclusive list of feed materials

Option 2: Retention of the *status quo*

Option 3: Extending the current non-exclusive list of feed materials

Option 4; Elaboration of an EU-list of feed materials by stakeholders as a *code of practice*

Social Impacts

Impact on public health, feed safety and user rights

The impacts on **public health and feed/food safety** of all options seem to be neutral. It has to be taken into account that the listing of a feed material even in a legal act (option 3) does not guarantee that all products on the market with this designation are per se safe. The feed material list containing the designation, description and the analytical constituents to be labelled is deemed to be rather an instrument of product identification than of feed safety. Hence there are some respondents stating that the extension of the list (option 3) would increase feed safety because the listing of new feed materials would entail some assessment covering e.g. production procedures. In terms of user rights, the mere deletion of the current list (option 1) could lead to poorer product identification whereas a completion of the list (option 3) is deemed to result in better user information.

Impact on employment and jobs

The consultation did not point out direct impacts on employment of neither option. Option 3 and especially option 4 could lead in the mid term to some increased employment in the feed industry and livestock sector due to better competitiveness, however no significant effects are expected.

Environmental impact

No significant impacts expected.

Economic Impacts

Impact on competitiveness, markets and trade

The simple deletion of the current non-exhaustive list (option 1) is seen to have a negative impact on **market transparency and product information** because it would abolish a valuable system for the feed sector. Stakeholders would have less legal assurance about the specification and properties of the products.

In terms of customer information to optimise their production process the extension of the list (option 3) would increase the coverage of the feed materials used and similarly the code of practice (option 4) would improve the specification and information on the feed materials and thus the quality of a labelling according to the code.

Considering the harder competition for raw materials between feed, food and fuel, there is an ongoing tendency for the feed industry to source co-products from the food or biofuel industry to produce feed. This development results in a positive impact of option 3 in terms of market information in order to improve the competitiveness of the EU livestock production as many of these co-products are not properly defined. Similarly, a comprehensive list in the form of a code (option 4) would increase the transparency and product information. Assuming that the stakeholders can fill this information gap between businesses better than the legislator in terms of flexibility, timeliness or prioritisation, option 4 seems, compared with option 3, to produce better results with respect to the coverage of products and the range of information given with the listing. However, as the code would be voluntary the legal rating would be weaker.

Experiences with comprehensive lists: Next to well established lists in several third countries, in Germany the feed sector works since 2002 with a voluntary complete list (http://www.dlg.org/de/landwirtschaft/futtermittelnet/positivliste/index.html). As foreseen in option 4, the list is elaborated and maintained by a consortium of industry, science and farmers under observation of the German Ministry. Both parties -feed producer and purchaser- report very positively about the system.

Hence, there is a steady increase from option 1 to 4 in terms of market transparency and product information with the effect of better allocation of resources and therefore to improved competitiveness and increased trade.

Impacts on trade with Third countries: The crucial principle on feed from outside the EU is that the feed business operator importing a feed into the Community has to assure that it complies with the requirement of the EU-feed law.

There is an overall positive impact seen due to the fact that the new legislation will be a Regulation to be uniformly implemented throughout the Union rather than the current situation where the MS have concrete, differing provisions in place for the labelling particulars which have to be respected by the importers e.g. concerning the approval number of establishments.

Impact on research, innovation and investment

No significant impacts expected.

Impact on SMEs

SMEs, particularly those located in MS with a smaller market volume, could take advantage of the comprehensive list (option 4) because of the harmonisation in designation and product information on the feed materials. Other than the big feed companies, smaller businesses often do not dispose of appropriate internal overhead services e.g. laboratory analytics delivering information on the properties of the sourced feed materials. So, SMEs could particularly take advantage of the code where they participate through their European organisation.

Impacts on administrative burden

Whereas the deletion of the current list (option 1) would decrease administrative burden because the competent authorities need no more to control their application, the retention of the current list (option 2) would not imply a change in administrative burden. However, according to the competent authorities, especially since the feed law introduced the principle of risk based control systems, the efforts to control qualitative features of the label are reduced from a former dominant significance to nowadays subordinate levels (less than 20%) favouring the focus on safety related issues of feed. Hence the potential reduction in administrative burden of option 1 is very limited.

The extension of the list by the legislator (option 3) would increase significantly the administrative burden for the Commission services and the MS to cope with the notifications for the listing of new feed materials. A working group of the SCoFCAH section animal nutrition would have to be established presided by the Commission and comprising the 27 MS. The amount of notifications can easily yield 200 to 400 different feed materials. Depending on the quality of data delivered with the notification, the working group would have to verify, possibly request further information and finally propose the listing of the respective product to the SCoFCAH. The experience with such kind of administrative procedures shows that even if it would be possible to gather once a month the time to get the list for the first time extended to cover the most significant products would take more than a year. On the other side, the costs for the stakeholders would be marginal. Based on the assumption that the coordination costs within the Commission would be equal to those of the stakeholder consortium (see option 4) and that the SCoFCAH-working group would be able to elaborate the list in ten 2-days-meeting, the total costs would be estimated at 938.000 €.

The external study on the feasibility of a positive list of authorised feed materials at Community level[26] estimated the costs for such a list. Based on this calculation the costs of the elaboration and maintenance of a comprehensive list as outlined in option 4 have been estimated[27]: for the stakeholders the estimation for the elaboration of the first version resulted in 629.000 € and for the maintenance in 91.800€ p.a. The calculation takes into account cost for the secretariat of the consortium, travel costs and per diem payments for the experts in the consortium and translation costs. To a considerable extent these costs are only opportunity costs (no real expenses) as e.g. experts from stakeholders must in general not be reimbursed (travel expenses, per diem) as the elaboration of the community guide to good feed hygiene practice has shown. The calculation can be found in Annex 3. Impacts on administrative burden for the competent authorities have been identified for the assessment of the code and the monitoring the use of the code in practice. Depending on the current status quo in the MS allowing different regulations, 70% of the responding competent authorities indicated that their costs inherent with this system would remain similar or decrease fairly significantly (10-25%).

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[26] B. R. Cottrill and G. Tran: An evaluation of the feasibility of a positive list of authorised feed materials at Community level, March 2002, ADAS.

[27] The adjustment of the calculation in the feasibility study of 2002 took into account the considerable work meantime done, e.g. by different organisations having already compiled sectoral lists.

6.2. Policy issue 2 - Authorisation procedures for feed

Option 1-1: Bio-proteins - abandon the pre-market authorisation procedure

Option 1-2: Bio-proteins - retain status quo

Option 1-3: Bio-proteins - alleviate authorisation procedure

Option 2-1: Emerging feed - retain the status quo

Option 2-2: Emerging feed - request pre-market authorisation procedure

The imports of protein rich feed materials are overwhelmingly oilcakes/–meals and corn gluten. These feed materials are increasingly produced from GMO-plants and hence have to be authorised for imports in the EU under the GM-food/feed Regulation. This issue is not at stake here.

Social Impacts

Impact on public health, feed safety and user rights

The options 1-1 and 2-1 (no pre-market authorisation) have a marginal impact on feed safety because of the risk that could inhere in bio-proteins or emerging feed placed on the EU-market without an ex ante risk assessment done by EFSA. In any case the magnitude of this impact is not significant considering the responsibility of the feed business operator, comprising a main pillar of the food safety system since the implementation of the General Food Law (2002), in other words that he has the first responsibility with all consequences that the feed he places on the EU-market is safe.

Pre-market authorisation for feed:

Currently, a pre-market authorisation procedure including a full risk assessment is required for GM feed or feed produced from GMOs (Reg. (EC) No 1829/2003)[28], feed additives (Reg. (EC) No 1831/2003) and bio-proteins (Dir. 82/472/EEC).

Since the entry into force of Reg. 1831/2003, the most significant groups of bio-proteins have been transferred from the bio-protein Directive to the feed additive Regulation. The remaining bio-proteins comprise a very limited risk per se as the micro-organisms (not genetically modified; otherwise authorisation under) are inactivated and solely are intended to provide for proteins to the animals. They cannot be compared to feed additives or GMOs. Currently we prohibit the placing on the market of bio-proteins that are not only commonly used outside the EU but as well legally incorporated in EU-food.

[28] In the field of GM-feed there are significant difficulties for trade because of many GMOs authorised in exporting Third Countries but not (yet) in the EU. According to USDA data for the current corn marketing year which began on September 1, 2006, U.S. corn gluten exports are 38% below the year earlier to the European Union-27 for the September to March period and the EU has been by far the most important export market for U.S. corn gluten feed. The reason behind is that only 26% of the elevators surveyed report that they require the segregation of GMO varieties from non-GMO varieties.

Experience with the status quo (bio-proteins: authorisation – emerging feed materials: no authorisation) shows that feed hazards leading to recalls or bans mainly occur irrespective of a possible authorisation or registration act. The majority of feed rejections is because of contamination with chemicals or germs. It can not be concluded that protein rich feed materials embody a higher risk per se.

Options 1-2 and 2-2 requiring a pre-market authorisation procedure for these products including a full risk assessment by EFSA would consequently produce slightly better results concerning public health and feed/food safety. Option 1-3 could be expected to have a more positive impact than option 1-1 because even in a lighter authorisation procedure the safety related aspects would be covered. The level of the risk in case of no mandatory pre-market authorisation procedure (options 1-1 and 2-1) would depend on the care of the MS in monitoring the market for possibly hazardous product and thus lies in the time lag between the first circulation and the detection of such products by the competent authorities. Experience suggests this time lag is short.

With respect to the user rights, options 1-2 and 2-2 are seen to increase assurance due to a more comprehensive risk assessment of the products on the market. This is valid in an alleviated manner for option 1-3.

To conclude, options 1-1 and 2-1 would marginally affect feed safety and user rights but the value added of options 1-2 and 2-2 in this respect is rather limited considering the measures in policy issue 1 on listing of feed materials and the meanwhile implemented feed safety systems.

Impact on employment and jobs

Considering the positive economic impacts of options 1-1 of 2-1, these seem to have a favourable impact on jobs.

Environmental impact

No significant impacts expected

Economic Impacts

Impact on competitiveness, markets and trade

The simple abandonment of the current authorisation procedure for bio-proteins (option 1-1) and not foreseeing one for emerging feed (option 2-1) might negatively influence market transparency and product information. New bio-proteins would come on the market with poor identification and the missing information on properties of emerging feed materials would remain. The system chosen in policy issue 1 on listing of feed materials should be taken into account to qualify the impact on market transparency.

Concerning **trade** with Third Countries, options 1-1 and 2-1 would facilitate imports considering the possible gap between the authorisation of these products inside and outside the EU. Other than for options 1-2 and 2-2 with burdensome and thus sometimes prohibitive authorisation procedures, the EU-markets would not be cut of supply sources that are used outside the EU commonly. Third countries would not have to implement burdensome separations systems for feed materials that are in line with the EU-approved feed materials.

Similarly, the **competitiveness** of both the companies putting into circulation and the potential purchasers of such products would be very positively influenced by options 1-1 and 2-1 and slightly positive by option 1-3. In option 1-2 and 2-2, sellers in the EU would either have to invest significant costs to get the authorisation or even would not get started with the marketing. The potential purchaser (compound feed industry and livestock farmers) would have to bear higher product prices (in case of EU-production) or be totally cut off from these sources if they could be only available on the world market as long as they are not authorised in the EU.

Impact on research, innovation and investment

In line with the impacts on competitiveness, options 1-1 and 2-1 could release means for R&D to market new feed materials.

Impact on SMEs

SMEs do not usually have the resources to introduce and accompany applications for authorisation. Therefore options 1-1 and 2-1 would expand their potential business field.

Impacts on administrative burden

The impacts have to be assessed for the potential producing company, for the institution doing the risk assessment (EFSA) and for the competent authorities in term of the accompanying the authorisation process and the market controls.

In the cost analysis for a potential producer under option 1-2 the following factors were assessed:

- Familiarising with the application procedure
- Preparation of the dossier
- Analysis of available studies
- Compiling data for safety
- Presentation and introduction of the dossier
- Cooperation with risk assessor (EFSA) and -manager (Commission + MS)
- Follow – up activities.

Costs for the industry:

For a new bio-protein authorisation the total costs for the industry have been estimated at 481.000€. As explained in Chapter 3.2.2 the number of applications for new bio-proteins is for several reasons pretty small. As it can not been anticipated to which extent the status quo (option 1-2) has been prohibitive the extrapolation of the reduction in administrative costs for option 1 for the EU is not undertaken. The authorisation procedure for emerging feed materials (option 2-2) is expected to be less costly than for bio-proteins but a range for the industry between 100.000€ and 300.000€ per product seems to be plausible. In line with the estimation for the feed material list (policy issue 1) the assumption would be that there are 20 emerging feed materials per year to be assessed under options 2-2.

Costs of the risk assessment:

For options 1-1 and 2-1 there are no risk assessment costs foreseen. For assessing a bio-protein dossier in option 1-2 EFSA estimates the cost to amount at 30.000€. It is plausible that for emerging feed materials (option 2-2) is not significantly lower. There are no profound calculations to what extent option 1-3 could reduce these administrative costs because the experiences with such alleviated procedures are poor and resilient parameters are very hard to find. Rough estimated indicate that the order of reduction could be in a range of 30 and 70%.

Costs for the MS:

In the consultation issued in February 2007, MS compared the costs for the expert monitoring of the authorisation procedures in their services for option 1-2 (status quo) with the abolishment of the authorisation procedure (option 1-1). They reported a significant decrease in costs for option 1-1; this statement weights strong considering the few dossiers in the last years. However, with respect to the control activities the most MS reported for option 1-1 a fairly significant increase of costs due the isolated fact that there would no more be a positive list with authorised bio-proteins. This evidence has to be qualified depending on the system chosen in policy issue 1 on listing of feed materials.

To resume, option 1-1 would have very positive effects on administrative burden. Option 1-3 could lead to a slight decrease compared with option 1-2. On emerging feed, only option 2-2 would cause significant administrative costs.

6.3. Policy issue 3 - Labelling of compound feed for food producing animals

Option 1-1: Feed materials - retention of the *status quo*

Option 1-2: Feed materials - indication in descending order by weight

Option 2-1: Feed additives - retention of the *status quo*

Option 2-2: Feed additives - mandatory declaration of the names

Social Impacts

Impact on public health, feed safety and user rights

The impacts on public health and feed/food safety of all options seem to be pretty neutral.

Though the percentage declaration of the **feed materials** (option 1-1) has been introduced as a means of public health and feed safety, the meantime developed framework implementing the General food law suggest that the value added of the percentage declaration to support feed safety is marginal. Thus there is still a slight reluctance of some MS to abolish the general obligation to indicate the percentages (option 1-2) for safety reasons.

On **feed additives** the difference between option 2-1 and 2-2 is that option 2-2 requires the indication of all additives and not only of the ones that are deemed to pose a higher risk. Nevertheless, feed users and competent authorities stated in the consultation option 2-2 to be beneficial for feed safety. This can be explained by easier tracing back if e.g. an additive, which is must not be labelled, is found to contain high levels of an undesirable substance. Considering on the one hand the basic principle that all feed additives have to be authorised and safe, on the other hand that traceability is assured via identification systems for both the manufacturer and the concrete batch, the potential negative impact of option 2-1 is deemed to be marginal.

Impact on employment and jobs

Option 1-2 could lead in the mid term to increased employment in the feed industry because of positive economic impacts (see below) whereas option 2-2 would have a negative effect due to more labelling burden for the industry.

Environmental impact

No significant impacts expected.

Economic Impacts

Impact on competitiveness, markets and trade (intra/extra)

The retention of the mandatory percentage declaration of **feed materials** (option 1-1) is seen very negative in the sense on the competitiveness of the EU feed industry whereas the descending order (option 1-2) is supposed to improve it by releasing entrepreneurial freedom. According to the stakeholder consultation option 1-1 results in higher cost for compound feed produced in the EU reducing the competitiveness of either the EU feed industry in case they can not pass the increased prices to farmers or of the EU-livestock farmers if the feed prices increase. The consequence would be that the animal products produced in the EU would cost more and/or increased food imports.[29]

Concerning the market conditions, the abrogation of the mandatory percentage declaration (option 1-2) is seen to have a negative impact on market transparency and product information because farmers would not get in any cases the percentage of the used feed materials. However, the status quo does not allow them to get the exact percentage of the components used because the feed manufacturer has a tolerance of +/- 15% to bias from the declared value. Thus, even with the status quo the information is not completely precise. So, the difference between a percentage combined with a significant tolerance and descending order seems to be marginal.

As outside the EU there is no comparable system to the mandatory percentage declaration (option 1-1) known to be in force, the abandonment (option 2-1) could facilitate the trade with Third Countries.[30]

In terms of **labelling the feed additives** requesting all additives to be declared (option 2-2) is seen to have a positive effect on transparency for the customer. However, feed producers doubted the usefulness of all additives indicated on the label for the average feed user, some claimed the labels to become overloaded. Further the potential positive impact is overlaid by increased costs for the manufacturers leading to a loss in competitiveness of the EU-feed and farm sector. The criterion of usefulness for the average feed user in updating the status quo in option 1-2 is seen to have a positive effect for the customers.

To resume, there is a benefit of option 1-2 against option 1-1 whereas between option 2-1 and 2-2 there might be a marginal disadvantage of option 2-2.

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29 N.b. that feed costs are the most significant cost factor in animal production; just the expenses for compound feed amount for 29% (see chapter 3.1.1).

30 N.b. that according to FEFAC both imports and exports of compound feed are below 1% of the market volume.

Impact on research, innovation and investment

The impacts on R&D of the abandonment of the percentage declaration of **feed materials** (option 1-2) are seen to be strongly positive thereby boosting innovation and investment in the feed industry. The yearly R&D spending of the EU compound feed industry related to feed composition and raw materials amounts according to a FEFAC survey to 450 Mio € i.e. in average about 3€/t compound feed or 1,2 % of the turn over.[31] Depending on company size and whether the product range is mainly standard feed or covers as well speciality feeds the expenses ranged between 2,5 and 44 million € per company and year. According to FEFAC, feed manufacturers claim that the incidence of the mandatory percentage labelling of all feed materials would reduce the R&D expenses between 25% and 80% with an average of approximately 50%. In case of the legislative frame would better protect industry secrets (options 1-2 and 2-1) than the status quo they announced an increase in R&D investment by app. 25%. The companies stated that the R&D efforts focussed on better efficiency, animal health, quality of the animal products e.g. fatty acid patterns, environment and society concerns like GMOs, animal welfare, sustainability or use of antibiotics. These efforts are reported to have resulted in a well filled pipeline of products for innovation.

The negative impacts on know how protection have been stated for option 1-1 and for the mandatory labelling of all **feed additives** incorporated in the compound feed (option 2-2).

Impact on SMEs

There is no clear correlation between size and R&D investment. Whereas in tendency the big companies have the dimension to dispose of well equipped R&D departments, there are SMEs successfully marketing speciality feeds based on extraordinary investment in product development. So, SMEs could as well have **intellectual property rights** that would be at risk with option 1-1 and 2-2.

Hence, the additional labelling requirements inherent with options 1-1 and option 2-2 discriminate in tendency the SMEs because the additional **labelling costs per product unit are higher.**

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31 FEFAC estimates that about the same dimension of money is spent for animal nutrition research in public institutes and approximately half of the amount by the feed material industry.

Impacts on administrative burden

For the industry:

The impacts of the status quo (option 1-1) on the industry have been reported mainly in terms know how protection (see above). The costs for a change of the status quo on the feed material labelling[32] and similarly for the indication of all the additives (option 2-2) seem to be of lower significance considering the state of the art in the industries' packaging systems.

For the MS:

Concerning the impacts on the competent authorities the situation is mixed. According to the COM-Report on compound feed labelling[33] covering as well the implementation of the percentage declaration there are different situations: the mandatory percentage declaration was suspended by national court decisions in several MS. The majority implemented it in 2006 after the ruling of the Court of Justice of the EC but 2 MS still did not. The second group of MS had decided to be flexible on the occasion of official controls and even not to impose penalties to operators in case of non-compliance. The third group of MS transposed, enforced and controlled repressively the provisions. According to the consultation issued in February 2007, the MS implementing not or late and the MS not pursuing repressive controls (groups 1 and 2) mainly reported a fairly significant decrease in administrative costs[34] for option 1-2 compared with option 1-1. The third group which implemented and controlled the percentage declaration since years stated mainly that the administrative burden would remain similar or decrease fairly significantly if option 1-2 would be chosen.

To resume there seems to be for the MS significant administrative burden linked to option 1-1 with difficult analytical verification of the labelled values given as strongest argument. Concerning the labelling of additives the majority of MS saw a fairly significant increase in administrative costs (10-25%) if all additives would have to indicated on the label (option 2-2) compared with option 2-1.

6.4. Policy issue 4 - Labelling of pet food

Option 1: Retention of the status quo and update additive labelling

Option 2: Indication of all the feed materials in descending order of weight and name all feed additives

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32 FEFAC estimates the average cost for a change from the current percentage labelling of feed materials (option 1) to a descending order (option 2) to amount to 3000 € per compound feed mill being independent from size. This would result in total costs for the EU of 12 Mio € i.e. 0.03% of the turn over or 8 ct per ton compound feed.

33 Report from the Commission to the European Parliament and to the Council on the implementation of the measures introduced by Directive 2002/2/EC amending Directive 79/373/EEC on the circulation of compound feedingstuffs (COM(2006) 839 final).

34 Member States were asked to estimate the costs linked to the change of the status quo (legal implementation) and including the control activities in practice.

Option 3: Provide additional information by means of a code of good practice

Social Impacts

Impact on public health, feed safety and user rights

The impacts on **public health and feed/food safety** of the options are seen to be neutral. First of all, pets do not enter the food chain. Secondly, the standard in the production process is meanwhile assured e.g. by means of the Feed hygiene Regulation with the effect that the labelling as a whole has only a very limited effect on safety.

The **impacts on user rights** of the options are ambivalent because on the one hand option 2 offers in all cases more information on the label suggesting on the first sight a positive effect. On the other hand the average pet food customer wants a simple label easy to understand. As explained in Chapter 3.2.4 only 4 % of the pet owners contacting the feed manufacturer asked for the ingredients of the feed. Further, it became evident that the pet owners are not acquainted with very technical expressions be it for feed materials or for additives. Thus, the principle of more information to strengthen user rights has to be relativized considering pet food labelling. If the aim that labels should be simple and understandable is included into the issue of user rights the impacts of option 3 seems to have all in all a positive effect.

Impact on employment and jobs

The consultation did point out a negative impact on employment of option 2 resulting in the negative consequences on competitiveness, know-how protection and administrative costs. Option 3 could lead in the mid term to marginally increased employment in the feed industry because of the positive economic impacts and more appropriate user information.

Environmental impact

Knock-on effects of option 2 concern the environment directly because of the increase of by-products with unappealing denominations like "chicken viscera" that has to be disposed of instead of being fed to pets. Further, abattoirs would have to undertake significant logistical investments to adapt themselves to the changed demand of the pet food industry: separation of by-products, e.g. lungs, livers, intestines etc from beef which are often mixed at the abattoir into "beef material"; similarly for poultry or pork. Consequently, the economic incentive of EU abattoirs' to sell by-products to the EU pet food industry would decrease. Thus, option 2 would increase the costs for farmers, abattoirs and the food industry which would have to dispose of more products in the environment. Currently, the EU pet food industry sources nearly 5 million tonnes per annum of by-products from the food chain (slaughter houses or cereal mills) which would often have no or only limited economic value.

Finally, in decreasing the flexibility of the industry for the raw material sourcing option 2 would increase transport distances and cause therefore negative environmental impacts. In tendency limitations in the flexibility of sourcing raw materials would lead to companies buying raw materials in third countries.

Economic Impacts

Impact on competitiveness, markets, trade (intra/extra)

In relation to the status quo allowing category labelling of feed materials and selective additive labelling (option 1), option 2 with indication of all feed materials and additives by their name would increase **market transparency and product information.**

However, for the **competitiveness** of the EU feed industry option 2 would have a negative effect because of the increased disclosure of their recipes.[35] In addition to the supplementary costs explained in the below paragraph on administrative cost, there seems to be a clear link between the cost advantage of option 1 and competitiveness. Current category labelling permits manufacturers to purchase flexibly according to market availability and to formulate pet food recipes, including the companies' know how (secrecy of recipe, intellectual property).

[35] Recipes for a specific pet food change on a regular basis and pet food manufacturers need to adapt their recipes whilst maintaining the same functionalities of nutrition, taste and appearance. Therefore, different raw materials with the same functionalities can replace each other such as e.g. beef lungs replacing pork lungs or wheat replacing barley. The volume ratios between raw materials may change; additives may need adjustments or replacement depending on the raw materials available and seasonal variations in fish or poultry (summer and winter).

Further, up to 40% of pet food products are unbranded products produced specifically for retail (supermarkets own brands, pet shop brands, no-name products). Some larger companies produce mainly unbranded products and a number of SMEs depend entirely on producing exclusively unbranded products for retailers. These retailers impose product specifications, fixed prices applicable and commercially enforceable for periods spanning from several months to over a year. Option 2 would limit or even exclude the possibility to engage on long-term contracts with retailers or at least massively increase the economic risk for producers, whereas category labelling allows the flexibility of complying with specifications and price.

Another market aspect of option 2 would be the fact that for marketing reasons some materials with unappealing denominations like "chicken heads and feet" might not be used by pet food manufacturers. Abattoirs would no longer be able to sell these by-products but would have to dispose of them in a different, more costly way (see environmental effects). Pet food companies would compete for the remainder of by-products and unprocessed feed materials thereby increasing the price of raw materials for the entire industry. This would increase the product prices. Option 3 could improve competitiveness consequently to more entrepreneurial freedom.

The impacts of option 2 on intra- and extra-trade would be in the first place a significant disruption in traditional trade flows which could hit the Third Countries heavily, considering that a significant part of the raw materials of the pet food industry is imported.

To resume, considering that the aspect of product information is covered in the last paragraph in relation with user rights there seems to be a negative effect of option 2 on the competitiveness. Having a good code of practice in force (option 3) could improve the product information compared with option 1 and in the same time avoid the negative effects of option 2.

Impact on research, innovation and investment

The impacts on R&D of option 2 can be assessed in correlation with the impacts on the competitiveness. As option 2 would foil know how protection a negative effect on research and investment is seen.

Impact on SMEs

SMEs buying at "best market prices" to maintain competitiveness would be particularly concerned by option 2 because they can not to the same extent than the big, multinational companies compensate fluctuating raw material sources; option 2 would limit their practice to produce with pre-printed labels significantly. Buying power, larger quantities and bigger storage facilities of big companies (economies of scale) would put SMEs at an even greater disadvantage. Option 3 would support SMEs because they could be take advantage of the code without the need of a respective in-house department to provide for such benefits.

Impacts on administrative burden and production costs for the industry

The impacts of the indication of all feed materials and additives by name (option 2) on the **industry** are seen to be **very negative**. FEDIAF issued a cost analysis for the whole EU based on the specific character of pet food, the variety of pet food products and the numerous pet food operators[36]. The following cost factors have been assessed:

(a) Costs for sourcing raw materials: To be able to have same raw materials, industry will be forced to source raw materials from longer distance and at higher market prices, no longer being able to choose according to flexible recipes.

(b) Costs for unbranded products manufacturers. The flexibility inherent with the categories eases manufacturers to engage in these transactions resulting in costs for adapting contracts and production methods if the flexibility would abolished.

(c) Costs for additional storage facilities, including staff.

(d) Costs for changes long-term marketing strategies, including advertising.

(e) Costs for lost re-work option. No re-using of faulty (safe) factory raw materials and having to bear the costs for destruction.

(f) Costs for competition with human food sector, because the sourcing of surplus products from the food industry would decrease.

(g) Costs for labels, bags, cans, trays, pouches, cartons, boxes based on the labelling changes (printing, labour, several changes according to the products and product varieties, number of pet food companies, the increased likelihood that printed labels cannot be used).

(h) Costs for increased pet owner inquiries. All companies employ staff to deal with customer inquiries. Currently customer questions on product composition average around 4% of all pet owner, which is expected to increase massively.

The cost analysis for option 2 resulted in annually 355 million € for the EU pet food industry (n.b. turn over app. 9 billion €). Strictly, only position f) amounting at 70 million € is administrative burden, the rest are other costs for the industry. The knock-on effects in related sectors are not included (see paragraph on environmental impact).

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36 An estimation based on tons of pet food is not presentable, since labelling costs for a small fish food box can be as high, or higher, as the labelling costs for a one kilogram can of dog food.

Concerning the impacts on the **competent authorities,** option 2 seems to cause positive effects because of a better alignment with the rules for food producing animals. However this would be counterbalanced by an increase in labelling particulars to be controlled i.e. more operational control work. According to the competent authorities' answers to the questionnaire of February 2007, option 2 is seen to have a **slightly negative** effect on administrative burden for the MS.

As option 3 foresees the elaboration of a code of good labelling practice for pet food this would implicate administrative costs. As demonstrated in Chapter 6.1 and taking into account that the industry has already on her own initiative started to work on such a code the supplementary costs seem to be marginal.

7. COMPARING THE OPTIONS

7.1. Policy issue 1 - Listing of feed materials

Type of impact	Option 1	Option 2	Option 3	Option 4
Description of option	Deletion of the current list	Retention of the current list	Extension of the current list in comitology	Code of practice by stakeholders
Social impacts:				
Impact on public health and feed safety	0	0	0	0
Impact on user rights	-	0	+	+
Impact on employment and jobs	0	0	0	0
Environmental impact	0	0	0	0
Economic impacts:				
Impact on research, innovation and investment	0	0	0	0
Impacts on SMEs	0	0	+	+
Impact on competitiveness, markets and trade	-	0	+	++
Impact on administrative burden	+	0	--	-

++ Very beneficial impact
+ Fairly beneficial impact
0 Low/neutral/not relevant/marginal impact
- Not very beneficial impact
-- Not at all beneficial impact

Potential for optimising options

As indicated by the majority of experts, the coverage of new products by the list would be an appreciated progress. Hence there is reluctance if this would be done under the responsibility of the EU-legislator (option 3) and especially if the legislator would have the lead in the elaboration a comprehensive list. The main reason is the supplementary administrative burden for a measure that is not focussed on risk management. The solution could be the delegation to stakeholders for self-regulation so that the expected benefit of the list would decide on the costs they invest in it. Experiences on national levels show that all concerned parties take advantage of such a list. The optimisation of the option would be the level of detail envisaged in terms of designation and description[37] of the feed materials. In order to ensure that, in particular, the interests of feed users are adequately met, a stronger involvement of the Commission could be envisaged in terms of approval of the list. This would mean that instead of pure self-regulation the list would be produced through co-regulation.

Analysis of current situation and justification

The current situation leads between the MS to an inhomogeneous situation for the labelling of feed materials. This is perceived by MS and stakeholders as sub-optimal especially with respect to emerging feed material like by-products from the food or bio-fuel industry. The impact assessment confirms that there are measures to improve market transparency resulting in positive impacts on the smooth functioning of the internal market, on trade and on competitiveness particularly of SMEs. The initiatives of the industry in elaborating sectoral lists are encouraging to dispose of good groundwork. Further, the very good experiences with the feed hygiene guides[38] are an encouragement to delegate tasks for the elaboration of a code for feed materials to the stakeholders.

Preferred option

The results of the impact assessment suggest the elaboration of a comprehensive list of feed materials through co-regulation as the value added refers mainly to qualitative elements of feed marketing. The measure highlights the responsibility of the feed business operators and of the market principles.

7.2. Policy issue 2 - Authorisation procedures for feed

7.2.1. Bio-proteins

Type of impact	Option 1-1	Option 1-2	Option 1-3
Description of option	Abandon pre-market authorisation procedure	status quo	Alleviated authorisation procedure

[37] The assumption for the cost estimation in chapter 6.1 was 600 listed feed materials with 200 words for each to describe.

[38] Based on the mandate in the feed hygiene Regulation (No 183/2005) already 3 Community guides to good practice for hygiene have been voluntarily elaborated by stakeholders and assessed by SCoFCAH.

Social impacts:			
Impact on public health/feed safety	0	0	0
Impact on user rights	0	0	0
Impact on employment and jobs	+	0	0
Environmental impact	0	0	0
Economic impacts:			
Impact on research, innovation and investment	++	0	+
Impacts on SMEs	+	0	0
Impact on competitiveness, markets and trade (intra/extra)	++	0	+
Impact on administrative burden	++	0	+

Potential for optimising options

Taking into account the completion of the list of feed materials suggested in policy issue 1 the marginal impact on the user rights of option 1-1 here would be absorbed because the product information on the bio-proteins would be given in the list of feed materials. The co-regulation approach outlined for the listing of the feed material could ensure this is the case.

Analysis of current situation and justification

The current situation results in very little new bio-protein applications. The mandatory pre-market authorisation with significant burden seems to be superfluous for the vast majority of bio-proteins and emerging feed materials. If the control authorities would detect new products that might comprise a risk they could initiate a risk assessment. Hence, the delay between the circulation of such product and its detection would be the only, very limited supplementary risk of this option. As experience shows, the detection of such products is nowadays speeded up by notifications of the competitors in the business. This targeted approach would mean that not 100% of new bio-proteins would have to undergo a risk assessment followed by a risk management decision but only a very limited part of it. The potential risk for feed safety inherent to bio-proteins a priori is deemed to be marginal and thus does not justify the burdensome instrument of a pre-market authorisation procedure for any possible bio-protein considering the meanwhile implemented safety systems in terms of feed hygiene, responsibility of the feed business operators, traceability or controls. There is a significant difference in terms of risk between bio-proteins and GMOs where by means of a pre-market authorisation procedure a positive list of authorised products is produced.

Preferred option

In order to modernise the legislation a reduction of the burden for bio-protein authorisation would be appropriate. The value added of a pre-market authorisation procedure for bio-proteins in terms of feed safety does not reach a level to justify the provision that all such products would have to undergo the procedure. Therefore the new regulation would not foresee such a requirement.

7.2.2. *Emerging feed*

Type of impact	**Option 2-1**	**Option 2-2**
Description of option	status quo	pre-market authorisation procedure
Social impacts:		
Impact on public health/feed safety	0	+
Impact on user rights	0	+
Impact on employment and jobs	0	-
Environmental impact	0	0
Economic impacts:		
Impact on research, innovation and investment	0	--
Impacts on SMEs	0	-
Impact on competitiveness, markets	0	--

and trade (intra/extra)		
Impact on administrative burden	0	--

Potential for optimising options

If emerging feed is included into the list of feed materials containing designation, description including production process and analytical constituents to be labelled as suggested in policy issue 1, proper product identification for emerging feed would be available to the users.

Analysis of current situation and justification

The current situation results in poor product information on a significant number of emerging feed materials. This is particularly problematic because of the increasing significance of co-products from food or bio-fuel production as feed materials.

Preferred option

The value added of a pre-market authorisation procedure for emerging feed materials in terms of feed safety and considering policy issue 1 for market transparency does not reach a level to justify the provision that all such products would have to undergo the procedure. Therefore the new regulation would not foresee such a requirement.

Depending on technological developments there could be in future certain types of emerging feed materials e.g. by-products from the pharmaceutical industry that give general raise to safety risks, the Regulation could foresee a mandate to request an authorisation based on known risk. This authorisation procedure for a strictly limited product range should be designed according to the simplified approach as explained in option 1-3 or if appropriate be tackled with little effort directly in the margins of the authorisation procedure of the main product.

Thus, bio-proteins and emerging feed would generally become normal feed materials that circulate under the responsibility of the feed business operator, the surveillance of the competent authorities and with the product identification laid down in the voluntary feed material list whose elaboration could be controlled by the Commission (co-regulation).

7.3. Policy issue 3 - Labelling of compound feed for farm animals

7.3.1. Feed materials:

Type of impact	Option 1-1	Option 1-2
Description of option	Status quo	Descending order
Social impacts:		
Impact on public health and feed safety	0	0
Impact on user rights	0	-
Impact on employment and jobs	0	+
Environmental impact	0	0
Economic impacts:		
Impact on research, innovation and investment	0	++
Impacts on SMEs	0	+
Impact on competitiveness, markets and trade (intra/extra)	0	++
Impact on administrative burden	0	++

Potential for optimising options

The key to overcome the effect of less customer information in abrogating from the mandatory percentage indication of the feed materials would be a prudent system to assure that the farmer can gets access to the composition data of the compound feed. By any means manufacturer and customer liaise regularly on a sound business relationship. Exemplary the guide for the information on the composition of cosmetic products could be helpful[39]. Thus, this would allow know how protection and proper information of the user.

Analysis of current situation and justification

The status quo situation leads to a business environment that is not innovation friendly. According to the stakeholder consultation there are systems feasible that improve the flexibility for the industry and the business environment not compromising feed safety.

Preferred option

The results of the impact assessment support the deletion of the mandatory indication of the percentage by weight of feed materials incorporated in compound feed combined on the one hand with the possibility to voluntarily indicate the percentages and on the other side with the provision that, on the basis of a solid business relation between producer and purchaser, the latter can get more detailed information on the composition of the product on request.

7.3.2. Feed additives:

Type of impact	**Option 2-1**	**Option 2-2**
Description of option	Updated status quo	Indication of all additives
Social impacts:		
Impact on public health and feed safety	0	0
Impact on user rights	0	+
Impact on employment and jobs	0	-
Environmental impact	0	0
Economic impacts:		
Impact on research, innovation and investment	0	-
Impacts on SMEs	0	-

[39] http://ec.europa.eu/enterprise/cosmetics/doc/guide_access_info.pdf

Impact on competitiveness, markets and trade	0	0
Impact on administrative burden	0	-

Potential for optimising options

Option 2-1 could be optimised if it would be combined with a stakeholder driven code of good additive labelling in order to meet the demand for comprehensive information by MS and feed users. The code would mean that the average consumer gets the information on additives he needs for his business in a form he can take advantage of. To ensure this is the case, approval of the code by Comitology could be foreseen.

Analysis of current situation and justification

Experiences with the current labelling system of feed additives in compound feed proved that it could be simpler and focus better on the appropriateness of the information for the farmer.

Preferred option

The labelling of feed additives in compound feed would be generally mandatory not for all but limited to the sensitive ones[40]. The remaining additives could be labelled on a voluntary basis possibly in line with a code of good practice to be elaborated by stakeholders and to be approved by Comitology (co-regulation). On request, the user should be able to obtain the name of all additives incorporated.

7.4. Policy issue 4 - Labelling of pet food

Type of impact	Option 1	Option 2	Option 3
Description of option	Status quo on indication of feed materials + updated additive labelling	Descending order of feed materials + indication of all additives	Option 1 supplemented by a code of good practice
Social impacts:			
Impact on public health/feed safety	0	0	0
Impact on user rights	0	+	+
Impact on employment and jobs	0	-	0
Environmental impact	0	-	0
Economic impacts:			
Impact on research, innovation and investment	0	-	0
Impacts on SMEs	0	-	+
Impact on competitiveness, markets and trade (intra/extra)	0	--	+
Impact on administrative burden and industry costs	0	--	0

Potential for optimising options

Considering the current categories for the labelling of feed materials incorporated in pet food there would be some margin for improvement with respect to the level of detail and appropriateness. To improve the quality of the code of good practice the involvement of pet holders and of independent scientists could be intensified and approval of the code by Comitology could be foreseen. Additionally, the possibility for the customer to get the names of the used feed materials and additives could be settled.

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40 N.b. that each authorisation act can foresee special labelling requirements of the respective additive once incorporated in compound feed.

Analysis of current situation and justification

The status quo seems to produce acceptable results but there is room for improvement in terms of delivering better information that can be understood by the average customer.

Preferred option

The results of the impact assessment support the general retention of the status quo allowing the pet food industry to label their raw materials with categories. Concerning the feed additives the update of the status quo would focus on the adequateness of the information for the average pet holder. Both on feed materials and on additives the pet owner should be allowed to obtain the names on request. The regulation would encourage the stakeholders to elaborate a code of good pet food labelling which would have to be approved by Comitology (co-regulation).

Modernisation and simplification package – added value of the new Community act

The **combination of the preferred options** results in a vision for the rules on the circulation of feed that **–based on the principles of food and feed safety–**

- simplifies and harmonises the legal frame by one legally clear, stringent and consistent Regulation,
- changes the development of quality-relevant **marketing provisions into co-regulation** for the stakeholders to encourage entrepreneurial innovation,
- improves market transparency because there will be **more feed materials uniformly and better identified** in particular with respect to the current unclear situation on **emerging feed materials,**
- **removes the burden** of a pre-market **authorisation procedure** for the current category "bio-**proteins**", simultaneously highlighting **the responsibility of the feed business operator** for the safety of the feed in combination with the **negative list of prohibited feed materials** to be the preferred and proportionate approach for the legislator in his function as risk manager and for the control authorities,
- increases competitiveness and innovation in the EU-feed business because it **abstains from the mandatory percentage declaration** of feed materials in compound feed and
- improves the appropriateness of **pet food labels** so that the **average pet owner can understand them better** and gets the information he needs.

8. MONITORING AND EVALUATION

The general monitoring of the new Regulation on the circulation of feed is embedded into the Regulation 882/2004 on official controls of food and feed (OJ L 165, 30.4.2004, p. 1–141). This Regulation foresees that the MS implement efficiently the requirements as well in the feed sector. The Commission (Food and Veterinary Office) controls the correct enforcement of the MS.

Particular efforts in terms of monitoring should be dedicated to issues released into self-regulation, where it is necessary to put a system in place. The monitoring would be done by the SCoFCAH (Commission and MS). The following settings are proposed:

Problem	Potential Indicators	Data Source	Frequency in SCoFCAH	Rationale
Elaboration of the complete feed material list	Number of feed materials listed	Reports from the involved stakeholder consortium	yearly	Considering the awaited benefits in terms of product identification the progress in the elaboration has to be monitored
Quality of the feed material list in terms of description and analytical to be labelled	Analytical properties of the listed products	Random samples of competent authorities	yearly	Due to the possibility of imbalanced powers in the consortium of stakeholders the EU has to verify that the interests of the feed users are pursued
Detection of circulating feed materials that might represent a risk	Hazards with an adverse health effect	Competent authorities	In case of notification by competent authority	As there is no pre-market authorisation procedure for the majority of the feed materials, the risk managers have to be vigilant.
Appropriateness of pet food labels	- extent and level of detail of the code for good pet food labelling - consumer contentment	- Pet food labelling code - Euro-barometer	- Yearly - Bi-annually	- The EU should observe the progress in the works on the code - Surveys should be undertaken to verify that the pet owners get the information they need.

Thus, the monitoring tackles the questions

- whether the objectives are achieved and to which extent,
- if the options have been implemented adequately and
- if the impacts have been predicted correctly or if other impacts have occurred.

Based on the outcome of the monitoring an evaluation of the relevant issues should be envisaged after 3 to 5 years depending on the gravidity of the issues to change. This evaluation could be part of a comprehensive evaluation project of the food chain.

ANNEX 1

List of **competent authorities** that returned the questionnaire on **administrative burden**

Animal Health and Veterinary Medicinal Products Directorate - Ministry of Health, Italy

Bundesamt für Ernährungssicherheit - Österreich (Austrian Federal Office for Food Safety)

Central Control and Testing Institute of Agriculture Bratislava, Slovak Republic

Central Institute for Supervising and Testing in Agriculture of the Czech Republic

Danish Plant Directorate, DENMARK

Department of Agriculture and Food, Ireland

DGCCRF/FRANCE DGAL/FRANCE

DIRECÇÃO GERAL DE VETERINÁRIA, LISBOA - PORTUGAL

Belgium and Federal Agency for the Safety of the Food Chain (FASFC) - Belgium

Food Standards Agency, United Kingdom

Lithuanian State Inspection on Veterinary Preparations

Ministerio de Agricultura, Pesca y Alimentación, España (Spain)

Ministry of Agriculture and Forestry, Department of food and health, Finland

Ministry of agriculture of Latvia

Ministry of Agriculture, Natural Resources and Environment, CYPRUS

Netherlands, Food and Consumer Products safety authority (VWA)

Norwegian Food Safety Authority, NORWAY

Republic of Slovenia, Ministry of Agriculture, Forestry and Food

Swedish Board of Agriculture/Ministry of Agriculture

ANNEX 2

List of focussed interviews with experts for information compilation

Nr.	Name	Date	Topic
1.	Dr. Steinruck, R. Mauser	9/11/2006	Impacts on compound feed manufacturer
2.	P. Radewahn	7/12/2006	Impacts on compound feed manufacturer
3.	T. Meyer	7/12/2006	Impacts on pet food industry
4.	Prof. Schenkel	25/1/2007	Analytical constituents labelling – new developments in methodology
5.	J. Taieb	29/1/2007	Use of bio-proteins in the EU
6.	A. Bouxin	5/2/2007	Extra and intra EU-trade with feed
7.	J. Schulte-Domhof	15/2/2007	Impacts on farmers
8.	Dr. Guidon	19/2/2007	Assessment of the Swiss competent authority
9.	Dr. Baum, Dr. Heseker, Dr. Mueller-Mussmann	14/3/2007	Impacts on compound feed manufacturer
10.	H. Stam	15/3/2007	Developments on raw material markets for feed
11.	A. Döring	21/3/2007	Research & development expenditures and innovation pipeline of feed industry
12.	M. Bellingham, G. Grantham	11/4/2007	Customer surveys for pet food
13.	O. Ruiz de Imana	17/4/2007	Listing and labelling of feed materials from the food industry
14.	R. Feller, J. Hansen	14/5/2007	Impacts on farmers and cooperatives

ANNEX 3

Cost estimation for the establishment and maintenance of a comprehensive list of feed materials

Establishment:									
Full-time	coordinator		1 years	x	12 months	x	6000	€	72000
Part-time	secretariat	0,5 x	1 years	x	12 months	x	3000	€	18000
Per	diem	expenses	15 experts		20 days		400	€	120000
Travel	expenses		15 experts	x	10 meetings	x	600	€	90000
Documentation,	computers	+databases	+maintenance		+documentation			€	20000
Translation	of existing lists	5 lists	300 items	x	100 words*	x	0,1	€	15000
Translation	of final list	22 languages	600 items	x	200 words	x	0,1	€	264000
Other	(publication	etc.)						€	30000
Total								**€**	**629000**
Maintenance:									
co-coordinator/secretariat		0,5	1 years	x	12 months	x	6000	€	36000
Per	diem	expenses	15 experts		4 days		400	€	24000
Travel	expenses		15 experts	x	2 meetings	x	600	€	18000
Documentation,	computers	+databases	+maintenance		+documentation			€	3000
Translation	of final list	22 languages	20 items	x	200 words	x	0,1	€	8800
Other	(publication	etc.)						€	2000
Total								**€**	**91800**

SCHEMA DI DECRETO LEGISLATIVO RECANTE DISCIPLINA SANZIONATORIA PER LE VIOLAZIONI DELLE DISPOSIZIONI DI CUI AL REGOLAMENTO (CE) N. 767/2009 DEL 13 LUGLIO 2009 SULL'IMMISSIONE SUL MERCATO E SULL'USO DEI MANGIMI.

IL PRESIDENTE DELLA REPUBBLICA

Visti gli articoli 76 e 87 della Costituzione;

Vista la legge 24 dicembre 2012, n. 234, recante norme generali sulla partecipazione dell'Italia alla formazione e all'attuazione della normativa e delle politiche dell'Unione europea ed, in particolare, l'articolo 33;

Vista la legge 7 ottobre 2014 n. 154, recante delega al Governo per il recepimento delle direttive europee e l'attuazione di altri atti dell'Unione europea - Legge di delegazione europea 2013 – secondo semestre ed, in particolare, l'articolo 2;

Vista la legge 15 febbraio 1963, n. 281, recante disciplina della preparazione e del commercio dei mangimi;

Vista la legge 24 novembre 1981, n. 689, recante modifiche al sistema penale, e successive modificazioni;

Visto il decreto legislativo 30 dicembre 1999, n. 507, recante depenalizzazione dei reati minori e riforma del sistema sanzionatorio, ai sensi dell'articolo 1 della legge 25 giugno 1999, n. 205;

Visto il regolamento (CE) n. 767/2009 del 13 luglio 2009 sull'immissione sul mercato e sull'uso dei mangimi, che modifica il regolamento (CE) n. 1831/2003 e che abroga le direttive 79/373/CEE del Consiglio, 80/511/CEE della Commissione, 82/471/CEE del Consiglio, 83/228/CEE del Consiglio, 93/74/CEE del Consiglio, 93/113/CE del Consiglio e 96/25/ CE del Consiglio e la decisione 2004/217/CE della Commissione e in particolare l'articolo 31;

Vista il decreto-legge 11 gennaio 2001, n. 1 recante disposizioni urgenti per la distruzione del materiale specifico a rischio per encefalopatie spongiformi bovine e delle proteine animali ad alto rischio, nonché per l'ammasso pubblico temporaneo delle proteine animali a basso rischio, convertito, con modificazioni, dalla legge 9 marzo 2001, n. 49,

Vista la legge del 3 febbraio 2011, n. 4 recante disposizioni in materia di etichettatura e di qualità dei prodotti alimentari;

Visto il decreto legislativo 10 maggio 2004, n. 149, recante attuazione della direttiva 2001/102/CE, della direttiva 2002/32/CE, della direttiva 2003/57/CE e della direttiva 2003/100/CE, relative alle sostanze ed ai prodotti indesiderabili nell'alimentazione degli animali;

Visto il decreto legislativo 24 febbraio 1997, n. 45, recante attuazione delle direttive 93/74/CEE, 94/39/CE, 95/9/CE e 95/10/CE in materia di alimenti dietetici per animali;

Visto il decreto legislativo del 5 aprile 2006, n. 190, recante disciplina sanzionatoria per le violazioni del regolamento (CE) n. 178/2002 che stabilisce i principi e i requisiti generali della

legislazione alimentare, istituisce l'Autorità europea per la sicurezza alimentare e fissa procedure nel settore della sicurezza alimentare;

Visto il regolamento (CE) n. 183/2005 del Parlamento europeo e del Consiglio del 12 gennaio 2005 che stabilisce requisiti per l'igiene dei mangimi;

Visto il decreto legislativo 14 settembre 2009, n. 142, recante disciplina sanzionatoria per la violazione delle disposizioni del regolamento (CE) n. 183/2005 che stabilisce i requisiti per l'igiene dei mangimi;

Visto il decreto legislativo 17 giugno 2003, n. 223, attuazione delle direttive 2000/77/CE e 2001/46/CE relative all'organizzazione dei controlli ufficiali nel settore dell'alimentazione animale;

Vista la preliminare deliberazione del Consiglio dei ministri, adottata nella riunione del... ;

Acquisito il parere della Conferenza permanente per i rapporti tra Stato, Regioni e Province autonome di Trento e di Bolzano nella seduta del... ;

Acquisiti i pareri delle competenti Commissioni della Camera dei deputati e del Senato della Repubblica;

Vista la deliberazione del Consiglio dei ministri, adottata nella riunione del... ;

Su proposta del Presidente del Consiglio dei ministri e del Ministro della giustizia, di concerto con il Ministro della salute, il Ministro delle politiche agricole alimentari e forestali, il Ministro dello sviluppo economico, il Ministro dell'economia e delle finanze, il Ministro degli affari esteri e della cooperazione internazionale e il Ministro per gli affari regionali e le autonomie;

E M A N A
il seguente decreto legislativo:

ART. 1
(Campo di applicazione)

1. Il presente decreto reca la disciplina sanzionatoria, relativamente alle materie prime per mangimi e ai mangimi composti, per la violazione delle disposizioni di cui al regolamento (CE) n. 767/2009 del 13 luglio 2009 del Parlamento europeo e del Consiglio sull'immissione sul mercato e sull'uso dei mangimi, che modifica il regolamento (CE) n. 1831/2003 e che abroga le direttive 79/373/CEE del Consiglio, 80/511/CEE della Commissione, 82/471/CEE del Consiglio, 83/228/CEE del Consiglio, 93/74/CEE del Consiglio, 93/113/CE del Consiglio e 96/25/CE del Consiglio e la decisione 2004/217/CE della Commissione, di seguito denominato "regolamento".
2. Ai fini del presente decreto si applicano le definizioni dell'articolo 3 e dell'articolo 12, paragrafo 2, del regolamento.

ART. 2
(Autorità competenti)

1. All'accertamento e all'irrogazione delle sanzioni previste dal presente decreto provvedono le strutture competenti del Ministero della salute, del Ministero delle politiche agricole alimentari e forestali, ai sensi del decreto legislativo 17 giugno 2003, n. 223, del Ministero dello sviluppo economico, delle regioni, delle province autonome, delle Aziende unità sanitarie locali, secondo gli ambiti di rispettiva competenza.

2. Ai fini dell'accertamento e dell'irrogazione delle sanzioni previste dal presente decreto si applicano le disposizioni della legge 24 novembre 1981, n.689, e successive modificazioni in quanto compatibili.

ART. 3

(Violazioni riguardanti le prescrizioni in materia di sicurezza e di commercializzazione)

1. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola le disposizioni in materia di sicurezza e di commercializzazione di cui all'articolo 4, paragrafo 1, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.500 a euro 15.000.
2. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 4, paragrafo 2, lettera a), del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.
3. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 4, paragrafo 3, in relazione all'allegato I, paragrafi 1, 2, 4 e 5, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 150 a euro 1.000.
4. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 4, paragrafo 3, in relazione all'allegato I, paragrafo 3, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 500 a euro 3.000.

ART. 4

(Violazioni riguardanti le responsabilità e gli obblighi delle imprese nel settore dei mangimi)

1. La persona responsabile dell'etichettatura che non fornisce alle autorità competenti ogni informazione concernente la composizione o le proprietà dichiarate dei mangimi che immette sul mercato, ai sensi dell'articolo 5, paragrafo 2, è soggetta alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.

ART. 5

(Violazioni riguardanti restrizioni e divieti)

1. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola l'articolo 6, paragrafo 1, del regolamento, immettendo in commercio o utilizzando ai fini dell'alimentazione animale materiali soggetti a restrizioni o vietati contenuti nell'allegato III del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 5000 a euro 30.000.

ART. 6

(Violazioni riguardanti il tenore di additivi)

1. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 8, paragrafo 1, del regolamento, in merito alla concentrazione massima di additivi coccidiostatici e istomonostatici ammessi per materie prime per mangimi e per mangimi complementari, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 10.000.
2. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola le disposizioni di cui all'art. 8, paragrafo 1, del regolamento, superando il tenore massimo di additivi ammessi per materie prime per mangimi e per mangimi complementari, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000, salvo quanto previsto dall'articolo 8, paragrafo 2, e dall'articolo 32, paragrafo 2, del regolamento.

ART. 7

(Violazioni riguardanti la commercializzazione di mangimi destinati a particolari fini nutrizionali)

1. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 9 del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 500 a euro 3.000.

ART. 8

(Violazioni riguardanti i principi per l'etichettatura e la presentazione)

1. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 11, paragrafo 1, lettere a) e b), del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 3.000 a euro 12.000.
2. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 11, paragrafi 2 e 3, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.
3. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che prepara o immette in commercio materie prime o mangimi composti che, a seguito di un controllo ufficiale, non risultano rispettare uno o più margini di tolleranza ammessi di cui all'articolo 11, paragrafo 5, e contenuti nell'allegato IV, parte A, del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 500 a euro 3.000.
4. Salvo che il fatto costituisca reato, l'operatore del settore dei mangimi che prepara o immette in commercio materie prime o mangimi composti che, a seguito di un controllo ufficiale, non risultano rispettare uno o più margini di tolleranza ammessi di cui all'articolo 11, paragrafo 5, e contenuti nell'allegato IV, parte B del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.

ART. 9

(Violazioni riguardanti le responsabilità)

1. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 12, paragrafo 4, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.
2. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 12, paragrafo 5, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 500 a euro 3.000.

ART. 10

(Violazioni riguardanti le allegazioni)

1. Fatta salva la deroga di cui all'articolo 13, paragrafo 2, del regolamento, il responsabile dell'etichettatura che utilizza allegazioni in maniera non conforme a quanto prescritto dall'articolo 13, paragrafo 1, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.
2. Il responsabile dell'etichettatura che viola le disposizioni di cui all'articolo 13, paragrafo 3, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 2.000 a euro 12.000.

ART. 11

(Violazioni riguardanti la presentazione delle indicazioni di etichettatura)

1. Il responsabile dell'etichettatura che viola le disposizioni di cui all'articolo 14, paragrafi 1 e 2, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 500 a euro 3.000.

ART. 12

(Violazioni riguardanti le prescrizioni obbligatorie in materia di etichettatura)

1. Il responsabile dell'etichettatura che immette sul mercato materie prime per mangimi o mangimi composti privi di una o più indicazioni obbligatorie di etichettatura o con una o più indicazioni non rispondenti, in violazione delle disposizioni di cui agli articoli 15, 16, 17, 18 e 19 e di cui agli allegati II, V, VI e VII del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000, salvo quanto previsto dall'articolo 21 del regolamento.

2. L'operatore del settore dei mangimi che immette sul mercato materie prime per mangimi o mangimi composti oltre la durata minima di conservazione da indicarsi ai sensi dell'articolo 16, paragrafo 2, lettera c), e dell'articolo 17, paragrafo 1, lettera d), del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 250 a euro 2500 euro.

ART. 13

(Violazioni riguardanti le prescrizioni obbligatorie aggiuntive in materia di etichettatura di mangimi non conformi)

1. Salvo che il fatto costituisca reato, il responsabile dell'etichettatura che immette sul mercato, in violazione delle disposizioni di cui all'articolo 20 del regolamento, mangimi non conformi privi delle indicazioni obbligatorie specifiche di etichettatura o con indicazioni non rispondenti a quelle contenute nell'allegato VIII del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 8.000 a euro 30.000.

ART. 14

(Violazioni riguardanti l'etichettatura facoltativa)

1. Si applica la sanzione di cui all'articolo 12, comma 1, al responsabile dell'etichettatura che utilizza nell'etichettatura delle materie prime per mangimi e dei mangimi composti una o più indicazioni a carattere facoltativo in violazione delle disposizioni di cui all'articolo 22 del regolamento.

ART. 15

(Violazioni riguardanti il confezionamento)

1. L'operatore del settore dei mangimi che viola le disposizioni di cui all'articolo 23 del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 1.000 a euro 6.000.

ART. 16

(Violazioni riguardanti il catalogo comunitario delle materie prime per mangimi)

1. Il responsabile dell'etichettatura che viola le condotte di cui all'articolo 24, paragrafo 5, del regolamento, utilizzando la denominazione di una materia prima per mangimi figurante nel catalogo senza che siano rispettate tutte le pertinenti disposizioni, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 150 a euro 1.000.

2. Il responsabile dell'etichettatura che viola le disposizioni di cui all'articolo 11, paragrafo 1, lettera c), del regolamento, è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 150 a euro 1.000.

ART. 17

(Violazioni riguardanti i codici comunitari di buona pratica in materia di etichettatura)

1. Il responsabile dell'etichettatura che viola le disposizioni di cui all'articolo 25, paragrafo 4, del regolamento è soggetto alla sanzione amministrativa pecuniaria del pagamento della somma da euro 300 a euro 1.500.

ART. 18

(Sanzioni accessorie)

1. In presenza di reiterate violazioni di cui agli articoli 3, comma 1; 5, comma 1; 13, comma 1, del presente decreto, gli organi preposti al controllo possono proporre all'autorità competente l'adozione del provvedimento di sospensione dell'attività da tre giorni a tre mesi.
2. In presenza di gravi violazioni di cui al comma 1, l'autorità competente può disporre la revoca della registrazione o del riconoscimento effettuati ai sensi degli articoli 9 e 10 del regolamento (CE) n. 183/2005.

ART. 19

(Abrogazioni)

1. Dalla data di entrata in vigore del presente decreto l'articolo 6, comma 3 e l'articolo 7 del decreto legislativo 24 febbraio 1997, n. 45 sono abrogati.

ART. 20

(Clausola di invarianza finanziaria)

1. Dal presente decreto non devono derivare nuovi o maggiori oneri a carico della finanza pubblica.
2. Le Amministrazioni interessate svolgono le attività previste dal presente decreto con le risorse umane, finanziarie e strumentali disponibili a legislazione vigente.

ART. 21

(Proventi delle sanzioni amministrative pecuniarie di spettanza statale)

1. I proventi derivanti dalla riscossione delle sanzioni amministrative pecuniarie di spettanza statale comminate per le violazioni di cui agli articoli 3, 5, 7, 8, 9, 10, 11, 12, 14, 15 e 18 del presente decreto affluiscono all'entrata del bilancio statale.
2. I proventi derivanti dalla riscossione delle sanzioni amministrative pecuniarie di spettanza statale comminate per le violazioni di cui agli articoli 4, 6, 13, 16 e 17, sono versati ad apposito capitolo di entrata del bilancio statale, e, successivamente, sono riassegnati in favore delle Amministrazioni statali previste dall'articolo 2 del presente decreto, ~~anche~~ per migliorare le attività di controllo previste dal presente decreto.

ART. 22

(Disposizioni finali)

1. Le disposizioni contenute nel presente decreto nonché le eventuali successive modifiche sono notificate, ai sensi dell'articolo 31 del regolamento, alla Commissione.

Il presente decreto, munito del sigillo di Stato, è inserito nella raccolta ufficiale degli atti normativi della Repubblica italiana. E' fatto obbligo a chiunque spetti d'osservarlo e di farlo osservare.